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THE AFFORDABLE CARE ACT: U.S. Vaccine Policy and Practice

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Fall, 2010

This report was supported by DHHS/OASH/NVPO under Contract Number HHSP223320095635WC.

The report was intended to: 1) examine how the Affordable Care Act addresses vaccine and immunization policy and practice; 2) assess the implications of the Act for vaccine and immunization policy; and 3) assess the extent to which the Act addresses the National Vaccine Advisory Committee's (NVAC) Vaccine Finance Working Group's Recommendations. This report does not represent official DHHS policy guidance.

The authors wish to acknowledge Elizabeth Orlan, Research Assistant, for her invaluable support in preparing this report.

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EXECUTIVE SUMMARY

When fully implemented, the Patient Protection and Affordable Care Act, amended by the Health and Education Reconciliation Act will extend health insurance coverage to 94 percent of Americans while establishing a comprehensive set of strategies to improve care and contain costs. The central provisions of the Act – guaranteed affordable and accessible coverage – take effect January 1, 2014. Important insurance reforms aimed at improving coverage become effective before that date, as do a series of investments aimed at improving the accessibility and quality of health care.

This report has several aims: 1) to examine how the laws address vaccine policy and practice; 2) to assess how access to vaccines and immunization services will be affected; and 3) to assess the extent to which health reform addresses recommendations of the National Vaccine Advisory Committee’s (NVAC) Vaccine Finance Working Group (VFWG) 2008.¹

Several provisions provide opportunities to increase access to vaccines and immunizations by improving insurance coverage and affordability, increasing funding for programs that provide immunization services, and expanding the national investment in prevention, wellness and primary health care.

Coverage and Affordability through Private Insurance and Medicaid/CHIP: Health reform ensures increased access to health insurance. Health insurers and group health plans (even if granted grandfathered status) will be required to extend dependent coverage to age 26. With the exception of grandfathered plans, the law requires health insurers and group health plans to cover, without cost-sharing, preventive services, including immunizations recommended by the Advisory Committee on Immunization Practice (ACIP). Insurers and group health plans must implement coverage of vaccines for plan years beginning one year after the recommendation is adopted by the Centers for Disease Control and Prevention (CDC).

The law establishes health insurance exchanges whose purpose is to aid the purchase of health insurance in the individual and small group markets. Individuals and families with low and moderate income will qualify for tax credits to be used to purchase insurance.

Medicaid eligibility will be expanded to cover all non-elderly persons with family incomes below 133 percent of the Federal poverty level regardless of health status or the presence of minor dependent children. For newly eligible adults, Medicaid coverage will consist of a “benchmark” plan that includes preventive services. In the case of “traditionally eligible individuals” (i.e., those falling within pre-ACA Medicaid eligibility categories), states will receive additional financial incentives to promote coverage of preventive services including ACIP-recommended immunizations. Federal funding for CHIP continues through FY 2015.

¹ Lindley M.C., et al., *Assuring Vaccination of Children and Adolescents without Financial Barriers: Recommendations from the National Vaccine Advisory Committee (NVAC)*, U.S. Department of Health and Human Services, 2009.

Medicare: Changes to Medicare include the addition of preventive benefits identified by the Secretary as well as payment for Part B-covered immunizations furnished by hospital outpatient departments.

Promoting Health Care Quality: A National Strategy to Improve Health Care Quality was established. The Secretary and subject matter experts will develop requirements for insurers to report on their initiatives and programs that: 1) improve health outcomes using care coordination and chronic disease management; 2) prevent hospital readmissions and improve patient safety; and 3) promote wellness and health. In addition, the law establishes a Center for Medicare and Medicaid Innovation (CMI). CMI will design, implement, and evaluate innovative service delivery and payment models that have the potential to reduce costs while preserving or enhancing health care quality for Medicare and Medicaid enrollees and dual eligibles.

Comparative Clinical Effectiveness Research: A new non-governmental, nonprofit corporation will be established. The Patient-Centered Outcomes Research Institute (Institute) will evaluate and compare health outcomes and the clinical effectiveness, risk, and benefits of two or more medical treatments, services, and items. The Institute will identify national priorities for research and conduct, support, and synthesize comparative effectiveness research.

Federal Funding for Vaccine Programs: The Act authorizes state immunization programs to use state funds to purchase vaccines for adults using the Federal purchase price negotiated by the CDC.

Demonstration Program: The Act authorizes the Secretary and the Director of the CDC to award grants to states to improve the provision of recommended immunizations for children, adolescents, and adults through the use of evidence-based and population-based interventions.

Prevention and Health Promotion: The law establishes a national prevention and public health promotion strategy and appropriates a Prevention and Public Health Fund. The Act specifies that the strategy includes provider educational activities and projects to improve community-wide prevention.

Research and Evaluation Activities: The Act provides new funding to support research in the following areas: 1) Medicare beneficiary access to immunizations; 2) the effectiveness of existing Federal health and wellness initiatives for the Federal workforce; and 3) evidence-based practices and strategies in the area of public health services and systems.

Community Health Centers: Between FY 2011 and FY 2015 the Federal government will invest \$11 billion in the expansion of community health centers, a major source of immunization coverage for medically underserved populations.

School-Based Health Centers: The law appropriates funding to establish, staff, and equip school-based health centers (SBHCs), that will provide comprehensive primary health services during school hours.

Supporting the Existing Workforce: The law requires the Secretary to establish a Primary Care Extension Program to educate primary care providers about preventive medicine, health promotion, evidence-based and evidence-informed therapies and techniques. The Act also authorizes the Agency for Healthcare Research and Quality (AHRQ), to award grants to establish primary care extension agencies to organize and administer grants whose purpose is to improve the accessibility, quality, and efficiency of primary care services.

Recommendations: NVPO might consider ensuring that the accessibility and quality of immunization services is prioritized throughout implementation, with emphasis on the integration of coverage requirements in the individual and group health markets, the inclusion of immunization services in all health care quality improvement demonstrations, investments in community primary care access programs and prevention and public health efforts.

INTRODUCTION

On March 23, 2010, President Barack Obama signed landmark health reform legislation considered: “the most important piece of social legislation since the Social Security Act passed in the 1930's and the most important reform of our health care system since Medicare passed in the 1960's.”² The law creates a national framework for near universal coverage and outlines strategies to increase access to affordable, improved care while containing costs.

The health reform law consists of two statutes: The Patient Protection and Affordable Care Act (PPACA), (March 23, 2010), The Health Care and Education Reconciliation Act (March 30, 2010), and implementing regulations.³ These two laws will be referred to as the Affordable Care Act.

This report is intended to: 1) examine how the laws address vaccine and immunization policy and practice; 2) assess the implications of the Act for vaccine and immunization policy; and 3) assess the extent to which the Act addresses the National Vaccine Advisory Committee’s (NVAC) Vaccine Finance Working Group (VFWG) 2008 recommendations.⁴ The report concludes with recommendations for further NVAC consideration.

STUDY METHODOLOGY

Researchers at the George Washington University’s Department of Health Policy completed this report through a four-step process. Researchers—

1. Consulted primary data sources, including:
 - a) The enrolled⁵ version of the Affordable Care Act comprised of:
 - i. The Patient Protection and Affordable Care Act (PPACA)⁶ and
 - ii. The Health Care and Education Reconciliation Act of 2010 (HCERA)⁷
 - b) Health reform related regulations, including:
 - i. Group Health Plans and Health Insurance Issuers Relating to Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act Interim Final Rule and Proposed

² *Remarks by the President on Senate Passage of Health Insurance Reform*, The White House, Office of the Press Secretary, December 24, 2009, available at: <http://www.whitehouse.gov/the-press-office/remarks-president-senate-passage-health-insurance-reform>.

³ The Patient Protection and Affordable Care Act (PPACA), Pub. L. 111-148, 124 Stat. 119 (to be codified, as amended, at various sections of Title 42 of the United States Code); The Health Care and Education Reconciliation Act (HCERA), Pub. L. 111-152, 124 Stat. 1029.

⁴ Lindley, M.C. *et al.*, *Assuring Vaccination of Children and Adolescents without Financial Barriers: Recommendations from the National Vaccine Advisory Committee (NVAC)*, U.S. Department of Health and Human Services, 2009.

⁵ An enrolled version of a Federal statute is the final version approved by both houses of Congress.

⁶ PPACA, Pub.L. 111-148, 124 Stat. 119 (to be codified, as amended, at various sections of Title 42 of the United States Code).

⁷ HCERA, Pub.L. 111-152, 124 Stat. 1029.

- Rule (to be codified at 26 CFR Parts 54 and 602; 29 CFR Part 2590; and 45 CFR Part 147);
- ii. Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act Interim Final Rule and Proposed Rule (to be codified at 26 CFR Parts 54 and 602; 29 CFR Part 2590; and 45 CFR parts 144, 146, and 147);
 - iii. Patient Protection and Affordable Care Act; Requirements for Group Health Plans and Health Insurance Issuers Under the Patient Protection and Affordable Care Act Relating to Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections Final Rule and Proposed Rule (to be codified at 26 CFR Parts 54 and 602; 29 CFR Part 2590; and 45 CFR Parts 144, 146, and 147); and
 - iv. Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act (to be codified at 26 CFR Part 54; 29 CFR Part 2590; and 45 CFR Part 147).
- c) NVAC recommendations focusing on immunizations for children and adolescents (approved in 2008, published in 2009); and
 - d) NVAC's "Recommendations for Federal Adult Immunization Programs regarding Immunization Delivery, Assessment, Research, and Safety Monitoring," approved in 2009.⁸
2. Identified all vaccine-related language in the Affordable Care Act and reviewed summaries of health reform, including:
- a) U.S. Senate, *The Patient Protection and Affordable Care Act: Section-by-Section Analysis with Changes Made by Title X and Reconciliation*;⁹
 - b) CCH's *Law, Explanation and Analysis of the Patient Protection and Affordable Care Act, Including Reconciliation Act Impact, Volume I*;¹⁰
 - c) The GW School of Public Health and Health Services, Department of Health Policy, National Health Reform Law and Policy Project and Health Reform GPS;¹¹ and
 - d) The Kaiser Family Foundation Health Reform Gateway.¹²

⁸ *Reports, Recommendations, and Resolutions*, National Vaccine Advisory Committee, available at: <http://www.hhs.gov/nvpo/nvac/reports/index.html>.

⁹ *U.S. Senate, The Patient Protection and Affordable Care Act: Section-by-Section Analysis with Changes Made by Title X and Reconciliation*, available at: <http://dpc.senate.gov/healthreformbill/healthbill96.pdf>.

¹⁰ CCH Editorial Staff, *CCH's Law, Explanation and Analysis of the Patient Protection and Affordable Care Act, Including Reconciliation Act Impact*, Aspen Publishers, 2010.

¹¹ *Comparative Legislative Tables*, National Health Reform Law and Policy Project, George Washington University, School of Public Health and Health Services, Department of Health Policy, available at: <http://www.gwumc.edu/sphhs/departments/healthpolicy/healthReform/Tables.cfm>.

HealthReform GPS, George Washington University Hirsch Health Law and Policy Program and the Robert Wood Johnson Foundation, available at www.healthreformgps.org.

3. Compared the Act to existing Federal initiatives, including: 1) the Vaccines for Children (VFC) program; 2) Section 317 of the Public Health Service Act; 3) Medicaid; and 4) Medicare; and
4. Analyzed the elements of the Act in relation to NVAC recommendations.
5. Developed recommendations for NVPO to consider during the implementation of the Act.

PRESENTATION OF FINDINGS

This report is organized as follows: 1) Private Health Insurance and Group Health Benefit Plans; 2) State Regulated Plans Sold in Exchanges; 3) Community Health Centers; 4) Medicaid/CHIP; 5) Medicare; 6) Health Care Quality and Innovation; 7) Federal Funding for Vaccine Programs; 8) Population Health and Prevention Initiatives; 9) Research; 10) School-Based Health Centers; 11) Supporting the Health Workforce; and 12) Implementation Recommendations.

The report also includes four appendices as follows: Appendix I: Excerpts from the Affordable Care Act and existing Federal laws; Appendix II: Interim Final and Proposed Regulations; Appendix III: Implementation Timeline, and Appendix IV: Interaction between Health Reform and NVAC Vaccine Financing Recommendations.

Within each section of this report, analysts provide an overview of the pre-health reform environment, highlight changes required by the Affordable Care Act, discuss implications for immunization policy and practice, and assess how the NVAC recommendations are addressed. The analysis concludes with recommendations for implementing vaccine-related changes under health reform.

In several instances, the Act references immunizations explicitly. However, vaccination services may be implied through provisions discussing preventive, primary care, and pediatric services and “well-child care”. Because these areas reflect potential opportunities for advancing vaccine policy, they have been included in this report.

¹² The Kaiser Family Foundation Health Reform Gateway, available at: <http://healthreform.kff.org/>.

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

Background

Historically, states regulated private health insurance under the McCarran Ferguson Act of 1945.¹³ The enactment of the Employee Retirement Income Security Act (ERISA), in 1974, established additional Federal standards for employer-sponsored group health benefit plans, whether offered by employers on a self-insured basis or through the purchase of state-regulated health insurance.¹⁴ ERISA preempts most state laws that relate to employee health benefit plans, while “saving” state laws that regulate insurance. Thus, state laws govern ERISA health benefit plans that purchase insurance. State laws do not control those ERISA plans that self-insure.

When health reform was enacted, employer-sponsored group health benefit plans covered approximately 176 million persons. The large group market, predominantly self-insured, covered 133 million individuals, representing 55 percent of the workforce.¹⁵ Self-insured plans typically contract with plan administrators but retain fiduciary powers over coverage decisions.

Forty-three million Americans were covered in the small group market, under state-regulated group insurance. Employers that purchase insurance products, rather than self-insure, transfer both administrative and fiduciary obligations to insurers.

Finally, approximately 17 million Americans secured coverage through the direct purchase of individual insurance plans.¹⁶ Table 1 compares fully-insured and self-insured ERISA plan coverage arrangements.

¹³ 59 Stat. 33, 15 U.S.C. 1011 et seq. (March 9, 1945).

¹⁴ Pub. L. 93-406, 29 U.S.C. 1001 et seq. (September 2, 1974).

¹⁵ *Health Plan Differences: Fully-Insured vs. Self-Insured, Fast Facts*, Employee Benefit Research Institute, February 2009, available at: <http://www.ebri.org/pdf/FFE114.11Feb09.Final.pdf>.

¹⁶ *Id.*

Table 1. Comparison of Insured and Self-Insured Group Health Care Plans		
CHARACTERISTIC	GROUP HEALTH PLANS	
	INSURED	SELF-INSURED
Category of Employer	Primarily small employers	Primarily large employers (>100 employees)
How Health Coverage is Financed	Through annual premiums paid to state-licensed health insurers	Self-funded plans with contracts to plan administrators ^{17,18}
Plan Design	Purchase available products	May be the same products sold on an insured basis; also may include tailored benefit and coverage rules
Assumption of Risk	Health insurer ¹⁹	Employer ²⁰
Plan Administration	Health insurer	Employer may administer directly or may contract with a third party administrator (frequently companies that also sell state-licensed insurance products)
Subject to State Laws	Insurance products sold to employers are subject to state laws that regulate insurance	State insurance laws are preempted in the case of self-insured plans, which are not considered to be insurance for purposes of state law regulation under the Employee Retirement Income Security Act of 1974 (ERISA) ²¹
Source: <i>The Affordable Care Act: U.S. Vaccine Policy and Practice</i> , GW Department of Health Policy (Fall, 2010); Employee Benefit Research Institute (2010), http://www.ebri.org		

Changes Made by Health Reform

The Act establishes new Federal standards for state-regulated private health insurance products sold in the individual and group health markets. Many of these standards are also extended to self-insured ERISA group health plans.

“Grandfathered” plans: The Act grandfathers state regulated health insurance coverage sold in the individual and group markets, as well as self-insured group health benefit plans.²² Implementing Federal regulations issued on June 17, 2010, establish standards for determining when grandfathering status is forfeited.

Plans may implement routine changes without losing grandfathered status, including: 1) cost adjustments to keep pace with medical inflation; 2) adding new benefits; 3) making modest adjustments to existing benefits; 4) voluntarily adopting consumer protections under the new law; and 5) making changes to comply with state or other Federal requirements. Premium changes are not considered when determining whether a plan is grandfathered.²³

Plans that implement significant changes will forfeit grandfathered status, including: 1) reducing or eliminating existing coverage; 2) increasing deductibles or co-payments by more

¹⁷ Some purchase stop-loss coverage to shield the company from the risks

¹⁸ *Health Plan Differences: Fully-Insured vs. Self-Insured, Fast Facts*, Employee Benefit Research Institute, February 2009, available at: <http://www.ebri.org/pdf/FFE114.11Feb09.Final.pdf>.

¹⁹ *Id.*

²⁰ Sufficient numbers of employees to allow formation of company-specific risk pools.

²¹ 42 U.S.C. 1003(b); Mitchell J. Nathanson, *et al. Litigation and Regulatory Issues Affecting Managed Care*, Treatise on Health Care Law sec. 8A.03, 1 (2010).

²² Title I, Subtitle C, Sec. 1251.

²³ *Id.*

than the rate of medical inflation plus 15 percent; 3) requiring consumers to switch to another grandfathered plan with fewer benefits or higher cost sharing to avoid new consumer protections; or 4) being acquired by or merging with another plan to avoid complying with the law.²⁴

In 2011, more than half of all plans are expected to be granted grandfathered status. However, over several years, approximately one-third of all plans will retain grandfathered status as a result of plan administrators' decisions.²⁵ Small plans are more likely to make substantial changes to cost sharing and benefit design than large plans.²⁶ As a result, small plans are expected to lose grandfathered status before large plans.

By 2014, remaining grandfathered plans will be considered to provide "minimum essential coverage" for purposes of the individual coverage mandate.²⁷

Preventive Services: For plan years beginning on or after September 23, 2010, non-grandfathered private insurers will be required to cover preventive services and immunizations recommended by the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee for Immunization Practice (ACIP), and the Health Resources and Services Administration (HRSA) without cost-sharing.²⁸

Insurers must implement recommendations related to preventive services for plan years beginning one year after the recommendation is adopted by the CDC.²⁹ With regard to effective dates of ACIP recommendations, "a recommendation or guideline of the Advisory Committee is considered to be issued on the date on which it is adopted by the Director of the CDC."³⁰

Plan Discretion to Cover Out-of-Network Services: No plan will be required to cover recommended immunizations and preventive services delivered to an enrollee by an out-of-network provider. However, plans that do permit out-of-network coverage of immunizations and preventive services will be allowed to implement out-of-network cost-sharing standards.³¹

Adult Children: For plan years beginning on or after September 23, 2010, private insurers, including grandfathered plans, must provide coverage for adult children (up to age 26) who do not have employer-based coverage.^{32,33} Effective January 1, 2014, grandfathered plans

²⁴ Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act; Interim Final Rule and Proposed Rule, 75 Fed. Reg. 34,538 at 34,543 (June 17, 2010) (to be codified at 26 CFR Parts 54 and 602; 29 CFR Part 2590; and 45 CFR Part 147).

²⁵ *Fact Sheet: Keeping the Health Plan you Have: The Affordable Care Act and "Grandfathered" Health Plans*, US Department of Health and Human Services, available at: http://www.healthreform.gov/newsroom/keeping_the_health_plan_you_have.html.

²⁶ *Id.*

²⁷ Title I, Subtitle F, Sec. 1501.

²⁸ Title I, Subtitle A, Sec. 1001 (amending PHS Act by adding sections 2713, 2714, and 2717).

²⁹ Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41,726 at 41,728 (July 19, 2010) (to be codified at 26 CFR Part 54; 29 CFR Part 2590; and 45 CFR Part 147).

³⁰ *Id.* at 41,729.

³¹ *Id.* at 41,728.

³² Title I, Subtitle C, Sec. 1251

³³ HCERA, Title II, Subtitle B, Sec. 2301.

must provide coverage “without regard to whether an adult child is eligible to enroll in any other coverage.”³⁴ Table 2 provides an overview of the implementation dates for this change.

Table 2. Private Plans - Effective Dates for Coverage of Adult Children		
CONDITION	PRIVATE PLANS	GRANDFATHERED PLANS (GROUP OR INDIVIDUAL)
Contingent on Availability of Other Employer-Sponsored Health Plan	n/a	09/23/2010
Without Consideration of other available coverage	09/23/2010	01/01/2014
Source: <i>The Affordable Care Act: U.S. Vaccine Policy and Practice</i> , GW Department of Health Policy (Fall, 2010); Grandfathered Plans and Preventive Services Regulations, 75 Fed. Reg. 34,358 and 75 Fed. Reg. 27,122.		

Employee Wellness Programs: Established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA),³⁵ employee wellness programs are designed to encourage participation in activities that promote healthy lifestyles and lower health care costs for employers.

Pre-health reform, health insurers that offered this product could discount premiums or provide rebates for employees who participated in wellness activities. Copayments and deductibles could be modified for participating beneficiaries. These incentives could equal 20 percent of the cost of coverage. However, insurers were prohibited from charging different premiums to beneficiaries based on health status or outcome.

The Act expands incentives for employee wellness programs. Under certain circumstances, employers may tie premiums to actual health outcomes and incentivize the development of wellness programs through employers³⁶ and state exchanges.³⁷

The Secretary and CDC Director must conduct a national survey of worksite wellness programs. The CDC Director must provide employers with technical assistance, consultation and resources to evaluate employer-based wellness programs.³⁸ Additionally, the Department of Labor may increase employee incentives from 20 percent to 50 percent.³⁹

The Secretary is required to evaluate and report to Congress regarding the effectiveness of existing Federal wellness programs, focusing on absenteeism, productivity, rate of injury,

³⁴ Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act; Interim Final Rule and Proposed Rule, 75 Fed. Reg. 34,538 at 34,559 (June 17, 2010) (to be codified at 26 CFR Parts 54 and 602; 29 CFR Part 2590; and 45 CFR Part 147).

³⁵ Health Insurance Portability and Accountability Act of 1996, P.L. 104-191 (Aug. 21, 1996).

³⁶ Title X, Subtitle D, Sec. 10408.

³⁷ Title I, Subtitle C, Sec. 1201 (4).

³⁸ Title IV, Subtitle D, Sec. 4303.

³⁹ Title I, Subtitle C, Sec. 1201(4).

employee medical costs and health conditions, and incentives provided through the Federal Employee Health Benefits Program.⁴⁰

As of July 1, 2014, the Secretary in consultation with the Secretaries of Treasury and Labor, will establish a ten-state demonstration project for states to offer similar rewards to the individual insurance market, as are offered in group insurance plans. If the demonstrations are effective, they will be expanded in 2017.⁴¹

Implications for Immunization Practice under Private Insurance and Group Health Plan Reforms

Reforms effective before 2014 will facilitate access to immunizations for more than 190 million privately-insured Americans. However, plans that maintain their grandfathered status (primarily large group plans) will not be required to cover immunizations. However, there is at least anecdotal evidence suggesting that large plans (both self-insured and fully-insured) may be moving toward coverage of preventive services without cost sharing. However, it is unknown whether coverage will include all ACIP-recommended vaccines.

Small employer-sponsored group health plans and individually purchased coverage may lose grandfathered status more rapidly. These plans are more likely to institute steeper price increases, shift escalating costs to participants, decrease coverage, and increase cost sharing. Thus, the preventive benefit requirement may be more quickly realized in the small group and individual markets.

⁴⁰ Title IV, Subtitle E, Sec. 4402.

⁴¹ Title I, Subtitle C, Sec. 1201 (4).

Interaction with NVAC-VFWG Recommendations

NVAC recommendations related to changes under health reform and private insurance interact as follows:

Recommendation 11

Health insurers and all private healthcare purchasers should adopt contract benefit language that is flexible enough to permit coverage and reimbursement for new or recently altered ACIP recommendations as well as vaccine price changes that occur in the middle of a contract period.

The Affordable Care Act requires group health plans and health insurance sold in the individual and group markets to extend coverage for ACIP-recommended vaccines. (Exemption for grandfathered plans)

The Affordable Care Act mandates coverage of “essential health benefits” including preventive benefits by insurers operating in the individual and small group markets (under 100 employees)

Recommendation 12

All public and private health insurance plans should voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents.

The Affordable Care Act specifies first-dollar coverage for all ACIP-recommended vaccines and their administration.

Recommendation 18

CDC should substantially decrease the time from creation to official publication of ACIP recommendations in order to expedite coverage decisions by payers to cover new vaccines and new indications for vaccines currently available.

ACA implementing regulations permit a delay in coverage of ACIP-recommended vaccines.⁴² HHS has outlined how plans can determine whether a recommendation has been adopted.

⁴² *Id.*

STATE-REGULATED HEALTH INSURANCE SOLD IN THE INDIVIDUAL AND SMALL GROUP MARKETS: Essential Health Benefits, Qualified Health Plans, State Health Insurance Exchanges

Background

Health insurance exchanges are derived from the 1970s concept of “managed competition.” Over the last twenty years, exchanges have been referred to as purchasing cooperatives, health alliances and connectors.⁴³ The “health alliance” was a key element in the Clinton Health Security Act of 1993.

During the 1990s, several states encouraged health insurance purchasing cooperatives. However, these cooperatives usually covered a small portion of the market, and often failed to produce cost savings. Insurers who retained the option to sell outside of the exchange found these arrangements unattractive because they included higher-risk individuals and did not reduce administrative costs. However, the Federal Employees Health Benefits Program (FEHBP) and the Massachusetts Connector are often recognized as successful exchanges.⁴⁴

Advantages to implementing an exchange model include: creation of a large risk pool, cost savings related to administration, and increased consumer influence. Exchanges established under health reform have the potential to extend these benefits to the small group and individual market.⁴⁵

Changes under Health Reform

The Affordable Care Act establishes market standards for state regulated health insurance products sold in the individual and group markets, regardless of whether products are sold through an exchange or on the open market. Among these standards is coverage of preventive services without cost sharing.

The Act requires that all state licensed health insurance products sold in the individual or small group markets cover essential health benefits, including preventive services. Separate state benefit mandates may continue to apply to health insurance products sold in state exchanges. However, states will be responsible for 100 percent of the cost of the premium increment reflecting these benefits. The extent to which state benefit mandates actually exceed the essential health benefit requirements of the Affordable Care Act is unknown.

The Act requires states to establish state health insurance exchanges. Employees of small employers, (firms with 100 or fewer employees) and individuals will be permitted to purchase health insurance through the exchanges. Until 2016, states will have the option to define small

⁴³ Jost, T. S. *Health Insurance Exchanges and the Affordable Care Act: Key Policy Issues*, The Commonwealth Fund, July 2010.

⁴⁴ Jost, T. S. *Health Insurance Exchanges in Health Care Reform: Legal and Policy Issues*, The Commonwealth Fund, December 2009.

⁴⁵ Jost, T. S. *Health Insurance Exchanges and the Affordable Care Act: Key Policy Issues*, The Commonwealth Fund, July 2010.

businesses as those with 50 or fewer employees.⁴⁶ Additionally, small employers will be permitted to purchase health plans through the exchanges. Individuals and families with low and moderate income will be able to secure subsidies.

Exchanges will certify products as “qualified health plans” that offer essential health benefits, meet quality, access, and disclosure requirements, and assist individuals and groups to enroll.⁴⁷ Consumers will be able to review and compare plan features including: covered services, premiums, co-pays and deductibles, and annual limits on out-of-pocket expenses.

The Act specifies that exchanges must offer four levels of qualified health plans, characterized by varying cost-sharing levels:⁴⁸ platinum, gold, silver and bronze.⁴⁹ Each level of coverage must include the “essential health benefits package,” (EHBP), a predetermined set of services, including: 1) ambulatory patient services; 2) maternity and newborn care; 3) prescription drugs; 4) preventive⁵⁰ and wellness services and chronic disease management; and 5) pediatric services. Preventive services must include ACIP-recommended immunizations without cost sharing.⁵¹

Once a preventive service is recommended by the U.S. government, exchange plans must cover the service in plan years beginning one year after the issuance of the recommendation.⁵² With regard to effective dates of ACIP recommendations, “a recommendation or guideline of the Advisory Committee is considered to be issued on the date on which it is adopted by the Director of the CDC.”⁵³

States have the option under the Act to establish exchanges on a regional or sub-state basis, or may opt out entirely in favor of a federally administered system. As of January 2013, the Secretary is directed to determine how many states will establish state exchanges and whether a federally administered exchange system will be required.

Implications for Immunization Practice under Exchange Reforms

State regulated insurance products sold in the individual and group markets and not subject to grandfathering will be required to cover ACIP recommended immunizations regardless of whether sold inside or outside exchanges. In addition, exchange-certified qualified health plans will be required to meet network adequacy, quality performance, and disclosure requirements.

⁴⁶ Title I, Subtitle D, Sec. 1304.

⁴⁷ PPACA §1311.

⁴⁸ *Id.*

⁴⁹ Title I, Subtitle D, Sec. 1302.

⁵⁰ Title IV, Subtitle B, Sec. 4106 (describing “preventive services” to include the “approved vaccines recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) and their administration”).

⁵¹ Title I, Subtitle D, Sec. 1302.

⁵² Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41,726 at 41,728 (July 19, 2010) (to be codified at 26 CFR Part 54; 29 CFR Part 2590; and 45 CFR Part 147).

⁵³ *Id.* at 41,729.

Interaction with NVAC-VFWG Recommendations

NVAC recommendations related to changes under health reform and exchange plans interact as follows:

Recommendation 12

All public and private health insurance plans should voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents.

The Affordable Care Act requires state regulated health insurance products, whether sold through exchanges as certified health plans or on the open market, to cover ACIP recommended immunizations.

Recommendation 18

CDC should substantially decrease the time from creation to official publication of ACIP recommendations in order to expedite coverage decisions by payers to cover new vaccines and new indications for vaccines currently available.

Interim final regulations issued in 2010 require coverage of ACIP-recommended vaccines⁵⁴ and specify a grandfathering test.⁵⁵ HHS has outlined how plans can determine whether a recommendation has been adopted.

⁵⁴ Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41,726 (July 19, 2010) (to be codified at 26 CFR Part 54; 29 CFR Part 2590; and 45 CFR Part 147).

⁵⁵ Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act; Interim Final Rule and Proposed Rule, 75 Fed. Reg. 34,538 at 34,559 (June 17, 2010) (to be codified at 26 CFR Parts 54 and 602; 29 CFR Part 2590; and 45 CFR Part 147).

MEDICAID AND THE CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP)

Background

In 2007, Medicaid, the nation's largest health insurance program, provided coverage to more than 46 million low-income and uninsured Americans.⁵⁶ Each state administers its Medicaid program in accordance with broad Federal standards governing eligibility, benefits and coverage, provider certification and payment, and plan administration.⁵⁷ As a companion of Medicaid, the Children's Health Insurance Program (CHIP), covers more than 7 million "qualified low-income" children who are ineligible for Medicaid.⁵⁸

Traditionally eligibility has depended on both categorical and financial factors. Unlike separately administered CHIP programs, Medicaid is a legal entitlement and states cannot use waiting lists.⁵⁹

The Federal government and the states jointly finance Medicaid, with Federal payments for medical assistance benefits and services varying between 50 percent and 83 percent of total medical assistance costs, and separate Federal financial participation rates for administrative costs.⁶⁰

Childhood immunizations are a required benefit under both Medicaid and CHIP. Under Medicaid, immunizations are furnished as part of the Vaccines for Children Program (VFC), which provides 100 percent Federal financing for the cost of vaccines and also distributes vaccines to enrolled providers.

Immunization coverage for adults is a state option. A 2003 review of Medicaid immunization coverage of non-institutionalized adults showed that 32 states reported *full coverage* for adult immunizations according to ACIP standards.⁶¹ Of these 32 states, only Michigan and Ohio required programs to follow ACIP recommendations.

States may impose immunization copayments for adult immunizations. Payments range from a low of \$0.50 up to \$6.00, with most states charging between \$1.00 and \$3.00. Twenty-seven states require copayments and 20 states do not indicate cost sharing.⁶²

⁵⁶ *Medicaid: A Primer, 2010*, Kaiser Family Foundation, The Kaiser Commission on Medicaid and the Uninsured, p 10, available at: <http://www.kff.org/medicaid/7334.cfm>.

⁵⁷ *The Medicaid Program at a Glance*, Kaiser Family Foundation, Kaiser Commission on Medicaid Facts, November 2008, available at: <http://www.kff.org/medicaid/7235.cfm>.

⁵⁸ *Medicaid: A Primer, 2010*, Kaiser Family Foundation, The Kaiser Commission on Medicaid and the Uninsured, p 10, available at: <http://www.kff.org/medicaid/7334.cfm>.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ Rosenbaum, S. et al. *The Epidemiology of U.S. Immunization Law: Medicaid Coverage of Immunizations for Non-Institutionalized Adults*, GW Department of Health Policy, November 2003, available at <http://www.gwhealthpolicy.org>.

⁶² *Id.*

Changes under Health Reform

The Act mandates Medicaid eligibility for all persons with family incomes under 133 percent of the Federal poverty level (FPL)⁶³ thereby eliminating the categorical restrictions on coverage of the poor that have characterized the program. The mandatory expansions take effect January 1, 2014. The law also gives states the option of extending coverage of all low income persons at an earlier date.⁶⁴

States are required to extend “benchmark” coverage to newly eligible enrollees,⁶⁵ including all early and periodic screening diagnosis and treatment benefits (EPSDT) for individuals under 21, and preventive benefits for adults, including immunization services. For those enrollees who were eligible for Medicaid before health reform, immunizations remain an optional benefit.

Beginning January 1, 2013, states that elect to cover ACIP-recommended adult immunizations and their administration costs while prohibiting cost-sharing, will receive a 1 percent increased FMAP for vaccination services.⁶⁶

The Act also requires states to pay for primary care physician services at levels equal to at least 100 percent of Medicare Part B payment rates in 2013 and 2014.⁶⁷ Providers who are eligible to receive the increased payment rate include physicians with a primary specialty designation of family medicine, general internal medicine or pediatric medicine.⁶⁸ Primary care services include services related to immunization administration for vaccines and toxoids.⁶⁹ Federal funding will be available to pay 100-percent of the difference between existing state payment rates and the Medicare payment rate.⁷⁰

Implications for Immunization Practice under Medicaid Reforms

The Medicaid coverage expansions for low-income adults will result in increased coverage for immunizations for newly eligible enrollees. However, for enrollees who are in traditional eligibility categories, immunizations remain a state coverage option.

⁶³ In 2010, 133% of Federal Poverty Level was \$14,404 for an individual and \$29,327 for a family of four. *2010 Poverty Guidelines*, Center for Medicaid and Medicare Services, available at: <https://www.cms.gov/MedicaidEligibility/downloads/POV10Combo.pdf>

⁶⁴ Title II, Subtitle A, Sec. 2001.

⁶⁵ Section 1937 of the Social Security Act (defining benchmark coverage as: the standard Blue Cross/Blue Shield PPO plan; state employee coverage; coverage through HMOs; or secretary approved coverage. Benchmark equivalent coverage includes well-baby and well-child care, including age-appropriate immunizations; and other appropriate preventive services designated so by the Secretary of HHS).

⁶⁶ Title IV, Subtitle B, Sec. 4106.

⁶⁷ HCERA, Title I, Subtitle C, Sec. 1202.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

The Act will increase immunization payment rates for vaccines provided by physicians who specialize in family, general internal, or pediatric medicine as part of primary care physician services.

Additionally, incentives for immunization coverage may impact the quality of Medicaid coverage. Since most states already cover at least some adult immunizations, health reform may provide sufficient incentives for most states to add full coverage without cost sharing.

Interaction with NVAC-VFWG Recommendations

NVAC recommendations related to changes under health reform and Medicaid interact as follows:

Recommendation 5

Proposes an increase in the Federal match for vaccine administration reimbursement in Medicaid to levels for other services of public health importance (e.g. family planning services)

The ACA creates a 1% FMAP incentive to cover ACIP-recommended vaccines for the poorest traditional Medicaid adult beneficiaries without cost-sharing. Enhanced payments for Medicaid physician primary care services during 2013 and 2014 should aid payment rates for immunization services.

Recommendation 12

Indicates that all public and private health insurance plans should voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents

The ACA expands previous Medicaid and CHIP coverage of immunizations for children to include immunizations without cost-sharing for newly eligible adults. Immunizations for traditionally eligible adults remain an optional benefit, with enhanced cost-sharing as an incentive to improve coverage..⁷¹

⁷¹ *Deficit Reduction Act Important Facts for State Policymakers*, Centers for Medicare and Medicaid Services, February 21, 2008, available at: www.cms.gov/DeficitReductionAct/Downloads/Costsharing.pdf.

MEDICARE

Background

As of 2010, Medicare insured 47 million individuals, including 39 million persons ages 65 and over and 8 million non-elderly adults with disabilities.⁷² United States citizens and permanent legal residents who qualify for Social Security gain Medicare eligibility on their 65th birthday, regardless of income or health status.⁷³ Adults with disabilities are eligible if they have received Social Security Disability Insurance (SSDI) payments for 24 months.⁷⁴ Medicare also covers all persons of any age with end stage renal disease (ESRD).

Financed through trust fund payments, general revenues and individual contributions, Medicare consists of four parts. Part A covers inpatient hospital services, skilled nursing facility, home health, and hospice care. Part B covers physician, outpatient, home health, medically related diagnostic and treatment services, and certain preventive services. Part C establishes the Medicare Advantage program, and Part D offers voluntary coverage of prescription drug plans, including vaccines not covered by Part B.⁷⁵ Approximately 28 million beneficiaries are enrolled in a Part D prescription drug plan. Sixty percent of those enrolled are in stand-alone plans.⁷⁶

Part B limits vaccine coverage to: 1) pneumococcal (once per lifetime); 2) Hepatitis B (risk-based); and 3) influenza (annually).⁷⁷ CMS has directed all Part D plans to cover all vaccines that are not covered under Part B.⁷⁸ Part B covers immunization administration fees for both Part B and Part D vaccines. No coinsurance payments are required for either the influenza or pneumococcal vaccines. A 20-percent coinsurance is applied to the Hepatitis B vaccine after the annual Part B deductible (\$155) is satisfied.⁷⁹

Medicare Changes under Health Reform

The health care reform law makes the following changes: 1) establishes coverage for additional preventive benefits; 2) alters reimbursement policy for Part B-covered immunizations furnished by hospital outpatient departments; 3) creates new research options related to beneficiary access to immunizations; and 4) expands coverage of prescription drug and prevention benefits.

⁷² *Medicare: A Primer 2010*, Kaiser Family Foundation, available at: <http://www.kff.org/medicare/7615.cfm>.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Medicare Part D Spotlight: Part D Plan Availability in 2011 and Key Changes Since 2006*, Kaiser Family Foundation, October 2010, available at: <http://www.kff.org/medicare/8107.cfm>.

⁷⁷ *Medicare: A Primer 2010*, Kaiser Family Foundation, available at: <http://www.kff.org/medicare/7615.cfm>.

⁷⁸ *Reimbursement for Vaccines and Vaccine Administration under Medicare Part D*, Centers for Medicaid and Medicare Services, available at: www.cms.hhs.gov/MLNMArticles/downloads/SE0727.pdf.

⁷⁹ *Id.*

New Prevention Benefits: Effective January 1, 2011, all beneficiaries will be entitled to annual wellness visits and will receive comprehensive health risk assessments that include the development of personalized prevention plans (PPP). The PPP will include a 5 to 10-year screening schedule; a list of identified risk factors and conditions, and a strategy to address them; health advice; and referral to education and preventive counseling or community-based interventions to address modifiable risk factors. The PPP will incorporate USPSTF and ACIP recommendations.⁸⁰

Co-insurance/Deductible: Effective January 1, 2011, cost-sharing will be eliminated for personalized prevention plan services.⁸¹

Reimbursement for Preventive Services, Hospital Outpatient Department: Any preventive service furnished on or after January 1, 2011, by an outpatient department of a hospital, must be reimbursed at 100 percent.⁸² Preventive services include pneumococcal, influenza and Hepatitis B vaccines, initial preventive physical examinations, and personalized prevention plan services.⁸³

Coverage Modification: Effective January 1, 2010, the Secretary may modify coverage of any currently covered Medicare preventive service when the change is consistent with USPSTF recommendations and the services are not used for diagnosis or treatment. However, if immunizations are considered treatment, coverage policy related to prophylactic immunizations may not change.⁸⁴

Implications for Immunization Practice under Medicare Reforms

Medicare beneficiaries may have greater access to immunizations as a result of the increased reimbursement rate for Part B vaccines delivered in hospital outpatient departments.

While the Secretary has discretion to modify preventive services, as long as immunizations are considered treatment, they may not qualify under this provision.

Interaction with NVAC-VFWG Recommendations

There are no NVAC recommendations related to changes under health reform and Medicare.

⁸⁰ Title IV, Subtitle B, Sec. 4103.

⁸¹ *Id.*

⁸² Title IV, Subtitle B, Sec. 4104.

⁸³ *Id.*

⁸⁴ Title IV, Subtitle B, Sec. 4105.

HEALTH CARE QUALITY AND INNOVATION

Background

Pre-health reform, Federal and state governments had not engaged in a coordinated effort to strengthen the quality of care or achieve greater program integration for Medicaid and Medicare. The Center for Medicare and Medicaid Services (CMS) was authorized to allow Medicaid programs to develop limited innovative research and demonstration projects related to program design, administration,⁸⁵ payment, delivery systems, benefits, and coverage.⁸⁶

However, the Department of HHS was not permitted to test different Medicare service delivery and payment structures, including approaches that focus on the intersection between Medicare and Medicaid and individuals who are enrolled in both programs.

Dual Eligibility under Medicare and Medicaid

Nine million individuals are covered by both Medicare and Medicaid and are referred to as “dual eligibles”. These beneficiaries include those with the lowest income and the most complex medical conditions that result in the highest medical expenses.⁸⁷ Dual eligibles account for a disproportionate share of individuals who are under-65, have a disability, are Medicare beneficiaries, and are much more likely than others on Medicare to reside in nursing homes.⁸⁸

Nearly half of all Medicaid spending is directed towards care for dual eligibles, including: Medicare premiums, cost-sharing, and benefits not covered by Medicare, (long-term care, dental care, eyeglasses), Part D prescription drugs, and low-income subsidy programs.⁸⁹

Dual eligibles and their providers face significant barriers to receiving and providing appropriate and timely care. The two programs have different rules and financing incentives, which complicates care coordination and can result in cost-shifting between the programs.

Changes under Health Reform

Provisions that address health care quality and innovation are intended to improve health outcomes and service delivery, coordinate care, prevent hospital readmissions, improve patient safety, and promote wellness and health.

⁸⁵ Section 1115(a) of the Social Security Act (42 USC 1415).

⁸⁶ Section 1915 of the Social Security Act (42 USC 1396n).

⁸⁷ Health Reform Opportunities: Improving Policy for Dual Eligibles, Focus on Health Reform, Kaiser Family Foundation, (August 2009).

⁸⁸ *Dual Eligibles: Medicaid's Role for Low-Income Medicare Beneficiaries*, Medicaid and the Uninsured, Kaiser Family Foundation, Kaiser Commission on Medicaid Facts, February 2009, available at: www.kff.org/medicaid/upload/4091_06.pdf

⁸⁹ *Id.*

Ensuring Quality Care under Medicaid/Medicare: The Act requires CMS to create and oversee a new Center for Medicare and Medicaid Innovation (CMI). CMI must be operational by January 1, 2011, and has been allocated \$10 billion from 2011 to 2019 and \$5 million for the “design, implementation, and evaluation of models”.⁹⁰

The Secretary has been granted broad authority to implement the CMI without the possibility for either administrative or judicial review. After consultation with states, Federal agencies, and clinical and analytical experts in medicine and health care management, the CMI will test innovative service delivery and payment models that have the potential to reduce costs while preserving or enhancing health care quality for Medicare and Medicaid enrollees and dual eligibles.⁹¹ Preference will be given to models that could improve the coordination, quality, and efficiency of health care services and may be limited to particular geographic areas.⁹²

The Secretary will select from 20 models identified in the law. The goals of the models include: increasing the use of: 1) medical homes; 2) community-based health teams; 3) new provider payment methodologies; 4) health information technology; 5) non-health professionals to support patients; 6) medication therapy management services; 7) assisting beneficiaries in making informed health care choices; and 8) collaboratives of health care institutions to design and implement best practices.⁹³

The Secretary will be required to evaluate how each model impacts the quality of care and spending under Medicare and Medicaid. If the Secretary and the Chief Actuary of CMS determine that the model fails to achieve quality improvement and reduction of spending, the model may be terminated or modified.⁹⁴ Based upon the results of the evaluations, the Secretary may expand the models nationwide, without regard to existing administrative requirements.

Clinical Effectiveness Research: Clinical effectiveness research (CER) informs clinicians and patients about the best options for patient care. In 2009, the Federal Coordinating Council (FCC) was established to develop recommendations related to Federal CER initiatives.⁹⁵

In 2009, the Institute of Medicine (IOM) broadened the definition of CER to include alternative strategies that reflect population and community interventions. Additionally, 100 “initial priority topics” were identified, including three that may be applicable to vaccine policy and practice. These include comparisons of different strategies related to: 1) quality improvement and disease prevention, 2) engagement and retention of patients in care and the delineation of barriers to care for members of populations who experience health disparities, and 3) techniques to educate patients about proposed treatments during the process of informed consent.⁹⁶

⁹⁰ Title III, Subtitle A, Sec. 3021 and Title X, Subtitle C, Sec. 10306.

⁹¹ Title III, Subtitle A, Sec. 3021.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ Lopez, N. and Thorpe, J., *Comparative Clinical Effectiveness Research, Health Reform GPS: Navigating the Implementation Process/Comparative Clinical Effectiveness*, GW Department of Health Policy, (2010), available at: <http://www.healthreformgps.org/resources/comparative-clinical-effectiveness-research/>.

⁹⁶ *Id.*

The Patient-Centered Outcomes Research Institute: The Act establishes a new non-governmental, nonprofit corporation. The Patient-Centered Outcomes Research Institute (Institute) will evaluate and compare health outcomes and the clinical effectiveness, risk, and benefits of two or more medical treatments, services, and items.^{97,98} The Institute will identify national priorities for research and conduct, support, and synthesize comparative effectiveness research. Findings may be used to guide coverage and payment. However, the Secretary may not use the Institute’s findings to mandate, supersede or modify coverage, reimbursement or other policies for any public or private payer”.⁹⁹

The Institute will disseminate the research results to the general public, patients, clinicians, purchasers, and policymakers who could use the findings to make informed health care decisions. The Institute will be directed by a Board of Governors consisting of the Director of the Agency for Healthcare Research and Quality (AHRQ), the Director of the National Institutes of Health (NIH), and 17 members appointed by the Comptroller General who will represent patients, providers, drug and device manufacturers, private health insurers, health services researchers, experts in quality improvement, and Federal and state government officials.¹⁰⁰

The new Patient-Centered Outcomes Research Trust Fund (PCORTF) will finance the Institute. Funding levels for the PCORTF have been specified by fiscal year (FY) through September 30, 2019. These funds will be made available to HHS, AHRQ, and NIH to support the dissemination of Institute research findings.¹⁰¹

Funding has been appropriated as follows: FY 2010, \$10,000,000; FY 2011, \$50,000,000; and FY 2012, \$150,000,000. For FY 2013, \$150,000,000, fees on health insurance and self-insured plans, and an amount equal to \$1 multiplied by the average number of individuals entitled to benefits under Medicare Part A or enrolled under Part B. For FYs 2014 through 2019, \$150,000,000, fees on health insurance and self-insured plans, and an amount equal to \$2 multiplied by the average number of individuals entitled to benefits under Medicare Part A or enrolled under Part B.

Ensuring Quality Care, Private Insurers: The Act requires the Secretary, in consultation with experts in health care quality and other stakeholders, to develop requirements for insurers to report on their initiatives and programs that: 1) improve health outcomes by using care coordination and chronic disease management; 2) prevent hospital readmissions and improve patient safety, and 3) promote wellness and health.¹⁰²

⁹⁷ Title VI, Subtitle D, Sec. 6301.

⁹⁸ Medical treatments, services, and items include: health care interventions; protocols for treatment; care management; procedures; medical devices; diagnostic tools; pharmaceuticals (including drugs and biologicals); integrative health practices; and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in individuals. Title VI, subtitle D, sec. 6301(a).

⁹⁹ Title VI, Subtitle D, Sec. 6301.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² Title I, Subtitle A, Sec. 1001 (amending PHSA by adding sections 2713, 2714, and 2717).

National Strategy to Improve Health Care Quality: The Act requires the Secretary to establish and annually update a national strategy to improve the delivery of health care services, patient outcomes and population health. The strategy must address national priorities that improve: health outcomes, efficiency, comparative effectiveness information, payment policies, research, patient safety, health disparities, and patient centeredness of health care for all populations, and address other priorities as the Secretary deems appropriate.¹⁰³ The strategy must include:

- 1) Coordination among HHS agencies to minimize duplication of efforts and utilize common quality measures;
- 2) Agency-specific national plans to achieve priorities and establish annual benchmarks;
- 3) Regular reporting to the Secretary regarding implementation;
- 4) Strategies to align public and private payers regarding quality and patient safety efforts; and
- 5) Quality improvement and measurement for health information technology as required under ARRA.¹⁰⁴

The Secretary will submit a report describing the strategy and oversee a Federal health care quality website that must be launched by January 1, 2011. The website will feature: 1) national priorities for health care quality improvement; 2) agency-specific plans for health care quality, and; 3) additional information that the Secretary considers appropriate.¹⁰⁵

Implications for Immunization Practice under Health Quality and Innovation Reforms

Center for Medicare and Medicaid Innovation (CMI): Four models proposed under the new CMI could prove effective in promoting comprehensive immunization policy. These models would: 1) Permit providers to receive increased reimbursement for immunization services, 2) Permit providers to receive reimbursement for providing patient education related to vaccines, 3) Permit community vaccination programs to alleviate the burden of screening for and administration of routine vaccinations for small practices, and 4) Permit new categories of professionals to assess, prescribe and administer immunizations without authorization from a physician or other health professional.

Patient-Centered Outcomes Research Institute: The development of the national agenda for CER research provides an opportunity to highlight the value of community vaccination. The research agenda could incorporate various strategies to identify barriers to immunization for those who experience health disparities, and encourage the identification of tools to educate patients about immunizations.

¹⁰³ Title III, Subtitle A, Sec. 3011 (amending PHS A by adding section 399HH).

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

Private Quality Initiatives: Mandatory reporting on patient safety initiatives may encourage provider-organizations to require health care workers (HCWs) to receive all recommended vaccines, including annual influenza immunizations. HCWs who have direct contact¹⁰⁶ with patients represent the primary source of infectious disease outbreaks in healthcare facilities.¹⁰⁷ Studies show that high levels of staff vaccination protect patients, HCWs and their families from the complications of seasonal influenza.¹⁰⁸

National Strategy to Improve Health Care Quality: The development of a National Strategy provides an opportunity to prioritize immunization services as an intervention with significant potential to improve the health status of individual patients and communities. Emphasizing community immunization initiatives will also support efforts to reduce disparities and deliver quality care.

Interaction with NVAC-VFWG Recommendations

NVAC recommendations related to changes under health reform and health care quality and innovation do not address quality innovation in areas addressed by the Act.

¹⁰⁶ “Direct contact” refers to persons who, if they were injected with influenza, could transmit the disease to a patient, either through sharing a 6-foot space with a patient (person-to-person contact) or a surface that comes in contact with a patient (equipment-to-patient contact).

¹⁰⁷ Poland, G.A. *Requiring influenza vaccination for health care workers: seven truths we must accept*, 23 *Vaccine* 2251, 2251 (Jan. 2005).

¹⁰⁸ Larson, E.L. *et. al.*, *APIC Position Paper: Improving Healthcare Worker Influenza Immunization Rates*, 32 *Am. J. Infect. Control* 123, 123 (2004).

FEDERAL FUNDING FOR VACCINE PROGRAMS

Background

Immunization Grant Program (Section 317): Authorized under section 317 of the Public Health Service Act, the Immunization Grant Program is a discretionary program that provides funds for states (and U.S. territories) seeking to provide vaccines to children and adults who do not qualify for VFC.¹⁰⁹ The program currently supports 64 immunization programs including: all 50 states, the District of Columbia, five urban areas,¹¹⁰ the U.S. Territories, and selected Pacific Island nations.¹¹¹ States may also receive funding to improve vaccination operations and infrastructure.¹¹² Funding for the Section 317 program is contingent on annual appropriations.¹¹³

Vaccines for Children (VFC): The VFC is a Federal entitlement program that finances immunizations for eligible children who would otherwise be unable to afford them. Eligible children, under age 19, include: those who are Medicaid-eligible, American Indian, Alaska Native, uninsured, or underinsured children who receive immunizations at Federally Qualified Health Centers (FQHC) or Rural Health Clinics (RHCs).^{114,115}

Under the Program, the CDC purchases vaccines at discounted rates and distributes them to registered VFC providers.¹¹⁶ Eligible children include those who are Medicaid-eligible, uninsured, American Indian, Alaska Native, and underinsured who are served at FQHCs or RHCs are entitled to participate.

Changes under Health Reform

The law provides additional Federal funding to increase coverage for all age groups.

Section 317 Program: The Immunization Program in Section 317 of the Public Health Service Act was reauthorized.¹¹⁷ The U.S. House of Representatives has allocated approximately \$662 million for the 317 program for FY2011.¹¹⁸ This amount reflects an

¹⁰⁹ *Id.*

¹¹⁰ Chicago, New York City, Philadelphia, Houston, and San Antonio. *American Recovery and Reinvestment Act, Section 317 Funding*, US Department of Health and Human Services, 2009, available at: transparency.cit.nih.gov/RecoveryGrants/grant.cfm?grant=vaccines.

¹¹¹ *Centers for Disease Control and Prevention: Section 317 Immunization Program*, American Recovery and Reinvestment Act, Promoting Prevention and Wellness, Centers for Disease Control and Prevention, available at: <http://www.hhs.gov/recovery/programs/cdc/immunizationgrant.html>

¹¹² *Program in Brief: Immunization Grant Program (Section 317)*, Centers for Disease Control and Prevention, February 2007, available at: www.cdc.gov/ncird/progbriefs/downloads/grant-317.pdf.

¹¹³ *Id.*

¹¹⁴ Orenstein, W. *Vaccine Finance: An Overview of Stakeholder Input and NVAC Working Group Draft White Paper*, Presentation to the National Vaccine Program Office, July 24, 2008.

¹¹⁵ Children who are underinsured must access VFC through a Federally Qualified and Rural Health Centers (FQHCs/RHCs).

¹¹⁶ *Vaccines for Children Program (VFC), Programs and Tools*, Centers for Disease Control and Prevention, July 14, 2010, available at: <http://www.cdc.gov/vaccines/programs/vfc/default.htm>.

¹¹⁷ *Id.*

¹¹⁸ *Legislative Update*, 317 Coalition, August 2010, available at: <http://www.317coalition.org/legislativeupdate/>.

increase of over \$100 million from FY2010 to be provided from the Act's Prevention and Public Health Fund (PPHF). However, this appropriation for FY2011 amount has not been approved.¹¹⁹

Increasing State Purchasing Power: Effective March 23, 2010, states are permitted to purchase adult vaccines with state funds at CDC-negotiated rates.¹²⁰

Demonstration Program: Effective March 23, 2010, the Secretary and the Director of the CDC may award grants to states to improve the provision of recommended immunizations for children, adolescents and adults through the use of evidence-based and population-based interventions. Funds, if appropriated, may be used to implement interventions recommended by the Community Preventive Services Task Force such as recalls, reminders for patients or providers, or home visits.¹²¹

Vaccines for Children Program: The Act does not alter the VFC program.

¹¹⁹ As of August 25, 2010.

¹²⁰ Title IV, Subtitle C, Sec. 4204.

¹²¹ *Id.*

Implications for Immunization Practice under Reforms of Federal Funding of Vaccine Programs

The demonstration programs provide opportunities for states to implement a broad range of innovative initiatives relating to immunizations. Programs may incorporate assistance and education for consumers and providers. States could use the funds to develop comprehensive, sustainable immunization information systems or establish other projects to increase coverage among all populations.

It is unclear whether exchange plans will be able to benefit from CDC-negotiated rates. Exchange plans may be considered public/private partnerships. States have been authorized to develop and administer the plans, which may present an opportunity for exchanges to obtain discounted vaccines.

Interaction with NVAC-VFWG Recommendations

NVAC recommendations related to changes under health reform and Federal funding for vaccine programs interact as follows:

Immunization Grant Program

Recommendation 14

Congress should request an annual report on the CDC's professional judgment of the size and scope of the Section 317 program appropriation needed for vaccine purchase, vaccination infrastructure, and vaccine administration. Congress should ensure that Section 317 funding is provided at levels specified in CDC's annual report to Congress.

Recommendation 19

Congress should expand Section 317 funding to support the additional national, state and local public health infrastructure (e.g., widespread and effective education and promotion for healthcare providers, adolescents, and their parents; coordination of complementary and alternative venues for adolescent vaccinations; record keeping and immunization information systems; vaccine safety surveillance; disease surveillance) needed for adolescent vaccination programs as well as childhood vaccination programs for new recommendations such as universal influenza vaccination.

Health reform established the Prevention and Public Health Fund to invest in prevention programs. The 317 program has been authorized to receive an increase of over \$100 million from FY2010; however, this amount has not been approved.

Demonstration Projects

Recommendation 9

Medical providers, particularly in smaller practices, should participate in pools of vaccine purchasers to obtain volume ordering discounts. This may be done by individual providers joining or forming purchasing collaboratives, or through a regional vaccine purchasing contract held by professional medical organizations on behalf of providers.

The Secretary and the Director of the CDC may award grants to states to improve the provision of recommended immunizations for all age groups through the use of evidence-based and population-based interventions.

POPULATION HEALTH AND PREVENTION INITIATIVES

Background

Prior to health reform, the United States did not have a national strategy for prevention initiatives. Similarly, there was no national effort to coordinate community investment with clinical preventive care.¹²²

Changes under Health Reform

New Federal population health and prevention initiatives will foster collaboration between public and private partners to develop a national prevention and health promotion strategy.

National Prevention, Health Promotion and Public Health Council: The Act requires the Departments of Health and Human Services, Agriculture, Education, Labor, and Transportation to form an interagency council that will establish a national prevention and health promotion strategy. The Council will report annually to Congress on health promotion activities and progress toward meeting the goals of the national strategy. The first report is due March 23, 2011.¹²³

Prevention and Public Health Fund: The Act establishes the Fund to increase investment in prevention, wellness, immunizations and other public health programs or activities authorized by the Public Health Service Act.¹²⁴ The Secretary is required to administer the Fund that has been appropriated \$15 billion over 10 years: \$500 million in FY 2010; \$750 million in FY2011, \$1 billion in FY2012; \$1.25 billion in FY2013; \$1.5 billion in FY2014; and \$2 billion per year beginning in FY2015.¹²⁵

Clinical and Community Preventive Services: The Community Preventive Services Task Force will be created to improve the coordination between USPSTF and ACIP.¹²⁶ The Act pays particular attention to the interaction of the recommendations issued by these groups because they are implemented in clinics and communities. Unknown levels of funding have been appropriated for the Task Force.

Outreach: The Secretary must convene a public/private partnership to conduct national prevention and health promotion outreach and education campaigns. One of the goals is to describe the preventive measures supported by ACIP. Funding for this partnership cannot exceed \$500 million.¹²⁷

¹²² Rosenbaum, S., *Health Reform and Immunization Policy*, presentation to the Second Immunization Congress August 2010.

¹²³ Title IV, Subtitle D, Sec. 4001.

¹²⁴ Title IV, Subtitle D, Sec. 4002.

¹²⁵ *Id.*

¹²⁶ Title IV, Subtitle D, Sec. 4003.

¹²⁷ Title IV, Subtitle D, Sec. 4004.

Evaluation Activity: The Secretary will evaluate the effectiveness of existing Federal health and wellness initiatives, report to Congress on program performance, and assess the program's effect on the health and productivity of the Federal workforce.¹²⁸ The Act does not designate a funding mechanism for this evaluation.¹²⁹

Implications for Immunization Practice under Population Health and Prevention Initiatives

These new programs create opportunities for interagency collaboration and ensure that immunizations are identified as a core component of the national prevention strategy.

Interaction with NVAC-VFWG Recommendations

NVAC recommendations related to health reform and population health and prevention initiatives interact as follows:

Recommendation 8

Professional medical organizations should provide their members with technical assistance on efficient business practices associated with providing immunizations, such as how to contract and bill appropriately. Medical organizations should identify best business practices to assure efficient and appropriate use of ACIP recommended vaccines and appropriate use of CPT codes, including Evaluation and Management (E&M) codes, when submitting claims for vaccines and vaccine administration. These organizations may receive Federal assistance from CMS or other relevant agencies.

Education campaigns developed through the public/private partnerships could offer technical assistance to professional medical organizations on the best strategies to provide immunizations.

Recommendation 10

CDC, professional medical organizations, and other relevant stakeholders should develop and support additional employer health education efforts. These efforts should communicate the value of good preventive care including recommended vaccinations.

Public/private partnerships could participate in employer health education campaigns.

Recommendation 21

State, local and Federal governments along with professional organizations should conduct outreach to physicians and non-physician providers who currently serve VFC-eligible children and adolescents to encourage these providers to participate in VFC if they currently do not. Outreach directed at providers serving adolescents who may not have provided vaccinations in the past (e.g. obstetrician-gynecologists) is a particular priority.

The public/partnership could include promotional outreach to encourage providers to become registered VFC providers.

¹²⁸ Title IV, Subtitle E, Sec. 4402.

¹²⁹ *Id.*

RESEARCH

Background

Prior to health reform, various Federal authorities authorized research under Medicare, Medicaid, and Public Health Service Act programs.

Changes Made by Health Reform

Medicare: The Act authorized two studies related to whether and how Medicare beneficiaries access immunizations:

1. The Office of Inspector General (OIG) will compare prescription drug prices paid under Medicare Part D to those paid under state Medicaid programs.¹³⁰
2. The Government Accountability Office (GAO) will study the ability of Medicare beneficiaries to access recommended vaccines covered under the Medicare Part D program.¹³¹

Public Health Services and Systems: The Secretary, through the Director of the CDC, is required to fund research in the area of public health services and systems that will:¹³²

1. Examine evidence-based practices relating to prevention, with a particular focus on high priority areas identified in the National Prevention Strategy or Healthy People 2020,¹³³
2. Analyze the translation of interventions from academic to real world settings; and
3. Identify effective strategies for organizing, financing, or delivering public health services in community settings, including comparing effectiveness and cost of state and local health departments.

The research will be coordinated with the Community Preventive Services Task Force and carried out with existing Federal, state, local and private partnerships and initiatives. The Secretary will report findings to Congress annually.¹³⁴

¹³⁰ Title III, Subtitle D, Sec. 3313.

¹³¹ Title IV, Subtitle C, Sec. 4204.

¹³² Title IV, Subtitle D, Sec. 4301.

¹³³ *Immunization and Infection Diseases Objectives: Healthy People 2020*, US Department of Health and Human Services, October 30, 2009, available at: <http://www.healthypeople.gov/hp2020/Objectives/ViewProposedObjectives.aspx?id=30&TopicArea=Immunization+and+Infectious+Diseases>.

¹³⁴ Title IV, Subtitle D, Sec. 4301.

Implications for Immunization Practice under Research

The research outlined in this section will permit Federal policymakers to assess the current state of vaccine practice in several areas. The Medicare research will address long standing concerns related to immunization access and affordability. There are also opportunities for academic research to inform the standard of care by identifying best practice models.

Interaction with NVAC-VFWG Recommendations

NVAC recommendations related to changes under health reform and research interact as follows:

Recommendation 4

CMS should update the maximum allowable Medicaid administration reimbursement amounts for each state and include all appropriate non-vaccine related costs as determined by current studies. These efforts should be coordinated with the American Medical Association's (AMA) review of Relative Value Unit (RVU) coding (Recommendation #6).

The provisions commissioning the OIG study comparing prescription drug prices paid under Medicare Part D to those paid under Medicaid programs would provide current information relating to reimbursement amounts. It is unclear whether non-vaccine-related costs would be captured in the study.

Recommendation 6

AMA's RVS Update Committee (RUC) should review its RVU coding to ensure that it accurately reflects the non-vaccine costs of vaccination including the potential costs and savings from the use of combination vaccines.

The provisions related to public health services and systems studies offer a mechanism to fund research in this area.

Recommendation 7

Vaccine manufacturers and third-party vaccine distributors should work with providers on an individual basis to reduce the financial burden for initial and ongoing vaccine inventories, particularly for new vaccines. This may include extending payment periods (e.g. from 60 days to 90 or over 120 days), or until vaccine has been administered and reimbursed. It may also include options not related to payment terms for vaccine inventory.

The provisions related to public health services and systems studies offer a mechanism to fund research in this area.

Recommendation 13

Insurers and healthcare purchasers should develop reimbursement policies for vaccinations that are based on methodologically sound cost studies of efficient practices. These cost studies should factor in all costs associated with vaccine administration (including, for example, purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping).

Recommendation 15

CDC and CMS should continue to collect and publish data on the costs and reimbursements associated with public and private vaccine administration according to NVAC standards for vaccinating children and adolescents. These costs include costs associated with the delivery of vaccines, such as purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping. These published data should be updated every five years and also include information about reimbursement by provider type, geographic region, and insurance status. State governments should use this information in determining vaccine administration reimbursements rates in Medicaid.

Recommendation 16

NVPO should calculate the marginal increase in insurance premiums if insurance plans were to provide coverage for all routinely ACIP-recommended vaccines.

Recommendation 20

Continue Federal funding for cost-benefit studies of vaccinations targeted for children and adolescents.

The public health services and systems provisions of the Act permit research related to reimbursement.

COMMUNITY HEALTH CENTERS

Background

In 2008, 1,080 community health centers furnished comprehensive primary health care to more than 17 million patients.¹³⁵ By law, health centers must be located in or serve urban and rural communities designated as medically underserved as a result of population health status, a primary health care shortage, or both.¹³⁶ CHCs employ approximately 5,350 full-time clinicians, and 51,187 medical, dental, mental health, and substance abuse staff. The National Health Service Corps (NHSC) staffs CHCs and offers scholarships and loan repayment programs.¹³⁷

In 2009, CHCs administered 3.7 million non-influenza immunizations to 2.6 million patients. Approximately 3.3 million doses of seasonal and H1N1 influenza vaccines were administered to 2.9 million patients.¹³⁸

Changes to CHCs under Health Reform

Funding: The Affordable Care Act establishes the Community Health Center Fund¹³⁹ to expand CHCs, with funding appropriated during FY 2011-2015. The Fund will allocate \$9.5 billion to expand CHC operations and \$1.5 billion for CHC capital investment. In addition, the law provides \$1.5 billion for enhanced funding for the National Health Service Corps.¹⁴⁰

Workforce-Related Reforms: The Act appropriates \$1.5 billion for the National Health Service Corps for FY 2011-2015. Additionally, the Act establishes financing for “teaching health centers” in order to increase funding available for recruitment and training to support the primary care workforce.¹⁴¹

Delivery System Reforms: Community Health Centers will be eligible to participate in pilot and demonstration programs undertaken by the Center for Medicare and Medicaid Innovation (CMI) and other demonstration activities that emphasize comprehensive care, quality improvement, and health system transformation.

Implications for Immunization Practice under CHC Reforms

As a result of the significant investment in CHCs, the number of patients served is expected to double by 2019. This expansion offers an opportunity for collaboration among

¹³⁵ Rosenbaum, S. et. al., *Community Health Centers: Opportunities and Challenges of Health Reform*, Kaiser Family Foundation, August 2010, available at: <http://www.kff.org/uninsured/8098.cfm>.

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *2009 Uniform Data System*, Health Resources and Services Administration, available at: <http://www.hrsa.gov/data-statistics/health-center-data/index.html>, calculation by the George Washington University Medical Center, Department of Health Policy.

¹³⁹ Title X, Subtitle E, Sec. 10503.

¹⁴⁰ *Id.*

¹⁴¹ Title V, Subtitle F, Sec. 5508.

NVPO, CDC, and HRSA to strengthen immunization practice, particularly for patients who will be covered under Medicaid and health insurance exchanges, as well as those who remain uninsured.

The Community Health Center Fund will increase access to immunizations for millions of children and adults in medically underserved communities including both currently and newly insured persons, as well as the estimated 23 million persons who will remain uninsured. Underinsurance for immunizations among low-income children with private health insurance will continue to create barriers to vaccine uptake. As a result, pending full implementation of preventive services coverage under health reform, CHCs and rural health clinics will provide low cost immunizations for this population. Workforce reforms will provide funding to increase the number of primary care providers available to counsel and provide immunization services to CHC patients.

SCHOOL-BASED HEALTH CENTERS

Background

School-based health centers (SBHCs) were established in the 1970s, and provided behavior-related health interventions to adolescents. SBHCs provide a range of comprehensive services including treatment and referral for acute illnesses, injuries, pregnancy and sexually transmitted infections (STIs); routine screenings and preventive care; care for chronic diseases and disorders; and care, consultation and referral for psychosocial problems.¹⁴²

By 1998, there were 1,100 SBHCs across the country. The majority of health centers are housed in high schools. All SBHCs receive public funding from local, state and Federal grants, or private funding from foundations and hospitals. However, these funding sources are not guaranteed, and have led SBHCs to seek reimbursements from third parties, including Medicaid and private insurers.¹⁴³

Approximately 2 million children rely on school based health centers for preventive medical, mental and social services.¹⁴⁴ In 2006, 6.4 percent of schools had a SBHC that provided physical health services to students.¹⁴⁵ Twenty-eight percent of states, 35 percent of districts and 14 percent of all schools offered immunization services.¹⁴⁶

Changes under Health Reform

The Act authorizes a grant program for the operation and development of SBHCs located in or adjacent to school facilities.¹⁴⁷ Fifty million dollars has been appropriated each year for FY2010 through FY2013 for facilities, equipment and staff.¹⁴⁸ Preference will be given to centers offering access to a significant Medicaid/CHIP population.¹⁴⁹ The SBHC will be integrated into the school environment and will coordinate health services with school personnel, including: administrators, teachers, nurses, counselors, support personnel, and other community providers co-located at the school.¹⁵⁰

¹⁴² Kisker, EE. and Brown, R.S, *Do School-Based Health Centers Improve Adolescents' Access to Health Care, Health Status and Risk-Taking Behavior?*, Journal of Adolescent Health, October 1997.

¹⁴³ Koppelman, J. and Lear, J.G. *The New Child Health Insurance Expansions: How Will School-Based Health Centers Fit In?*, Journal of School Health, available at: <http://onlinelibrary.wiley.com/doi/10.1111/j.1746-1561.1998.tb06327.x/pdf>.

¹⁴⁴ Johnson, T.D., *School-based health centers play important role, report finds*, The Nation's Health, available at: <http://thenationshealth.aphapublications.org/content/40/6/7.1.extract>

¹⁴⁵ Kann, L. et. al. *Overview and Summary: School Health Policies and Programs Study 2006*, Journal of School Health (77), October 2007, available at: <http://onlinelibrary.wiley.com/doi/10.1111/j.1746-1561.2007.00226.x/pdf>.

¹⁴⁶ *School Health Policies and Programs Study*, School Health Policies and Program Study 2006, Centers for Disease Control and Prevention, available at: http://www.cdc.gov/HealthyYouth/shpps/2006/factsheets/pdf/FS_HealthServices_SHPPS2006.pdf.

¹⁴⁷ Title IV, Subtitle B, Sec. 4101.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

To be eligible for a grant, the SBHC must employ licensed health professionals to provide comprehensive primary health services during school hours to children and adolescents. Comprehensive primary health services include: comprehensive health assessments, diagnosis and treatment of minor acute and chronic medical conditions and referrals to and follow-up for, specialty care and oral health services.¹⁵¹

Implications for Immunization Practice under School-Based Health Centers

Neither preventive services nor immunizations are specifically included in the definition of comprehensive primary health services offered by SBHCs. However, funding for these centers may create opportunities for qualified providers to administer vaccines to children and adolescents during school hours.

SBHCs could become VFC-registered providers. Qualified providers employed by SBHCs could administer vaccines under standing orders.

Interaction with NVAC-VFWG Recommendations

NVAC recommendations related to changes under health reform and school-based health centers interact as follows:

Recommendation 23

Ensure adequate funding to cover all costs (including those incurred by schools) arising from assuring compliance with child and adolescent immunization requirements for school attendance.

Recommendation 24

Promote shared public and private sector approaches to help fund school-based and other complementary-venue child and adolescent immunization efforts.

Funding authorized under SBHC provisions offers opportunities for school based health centers to support school entry requirements.

¹⁵¹ *Id.*

SUPPORTING THE HEALTH WORKFORCE

Background

Prior to health reform, there was no unified national strategy to improve and strengthen the health workforce, including health care and public health workers.¹⁵² The country's ability to count, track and make projections about the health workforce was limited and public investment was minimal.¹⁵³

The health workforce is largely responsible for determining the quality and effectiveness of healthcare. More than 800,000 physicians, 100,000 nurse practitioners, and 70,000 physician assistants are currently practicing in the United States. The distribution of physicians across the country favors metropolitan areas while economically disadvantaged areas are more likely to experience physician shortages. Additionally, primary care physicians comprise only 37 percent of the health workforce and the number of medical students interested in primary care has continued to decline.¹⁵⁴

The disparity in income and wealth in the United States results in a health workforce that is sensitive to the insured market. Communities where patients are largely uninsured must recruit physicians, nurses and other health professionals to settings that are often less technologically advanced and present geographic, and security concerns, with less competitive compensation.

The development and routine use of technology, more competitive salaries, and desirable work hours, have encouraged specialization and increased the barriers experienced by primary care physicians. The combination of these factors has led to a demand for a larger workforce.¹⁵⁵

Changes under Health Reform

Health reform addresses reimbursement, training and readiness of the healthcare workforce.

Primary Care Extension Program: The Act requires the Secretary to establish the Program to educate primary care providers about preventive medicine, health promotion, evidence-based and evidence-informed therapies and techniques. This curriculum will enable providers to incorporate these topics into practice. Providers will learn techniques to improve

¹⁵² *National Workforce Policy Development*. Health Reform GPS: Navigating the Implementation Process/National Workforce Policy, GW Department of Health Policy, 2010, available at:

<http://www.healthreformgps.org/resources/national-workforce-policy-development/>

¹⁵³ Mullan, F. *et.al.*, *Aging, Primary Care, and Self-Sufficiency: Health Care Workforce Challenges Ahead*, Health Care, Winter 2008.

¹⁵⁴ *National Workforce Policy Development*. Health Reform GPS: Navigating the Implementation Process/National Workforce Policy, GW Department of Health Policy, 2010, available at:

<http://www.healthreformgps.org/resources/national-workforce-policy-development/>

¹⁵⁵ Mullan, F. *et.al.*, *Aging, Primary Care, and Self-Sufficiency: Health Care Workforce Challenges Ahead*, Health Care, Winter 2008.

community health by working with local health extension agents. These agents can be any community-based health worker who aids primary care practices by improving systems; providing high-quality, effective, efficient and safe primary care; and offering culturally-competent guidance.¹⁵⁶

AHRQ Grants: The Act directs the Agency for Health Care Research and Quality (AHRQ) to award planning and program grants to establish state hubs. Hubs must include, at a minimum: the state health department, state-level entities administering Medicare and Medicaid (if other than the state health department) and at least one health professions school. Hubs may also include hospital associations, primary care practice-based research networks, health professional societies, state primary care associations, state licensing boards, and consumer groups.¹⁵⁷

Hubs will establish primary care extension agencies to organize and administer grants to organizations that provide the following services: assist primary care providers to implement a patient-centered medical home to improve the accessibility; quality and efficiency of primary care services; develop primary care learning communities to enhance the dissemination of research findings for evidence-based practice; provide technical assistance; conduct research related to performance improvement and strengthen the primary care health workforce.¹⁵⁸

Implications for Immunization Practice under Workforce-Related Reforms

AHRQ grants will incentivize collaboration among stakeholders involved in a wide range of public health activities that could include vaccine delivery.

Although immunizations are not explicitly addressed, permissible activities could incorporate education related to immunizations within primary health care workforce training initiatives and/or address disparities by assessing uptake rates.

Interaction with NVAC-VFWG Recommendations

Health reform provisions related to changes in the workforce do not interact with NVAC recommendations.

¹⁵⁶ Title V, Subtitle F, Sec. 5405.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

IMPLEMENTATION RECOMMENDATIONS

The Act presents NVPO with the opportunity to examine all immunization-related initiatives and programs. As a primary advisor for national vaccine policy, NVPO collaborates with Federal agencies to ensure that all goals, objectives, and strategies for reducing infectious disease through immunization are satisfied. NVPO is uniquely qualified to contribute to the implementation of all aspects of the Act that influence immunization policy.

Private Health Insurance and Employee Health Benefit Plans

Recommendation: NVPO might consider consulting with employer-sponsored health plans and health insurers regarding coverage of preventive benefits and expansion of immunization coverage up to ACIP-recommended levels. The consultation process could identify strategies for expediting changes in insurer coverage and adoption of new ACIP recommendations by health plans, best practices in provider payment, and the use of incentives to encourage methods to reduce missed opportunities in health care settings.

Recommendation: NVPO might consider consulting with the United States Department of Labor to ensure that immunization activities are included in workplace wellness programs. Additionally, NVPO might consider recommending that immunization status is one of the health outcomes that wellness programs use when providing incentives.

Medicaid/CHIP

Recommendation: NVPO might consider recommending that pre-health reform adult Medicaid beneficiaries receive full coverage for ACIP-recommended immunizations. Additionally, NVPO might consider recommending that adults, eligible for Medicaid post-health reform, receive coverage for all ACIP-recommended immunizations under benchmark coverage.

Recommendation: NVPO might consider recommending the expansion of the categories of providers who will be eligible to administer vaccines under “primary care physician services”. This change would allow additional providers to receive payment at 100 percent of Medicare Part B payment rates in 2013 and 2014.

NVAC Recommendations that may be Addressed by Medicaid Reforms

Recommendation 12: Indicates that all public and private health insurance plans should voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents

Health Care Quality and Innovation

Recommendation: NVPO might consider advising the Secretary to establish reporting requirements including insurers' efforts to increase the uptake of annual influenza vaccination among health care workers.

Recommendation: NVPO might consider advising the Secretary to use the following models developed by the Center of Medicare and Medicaid Innovation (CMI) to promote effective vaccine financing, distribution and administration in the U.S.:

- *Promoting broad payment and practice reform in primary care including patient centered medical home models:* NVPO might consider advising the Secretary to consider modifying the reimbursement schedules to increase payments to providers. This policy change would encourage provider participation in immunization programs.
- *Developing community-based health teams to assist primary care providers and small-practice medical homes to provide chronic care management:* NVPO might consider advising the Secretary to support community vaccination programs. Studies suggest that small medical practices may not offer routine immunizations due to concerns over rising costs that are often disproportionate to reimbursement levels. The continuation of this trend could jeopardize national immunization rates.¹⁵⁹ Community-based health teams could fill this gap in immunization service delivery by accessing immunization status and arranging for the administration of appropriate vaccines.
- *Providers would be reimbursed for using patient decision-support tools that improve individual and caregiver understanding of medical treatment options:* NVPO might consider advising the Secretary that this model could support patient counseling regarding routine immunizations and the development of comprehensive preventive health plans during their regular office visits. Because healthcare professionals often cite lack of time to discuss or screen for immunization status as well as the cost of administration,¹⁶⁰ this model could support the routine assessment of patients and increase the uptake of immunization services.
- *Using state laws to authorize professionals to provide outpatient services that do not require a physician's or health professional's referral or involvement:* NVPO might consider advising the Secretary to promote the enactment of state laws that permit the use of standing orders among various levels of health professionals to assess, prescribe, and administer immunizations. The use of standing orders reduces the

¹⁵⁹ Glazner, J.E. et. al., *The Cost of Giving Childhood Vaccinations: Differences Among Provider Types*, 113 *Pediatrics* 6 (2004).

¹⁶⁰ Broder, K.R. et. al. *Adolescent Immunizations and Other Clinical Preventive Services: A Needle and a Hook?* 121 *Pediatrics* S25-S34 (2008).

burden on physicians and increases access to immunization services.¹⁶¹ Increased use of standing orders would promote greater efficiencies and timely access to immunizations.

Recommendation: NVPO might consider coordinating with other HHS agencies to ensure that immunization services are a priority in the new national health care quality strategy. NVPO might consider identifying methods to promote quality and patient safety measures among public and private payers related to immunizations. Additionally, NVPO might consider encouraging increased use of health information technology to develop immunization information systems.

Recommendation: NVPO might consider working with Community Health Centers to ensure that comprehensive immunization programs are routinely available and that the providers are educated about the importance of immunization services.

Population Health and Prevention Initiatives

Recommendation: NVPO might consider advising the Secretary, as a member of the National Prevention, Health Promotion and Public Health Council, to recommend the inclusion of ACIP-recommended immunizations as a priority for the national health promotion and prevention strategy. Vaccines and immunizations could be a cornerstone of the national preventive health strategy. Accomplishing and maintaining the highest possible coverage rates are primary public health goals.

¹⁶¹ McKibben, L.J. *et al.*, *Use of Standing Orders Programs to Increase Adult Vaccination Rates: Recommendations of the Advisory Committee on Immunization Practices*, MMWR 49(RR01), 15-26, 2000.

Recommendation: NVPO might consider advising the Secretary to use the Prevention and Public Health Fund to address areas of need identified by the National Vaccine Advisory Committee (NVAC).

A purpose of the Fund is to “expand and sustain national investment in prevention and public health programs.” Permissible initiatives include prevention research, education and outreach regarding prevention benefits and immunization programs. Funding could be used to conduct research related to the five NVAC recommendations that have not been addressed under health reform as follows:

NVAC Recommendations not Addressed in the Affordable Care Act

Recommendation 1: The Vaccines for Children program (VFC) should be extended to include access to VFC eligible underinsured children and adolescents receiving immunizations in public health department clinics and thus not be limited to access only at Federally Qualified Health Centers and Rural Health Clinics.

Recommendation 2: VFC should be expanded to cover vaccine administration reimbursement for all VFC-eligible children and adolescents. (Currently the vaccine administration fee is not covered by VFC.) This should include children on Medicaid as this would provide for a single system and uniform vaccine administration fee. The vaccine administration reimbursement should be sufficient to cover the costs of vaccine administration (as referenced elsewhere in these recommendations).

Recommendation 3: The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) should annually update, publish, and disseminate actual Medicaid vaccine administration reimbursement rates by state.

Recommendation 17: NVAC should convene one or more expert panels representing all impacted stakeholders to consider whether tax credits could be a tool to reduce or eliminate underinsurance. The panel would determine if policy options that would be acceptable to stakeholders could be developed to address the burden of financing for private sector child and adolescent vaccinations by using tax credits as incentives for insurers.

Recommendation 22: States and localities should develop mechanisms for billing insured children and adolescents served in the public sector. CDC should provide support to states and localities by disseminating best practices and providing technical assistance to develop these billing mechanisms. (This may require additional resources not currently in CDC's immunization program budget.) Further, NVAC urges states and localities to reinvest reimbursements from public and private payers back into immunization programs.

Recommendation: NVPO might consider advising the Secretary to use the Community Preventive Services Task Force funds to implement vaccine-related outreach and education campaigns.

The Secretary is required to conduct a national prevention outreach and education campaign through a public/private partnership. The campaigns are intended to raise public awareness among consumers and providers regarding ACIP recommendations. The following NVAC recommendations could be addressed under Task Force activities:

NVAC Recommendations that may be Addressed by the Community Preventive Services Task Force

Recommendation 8: Professional medical organizations should provide their members with technical assistance on efficient business practices associated with providing immunizations, such as how to contract and bill appropriately. Medical organizations should identify best business practices to assure efficient and appropriate use of ACIP recommended vaccines and appropriate use of CPT codes, including Evaluation and Management (E&M) codes, when submitting claims for vaccines and vaccine administration. These organizations may receive Federal assistance from CMS or other relevant agencies.

Recommendation 10: CDC, professional medical organizations, and other relevant stakeholders should develop and support additional employer health education efforts. These efforts should communicate the value of good preventive care including recommended vaccinations.

Recommendation 21: State, local and Federal governments along with professional organizations should conduct outreach to physicians and non-physician providers who currently serve VFC-eligible children and adolescents to encourage these providers to participate in VFC if they currently do not. Outreach directed at providers serving adolescents who may not have provided vaccinations in the past (e.g. obstetrician-gynecologists) is a particular priority.

Research

Recommendation: NVPO might consider advising the Secretary and the Director of the CDC to prioritize immunization projects when funding is appropriated for public health services and systems research.

Public health services and systems research will focus on high priority prevention strategies. Research will focus on effective strategies for prevention, translational research, and comparative studies. Funding could support studies designed to monitor implementation of vaccine-related provisions in the Affordable Care Act, and methods to administer vaccines in school-based health centers. The following six NVAC recommendations could be addressed:

NVAC Recommendations that may be Addressed by Public Health Services and Systems Research

Recommendation 6: AMA's RVS Update Committee (RUC) should review its RVU coding to ensure that it accurately reflects the non-vaccine costs of vaccination including the potential costs and savings from the use of combination vaccines.

Recommendation 7: Vaccine manufacturers and third-party vaccine distributors should work with providers on an individual basis to reduce the financial burden for initial and ongoing vaccine inventories, particularly for new vaccines. This may include extending payment periods (e.g. from 60 days to 90 or over 120 days), or until vaccine has been administered and reimbursed. It may also include options not related to payment terms for vaccine inventory.

Recommendation 13: Insurers and healthcare purchasers should develop reimbursement policies for vaccinations that are based on methodologically sound cost studies of efficient practices. These cost studies should factor in all costs associated with vaccine administration (including, for example, purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping).

Recommendation 15: CDC and CMS should continue to collect and publish data on the costs and reimbursements associated with public and private vaccine administration according to NVAC standards for vaccinating children and adolescents. These costs include costs associated with the delivery of vaccines, such as purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping. These published data should be updated every five years and also include information about reimbursement by provider type, geographic region, and insurance status. State governments should use this information in determining vaccine administration reimbursements rates in Medicaid.

Recommendation 16: NVPO should calculate the marginal increase in insurance premiums if insurance plans were to provide coverage for all routinely ACIP-recommended vaccines.

Recommendation 20: Continue Federal funding for cost-benefit studies of vaccinations targeted for children and adolescents.

Community Health Centers

Recommendation: NVPO might consider consultation with the Health Resources and Services Administration (HRSA) regarding initiatives to further improve health centers' immunization performance among populations who will realize the benefits of Medicaid and private health insurance expansions.

Health centers have a long history of high-value performance in the area of childhood immunization practice. At the same time, health centers are positioning themselves for a surge of adult patients, particularly newly Medicaid-eligible adults who are older and in poorer health and who are likely to have gone for an extensive period with limited or no health care. Strengthening health centers' capacity to administer vaccines could be an effective means to reach vulnerable and harder-to-serve adult populations, including the increasing number of dually-enrolled Medicare and Medicaid patients.

School-based Health Centers

Recommendation: NVPO might consider using funds available through the public health services and systems research fund to conduct feasibility studies to incorporate immunization services into school-based health centers.

NVPO might consider identifying methods for school-based health centers to provide immunizations to students during school hours. Studies could explore all aspects of vaccine delivery in this setting, including: expanding the definition of comprehensive primary health services, registering centers as VFC providers, obtaining appropriate consent, securing vaccines, identifying qualified providers, and developing and implementing standing orders. Additionally, NVPO might consider understanding how Federal initiatives related to school health may interact with vaccine delivery in educational settings. School-based health centers could address the following NVAC recommendations:

NVAC Recommendations that may be Addressed by School-based Health Centers

Recommendation 23: Ensure adequate funding to cover all costs (including those incurred by schools) arising from assuring compliance with child and adolescent immunization requirements for school attendance.

Recommendation 24: Promote shared public and private sector approaches to help fund school-based and other complementary-venue child and adolescent immunization efforts.

Supporting the Existing Workforce

Recommendation: NVPO might consider advising the Secretary to integrate U.S. immunization policy and practice in Primary Care Extension Program curricula.

The Primary Care Extension Program could address continuing education related to immunizations, including: vaccine purchase for different patient populations, vaccine storage, administration, billing, and patient education.

Recommendation: NVPO might consider advising the Secretary to ensure that state immunization managers may act as Health Extension Agents (HEAs).

State immunization managers have the expertise to support primary care practices in the implementation of vaccine policy recommendations. Additionally, state immunization managers would provide guidance to patients and facilitate the dissemination of culturally and linguistically appropriate immunization educational materials.

CONCLUSION

This report: 1) examines how the Affordable Care Act addresses vaccine policy and practice; 2) assesses how the major vaccine programs will be impacted; and 3) determines whether the laws address the NVAC's VFWG 2008 recommendations.¹⁶²

The Affordable Care Act recognizes the vital role immunizations play in an efficient health care system and supports national vaccine policy goals. The Act strengthens public and private health insurance coverage and affordability, increases funding to states, and prioritizes national investment in prevention, quality, wellness, primary care, research, and provider education.

NVPO might consider contributing to the content of implementing rules as appropriate, collaborating with key stakeholders, and participating in initiatives that have the potential to enhance vaccine policy and practice. Finally, NVPO might consider monitoring the health reform implementation process to identify potential gaps and opportunities for immunization policy and practice.

¹⁶² Lindley, M.C *et al.*, *Assuring Vaccination of Children and Adolescents without Financial Barriers: Recommendations from the National Vaccine Advisory Committee (NVAC)*, U.S. Department of Health and Human Services, March 2, 2009, available at <http://www.hhs.gov/nvpo/nvac/nvacfwgreport.pdf>.

DEPARTMENT OF HEALTH POLICY
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THE AFFORDABLE CARE ACT: U.S. Vaccine Policy and Practice

APPENDICES

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Fall, 2010

APPENDIX I

Relevant Excerpts from the Affordable Care Act and Existing Federal Laws Impacted by the Act

FORMAT

Rows:

Act, title, subtitle, section,
effective date and brief synopsis

Columns:

ACA Provisions in the Left
Changed/Law Indicated in Right

Private Health Insurance and Group Health Benefit Plans

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010 TITLE I— HEALTH, EDUCATION, LABOR, AND PENSIONS

SUBTITLE B—HEALTH Section 2301. Insurance Reforms

Effective Date: Certain provisions (annual limits restricted; dependent coverage up to age 26) **September 23, 2010;**
other provisions (annual limits and preexisting condition exclusion prohibited) **January 1, 2014 (before January 1, 2015)**

Extends the prohibitions on lifetime limits and rescissions in addition to the requirement to provide coverage for adult children up to age 26 to all existing health insurance plans starting six months after enactment

AFFORDABLE CARE ACT LANGUAGE

LANGUAGE FROM EXISTING LAW

(a) EXTENDING CERTAIN INSURANCE REFORMS TO GRANDFATHERED PLANS.—Section 1251(a) of the Patient Protection and Affordable Care Act, as added by section 10103(d) of such Act, is amended by adding at the end the following:
“(4) APPLICATION OF CERTAIN PROVISIONS.—
“(A) IN GENERAL.—The following provisions of the Public Health Service Act (as added by this title) shall apply to grandfathered health plans for plan years beginning with the first plan year to which such provisions would otherwise apply:
“(i) Section 2708 (relating to excessive waiting periods).
“(ii) Those provisions of section 2711 relating to lifetime limits.
“(iii) Section 2712 (relating to rescissions).
“(iv) Section 2714 (relating to extension of dependent coverage).
“(B) PROVISIONS APPLICABLE ONLY TO GROUP HEALTH PLANS.—
“(i) PROVISIONS DESCRIBED.—Those provisions of section 2711 relating to annual limits and the provisions of section 2704 (relating to pre-existing condition exclusions) of the Public Health Service Act (as added by this subtitle) shall apply to grandfathered health plans that are group health plans for plan years beginning with the first plan year to which such provisions otherwise apply.
“(ii) ADULT CHILD COVERAGE.—For plan years beginning before January 1, 2014, the provisions of section 2714 of the Public Health Service Act (as added by this subtitle) shall apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if such adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code of 1986) other than such grandfathered health plan.”.

(b) CLARIFICATION REGARDING DEPENDENT COVERAGE.—Section 2714(a) of the Public Health Service Act, as added by section 1001(5) of the Patient Protection and Affordable Care Act, is amended by striking “(who is not married)”.

Provision unique to HCER

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE A – IMMEDIATE IMPROVEMENTS IN HEALTH CARE COVERAGE FOR ALL AMERICANS

Section 1001. Amendments to the Public Health Service Act (PHSA)

PHSA Section 2713. Coverage of Preventive Health Services

Effective Date: Plan years beginning on or after the date that is six (6) months after enactment (**September 23, 2010**)

Allows new plans to cover preventive health services without cost-sharing

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—</p> <p>“(1) evidence-based items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United States Preventive Services Task Force;</p> <p>“(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and</p> <p>“(3) with respect to infants, children, and adolescents, evidence- informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.</p> <p>“(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.</p> <p>“(5) for the purposes of this Act, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.</p> <p>Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.</p> <p>“(b) INTERVAL.—</p> <p>“(1) IN GENERAL.—The Secretary shall establish a minimum interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.</p> <p>“(2) MINIMUM.—The interval described in paragraph (1) shall not be less than 1 year.</p> <p>“(c) VALUE-BASED INSURANCE DESIGN.—The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs.</p>	<p>Section 1001 adds this new provision to the PHSA</p>

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS	
SUBTITLE A – IMMEDIATE IMPROVEMENTS IN HEALTH CARE COVERAGE FOR ALL AMERICANS Section 1001. Amendments to the Public Health Service Act (PHSA)	
PHSA Section 2714. Extension of Dependent Coverage Effective Date: Plan years beginning on or after the date that is six (6) months after enactment (September 23, 2010) <i>Requires plans to extend age of dependency to 26 (through age 25)</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage that provides dependent coverage of children shall continue to make such coverage available for an adult child (who is not married) until the child turns 26 years of age. Nothing in this section shall require a health plan or a health insurance issuer described in the preceding sentence to make coverage available for a child of a child receiving dependent coverage.</p> <p>“(b) REGULATIONS.—The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).</p> <p>“(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to modify the definition of ‘dependent’ as used in the Internal Revenue Code of 1986 with respect to the tax treatment of the cost of coverage.</p> <p style="text-align: center;">***</p>	<p>Section 1001 adds this new provision to the PHSA</p>

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS	
SUBTITLE A – IMMEDIATE IMPROVEMENTS IN HEALTH CARE COVERAGE FOR ALL AMERICANS Section 1001. Amendments to the Public Health Service Act (PHSA)	
PHSA Section 2717. Ensuring Quality of Care	
Effective Date(s): Secretary’s reporting guidelines to be developed within two (2) years of enactment (March 22, 2012)	
<i>Secretary to issue reporting guidelines that plans will use to provide information about health and wellness promotion campaigns</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(a) QUALITY REPORTING.—</p> <p>“(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary, in consultation with experts in health care quality and stakeholders, shall develop reporting requirements for use by a group health plan, and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures that—</p> <p>“(A) improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage;</p> <p>“(B) implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional;</p> <p>“(C) implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and</p> <p>“(D) implement wellness and health promotion activities.</p> <p>“(2) REPORTING REQUIREMENTS.—</p> <p>“(A) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall annually submit to the Secretary, and to enrollees under the plan or coverage, a report on whether the benefits under the plan or coverage satisfy the elements described in subparagraphs (A) through (D) of paragraph (1).</p> <p>“(B) TIMING OF REPORTS.—A report under subparagraph (A) shall be made available to an enrollee under the plan or coverage during each open enrollment period.</p> <p>“(C) AVAILABILITY OF REPORTS.—The Secretary shall make reports submitted under subparagraph (A) available to the public through an Internet website.</p> <p>“(D) PENALTIES.—In developing the reporting requirements under paragraph (1), the Secretary may develop and impose appropriate penalties for non-compliance with such requirements.</p> <p>“(E) EXCEPTIONS.—In developing the reporting requirements under paragraph (1), the Secretary may provide for exceptions to such requirements for group health plans and health insurance issuers that substantially meet the goals of this</p>	<p>Section 1001 adds this new provision to the PHSA</p>

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS**

SUBTITLE A – IMMEDIATE IMPROVEMENTS IN HEALTH CARE COVERAGE FOR ALL AMERICANS

Section 1001. Amendments to the Public Health Service Act (PHSA)

PHSA Section 2717. Ensuring Quality of Care

Effective Date(s): Secretary’s reporting guidelines to be developed within two (2) years of enactment (**March 22, 2012**)

Secretary to issue reporting guidelines that plans will use to provide information about health and wellness promotion campaigns

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>section.</p> <p>“(b) WELLNESS AND PREVENTION PROGRAMS.—For purposes of subsection (a)(1)(D), wellness and health promotion activities may include personalized wellness and prevention services, which are coordinated, maintained or delivered by a health care provider, a wellness and prevention plan manager, or a health, wellness or prevention services organization that conducts health risk assessments or offers ongoing face-to-face, telephonic or web-based intervention efforts for each of the program’s participants, and which may include the following wellness and prevention efforts:</p> <p>“(1) Smoking cessation. “(2) Weight management. “(3) Stress management. “(4) Physical fitness. “(5) Nutrition. “(6) Heart disease prevention. “(7) Healthy lifestyle support. “(8) Diabetes prevention.</p> <p>“(c) REGULATIONS.—Not later than 2 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations that provide criteria for determining whether a reimbursement structure is described in subsection (a).</p> <p>“(d) STUDY AND REPORT.—Not later than 180 days after the date on which regulations are promulgated under subsection (c), the Government Accountability Office shall review such regulations and conduct a study and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report regarding the impact the activities under this section have had on the quality and cost of health care.</p> <p align="center">***</p>	

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS
SUBTITLE C – QUALITY HEALTH INSURANCE COVERAGE FOR ALL AMERICANS,
PART I – HEALTH INSURANCE MARKET REFORMS
Section 1201(4). Amendment to the Public Health Service Act

PHSA Sections 2701-2703; 2705-2708.

Effective Date: Effective for plan years beginning on or after **January 1, 2014**

Establishes fair health insurance premiums; guarantee availability and renewability of coverage; prohibits preexisting condition exclusions or other health status-based discrimination; ensures comprehensive coverage; prohibits excessive waiting periods; and ensures continuity of coverage for individuals who participate in clinical trials treating cancer or other life-threatening diseases.

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(4) by inserting after the subpart heading (as added by paragraph (1)) the following:</p> <p>“SEC. 2701. FAIR HEALTH INSURANCE PREMIUMS. “(a) PROHIBITING DISCRIMINATORY PREMIUM RATES.— “(1) IN GENERAL.—With respect to the premium rate charged by a health insurance issuer for health insurance coverage offered in the individual or small group market— “(A) such rate shall vary with respect to the particular plan or coverage involved only by— “(i) whether such plan or coverage covers an individual or family; “(ii) rating area, as established in accordance with paragraph (2); “(iii) age, except that such rate shall not vary by more than 3 to 1 for adults (consistent with section 2707(c)); and “(iv) tobacco use, except that such rate shall not vary by more than 1.5 to 1; and “(B) such rate shall not vary with respect to the particular plan or coverage involved by any other factor not described in subparagraph (A). “(2) RATING AREA.— “(A) IN GENERAL.—Each State shall establish 1 or more rating areas within that State for purposes of applying the requirements of this title. “(B) SECRETARIAL REVIEW.—The Secretary shall review the rating areas established by each State under subparagraph (A) to ensure the adequacy of such areas for purposes of carrying out the requirements of this title. If the Secretary determines a State’s rating areas are not adequate, or that a State does not establish such areas, the Secretary may establish rating areas for that State. “(3) PERMISSIBLE AGE BANDS.—The Secretary, in consultation with the National Association of Insurance Commissioners, shall define the permissible age bands for rating purposes under paragraph (1)(A)(iii).</p>	<p>Amends the Public Health Service Act, 42 U.S.C. 300gg, by adding section 2704, modifying the language of sections 2701-2703; 2705-2708.</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS
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PART I – HEALTH INSURANCE MARKET REFORMS
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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(4) APPLICATION OF VARIATIONS BASED ON AGE OR TOBACCO USE.—With respect to family coverage under a group health plan or health insurance coverage, the rating variations permitted under clauses (iii) and (iv) of paragraph (1)(A) shall be applied based on the portion of the premium that is attributable to each family member covered under the plan or coverage.</p> <p>“(5) SPECIAL RULE FOR LARGE GROUP MARKET.—If a State permits health insurance issuers that offer coverage in the large group market in the State to offer such coverage through the State Exchange (as provided for under section 1312(f)(2)(B) of the Patient Protection and Affordable Care Act), the provisions of this subsection shall apply to all coverage offered in such market in the State.</p> <p>“SEC. 2702. GUARANTEED AVAILABILITY OF COVERAGE.</p> <p>“(a) GUARANTEED ISSUANCE OF COVERAGE IN THE INDIVIDUAL AND GROUP MARKET.—Subject to subsections (b) through (e), each health insurance issuer that offers health insurance coverage in the individual or group market in a State must accept every employer and individual in the State that applies for such coverage.</p> <p>“(b) ENROLLMENT.—</p> <p>“(1) RESTRICTION.—A health insurance issuer described in subsection (a) may restrict enrollment in coverage described in such subsection to open or special enrollment periods.</p> <p>“(2) ESTABLISHMENT.—A health insurance issuer described in subsection (a) shall, in accordance with the regulations promulgated under paragraph (3), establish special enrollment periods for qualifying events (under section 603 of the Employee Retirement Income Security Act of 1974).</p> <p>“(3) REGULATIONS.—The Secretary shall promulgate regulations with respect to enrollment periods under paragraphs (1) and (2).</p> <p>“SEC. 2703. GUARANTEED RENEWABILITY OF COVERAGE.</p> <p>“(a) IN GENERAL.—Except as provided in this section, if a health insurance issuer offers health insurance coverage in the individual or group market, the issuer must renew or continue in force such coverage at the option of the plan sponsor or the individual, as applicable.</p>	

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“SEC. 2705. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.</p> <p>“(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on any of the following health status-related factors in relation to the individual or a dependent of the individual:</p> <p>“(1) Health status.</p> <p>“(2) Medical condition (including both physical and mental illnesses).</p> <p>“(3) Claims experience.</p> <p>“(4) Receipt of health care.</p> <p>“(5) Medical history.</p> <p>“(6) Genetic information.</p> <p>“(7) Evidence of insurability (including conditions arising out of acts of domestic violence).</p> <p>“(8) Disability.</p> <p>“(9) Any other health status-related factor determined appropriate by the Secretary.</p> <p>“(j) PROGRAMS OF HEALTH PROMOTION OR DISEASE PREVENTION.—</p> <p>“(1) GENERAL PROVISIONS.—</p> <p>“(A) GENERAL RULE.—For purposes of subsection (b)(2)(B), a program of health promotion or disease prevention (referred to in this subsection as a ‘wellness program’) shall be a program offered by an employer that is designed to promote health or prevent disease that meets the applicable requirements of this subsection.</p> <p>“(B) NO CONDITIONS BASED ON HEALTH STATUS FACTOR.—If none of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals and the requirements of paragraph (2) are complied with.</p> <p>“(C) CONDITIONS BASED ON HEALTH STATUS FACTOR.—</p> <p>If any of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if the requirements of paragraph (3) are complied with.</p> <p>“(2) WELLNESS PROGRAMS NOT SUBJECT TO REQUIREMENTS.— If none of the conditions for obtaining a premium discount or rebate or other reward under a wellness program as described in paragraph (1)(B) are based on an individual</p>	

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PHSA Sections 2701-2703; 2705-2708.

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<p>satisfying a standard that is related to a health status factor (or if such a wellness program does not provide such a reward), the wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals. The following programs shall not have to comply with the requirements of paragraph (3) if participation in the program is made available to all similarly situated individuals:</p> <p>“(A) A program that reimburses all or part of the cost for memberships in a fitness center.</p> <p>“(B) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.</p> <p>“(C) A program that encourages preventive care related to a health condition through the waiver of the copayment or deductible requirement under group health plan for the costs of certain items or services related to a health condition (such as prenatal care or well-baby visits).</p> <p>“(D) A program that reimburses individuals for the costs of smoking cessation programs without regard to whether the individual quits smoking.</p> <p>“(E) A program that provides a reward to individuals for attending a periodic health education seminar.</p> <p>“(3) WELLNESS PROGRAMS SUBJECT TO REQUIREMENTS.— If any of the conditions for obtaining a premium discount, rebate, or reward under a wellness program as described in paragraph (1)(C) is based on an individual satisfying a standard that is related to a health status factor, the wellness program shall not violate this section if the following requirements are complied with:</p> <p>“(A) The reward for the wellness program, together with the reward for other wellness programs with respect to the plan that requires satisfaction of a standard related to a health status factor, shall not exceed 30 percent of the cost of employee-only coverage under the plan. If, in addition to employees or individuals, any class of dependents (such as spouses or spouses and dependent children) may participate fully in the wellness program, such reward shall not exceed 30 percent of the cost of the coverage in which an employee or individual and any dependents are enrolled. For purposes of this paragraph, the cost of coverage shall be determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward may be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan. The Secretaries of Labor, Health and Human Services, and the Treasury may increase the reward available under this subparagraph to up to 50 percent of the cost of coverage if the Secretaries determine that such an increase is appropriate.</p> <p>“(B) The wellness program shall be reasonably designed to promote health or prevent disease. A program complies with the preceding sentence if the program has a reasonable chance of improving the health of, or preventing disease in, participating</p>	

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PHSA Sections 2701-2703; 2705-2708.

Effective Date: Effective for plan years beginning on or after **January 1, 2014**

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health status factor, and is not highly suspect in the method chosen to promote health or prevent disease.</p> <p>“(C) The plan shall give individuals eligible for the program the opportunity to qualify for the reward under the program at least once each year.</p> <p>“(D) The full reward under the wellness program shall be made available to all similarly situated individuals. For such purpose, among other things:</p> <p>“(i) The reward is not available to all similarly situated individuals for a period unless the wellness program allows—</p> <p>“(I) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and</p> <p>“(II) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.</p> <p>“(ii) If reasonable under the circumstances, the plan or issuer may seek verification, such as a statement from an individual’s physician, that a health status factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.</p> <p>“(E) The plan or issuer involved shall disclose in all plan materials describing the terms of the wellness program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under subparagraph (D). If plan materials disclose that such a program is available, without describing its terms, the disclosure under this subparagraph shall not be required.</p> <p>“(k) EXISTING PROGRAMS.—Nothing in this section shall prohibit a program of health promotion or disease prevention that was established prior to the date of enactment of this section and applied with all applicable regulations, and that is operating on such date, from continuing to be carried out for as long as such regulations remain in effect.</p> <p>“(l) WELLNESS PROGRAM DEMONSTRATION PROJECT.—</p> <p>“(1) IN GENERAL.—Not later than July 1, 2014, the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall establish a 10-State demonstration project under which participating States shall apply the provisions of subsection (j) to programs of health promotion offered by a health insurance issuer that offers health insurance coverage in the individual market in such State.</p> <p>“(2) EXPANSION OF DEMONSTRATION PROJECT.—If the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, determines that the demonstration project described in paragraph (1) is effective, such Secretaries</p>	

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<p>may, beginning on July 1, 2017 expand such demonstration project to include additional participating States.</p> <p>“(3) REQUIREMENTS.—</p> <p>“(A) MAINTENANCE OF COVERAGE.—The Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall not approve the participation of a State in the demonstration project under this section unless the Secretaries determine that the State’s project is designed in a manner that—</p> <p>“(i) will not result in any decrease in coverage; and</p> <p>“(ii) will not increase the cost to the Federal Government in providing credits under section 36B of the Internal Revenue Code of 1986 or cost-sharing assistance under section 1402 of the Patient Protection and Affordable Care Act.</p> <p>“(B) OTHER REQUIREMENTS.—States that participate in the demonstration project under this subsection—</p> <p>“(i) may permit premium discounts or rebates or the modification of otherwise applicable copayments or deductibles for adherence to, or participation in, a reasonably designed program of health promotion and disease prevention;</p> <p>“(ii) shall ensure that requirements of consumer protection are met in programs of health promotion in the individual market;</p> <p>“(iii) shall require verification from health insurance issuers that offer health insurance coverage in the individual market of such State that premium discounts—</p> <p>“(I) do not create undue burdens for individuals insured in the individual market;</p> <p>“(II) do not lead to cost shifting; and</p> <p>“(III) are not a subterfuge for discrimination;</p> <p>“(iv) shall ensure that consumer data is protected in accordance with the requirements of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and</p> <p>“(v) shall ensure and demonstrate to the satisfaction of the Secretary that the discounts or other rewards provided under the project reflect the expected level of participation in the wellness program involved and the anticipated effect the program will have on utilization or medical claim costs.</p> <p>“(m) REPORT.—</p> <p>“(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall submit a report to the appropriate committees of Congress concerning—</p> <p>“(A) the effectiveness of wellness programs (as defined in subsection (j)) in promoting health and preventing disease;</p> <p>“(B) the impact of such wellness programs on the access to care and affordability of coverage for participants and non-participants of such programs;</p>	

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PHSA Sections 2701-2703; 2705-2708.

Effective Date: Effective for plan years beginning on or after **January 1, 2014**

Establishes fair health insurance premiums; guarantee availability and renewability of coverage; prohibits preexisting condition exclusions or other health status-based discrimination; ensures comprehensive coverage; prohibits excessive waiting periods; and ensures continuity of coverage for individuals who participate in clinical trials treating cancer or other life-threatening diseases.

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(C) the impact of premium-based and cost-sharing incentives on participant behavior and the role of such programs in changing behavior; and “(D) the effectiveness of different types of rewards. “(2) DATA COLLECTION.—In preparing the report described in paragraph (1), the Secretaries shall gather relevant information from employers who provide employees with access to wellness programs, including State and Federal agencies. “(n) REGULATIONS.—Nothing in this section shall be construed as prohibiting the Secretaries of Labor, Health and Human Services, or the Treasury from promulgating regulations in connection with this section.</p> <p>“SEC. 2706. NON-DISCRIMINATION IN HEALTH CARE. “(a) PROVIDERS.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider’s license or certification under applicable State law. This section shall not require that a group health plan or health insurance issuer contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer. Nothing in this section shall be construed as preventing a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures. “(b) INDIVIDUALS.—The provisions of section 1558 of the Patient Protection and Affordable Care Act (relating to non-discrimination) shall apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.</p> <p>“SEC. 2707. COMPREHENSIVE HEALTH INSURANCE COVERAGE. “(a) COVERAGE FOR ESSENTIAL HEALTH BENEFITS PACKAGE.— A health insurance issuer that offers health insurance coverage in the individual or small group market shall ensure that such coverage includes the essential health benefits package required under section 1302(a) of the Patient Protection and Affordable Care Act. “(b) COST-SHARING UNDER GROUP HEALTH PLANS.—A group health plan shall ensure that any annual cost-sharing imposed under the plan does not exceed the limitations provided for under paragraphs (1) and (2) of section 1302(c). “(c) CHILD-ONLY PLANS.—If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 1302(d) of the Patient Protection and Affordable Care Act, the issuer shall also offer such coverage in that level as</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS
SUBTITLE C – QUALITY HEALTH INSURANCE COVERAGE FOR ALL AMERICANS,
PART I – HEALTH INSURANCE MARKET REFORMS
Section 1201(4). Amendment to the Public Health Service Act

PHSA Sections 2701-2703; 2705-2708.

Effective Date: Effective for plan years beginning on or after **January 1, 2014**

Establishes fair health insurance premiums; guarantee availability and renewability of coverage; prohibits preexisting condition exclusions or other health status-based discrimination; ensures comprehensive coverage; prohibits excessive waiting periods; and ensures continuity of coverage for individuals who participate in clinical trials treating cancer or other life-threatening diseases.

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21. “(d) DENTAL ONLY.—This section shall not apply to a plan described in section 1302(d)(2)(B)(ii)(I).</p> <p>“SEC. 2708. PROHIBITION ON EXCESSIVE WAITING PERIODS. “A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not apply any waiting period (as defined in section 2704(b)(4)) that exceeds 90 days.”.</p>	

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS	
SUBTITLE C – QUALITY HEALTH INSURANCE COVERAGE FOR ALL AMERICANS, PART I – HEALTH INSURANCE MARKET REFORMS Section 1201. Amendment to the Public Health Service Act	
PHSA Section 2704. Prohibition of Preexisting Condition Exclusions or other Discrimination Based on Health Status Effective Date: Effective for plan years beginning on or after January 1, 2014	
<i>Establishes prohibition of exclusions based on preexisting condition exclusions or other health status-based discrimination.</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
Part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.), as amended by section 1001, is further amended— (1) by striking the heading for subpart 1 and inserting the following: “Subpart I—General Reform” ; (2)(A) in section 2701 (42 U.S.C. 300gg), by striking the section heading and subsection (a) and inserting the following: “SEC. 2704. PROHIBITION OF PREEXISTING CONDITION EXCLUSIONS OR OTHER DISCRIMINATION BASED ON HEALTH STATUS. “(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion with respect to such plan or coverage.” ; and (B) by transferring such section (as amended by subparagraph (A)) so as to appear after the section 2703 added by paragraph (4);	Amends the Public Health Service Act, 42 U.S.C. 300gg, by adding a new section, 2704.

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS
SUBTITLE C – QUALITY HEALTH INSURANCE COVERAGE FOR ALL AMERICANS,
PART II – OTHER PROVISIONS
Section 1251. Preservation of Right to Maintain Existing Coverage

Effective Date: January 1, 2014

Describes modified implementation guidelines for plans that qualify for grandfathering

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) NO CHANGES TO EXISTING COVERAGE.—</p> <p>(1) IN GENERAL.—Nothing in this Act (or an amendment made by this Act) shall be construed to require that an individual terminate coverage under a group health plan or health insurance coverage in which such individual was enrolled on the date of enactment of this Act.</p> <p>(2) CONTINUATION OF COVERAGE.—With respect to a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of this Act, this subtitle and subtitle A (and the amendments made by such subtitles) shall not apply to such plan or coverage, regardless of whether the individual renews such coverage after such date of enactment.</p> <p>(b) ALLOWANCE FOR FAMILY MEMBERS TO JOIN CURRENT COVERAGE.—With respect to a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of this Act and which is renewed after such date, family members of such individual shall be permitted to enroll in such plan or coverage if such enrollment is permitted under the terms of the plan in effect as of such date of enactment.</p> <p>(c) ALLOWANCE FOR NEW EMPLOYEES TO JOIN CURRENT PLAN.—A group health plan that provides coverage on the date of enactment of this Act may provide for the enrolling of new employees (and their families) in such plan, and this subtitle and subtitle A (and the amendments made by such subtitles) shall not apply with respect to such plan and such new employees (and their families).</p> <p>(d) EFFECT ON COLLECTIVE BARGAINING AGREEMENTS.—In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before the date of enactment of this Act, the provisions of this subtitle and subtitle A (and the amendments made by such subtitles) shall not apply until the date on which the last of the collective bargaining agreements relating to the coverage terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage which amends the coverage solely to conform to any requirement added by this subtitle or subtitle A (or amendments) shall not be treated as a termination of such collective bargaining agreement.</p> <p>(e) DEFINITION.—In this title, the term “grandfathered health plan” means any group health plan or health insurance coverage to which this section applies.</p>	<p>Provision unique to PPACA</p>

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS SUBTITLE F – SHARED RESPONSIBILITY FOR HEALTH CARE PART I – INDIVIDUAL RESPONSIBILITY Section 1501. Requirement to maintain minimum essential coverage	
Effective Date: Taxable Plan Years after December 31, 2013 <i>Includes findings of Congress with regard to the individual responsibility requirement under PPACA</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(b) IN GENERAL.—Subtitle D of the Internal Revenue Code of 1986 is amended by adding at the end the following new chapter:</p> <p>“CHAPTER 48—MAINTENANCE OF MINIMUM ESSENTIAL COVERAGE</p> <p>“Sec. 5000A. Requirement to maintain minimum essential coverage.</p> <p>“SEC. 5000A. REQUIREMENT TO MAINTAIN MINIMUM ESSENTIAL COVERAGE.</p> <p>“(a) REQUIREMENT TO MAINTAIN MINIMUM ESSENTIAL COVERAGE.— An applicable individual shall for each month beginning after 2013 ensure that the individual, and any dependent of the individual who is an applicable individual, is covered under minimum essential coverage for such month.</p> <p>“(b) SHARED RESPONSIBILITY PAYMENT.—</p> <p>“(1) IN GENERAL.—If an applicable individual fails to meet the requirement of subsection (a) for 1 or more months during any calendar year beginning after 2013, then, except as provided in subsection (d), there is hereby imposed a penalty with respect to the individual in the amount determined under subsection (c).</p> <p>“(2) INCLUSION WITH RETURN.—Any penalty imposed by this section with respect to any month shall be included with a taxpayer’s return under chapter 1 for the taxable year which includes such month.</p> <p>“(3) PAYMENT OF PENALTY.—If an individual with respect to whom a penalty is imposed by this section for any month—</p> <p>“(A) is a dependent (as defined in section 152) of another taxpayer for the other taxpayer’s taxable year including such month, such other taxpayer shall be liable for such penalty, or</p> <p>“(B) files a joint return for the taxable year including such month, such individual and the spouse of such individual shall be jointly liable for such penalty.</p> <p>“(c) AMOUNT OF PENALTY.—</p> <p>“(1) IN GENERAL.—The penalty determined under this subsection for any month with respect to any individual is an amount equal to 1/12 of the applicable dollar amount for the calendar year.</p> <p>“(2) DOLLAR LIMITATION.—The amount of the penalty imposed by this section on any taxpayer for any taxable year with respect to all individuals for whom the taxpayer is liable under subsection (b)(3) shall not exceed an amount equal to 300 percent the applicable dollar amount (determined without regard to paragraph (3)(C)) for the calendar year with or within which the taxable year ends.</p>	<p>Amends the Internal Revenue Code of 1986 by adding a new chapter, 48.</p>

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS**

**SUBTITLE F – SHARED RESPONSIBILITY FOR HEALTH CARE
PART I – INDIVIDUAL RESPONSIBILITY**

Section 1501. Requirement to maintain minimum essential coverage

Effective Date: Taxable Plan Years **after December 31, 2013**

Includes findings of Congress with regard to the individual responsibility requirement under PPACA

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(3) APPLICABLE DOLLAR AMOUNT.—For purposes of paragraph (1)—</p> <p>“(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the applicable dollar amount is \$750.</p> <p>“(B) PHASE IN.—The applicable dollar amount is \$95 for 2014 and \$350 for 2015.</p> <p>“(C) SPECIAL RULE FOR INDIVIDUALS UNDER AGE 18.— If an applicable individual has not attained the age of 18 as of the beginning of a month, the applicable dollar amount with respect to such individual for the month shall be equal to one-half of the applicable dollar amount for the calendar year in which the month occurs.</p> <p>“(D) INDEXING OF AMOUNT.—In the case of any calendar year beginning after 2016, the applicable dollar amount shall be equal to \$750, increased by an amount equal to—</p> <p>“(i) \$750, multiplied by</p> <p>“(ii) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year, determined by substituting ‘calendar year 2015’ for ‘calendar year 1992’ in subparagraph (B) thereof. If the amount of any increase under clause (i) is not a multiple of \$50, such increase shall be rounded to the next lowest multiple of \$50.</p> <p>“(4) TERMS RELATING TO INCOME AND FAMILIES.—For purposes of this section—</p> <p>“(A) FAMILY SIZE.—The family size involved with respect to any taxpayer shall be equal to the number of individuals for whom the taxpayer is allowed a deduction under section 151 (relating to allowance of deduction for personal exemptions) for the taxable year.</p> <p>“(B) HOUSEHOLD INCOME.—The term ‘household income’ means, with respect to any taxpayer for any taxable year, an amount equal to the sum of—</p> <p>“(i) the modified gross income of the taxpayer, plus</p> <p>“(ii) the aggregate modified gross incomes of all other individuals who—</p> <p>“(I) were taken into account in determining the taxpayer’s family size under paragraph (1), and</p> <p>“(II) were required to file a return of tax imposed by section 1 for the taxable year.</p> <p>“(C) MODIFIED GROSS INCOME.—The term ‘modified gross income’ means gross income—</p> <p>“(i) decreased by the amount of any deduction allowable under paragraph (1), (3), (4), or (10) of section 62(a),</p> <p>“(ii) increased by the amount of interest received or accrued during the taxable year which is exempt from tax imposed by this chapter, and</p> <p>“(iii) determined without regard to sections 911, 931, and 933.</p> <p>“(D) POVERTY LINE.—</p> <p>“(i) IN GENERAL.—The term ‘poverty line’ has the meaning given that term in section 2110(c)(5) of the Social Security Act (42 U.S.C. 1397jj(c)(5)).</p> <p>“(ii) POVERTY LINE USED.—In the case of any taxable year ending with or within a calendar year, the poverty line used shall be the most recently published poverty line as of the 1st day of such calendar year.</p> <p>“(d) APPLICABLE INDIVIDUAL.—For purposes of this section—</p> <p>“(1) IN GENERAL.—The term ‘applicable individual’ means, with respect to any month, an individual other than an individual described</p>	

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS**

**SUBTITLE F – SHARED RESPONSIBILITY FOR HEALTH CARE
PART I – INDIVIDUAL RESPONSIBILITY**

Section 1501. Requirement to maintain minimum essential coverage

Effective Date: Taxable Plan Years **after December 31, 2013**

Includes findings of Congress with regard to the individual responsibility requirement under PPACA

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>in paragraph (2), (3), or (4).</p> <p>“(2) RELIGIOUS EXEMPTIONS.—</p> <p>“(A) RELIGIOUS CONSCIENCE EXEMPTION.—Such term shall not include any individual for any month if such individual has in effect an exemption under section 1311(d)(4)(H) of the Patient Protection and Affordable Care Act which certifies that such individual is a member of a recognized religious sect or division thereof described in section 1402(g)(1) and an adherent of established tenets or teachings of such sect or division as described in such section.</p> <p>“(B) HEALTH CARE SHARING MINISTRY.—</p> <p>“(i) IN GENERAL.—Such term shall not include any individual for any month if such individual is a member of a health care sharing ministry for the month.</p> <p>“(ii) HEALTH CARE SHARING MINISTRY.—The term ‘health care sharing ministry’ means an organization—</p> <p>“(I) which is described in section 501(c)(3) and is exempt from taxation under section 501(a),</p> <p>“(II) members of which share a common set of ethical or religious beliefs and share medical expenses among members in accordance with those beliefs and without regard to the State in which a member resides or is employed,</p> <p>“(III) members of which retain membership even after they develop a medical condition,</p> <p>“(IV) which (or a predecessor of which) has been in existence at all times since December 31, 1999, and medical expenses of its members have been shared continuously and without interruption since at least December 31, 1999, and</p> <p>“(V) which conducts an annual audit which is performed by an independent certified public accounting firm in accordance with generally accepted accounting principles and which is made available to the public upon request.</p> <p>“(3) INDIVIDUALS NOT LAWFULLY PRESENT.—Such term shall not include an individual for any month if for the month the individual is not a citizen or national of the United States or an alien lawfully present in the United States.</p> <p>“(4) INCARCERATED INDIVIDUALS.—Such term shall not include an individual for any month if for the month the individual is incarcerated, other than incarceration pending the disposition of charges.</p> <p>“(e) EXEMPTIONS.—No penalty shall be imposed under subsection (a) with respect to—</p> <p>“(1) INDIVIDUALS WHO CANNOT AFFORD COVERAGE.—</p> <p>“(A) IN GENERAL.—Any applicable individual for any month if the applicable individual’s required contribution (determined on an annual basis) for coverage for the month exceeds 8 percent of such individual’s household income for the taxable year described in section 1412(b)(1)(B) of the Patient Protection and Affordable Care Act. For purposes of applying this subparagraph, the taxpayer’s household income shall be increased by any exclusion from gross income for any portion of the required contribution made through a salary reduction arrangement.</p> <p>“(B) REQUIRED CONTRIBUTION.—For purposes of this paragraph, the term ‘required contribution’ means—</p> <p>“(i) in the case of an individual eligible to purchase minimum essential coverage consisting of coverage through an eligible-employer-sponsored plan, the portion of the annual premium which would be paid by the individual (without regard to whether paid through salary reduction or otherwise) for self-only coverage, or</p>	

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS**

**SUBTITLE F – SHARED RESPONSIBILITY FOR HEALTH CARE
PART I – INDIVIDUAL RESPONSIBILITY**

Section 1501. Requirement to maintain minimum essential coverage

Effective Date: Taxable Plan Years **after December 31, 2013**

Includes findings of Congress with regard to the individual responsibility requirement under PPACA

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(ii) in the case of an individual eligible only to purchase minimum essential coverage described in subsection (f)(1)(C), the annual premium for the lowest cost bronze plan available in the individual market through the Exchange in the State in the rating area in which the individual resides (without regard to whether the individual purchased a qualified health plan through the Exchange), reduced by the amount of the credit allowable under section 36B for the taxable year (determined as if the individual was covered by a qualified health plan offered through the Exchange for the entire taxable year).</p> <p>“(C) SPECIAL RULES FOR INDIVIDUALS RELATED TO EMPLOYEES.—For purposes of subparagraph (B)(i), if an applicable individual is eligible for minimum essential coverage through an employer by reason of a relationship to an employee, the determination shall be made by reference to the affordability of the coverage to the employee.</p> <p>“(D) INDEXING.—In the case of plan years beginning in any calendar year after 2014, subparagraph (A) shall be applied by substituting for ‘8 percent’ the percentage the Secretary of Health and Human Services determines reflects the excess of the rate of premium growth between the preceding calendar year and 2013 over the rate of income growth for such period.</p> <p>“(2) TAXPAYERS WITH INCOME UNDER 100 PERCENT OF POVERTY LINE.—Any applicable individual for any month during a calendar year if the individual’s household income for the taxable year described in section 1412(b)(1)(B) of the Patient Protection and Affordable Care Act is less than 100 percent of the poverty line for the size of the family involved (determined in the same manner as under subsection (b)(4)).</p> <p>“(3) MEMBERS OF INDIAN TRIBES.—Any applicable individual for any month during which the individual is a member of an Indian tribe (as defined in section 45A(c)(6)).</p> <p>“(4) MONTHS DURING SHORT COVERAGE GAPS.—</p> <p>“(A) IN GENERAL.—Any month the last day of which occurred during a period in which the applicable individual was not covered by minimum essential coverage for a continuous period of less than 3 months.</p> <p>“(B) SPECIAL RULES.—For purposes of applying this paragraph—</p> <p>“(i) the length of a continuous period shall be determined without regard to the calendar years in which months in such period occur,</p> <p>“(ii) if a continuous period is greater than the period allowed under subparagraph (A), no exception shall be provided under this paragraph for any month in the period, and</p> <p>“(iii) if there is more than 1 continuous period described in subparagraph (A) covering months in a calendar year, the exception provided by this paragraph shall only apply to months in the first of such periods. The Secretary shall prescribe rules for the collection of the penalty imposed by this section in cases where continuous periods include months in more than 1 taxable year.</p> <p>“(5) HARDSHIPS.—Any applicable individual who for any month is determined by the Secretary of Health and Human Services under section 1311(d)(4)(H) to have suffered a hardship with respect to the capability to obtain coverage under a qualified health plan.</p> <p>“(f) MINIMUM ESSENTIAL COVERAGE.—For purposes of this section—</p> <p>“(1) IN GENERAL.—The term ‘minimum essential coverage’ means any of the following:</p> <p>“(A) GOVERNMENT SPONSORED PROGRAMS.—Coverage under—</p> <p>“(i) the Medicare program under part A of title XVIII of the Social Security Act,</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE F – SHARED RESPONSIBILITY FOR HEALTH CARE
PART I – INDIVIDUAL RESPONSIBILITY

Section 1501. Requirement to maintain minimum essential coverage

Effective Date: Taxable Plan Years **after December 31, 2013**

Includes findings of Congress with regard to the individual responsibility requirement under PPACA

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(ii) the Medicaid program under title XIX of the Social Security Act, “(iii) the CHIP program under title XXI of the Social Security Act, “(iv) the TRICARE for Life program, “(v) the veteran’s health care program under chapter 17 of title 38, United States Code, or “(vi) a health plan under section 2504(e) of title 22, United States Code (relating to Peace Corps volunteers). “(B) EMPLOYER-SPONSORED PLAN.—Coverage under an eligible employer-sponsored plan. “(C) PLANS IN THE INDIVIDUAL MARKET.—Coverage under a health plan offered in the individual market within a State. “(D) GRANDFATHERED HEALTH PLAN.—Coverage under a grandfathered health plan. “(E) OTHER COVERAGE.—Such other health benefits coverage, such as a State health benefits risk pool, as the Secretary of Health and Human Services, in coordination with the Secretary, recognizes for purposes of this subsection. “(2) ELIGIBLE EMPLOYER-SPONSORED PLAN.—The term ‘eligible employer-sponsored plan’ means, with respect to any employee, a group health plan or group health insurance coverage offered by an employer to the employee which is— “(A) a governmental plan (within the meaning of section 2791(d)(8) of the Public Health Service Act), or “(B) any other plan or coverage offered in the small or large group market within a State. Such term shall include a grandfathered health plan described in paragraph (1)(D) offered in a group market. “(3) EXCEPTED BENEFITS NOT TREATED AS MINIMUM ESSENTIAL COVERAGE.—The term ‘minimum essential coverage’ shall not include health insurance coverage which consists of coverage of excepted benefits— “(A) described in paragraph (1) of subsection (c) of section 2791 of the Public Health Service Act; or “(B) described in paragraph (2), (3), or (4) of such subsection if the benefits are provided under a separate policy, certificate, or contract of insurance. “(4) INDIVIDUALS RESIDING OUTSIDE UNITED STATES OR RESIDENTS OF TERRITORIES.—Any applicable individual shall be treated as having minimum essential coverage for any month— “(A) if such month occurs during any period described in subparagraph (A) or (B) of section 911(d)(1) which is applicable to the individual, or “(B) if such individual is a bona fide resident of any possession of the United States (as determined under section 937(a)) for such month. “(5) INSURANCE-RELATED TERMS.—Any term used in this section which is also used in title I of the Patient Protection and Affordable Care Act shall have the same meaning as when used in such title.</p> <p align="center">. . .</p> <p>(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years ending after December 31, 2013.</p>	

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE D – SUPPORT FOR PREVENTION AND PUBLIC HEALTH INNOVATION Section 4303. CDC and Employer-based Wellness Programs

Effective Date: March 23, 2010

The CDC shall evaluate best practices for employer-based wellness practices and promote the benefits through educational campaigns and technical assistance.

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>SEC. 4303. CDC AND EMPLOYER-BASED WELLNESS PROGRAMS. Title III of the Public Health Service Act (42 U.S.C. 241 et seq.), by section 4102, is further amended by adding at the end the following:</p> <p>“PART U—EMPLOYER-BASED WELLNESS PROGRAM</p> <p>“SEC. 399MM. TECHNICAL ASSISTANCE FOR EMPLOYER-BASED WELLNESS PROGRAMS. “In order to expand the utilization of evidence-based prevention and health promotion approaches in the workplace, the Director shall—</p> <p>“(1) provide employers (including small, medium, and large employers, as determined by the Director) with technical assistance, consultation, tools, and other resources in evaluating such employers’ employer-based wellness programs, including—</p> <p>“(A) measuring the participation and methods to increase participation of employees in such programs;</p> <p>“(B) developing standardized measures that assess policy, environmental and systems changes necessary to have a positive health impact on employees’ health behaviors, health outcomes, and health care expenditures; and</p> <p>“(C) evaluating such programs as they relate to changes in the health status of employees, the absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees; and</p> <p>“(2) build evaluation capacity among workplace staff by training employers on how to evaluate employer-based wellness programs by ensuring evaluation resources, technical assistance, and consultation are available to workplace staff as needed through such mechanisms as web portals, call centers, or other means.</p> <p>“SEC. 399MM-1. NATIONAL WORKSITE HEALTH POLICIES AND PROGRAMS STUDY. “(a) IN GENERAL.—In order to assess, analyze, and monitor over time data about workplace policies and programs, and to develop instruments to assess and evaluate comprehensive workplace chronic disease prevention and health promotion programs, policies and practices, not later than 2 years after the date of enactment of this part, and at regular intervals (to be determined by the Director) thereafter, the Director shall conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.</p> <p>“(b) REPORT.—Upon the completion of each study under subsection (a), the Director shall submit to Congress a report that includes the recommendations of the Director for the implementation of effective employer-based health policies and programs.</p>	<p>Amends Public Health Service Act by adding new sections: 399MM, 399M-1, and 399M-3</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE D – SUPPORT FOR PREVENTION AND PUBLIC HEALTH INNOVATION

Section 4303. CDC and Employer-based Wellness Programs

Effective Date: March 23, 2010

The CDC shall evaluate best practices for employer-based wellness practices and promote the benefits through educational campaigns and technical assistance.

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“SEC. 399MM–2. PRIORITIZATION OF EVALUATION BY SECRETARY. “The Secretary shall evaluate, in accordance with this part, all programs funded through the Centers for Disease Control and Prevention before conducting such an evaluation of privately funded programs unless an entity with a privately funded wellness program requests such an evaluation.</p> <p>“SEC. 399MM–3. PROHIBITION OF FEDERAL WORKPLACE WELLNESS REQUIREMENTS. “Notwithstanding any other provision of this part, any recommendations, data, or assessments carried out under this part shall not be used to mandate requirements for workplace wellness programs.”.</p> <p>SEC. 4304. EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS. Title XXVIII of the Public Health Service Act (42 U.S.C. 300hh et seq.) is amended by adding at the end the following: “Subtitle C—Strengthening Public Health Surveillance Systems “SEC. 2821. EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS. “(a) IN GENERAL.—Subject to the availability of appropriations, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an Epidemiology and Laboratory Capacity Grant Program to award grants to State health departments as well as local health departments and tribal jurisdictions that meet such criteria as the Director determines appropriate. Academic centers that assist State and eligible local and tribal health departments may also be eligible for funding under this section as the Director determines appropriate. Grants shall be awarded under this section to assist public health agencies in improving surveillance for, and response to, infectious diseases and other conditions of public health importance by— “(1) strengthening epidemiologic capacity to identify and monitor the occurrence of infectious diseases and other conditions of public health importance; “(2) enhancing laboratory practice as well as systems to report test orders and results electronically; “(3) improving information systems including developing and maintaining an information exchange using national guidelines and complying with capacities and functions determined by an advisory council established and appointed by the Director; and “(4) developing and implementing prevention and control strategies. “(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section \$190,000,000 for each of fiscal years 2010 through 2013, of which— “(1) not less than \$95,000,000 shall be made available each such fiscal year for activities under paragraphs (1) and (4) of subsection (a); “(2) not less than \$60,000,000 shall be made available each such fiscal year for activities under subsection (a)(3); and “(3) not less than \$32,000,000 shall be made available each such fiscal year for activities under subsection (a)(2).”.</p>	

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH**

SUBTITLE E – MISCELLANEOUS PROVISIONS

Section 4402. Effectiveness of Federal Health and Wellness Initiatives

Effective Date: March 23, 2010

Allows Secretary to evaluate the effectiveness of existing Federal health and wellness initiatives

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>SEC. 4402. EFFECTIVENESS OF FEDERAL HEALTH AND WELLNESS INITIATIVES. To determine whether existing Federal health and wellness initiatives are effective in achieving their stated goals, the Secretary of Health and Human Services shall—</p> <p>(1) conduct an evaluation of such programs as they relate to changes in health status of the American public and specifically on the health status of the Federal workforce, including absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees, and health conditions, including workplace fitness, healthy food and beverages, and incentives in the Federal Employee Health Benefits Program; and</p> <p>(2) submit to Congress a report concerning such evaluation, which shall include conclusions concerning the reasons that such existing programs have proven successful or not successful and what factors contributed to such conclusions.</p> <p style="text-align: center;">***</p>	<p>Provision unique to PPACA</p>

PRIVATE HEALTH INSURANCE AND GROUP HEALTH BENEFIT PLANS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE X – STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE D – PROVISIONS RELATING TO TITLE IV

Section 10408. Grants for Small Businesses to Provide Comprehensive Workplace Wellness Programs

Effective Date: March 23, 2010

Authorizes \$200 million to provide small business employees with access to comprehensive workplace wellness programs

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) ESTABLISHMENT.—The Secretary shall award grants to eligible employers to provide their employees with access to comprehensive workplace wellness programs (as described under subsection (c)).</p> <p>(b) SCOPE.—</p> <p>(1) DURATION.—The grant program established under this section shall be conducted for a 5-year period.</p> <p>(2) ELIGIBLE EMPLOYER.—The term “eligible employer” means an employer (including a non-profit employer) that—</p> <p>(A) employs less than 100 employees who work 25 hours or greater per week; and</p> <p>(B) does not provide a workplace wellness program as of the date of enactment of this Act.</p> <p>(c) COMPREHENSIVE WORKPLACE WELLNESS PROGRAMS.—</p> <p>(1) CRITERIA.—The Secretary shall develop program criteria for comprehensive workplace wellness programs under this section that are based on and consistent with evidence-based research and best practices, including research and practices as provided in the Guide to Community Preventive Services, the Guide to Clinical Preventive Services, and the National Registry for Effective Programs.</p> <p>(2) REQUIREMENTS.—A comprehensive workplace wellness program shall be made available by an eligible employer to all employees and include the following components:</p> <p>(A) Health awareness initiatives (including health education, preventive screenings, and health risk assessments).</p> <p>(B) Efforts to maximize employee engagement (including mechanisms to encourage employee participation).</p> <p>(C) Initiatives to change unhealthy behaviors and lifestyle choices (including counseling, seminars, online programs, and self-help materials).</p> <p>(D) Supportive environment efforts (including workplace policies to encourage healthy lifestyles, healthy eating, increased physical activity, and improved mental health).</p> <p>(d) APPLICATION.—An eligible employer desiring to participate in the grant program under this section shall submit an application to the Secretary, in such manner and containing such information as the Secretary may require, which shall include a proposal for a comprehensive workplace wellness program that meet the criteria and requirements described under subsection (c).</p>	<p>Provision unique to PPACA</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE X – STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE D – PROVISIONS RELATING TO TITLE IV

Section 10408. Grants for Small Businesses to Provide Comprehensive Workplace Wellness Programs

Effective Date: March 23, 2010

Authorizes \$200 million to provide small business employees with access to comprehensive workplace wellness programs

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(e) AUTHORIZATION OF APPROPRIATION.—For purposes of carrying out the grant program under this section, there is authorized to be appropriated \$200,000,000 for the period of fiscal years 2011 through 2015. Amounts appropriated pursuant to this subsection shall remain available until expended.</p>	
<p align="center">***</p>	

State-Regulated Health Exchanges

STATE-REGULATED HEALTH EXCHANGES

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS	
SUBTITLE D – AVAILABLE COVERAGE FOR ALL AMERICANS, PART I – ESTABLISHMENT OF QUALIFIED HEALTH PLANS	
Section 1302. Essential Health Benefits Requirements	
Effective Date: State option to phase-in employers with 50 to ≥ 100 employees ends in 2016	
<i>Sets ≤ 100 as cap for small group employer-based insurance; while allowing states the option of a phased implementation (cap the number of employees at ≤ 50 until 2016)</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) ESSENTIAL HEALTH BENEFITS PACKAGE.—In this title, the term “essential health benefits package” means, with respect to any health plan, coverage that—</p> <ol style="list-style-type: none"> (1) provides for the essential health benefits defined by the Secretary under subsection (b); (2) limits cost-sharing for such coverage in accordance with subsection (c); and (3) subject to subsection (e), provides either the bronze, silver, gold, or platinum level of coverage described in subsection (d). <p>(b) ESSENTIAL HEALTH BENEFITS.—</p> <p>(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall define the essential health benefits, except that such benefits shall include at least the following general categories and the items and services covered within the categories:</p> <p>(A) Ambulatory patient services; (B) Emergency services; (C) Hospitalization; (D) Maternity and newborn care; (E) Mental health and substance use disorder services, including behavioral health treatment; (F) Prescription drugs; (G) Rehabilitative and habilitative services and devices; (H) Laboratory services; (I) Preventive and wellness services and chronic disease management; (J) Pediatric services, including oral and vision care.</p> <p>(2) LIMITATION.—</p> <p>(A) IN GENERAL.—The Secretary shall ensure that the scope of the essential health benefits under paragraph (1) is equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary. To inform this determination, the Secretary of Labor shall conduct a survey of employer-sponsored coverage to determine the benefits typically covered by employers, including multiemployer plans, and provide a report on such survey to the Secretary.</p> <p>(B) CERTIFICATION.—In defining the essential health benefits described in paragraph (1), and in revising the benefits under paragraph (4)(H), the Secretary shall submit a report to the appropriate committees of Congress containing a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that such essential health benefits meet the limitation described in paragraph (2).</p> <p>(3) NOTICE AND HEARING.—In defining the essential health benefits described in paragraph (1), and in revising the benefits under paragraph (4)(H), the Secretary shall provide notice and an opportunity for public comment.</p> <p>(4) REQUIRED ELEMENTS FOR CONSIDERATION.—In defining the essential health benefits under paragraph (1), the Secretary shall—</p> <p>(A) ensure that such essential health benefits reflect an appropriate balance among the categories described in such subsection, so that benefits are not unduly weighted toward any category;</p> <p>(B) not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that</p>	<p>Provision unique to PPACA</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE D – AVAILABLE COVERAGE FOR ALL AMERICANS,
PART I – ESTABLISHMENT OF QUALIFIED HEALTH PLANS

Section 1302. Essential Health Benefits Requirements

Effective Date: State option to phase-in employers with 50 to ≥100 employees ends in **2016**

Sets ≤100 as cap for small group employer-based insurance; while allowing states the option of a phased implementation (cap the number of employees at ≤50 until 2016)

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>discriminate against individuals because of their age, disability, or expected length of life;</p> <p>(C) take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups;</p> <p>(D) ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals’ age or expected length of life or of the individuals’ present or predicted disability, degree of medical dependency, or quality of life;</p> <p>(E) provide that a qualified health plan shall not be treated as providing coverage for the essential health benefits described in paragraph (1) unless the plan provides that—</p> <p>(i) coverage for emergency department services will be provided without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services does not have a contractual relationship with the plan than the requirements or limitations that apply to emergency department services received from providers who do have such a contractual relationship with the plan; and</p> <p>(ii) if such services are provided out-of-network, the cost-sharing requirement (expressed as a copayment amount or coinsurance rate) is the same requirement that would apply if such services were provided in-network;</p> <p>(F) provide that if a plan described in section 1311(b)(2)(B)(ii) (relating to stand-alone dental benefits plans) is offered through an Exchange, another health plan offered through such Exchange shall not fail to be treated as a qualified health plan solely because the plan does not offer coverage of benefits offered through the standalone plan that are otherwise required under paragraph (1)(J); and</p> <p>(G) periodically review the essential health benefits under paragraph (1), and provide a report to Congress and the public that contains—</p> <p>(i) an assessment of whether enrollees are facing any difficulty accessing needed services for reasons of coverage or cost;</p> <p>(ii) an assessment of whether the essential health benefits needs to be modified or updated to account for changes in medical evidence or scientific advancement;</p> <p>(iii) information on how the essential health benefits will be modified to address any such gaps in access or changes in the evidence base;</p> <p>(iv) an assessment of the potential of additional or expanded benefits to increase costs and the interactions between the addition or expansion of benefits and reductions in existing benefits to meet actuarial limitations described in paragraph (2); and</p> <p>(H) periodically update the essential health benefits under paragraph (1) to address any gaps in access to coverage or changes in the evidence base the Secretary identifies in the review conducted under subparagraph (G).</p> <p>(5) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to prohibit a health plan from providing benefits in excess of the essential health benefits described in this subsection.</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE D – AVAILABLE COVERAGE FOR ALL AMERICANS,
PART I – ESTABLISHMENT OF QUALIFIED HEALTH PLANS

Section 1302. Essential Health Benefits Requirements

Effective Date: State option to phase-in employers with 50 to ≥ 100 employees ends in **2016**

Sets ≤ 100 as cap for small group employer-based insurance; while allowing states the option of a phased implementation (cap the number of employees at ≤ 50 until 2016)

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(c) REQUIREMENTS RELATING TO COST-SHARING.—</p> <p>(1) ANNUAL LIMITATION ON COST-SHARING.—</p> <p>(A) 2014.—The cost-sharing incurred under a health plan with respect to self-only coverage or coverage other than self-only coverage for a plan year beginning in 2014 shall not exceed the dollar amounts in effect under section 223(c)(2)(A)(ii) of the Internal Revenue Code of 1986 for self-only and family coverage, respectively, for taxable years beginning in 2014.</p> <p>(B) 2015 AND LATER.—In the case of any plan year beginning in a calendar year after 2014, the limitation under this paragraph shall—</p> <p>(i) in the case of self-only coverage, be equal to the dollar amount under subparagraph (A) for self only coverage for plan years beginning in 2014, increased by an amount equal to the product of that amount and the premium adjustment percentage under paragraph (4) for the calendar year; and</p> <p>(ii) in the case of other coverage, twice the amount in effect under clause (i).</p> <p>If the amount of any increase under clause (i) is not a multiple of \$50, such increase shall be rounded to the next lowest multiple of \$50.</p> <p>(2) ANNUAL LIMITATION ON DEDUCTIBLES FOR EMPLOYER-SPONSORED PLANS.—</p> <p>(A) IN GENERAL.—In the case of a health plan offered in the small group market, the deductible under the plan shall not exceed—</p> <p>(i) \$2,000 in the case of a plan covering a single individual; and</p> <p>(ii) \$4,000 in the case of any other plan.</p> <p>The amounts under clauses (i) and (ii) may be increased by the maximum amount of reimbursement which is reasonably available to a participant under a flexible spending arrangement described in section 106(c)(2) of the Internal Revenue Code of 1986 (determined without regard to any salary reduction arrangement).</p> <p>(B) INDEXING OF LIMITS.—In the case of any plan year beginning in a calendar year after 2014—</p> <p>(i) the dollar amount under subparagraph (A)(i) shall be increased by an amount equal to the product of that amount and the premium adjustment percentage under paragraph (4) for the calendar year; and</p> <p>(ii) the dollar amount under subparagraph (A)(ii) shall be increased to an amount equal to twice the amount in effect under subparagraph (A)(i) for plan years beginning in the calendar year, determined after application of clause (i). If the amount of any increase under clause (i) is not a multiple of \$50, such increase shall be rounded to the next lowest multiple of \$50.</p> <p>(C) ACTUARIAL VALUE.—The limitation under this paragraph shall be applied in such a manner so as to not affect the actuarial value of any health plan, including a plan in the bronze level.</p> <p>(D) COORDINATION WITH PREVENTIVE LIMITS.—Nothing in this paragraph shall be construed to allow a plan to have a deductible under the plan apply to benefits described in section 2713 of the Public Health Service Act.</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE D – AVAILABLE COVERAGE FOR ALL AMERICANS,
PART I – ESTABLISHMENT OF QUALIFIED HEALTH PLANS

Section 1302. Essential Health Benefits Requirements

Effective Date: State option to phase-in employers with 50 to ≥ 100 employees ends in **2016**

Sets ≤ 100 as cap for small group employer-based insurance; while allowing states the option of a phased implementation (cap the number of employees at ≤ 50 until 2016)

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(3) COST-SHARING.—In this title—</p> <p>(A) IN GENERAL.—The term “cost-sharing” includes—</p> <p>(i) deductibles, coinsurance, copayments, or similar charges; and</p> <p>(ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of the Internal Revenue Code of 1986) with respect to essential health benefits covered under the plan.</p> <p>(B) EXCEPTIONS.—Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.</p> <p>(4) PREMIUM ADJUSTMENT PERCENTAGE.—For purposes of paragraphs (1)(B)(i) and (2)(B)(i), the premium adjustment percentage for any calendar year is the percentage (if any) by which the average per capita premium for health insurance coverage in the United States for the preceding calendar year (as estimated by the Secretary no later than October 1 of such preceding calendar year) exceeds such average per capita premium for 2013 (as determined by the Secretary).</p> <p>(d) LEVELS OF COVERAGE.—</p> <p>(1) LEVELS OF COVERAGE DEFINED.—The levels of coverage described in this subsection are as follows:</p> <p>(A) BRONZE LEVEL.—A plan in the bronze level shall provide a level of coverage that is designed to provide benefits that are actuarially equivalent to 60 percent of the full actuarial value of the benefits provided under the plan.</p> <p>(B) SILVER LEVEL.—A plan in the silver level shall provide a level of coverage that is designed to provide benefits that are actuarially equivalent to 70 percent of the full actuarial value of the benefits provided under the plan.</p> <p>(C) GOLD LEVEL.—A plan in the gold level shall provide a level of coverage that is designed to provide benefits that are actuarially equivalent to 80 percent of the full actuarial value of the benefits provided under the plan.</p> <p>(D) PLATINUM LEVEL.—A plan in the platinum level shall provide a level of coverage that is designed to provide benefits that are actuarially equivalent to 90 percent of the full actuarial value of the benefits provided under the plan.</p> <p>(2) ACTUARIAL VALUE.—</p> <p>(A) IN GENERAL.—Under regulations issued by the Secretary, the level of coverage of a plan shall be determined on the basis that the essential health benefits described in subsection (b) shall be provided to a standard population (and without regard to the population the plan may actually provide benefits to).</p> <p>(B) EMPLOYER CONTRIBUTIONS.—The Secretary may issue regulations under which employer contributions to a health savings account (within the meaning of section 223 of the Internal Revenue Code of 1986) may be taken into account in determining the level of coverage for a plan of the employer.</p> <p>(C) APPLICATION.—In determining under this title, the Public Health Service Act, or the Internal Revenue Code of 1986 the percentage of the total allowed costs of benefits provided under a group health plan or health insurance coverage that are provided by such plan or coverage, the rules contained in the regulations under this paragraph shall apply.</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE D – AVAILABLE COVERAGE FOR ALL AMERICANS,
PART I – ESTABLISHMENT OF QUALIFIED HEALTH PLANS

Section 1302. Essential Health Benefits Requirements

Effective Date: State option to phase-in employers with 50 to ≥ 100 employees ends in **2016**

Sets ≤ 100 as cap for small group employer-based insurance; while allowing states the option of a phased implementation (cap the number of employees at ≤ 50 until 2016)

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(3) ALLOWABLE VARIANCE.—The Secretary shall develop guidelines to provide for a de minimis variation in the actuarial valuations used in determining the level of coverage of a plan to account for differences in actuarial estimates.</p> <p>(4) PLAN REFERENCE.—In this title, any reference to a bronze, silver, gold, or platinum plan shall be treated as a reference to a qualified health plan providing a bronze, silver, gold, or platinum level of coverage, as the case may be.</p> <p>(e) CATASTROPHIC PLAN.—</p> <p>(1) IN GENERAL.—A health plan not providing a bronze, silver, gold, or platinum level of coverage shall be treated as meeting the requirements of subsection (d) with respect to any plan year if—</p> <p>(A) the only individuals who are eligible to enroll in the plan are individuals described in paragraph (2); and</p> <p>(B) the plan provides—</p> <p>(i) except as provided in clause (ii), the essential health benefits determined under subsection (b), except that the plan provides no benefits for any plan year until the individual has incurred cost-sharing expenses in an amount equal to the annual limitation in effect under subsection (c)(1) for the plan year (except as provided for in section 2713); and</p> <p>(ii) coverage for at least three primary care visits.</p> <p>(2) INDIVIDUALS ELIGIBLE FOR ENROLLMENT.—An individual is described in this paragraph for any plan year if the individual—</p> <p>(A) has not attained the age of 30 before the beginning of the plan year; or</p> <p>(B) has a certification in effect for any plan year under this title that the individual is exempt from the requirement under section 5000A of the Internal Revenue Code of 1986 by reason of—</p> <p>(i) section 5000A(e)(1) of such Code (relating to individuals without affordable coverage); or</p> <p>(ii) section 5000A(e)(5) of such Code (relating to individuals with hardships).</p> <p>(3) RESTRICTION TO INDIVIDUAL MARKET.—If a health insurance issuer offers a health plan described in this subsection, the issuer may only offer the plan in the individual market.</p> <p>(f) CHILD-ONLY PLANS.—If a qualified health plan is offered through the Exchange in any level of coverage specified under subsection (d), the issuer shall also offer that plan through the Exchange in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21, and such plan shall be treated as a qualified health plan.</p>	

STATE-REGULATED HEALTH EXCHANGES

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS
SUBTITLE D – AVAILABLE COVERAGE FOR ALL AMERICANS,
PART I – ESTABLISHMENT OF QUALIFIED HEALTH PLANS
Section 1304. Related Definitions

Effective Date: January 1, 2014

Defines an essential health benefits package

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) DEFINITIONS RELATING TO MARKETS.—In this title:</p> <p>(1) GROUP MARKET.—The term “group market” means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by an employer.</p> <p>(2) INDIVIDUAL MARKET.—The term “individual market” means the market for health insurance coverage offered to individuals other than in connection with a group health plan.</p> <p>(3) LARGE AND SMALL GROUP MARKETS.—The terms “large group market” and “small group market” mean the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a large employer (as defined in subsection (b)(1)) or by a small employer (as defined in subsection (b)(2)), respectively.</p> <p>(b) EMPLOYERS.—In this title:</p> <p>(1) LARGE EMPLOYER.—The term “large employer” means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 101 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year.</p> <p>(2) SMALL EMPLOYER.—The term “small employer” means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year.</p> <p>(3) STATE OPTION TO TREAT 50 EMPLOYEES AS SMALL.— In the case of plan years beginning before January 1, 2016, a State may elect to apply this subsection by substituting “51 employees” for “101 employees” in paragraph (1) and by substituting “50 employees” for “100 employees” in paragraph (2).</p> <p>(4) RULES FOR DETERMINING EMPLOYER SIZE.—For purposes of this subsection—</p> <p>(A) APPLICATION OF AGGREGATION RULE FOR EMPLOYERS.—All persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986 shall be treated as 1 employer.</p> <p>(B) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is a small or large employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.</p>	<p>Provision unique to PPACA</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE D – AVAILABLE COVERAGE FOR ALL AMERICANS,
PART I – ESTABLISHMENT OF QUALIFIED HEALTH PLANS

Section 1304. Related Definitions

Effective Date: January 1, 2014

Defines an essential health benefits package

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(C) PREDECESSORS.—Any reference in this subsection to an employer shall include a reference to any predecessor of such employer.</p> <p>(D) CONTINUATION OF PARTICIPATION FOR GROWING SMALL EMPLOYERS.—If—</p> <p>(i) a qualified employer that is a small employer makes enrollment in qualified health plans offered in the small group market available to its employees through an Exchange; and</p> <p>(ii) the employer ceases to be a small employer by reason of an increase in the number of employees of such employer; the employer shall continue to be treated as a small employer for purposes of this subtitle for the period beginning with the increase and ending with the first day on which the employer does not make such enrollment available to its employees.</p> <p align="center">. . .</p>	
<p align="center">***</p>	

STATE-REGULATED HEALTH EXCHANGES

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS SUBTITLE D – AVAILABLE COVERAGE FOR ALL AMERICANS, PART II – CONSUMER CHOICES AND INSURANCE COMPETITION THROUGH HEALTH BENEFIT EXCHANGES Section 1311. Refundable Tax Credit Providing Premium Assistance for Coverage Under a Qualified Health Plan	
Effective Date: March 23, 2010	
<i>Requires the Secretary to award grants to states in order to plan and establish American Health Benefit Exchanges</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) ASSISTANCE TO STATES TO ESTABLISH AMERICAN HEALTH BENEFIT EXCHANGES.—</p> <p>(1) PLANNING AND ESTABLISHMENT GRANTS.—There shall be appropriated to the Secretary, out of any moneys in the Treasury not otherwise appropriated, an amount necessary to enable the Secretary to make awards, not later than 1 year after the date of enactment of this Act, to States in the amount specified in paragraph (2) for the uses described in paragraph (3).</p> <p>(2) AMOUNT SPECIFIED.—For each fiscal year, the Secretary shall determine the total amount that the Secretary will make available to each State for grants under this subsection.</p> <p>(3) USE OF FUNDS.—A State shall use amounts awarded under this subsection for activities (including planning activities) related to establishing an American Health Benefit Exchange, as described in subsection (b).</p> <p>(4) RENEWABILITY OF GRANT.—</p> <p>(A) IN GENERAL.—Subject to subsection (d)(4), the Secretary may renew a grant awarded under paragraph (1) if the State recipient of such grant—</p> <p>(i) is making progress, as determined by the Secretary, toward—</p> <p>(I) establishing an Exchange; and</p> <p>(II) implementing the reforms described in subtitles A and C (and the amendments made by such subtitles); and</p> <p>(ii) is meeting such other benchmarks as the Secretary may establish.</p> <p>(B) LIMITATION.—No grant shall be awarded under this subsection after January 1, 2015.</p> <p>(5) TECHNICAL ASSISTANCE TO FACILITATE PARTICIPATION IN SHOP EXCHANGES.—The Secretary shall provide technical assistance to States to facilitate the participation of qualified small businesses in such States in SHOP Exchanges.</p> <p>(b) AMERICAN HEALTH BENEFIT EXCHANGES.—</p> <p>(1) IN GENERAL.—Each State shall, not later than January 1, 2014, establish an American Health Benefit Exchange (referred to in this title as an “Exchange”) for the State that—</p> <p>(A) facilitates the purchase of qualified health plans;</p> <p>(B) provides for the establishment of a Small Business Health Options Program (in this title referred to as a “SHOP Exchange”) that is designed to assist qualified employers in the State who are small employers in facilitating the enrollment of their employees in qualified health plans offered in the small group market in the State; and</p> <p>(C) meets the requirements of subsection (d).</p> <p>(2) MERGER OF INDIVIDUAL AND SHOP EXCHANGES.—A State may elect to provide only one Exchange in the</p>	<p>Provision unique to PPACA</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE D – AVAILABLE COVERAGE FOR ALL AMERICANS,
PART II – CONSUMER CHOICES AND INSURANCE COMPETITION THROUGH HEALTH BENEFIT EXCHANGES
Section 1311. Refundable Tax Credit Providing Premium Assistance for Coverage Under a Qualified Health Plan

Effective Date: March 23, 2010

Requires the Secretary to award grants to states in order to plan and establish American Health Benefit Exchanges

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>State for providing both Exchange and SHOP Exchange services to both qualified individuals and qualified small employers, but only if the Exchange has adequate resources to assist such individuals and employers.</p> <p>(c) RESPONSIBILITIES OF THE SECRETARY.—</p> <p>(1) IN GENERAL.—The Secretary shall, by regulation, establish criteria for the certification of health plans as qualified health plans. Such criteria shall require that, to be certified, a plan shall, at a minimum—</p> <p>(A) meet marketing requirements, and not employ marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs;</p> <p>(B) ensure a sufficient choice of providers (in a manner consistent with applicable network adequacy provisions under section 2702(c) of the Public Health Service Act), and provide information to enrollees and prospective enrollees on the availability of in-network and out-of-network providers;</p> <p>(C) include within health insurance plan networks those essential community providers, where available, that serve predominately low-income, medically-underserved individuals, such as health care providers defined in section 340B(a)(4) of the Public Health Service Act and providers described in section 1927(c)(1)(D)(i)(IV) of the Social Security Act as set forth by section 221 of Public Law 111– 8, except that nothing in this subparagraph shall be construed to require any health plan to provide coverage for any specific medical procedure;</p> <p>(D)(i) be accredited with respect to local performance on clinical quality measures such as the Healthcare Effectiveness Data and Information Set, patient experience ratings on a standardized Consumer Assessment of Healthcare Providers and Systems survey, as well as consumer access, utilization management, quality assurance, provider credentialing, complaints and appeals, network adequacy and access, and patient information programs by any entity recognized by the Secretary for the accreditation of health insurance issuers or plans (so long as any such entity has transparent and rigorous methodological and scoring criteria); or</p> <p>(ii) receive such accreditation within a period established by an Exchange for such accreditation that is applicable to all qualified health plans;</p> <p>(E) implement a quality improvement strategy described in subsection (g)(1);</p> <p>(F) utilize a uniform enrollment form that qualified individuals and qualified employers may use (either electronically or on paper) in enrolling in qualified health plans offered through such Exchange, and that takes into account criteria that the National Association of Insurance Commissioners develops and submits to the Secretary;</p> <p>(G) utilize the standard format established for presenting health benefits plan options; and</p> <p>(H) provide information to enrollees and prospective enrollees, and to each Exchange in which the plan is offered, on any quality measures for health plan performance endorsed under section 399JJ of the Public Health Service Act, as applicable.</p> <p>(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1)(C) shall be construed to require a qualified health plan to contract with a provider described in such paragraph if such provider refuses to accept the generally applicable payment rates of such plan.</p>	

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I – QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS**

**SUBTITLE D – AVAILABLE COVERAGE FOR ALL AMERICANS,
PART II – CONSUMER CHOICES AND INSURANCE COMPETITION THROUGH HEALTH BENEFIT EXCHANGES
Section 1311. Refundable Tax Credit Providing Premium Assistance for Coverage Under a Qualified Health Plan**

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<p>(3) RATING SYSTEM.—The Secretary shall develop a rating system that would rate qualified health plans offered through an Exchange in each benefits level on the basis of the relative quality and price. The Exchange shall include the quality rating in the information provided to individuals and employers through the Internet portal established under paragraph (4).</p> <p>(4) ENROLLEE SATISFACTION SYSTEM.—The Secretary shall develop an enrollee satisfaction survey system that would evaluate the level of enrollee satisfaction with qualified health plans offered through an Exchange, for each such qualified health plan that had more than 500 enrollees in the previous year. The Exchange shall include enrollee satisfaction information in the information provided to individuals and employers through the Internet portal established under paragraph (5) in a manner that allows individuals to easily compare enrollee satisfaction levels between comparable plans.</p> <p>(5) INTERNET PORTALS.—The Secretary shall—</p> <p>(A) continue to operate, maintain, and update the Internet portal developed under section 1103(a) and to assist States in developing and maintaining their own such portal; and (B) make available for use by Exchanges a model template for an Internet portal that may be used to direct qualified individuals and qualified employers to qualified health plans, to assist such individuals and employers in determining whether they are eligible to participate in an Exchange or eligible for a premium tax credit or cost sharing reduction, and to present standardized information (including quality ratings) regarding qualified health plans offered through an Exchange to assist consumers in making easy health insurance choices. Such template shall include, with respect to each qualified health plan offered through the Exchange in each rating area, access to the uniform outline of coverage the plan is required to provide under section 2716 of the Public Health Service Act and to a copy of the plan’s written policy.</p> <p>(6) ENROLLMENT PERIODS.—The Secretary shall require an Exchange to provide for—</p> <p>(A) an initial open enrollment, as determined by the Secretary (such determination to be made not later than July 1, 2012);</p> <p>(B) annual open enrollment periods, as determined by the Secretary for calendar years after the initial enrollment period;</p> <p>(C) special enrollment periods specified in section 9801 of the Internal Revenue Code of 1986 and other special enrollment periods under circumstances similar to such periods under part D of title XVIII of the Social Security Act; and</p> <p>(D) special monthly enrollment periods for Indians (as defined in section 4 of the Indian Health Care Improvement Act).</p> <p>(d) REQUIREMENTS.—</p> <p>(1) IN GENERAL.—An Exchange shall be a governmental agency or nonprofit entity that is established by a State.</p> <p>(2) OFFERING OF COVERAGE.—</p> <p>(A) IN GENERAL.—An Exchange shall make available qualified health plans to qualified individuals and qualified employers.</p> <p>(B) LIMITATION.—</p> <p>(i) IN GENERAL.—An Exchange may not make available any health plan that is not a qualified health plan.</p> <p>(ii) OFFERING OF STAND-ALONE DENTAL BENEFITS.—</p> <p>Each Exchange within a State shall allow an issuer of a plan that only provides limited scope dental benefits meeting the</p>	

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<p>requirements of section 9832(c)(2)(A) of the Internal Revenue Code of 1986 to offer the plan through the Exchange (either separately or in conjunction with a qualified health plan) if the plan provides pediatric dental benefits meeting the requirements of section 1302(b)(1)(J)).</p> <p>(3) RULES RELATING TO ADDITIONAL REQUIRED BENEFITS.—</p> <p>(A) IN GENERAL.—Except as provided in subparagraph (B), an Exchange may make available a qualified health plan notwithstanding any provision of law that may require benefits other than the essential health benefits specified under section 1302(b).</p> <p>(B) STATES MAY REQUIRE ADDITIONAL BENEFITS.—</p> <p>(i) IN GENERAL.—Subject to the requirements of clause (ii), a State may require that a qualified health plan offered in such State offer benefits in addition to the essential health benefits specified under section 1302(b).</p> <p>(ii) STATE MUST ASSUME COST.—A State shall make payments to or on behalf of an individual eligible for the premium tax credit under section 36B of the Internal Revenue Code of 1986 and any cost-sharing reduction under section 1402 to defray the cost to the individual of any additional benefits described in clause (i) which are not eligible for such credit or reduction under section 36B(b)(3)(D) of such Code and section 1402(c)(4).</p> <p>(4) FUNCTIONS.—An Exchange shall, at a minimum—</p> <p>(A) implement procedures for the certification, recertification, and decertification, consistent with guidelines developed by the Secretary under subsection (c), of health plans as qualified health plans;</p> <p>(B) provide for the operation of a toll-free telephone hotline to respond to requests for assistance;</p> <p>(C) maintain an Internet website through which enrollees and prospective enrollees of qualified health plans may obtain standardized comparative information on such plans;</p> <p>(D) assign a rating to each qualified health plan offered through such Exchange in accordance with the criteria developed by the Secretary under subsection (c)(3);</p> <p>(E) utilize a standardized format for presenting health benefits plan options in the Exchange, including the use the uniform outline of coverage established under section 2715 of the Public Health Service Act;</p> <p>(F) in accordance with section 1413, inform individuals of eligibility requirements for the Medicaid program under title XIX of the Social Security Act, the CHIP program under title XXI of such Act, or any applicable State or local public program and if through screening of the application by the Exchange, the Exchange determines that such individuals are eligible for any such program, enroll such individuals in such program;</p> <p>(G) establish and make available by electronic means a calculator to determine the actual cost of coverage after the application of any premium tax credit under section 36B of the Internal Revenue Code of 1986 and any cost sharing reduction under section 1402;</p> <p>(H) subject to section 1411, grant a certification attesting that, for purposes of the individual responsibility penalty under section 5000A of the Internal Revenue Code of 1986, an individual is exempt from the individual requirement or from the penalty imposed by such section because—</p>	

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<p>(i) there is no affordable qualified health plan available through the Exchange, or the individual’s employer, covering the individual; or (ii) the individual meets the requirements for any other such exemption from the individual responsibility requirement or penalty;</p> <p>(I) transfer to the Secretary of the Treasury—</p> <p>(i) a list of the individuals who are issued a certification under subparagraph (H), including the name and taxpayer identification number of each individual;</p> <p>(ii) the name and taxpayer identification number of each individual who was an employee of an employer but who was determined to be eligible for the premium tax credit under section 36B of the Internal Revenue Code of 1986 because—</p> <p>(I) the employer did not provide minimum essential coverage; or</p> <p>(II) the employer provided such minimum essential coverage but it was determined under section 36B(c)(2)(C) of such Code to either be unaffordable to the employee or not provide the required minimum actuarial value; and</p> <p>(iii) the name and taxpayer identification number of each individual who notifies the Exchange under section 1411(b)(4) that they have changed employers and of each individual who ceases coverage under a qualified health plan during a plan year (and the effective date of such cessation);</p> <p>(J) provide to each employer the name of each employee of the employer described in subparagraph (I)(ii) who ceases coverage under a qualified health plan during a plan year (and the effective date of such cessation); and</p> <p>(K) establish the Navigator program described in subsection (i).</p> <p>(5) FUNDING LIMITATIONS.—</p> <p>(A) NO FEDERAL FUNDS FOR CONTINUED OPERATIONS.—</p> <p>In establishing an Exchange under this section, the State shall ensure that such Exchange is self-sustaining beginning on January 1, 2015, including allowing the Exchange to charge assessments or user fees to participating health insurance issuers, or to otherwise generate funding, to support its operations.</p> <p>(B) PROHIBITING WASTEFUL USE OF FUNDS.—In carrying out activities under this subsection, an Exchange shall not utilize any funds intended for the administrative and operational expenses of the Exchange for staff retreats, promotional giveaways, excessive executive compensation, or promotion of Federal or State legislative and regulatory modifications.</p> <p>(6) CONSULTATION.—An Exchange shall consult with stakeholders relevant to carrying out the activities under this section, including—</p> <p>(A) health care consumers who are enrollees in qualified health plans;</p> <p>(B) individuals and entities with experience in facilitating enrollment in qualified health plans;</p> <p>(C) representatives of small businesses and self-employed individuals;</p> <p>(D) State Medicaid offices; and</p> <p>(E) advocates for enrolling hard to reach populations.</p> <p>(7) PUBLICATION OF COSTS.—An Exchange shall publish the average costs of licensing, regulatory fees, and any other payments required by the Exchange, and the administrative costs of such Exchange, on an Internet website to educate</p>	

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<p>consumers on such costs. Such information shall also include monies lost to waste, fraud, and abuse.</p> <p>(e) CERTIFICATION.— (1) IN GENERAL.—An Exchange may certify a health plan as a qualified health plan if— (A) such health plan meets the requirements for certification as promulgated by the Secretary under subsection (c)(1); and (B) the Exchange determines that making available such health plan through such Exchange is in the interests of qualified individuals and qualified employers in the State or States in which such Exchange operates, except that the Exchange may not exclude a health plan— (i) on the basis that such plan is a fee-for-service plan; (ii) through the imposition of premium price controls; or (iii) on the basis that the plan provides treatments necessary to prevent patients’ deaths in circumstances the Exchange determines are inappropriate or too costly. (2) PREMIUM CONSIDERATIONS.—The Exchange shall require health plans seeking certification as qualified health plans to submit a justification for any premium increase prior to implementation of the increase. Such plans shall prominently post such information on their websites. The Exchange may take this information, and the information and the recommendations provided to the Exchange by the State under section 2794(b)(1) of the Public Health Service Act (relating to patterns or practices of excessive or unjustified premium increases), into consideration when determining whether to make such health plan available through the Exchange. The Exchange shall take into account any excess of premium growth outside the Exchange as compared to the rate of such growth inside the Exchange, including information reported by the States.</p> <p>(f) FLEXIBILITY.— (1) REGIONAL OR OTHER INTERSTATE EXCHANGES.—An Exchange may operate in more than one State if— (A) each State in which such Exchange operates permits such operation; and (B) the Secretary approves such regional or interstate Exchange. (2) SUBSIDIARY EXCHANGES.—A State may establish one or more subsidiary Exchanges if— (A) each such Exchange serves a geographically distinct area; and (B) the area served by each such Exchange is at least as large as a rating area described in section 2701(a) of the Public Health Service Act. (3) AUTHORITY TO CONTRACT.— (A) IN GENERAL.—A State may elect to authorize an Exchange established by the State under this section to enter into an agreement with an eligible entity to carry out 1 or more responsibilities of the Exchange. (B) ELIGIBLE ENTITY.—In this paragraph, the term “eligible entity” means— (i) a person—</p>	

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<p>(I) incorporated under, and subject to the laws of, 1 or more States;</p> <p>(II) that has demonstrated experience on a State or regional basis in the individual and small group health insurance markets and in benefits coverage; and</p> <p>(III) that is not a health insurance issuer or that is treated under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 as a member of the same controlled group of corporations (or under common control with) as a health insurance issuer; or</p> <p>(ii) the State Medicaid agency under title XIX of the Social Security Act.</p> <p>(g) REWARDING QUALITY THROUGH MARKET-BASED INCENTIVES.—</p> <p>(1) STRATEGY DESCRIBED.—A strategy described in this paragraph is a payment structure that provides increased reimbursement or other incentives for—</p> <p>(A) improving health outcomes through the implementation of activities that shall include quality reporting, effective case management, care coordination, chronic disease management, medication and care compliance initiatives, including through the use of the medical home model, for treatment or services under the plan or coverage;</p> <p>(B) the implementation of activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional;</p> <p>(C) the implementation of activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and</p> <p>(D) the implementation of wellness and health promotion activities.</p> <p>(2) GUIDELINES.—The Secretary, in consultation with experts in health care quality and stakeholders, shall develop guidelines concerning the matters described in paragraph (1).</p> <p>(3) REQUIREMENTS.—The guidelines developed under paragraph (2) shall require the periodic reporting to the applicable Exchange of the activities that a qualified health plan has conducted to implement a strategy described in paragraph (1).</p> <p>(h) QUALITY IMPROVEMENT.—</p> <p>(1) ENHANCING PATIENT SAFETY.—Beginning on January 1, 2015, a qualified health plan may contract with—</p> <p>(A) a hospital with greater than 50 beds only if such hospital—</p> <p>(i) utilizes a patient safety evaluation system as described in part C of title IX of the Public Health Service Act; and</p> <p>(ii) implements a mechanism to ensure that each patient receives a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional; or</p> <p>(B) a health care provider only if such provider implements such mechanisms to improve health care quality as the Secretary may by regulation require.</p>	

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<p>(2) EXCEPTIONS.—The Secretary may establish reasonable exceptions to the requirements described in paragraph (1).</p> <p>(3) ADJUSTMENT.—The Secretary may by regulation adjust the number of beds described in paragraph (1)(A).</p> <p>(i) NAVIGATORS.—</p> <p>(1) IN GENERAL.—An Exchange shall establish a program under which it awards grants to entities described in paragraph (2) to carry out the duties described in paragraph (3).</p> <p>(2) ELIGIBILITY.—</p> <p>(A) IN GENERAL.—To be eligible to receive a grant under paragraph (1), an entity shall demonstrate to the Exchange involved that the entity has existing relationships, or could readily establish relationships, with employers and employees, consumers (including uninsured and underinsured consumers), or self-employed individuals likely to be qualified to enroll in a qualified health plan.</p> <p>(B) TYPES.—Entities described in subparagraph (A) may include trade, industry, and professional associations, commercial fishing industry organizations, ranching and farming organizations, community and consumer-focused nonprofit groups, chambers of commerce, unions, small business development centers, other licensed insurance agents and brokers, and other entities that—</p> <p>(i) are capable of carrying out the duties described in paragraph (3);</p> <p>(ii) meet the standards described in paragraph (4); and</p> <p>(iii) provide information consistent with the standards developed under paragraph (5).</p> <p>(3) DUTIES.—An entity that serves as a navigator under a grant under this subsection shall—</p> <p>(A) conduct public education activities to raise awareness of the availability of qualified health plans;</p> <p>(B) distribute fair and impartial information concerning enrollment in qualified health plans, and the availability of premium tax credits under section 36B of the Internal Revenue Code of 1986 and cost-sharing reductions under section 1402;</p> <p>(C) facilitate enrollment in qualified health plans;</p> <p>(D) provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the Public Health Service Act, or any other appropriate State agency or agencies, for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and</p> <p>(E) provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange or Exchanges.</p> <p>(4) STANDARDS.—</p> <p>(A) IN GENERAL.—The Secretary shall establish standards for navigators under this subsection, including provisions to ensure that any private or public entity that is selected as a navigator is qualified, and licensed if appropriate, to engage in the navigator activities described in this subsection and to avoid conflicts of interest. Under such standards, a navigator shall not—</p>	

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<p>(i) be a health insurance issuer; or</p> <p>(ii) receive any consideration directly or indirectly from any health insurance issuer in connection with the enrollment of any qualified individuals or employees of a qualified employer in a qualified health plan.</p> <p>(5) FAIR AND IMPARTIAL INFORMATION AND SERVICES.—The Secretary, in collaboration with States, shall develop standards to ensure that information made available by navigators is fair, accurate, and impartial.</p> <p>(6) FUNDING.—Grants under this subsection shall be made from the operational funds of the Exchange and not Federal funds received by the State to establish the Exchange.</p> <p>(j) APPLICABILITY OF MENTAL HEALTH PARITY.—Section 2726 of the Public Health Service Act shall apply to qualified health plans in the same manner and to the same extent as such section applies to health insurance issuers and group health plans.</p> <p>(k) CONFLICT.—An Exchange may not establish rules that conflict with or prevent the application of regulations promulgated by the Secretary under this subtitle.</p>	

STATE-REGULATED HEALTH EXCHANGES

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B—INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

Section 4106. Improving Access to Preventive Services for Eligible Adults in Medicaid

Effective Date: January 1, 2013

Expands states options to include recommended preventive services and immunizations to eligible individuals. Defines preventive services.

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<p>(a) CLARIFICATION OF INCLUSION OF SERVICES.—Section 1905(a)(13) of the Social Security Act (42 U.S.C. 1396d(a)(13)) is amended to read as follows: “(13) other diagnostic, screening, preventive, and rehabilitative services, including— “(A) any clinical preventive services that are assigned a grade of A or B by the United States Preventive Services Task Force; “(B) with respect to an adult individual, approved vaccines recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) and their administration; and “(C) any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level;”</p> <p>(b) INCREASED FMAP.—Section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)), as amended by sections 2001(a)(3)(A) and 2004(c)(1), is amended in the first sentence— (1) by striking “, and (4)” and inserting “, (4)”; and (2) by inserting before the period the following: “, and (5) in the case of a State that provides medical assistance for services and vaccines described in subparagraphs (A) and (B) of subsection (a)(13), and prohibits cost-sharing for such services and vaccines, the Federal medical assistance percentage, as determined under this subsection and subsection (y) (without regard to paragraph (1)(C) of such subsection), shall be increased by 1 percentage point with respect to medical assistance for such services and vaccines and for items and services described in subsection (a)(4)(D)”</p> <p>(c) EFFECTIVE DATE.—The amendments made under this section shall take effect on January 1, 2013.</p>	<p><u>Section 4106(a) amends section 1905(a)(13) of the Social Security Act (42 U.S.C. 1396d(a)(13))</u> ... (13) other diagnostic, screening, preventive, and rehabilitative services, including any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level; ...</p> <p><u>Section 4106(b) amends section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)) (amended by sections 2001(a)(3)(A) and 2004(c)(1) of PPACA)</u> ... (b) Subject to subsection (y) and section 1933(d), the term “Federal medical assistance percentage” for any State shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum, (2) the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 50 per centum, (3) for purposes of this title and title XXI, the Federal medical</p>

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TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B—INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

Section 4106. Improving Access to Preventive Services for Eligible Adults in Medicaid

Effective Date: January 1, 2013

Expands states options to include recommended preventive services and immunizations to eligible individuals. Defines preventive services.

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
	<p>assistance percentage for the District of Columbia shall be 70 percent and (4) the Federal medical assistance percentage shall be equal to the enhanced FMAP described in section 2105(b) with respect to medical assistance provided to individuals who are eligible for such assistance only on the basis of section 1902(a)(10)(A)(ii)(XVIII). The Federal medical assistance percentage for any State shall be determined and promulgated in accordance with the provisions of section 1101(a)(8)(B). Notwithstanding the first sentence of this section, the Federal medical assistance percentage shall be 100 per centum with respect to amounts expended as medical assistance for services which are received through an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization (as defined in section 4 of the Indian Health Care Improvement Act). Notwithstanding the first sentence of this subsection, in the case of a State plan that meets the condition described in subsection (u)(1), with respect to expenditures (other than expenditures under section 1923) described in subsection (u)(2)(A) or subsection (u)(3) for the State for a fiscal year, and that do not exceed the amount of the State's available allotment under section 2104, the Federal medical assistance percentage is equal to the enhanced FMAP described in section 2105(b),</p>

Medicaid and the
Children's Health Insurance Program (CHIP)

MEDICAID AND CHIP

HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010

TITLE I—COVERAGE, MEDICARE, MEDICAID, AND REVENUES

SUBTITLE C—MEDICAID

Section 1202. Payments to primary care physicians.

Effective Date: Applies to services furnished on or after **January 1, 2013 through December 31, 2014 (before January 1, 2015)**

Requires Medicaid payment rates for primary care services be no less than 100% of Medicare rates for 2013 and 2014 providing 100% federal funding for additional cost(s) to states

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) IN GENERAL.—</p> <p>(1) FEE-FOR-SERVICE PAYMENTS.—Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by section 2303(a)(2) of the Patient Protection and Affordable Care Act, is amended—</p> <p>(A) in subsection (a)(13)—</p> <p style="text-align: center;">. . .</p> <p>(iii) by adding at the end the following new subparagraph: “(C) payment for primary care services (as defined in subsection (jj)) furnished in 2013 and 2014 by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine at a rate not less than 100 percent of the payment rate that applies to such services and physician under part B of title XVIII (or, if greater, the payment rate that would be applicable under such part if the conversion factor under section 1848(d) for the year involved were the conversion factor under such section for 2009);”; and</p> <p>(B) by adding at the end the following new subsection: “(jj) PRIMARY CARE SERVICES DEFINED.—For purposes of subsection (a)(13)(C), the term ‘primary care services’ means—</p> <p style="text-align: center;">. . .</p> <p>“(2) services related to immunization administration for vaccines and toxoids for which CPT codes 90465, 90466, 90467, 90468, 90471, 90472, 90473, or 90474 (as subsequently modified) apply under such System.”.</p> <p>(2) UNDER MEDICAID MANAGED CARE PLANS.—Section 1932(f) of such Act (42 U.S.C. 1396u–2(f)) is amended—</p> <p>(A) in the heading, by adding at the end the following: “; ADEQUACY OF PAYMENT FOR PRIMARY CARE SERVICES”; and (B) by inserting before the period at the end the following: “and, in the case of primary care services described in section 1902(a)(13)(C), consistent with the minimum payment rates specified in such section (regardless of the manner in which such payments are made, including in the form of capitation or partial capitation)”.</p>	<p><u>Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a))</u></p> <p>(a) A State plan for medical assistance must—</p> <p style="text-align: center;">. . .</p> <p>(13) provide—</p> <p>(A) for a public process for determination of rates of payment under the plan for hospital services, nursing facility services, and services of intermediate care facilities for the mentally retarded under which—</p> <p>(i) proposed rates, the methodologies underlying the establishment of such rates, and justifications for the proposed rates are published,</p> <p>(ii) providers, beneficiaries and their representatives, and other concerned State residents are given a reasonable opportunity for review and comment on the proposed rates, methodologies, and justifications,</p> <p>(iii) final rates, the methodologies underlying the establishment of such rates, and justifications for such final rates are published, and</p> <p>(iv) in the case of hospitals, such rates take into account (in a manner consistent with section 1923) the situation of hospitals which serve a disproportionate number of low-income patients with special needs; and</p> <p>(B) for payment for hospice care in amounts no lower than the amounts, using the same methodology, used under part A of title XVIII and for payment of amounts under section 1905(o)(3); except that in the case of hospice care which is furnished to an individual who is a resident of a nursing facility or intermediate care facility for the mentally retarded, and who would be eligible under the plan for nursing facility services or services in an intermediate care facility for the mentally retarded if he had not elected to receive hospice care, there shall be paid an additional amount, to take into account the room and board furnished by the facility, equal to at least 95 percent of the rate that would have been paid by the State under the plan for facility services in that facility for that individual;</p> <p><u>Section 1902(jj) of the Social Security Act (42 U.S.C. 1396a(jj))</u></p> <p>The definition of “Primary Care Services” is a new provision inserted at the end of this section, as amended by other provisions in the Affordable Care Act.</p>

HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010
TITLE I—COVERAGE, MEDICARE, MEDICAID, AND REVENUES

SUBTITLE C—MEDICAID

Section 1202. Payments to primary care physicians.

Effective Date: Applies to services furnished on or after **January 1, 2013 through December 31, 2014 (before January 1, 2015)**

Requires Medicaid payment rates for primary care services be no less than 100% of Medicare rates for 2013 and 2014 providing 100% federal funding for additional cost(s) to states

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(b) INCREASE IN PAYMENT USING INCREASED FMAP.—Section 1905 of the Social Security Act, as amended by section 1004(b) of this Act and section 10201(c)(6) of the Patient Protection and Affordable Care Act, is amended by adding at the end the following new subsection: “(dd) INCREASED FMAP FOR ADDITIONAL EXPENDITURES FOR PRIMARY CARE SERVICES.—Notwithstanding subsection (b), with respect to the portion of the amounts expended for medical assistance for services described in section 1902(a)(13)(C) furnished on or after January 1, 2013, and before January 1, 2015, that is attributable to the amount by which the minimum payment rate required under such section (or, by application, section 1932(f)) exceeds the payment rate applicable to such services under the State plan as of July 1, 2009, the Federal medical assistance percentage for a State that is one of the 50 States or the District of Columbia shall be equal to 100 percent. The preceding sentence does not prohibit the payment of Federal financial participation based on the Federal medical assistance percentage for amounts in excess of those specified in such sentence.”.</p>	<p><u>Section 1905(dd) of the Social Security Act (42 U.S.C. 1396d(dd))</u> The provision allowing for “Increased FMAP for Additional Expenditures for Primary Care Services” is a new provision inserted at the end of this section, as amended by other provisions in the Affordable Care Act.</p>

MEDICAID AND CHIP

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

TITLE II—ROLE OF PUBLIC PROGRAMS

SUBTITLE A—IMPROVED ACCESS TO MEDICAID

Section 2001. Medicaid coverage for the lowest income populations

Effective Dates:

1. Including eligible groups under the State Plan for Medical Assistance (**April 1, 2010**);
2. Mandatory eligibility category for eligible individuals with income \leq 133 percent of FPL (**January 1, 2014**)

Allows states to extend Medicaid coverage to all non-elderly, non-pregnant individuals who are not currently entitled to Medicare and have qualifying income levels. Also extends benchmark-equivalent coverage (under section 1937 of the Social Security Act [42 U.S.C. 1396u-7]) to these newly eligible groups.

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) COVERAGE FOR INDIVIDUALS WITH INCOME AT OR BELOW 133 PERCENT OF THE POVERTY LINE.—</p> <p>(1) BEGINNING 2014.—Section 1902(a)(10)(A)(i) of the Social Security Act (42 U.S.C. 1396a) is amended—</p> <p>(A) by striking “or” at the end of subclause (VI);</p> <p>(B) by adding “or” at the end of subclause (VII); and</p> <p>(C) by inserting after subclause (VII) the following:</p> <p>“(VIII) beginning January 1, 2014, who are under 65 years of age, not pregnant, not entitled to, or enrolled for, benefits under part A of title XVIII, or enrolled for benefits under part B of title XVIII, and are not described in a previous subclause of this clause, and whose income (as determined under subsection (e)(14)) does not exceed 133 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved, subject to subsection (k);”.</p> <p>(2) PROVISION OF AT LEAST MINIMUM ESSENTIAL COVERAGE.—</p> <p>(A) IN GENERAL.—Section 1902 of such Act (42 U.S.C. 1396a) is amended by inserting after subsection (j) the following:</p> <p>“(k)(1) The medical assistance provided to an individual described in subclause (VIII) of subsection (a)(10)(A)(i) shall consist of benchmark coverage described in section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2). Such medical assistance shall be provided subject to the requirements of section 1937, without regard to whether a State otherwise has elected the option to provide medical assistance through coverage under that section, unless an individual described in subclause (VIII) of subsection (a)(10)(A)(i) is also an individual for whom, under subparagraph (B) of section 1937(a)(2), the State may not require enrollment in benchmark coverage described in subsection (b)(1) of section 1937 or benchmark equivalent coverage described in subsection (b)(2) of that section.”.</p> <p style="text-align: center;">...</p> <p>(3) FEDERAL FUNDING FOR COST OF COVERING NEWLY ELIGIBLE INDIVIDUALS.—Section 1905 of the Social Security Act (42 U.S.C. 1396d), is amended—</p>	<p><u>Section 1902(a)(10)(A)(i)(VIII) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(i)(VIII))</u> The provision allowing for the expansion of eligibility under Medicaid is new language inserted at the end of this section.</p> <p><u>Section 1902(k) of the Social Security Act (42 U.S.C. 1396a(k))</u> Allowing for the expansion of eligibility under Medicaid, this new language is inserted after subsection “j” where a previous iteration of subsection “k” had been stricken.</p> <p><u>Section 1905(y) of the Social Security Act (42 U.S.C. 1396d(y))</u> The provision allowing for the increased FMAP is a new provision inserted at</p>

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE II—ROLE OF PUBLIC PROGRAMS**

SUBTITLE A—IMPROVED ACCESS TO MEDICAID

Section 2001. Medicaid coverage for the lowest income populations

Effective Dates:

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2. Mandatory eligibility category for eligible individuals with income \leq 133 percent of FPL (**January 1, 2014**)

Allows states to extend Medicaid coverage to all non-elderly, non-pregnant individuals who are not currently entitled to Medicare and have qualifying income levels. Also extends benchmark-equivalent coverage (under section 1937 of the Social Security Act [42 U.S.C. 1396u-7]) to these newly eligible groups.

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(A) in subsection (b), in the first sentence, by inserting “subsection (y) and” before “section 1933(d)”;</p> <p>and</p> <p>(B) by adding at the end the following new subsection:</p> <p>“(y) INCREASED FMAP FOR MEDICAL ASSISTANCE FOR NEWLY ELIGIBLE MANDATORY INDIVIDUALS.—</p> <p>“(1) AMOUNT OF INCREASE.—</p> <p>“(A) 100 PERCENT FMAP.—During the period that begins on January 1, 2014, and ends on December 31, 2016, notwithstanding subsection (b), the Federal medical assistance percentage determined for a State that is one of the 50 States or the District of Columbia for each fiscal year occurring during that period with respect to amounts expended for medical assistance for newly eligible individuals described in subclause (VIII) of section 1902(a)(10)(A)(i) shall be equal to 100 percent.</p> <p>“(B) 2017 AND 2018.—</p> <p>“(i) IN GENERAL.—During the period that begins on January 1, 2017, and ends on December 31, 2018, notwithstanding subsection (b) and subject to subparagraph (D), the Federal medical assistance percentage determined for a State that is one of the 50 States or the District of Columbia for each fiscal year occurring during that period with respect to amounts expended for medical assistance for newly eligible individuals described in subclause (VIII) of section 1902(a)(10)(A)(i), shall be increased by the applicable percentage point increase specified in clause (ii) for the quarter and the State.</p> <p>“(ii) APPLICABLE PERCENTAGE POINT INCREASE.—</p> <p>...</p> <p>“(II) EXPANSION STATE DEFINED.—For purposes of the table in subclause (I), a State is an expansion State if, on the date of the enactment of the Patient Protection and Affordable Care Act, the State offers health benefits coverage statewide to parents and nonpregnant, childless adults whose income is at least 100 percent of the poverty line, that is not dependent on access to employer coverage, employer contribution, or employment and is not limited to premium assistance, hospital-only benefits, a high deductible health plan, or alternative benefits under a demonstration program authorized under section 1938. A State that offers health benefits coverage to only parents or only nonpregnant childless adults described in the preceding sentence shall not be considered to be an expansion State.</p> <p>...</p> <p>“(D) LIMITATION.—The Federal medical assistance percentage determined for a State under subparagraph (B) or (C) shall in no case be more than 95 percent.</p>	<p>the end of this section.</p>

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AFFORDABLE CARE ACT LANGUAGE

“(2) DEFINITIONS.—In this subsection:

“(A) NEWLY ELIGIBLE.—The term ‘newly eligible’ means, with respect to an individual described in subclause (VIII) of section 1902(a)(10)(A)(i), an individual who is not under 19 years of age (or such higher age as the State may have elected) and who, on the date of enactment of the Patient Protection and Affordable Care Act, is not eligible under the State plan or under a waiver of the plan for full benefits or for benchmark coverage described in subparagraph (A), (B), or (C) of section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2) that has an aggregate actuarial value that is at least actuarially equivalent to benchmark coverage described in subparagraph (A), (B), or (C) of section 1937(b)(1), or is eligible but not enrolled (or is on a waiting list) for such benefits or coverage through a waiver under the plan that has a capped or limited enrollment that is full.

“(B) FULL BENEFITS.—The term ‘full benefits’ means, with respect to an individual, medical assistance for all services covered under the State plan under this title that is not less in amount, duration, or scope, or is determined by the Secretary to be substantially equivalent, to the medical assistance available for an individual described in section 1902(a)(10)(A)(i).”.

(4) STATE OPTIONS TO OFFER COVERAGE EARLIER AND PRESUMPTIVE ELIGIBILITY; CHILDREN REQUIRED TO HAVE COVERAGE FOR PARENTS TO BE ELIGIBLE.—

(A) IN GENERAL.—Subsection (k) of section 1902 of the Social Security Act (as added by paragraph (2)), is amended by inserting after paragraph (1) the following:

“(2) Beginning with the first day of any fiscal year quarter that begins on or after January 1, 2011, and before January 1, 2014, a State may elect through a State plan amendment to provide medical assistance to individuals who would be described in subclause (VIII) of subsection (a)(10)(A)(i) if that subclause were effective before January 1, 2014. A State may elect to phase-in the extension of eligibility for medical assistance to such individuals based on income, so long as the State does not extend such eligibility to individuals described in such subclause with higher income before making individuals described in such subclause with lower income eligible for medical assistance.

“(3) If an individual described in subclause (VIII) of subsection (a)(10)(A)(i) is the parent of a child who is under 19 years of age (or such higher age as the State may have elected) who is eligible for medical assistance under the State plan or under a waiver of such plan (under that subclause or under a State plan amendment under paragraph (2), the individual may not be enrolled under the State plan unless the individual’s child is enrolled under the State plan or under a waiver of the plan or is enrolled in other health insurance coverage. For purposes of the preceding sentence, the term ‘parent’ includes an individual

LANGUAGE FROM EXISTING LAW

Section 1902(k) of the Social Security Act (42 U.S.C. 1396a(k))

Further refining program expansion of eligibility under Medicaid, these provisions are inserted after the language inserted by paragraph 2 of PPACA section 2001.

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>treated as a caretaker relative for purposes of carrying out section 1931.”.</p> <p>(b) MAINTENANCE OF MEDICAID INCOME ELIGIBILITY.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended—</p> <p>(1) in subsection (a)—</p> <p>(A) by striking “and” at the end of paragraph (72);</p> <p>(B) by striking the period at the end of paragraph (73) and inserting “; and”; and</p> <p>(C) by inserting after paragraph (73) the following new paragraph:</p> <p>“(74) provide for maintenance of effort under the State plan or under any waiver of the plan in accordance with subsection (gg).”; and</p> <p>(2) by adding at the end the following new subsection:</p> <p>“(gg) MAINTENANCE OF EFFORT.—</p> <p>“(1) GENERAL REQUIREMENT TO MAINTAIN ELIGIBILITY STANDARDS UNTIL STATE EXCHANGE IS FULLY OPERATIONAL.—</p> <p>Subject to the succeeding paragraphs of this subsection, during the period that begins on the date of enactment of the Patient Protection and Affordable Care Act and ends on the date on which the Secretary determines that an Exchange established by the State under section 1311 of the Patient Protection and Affordable Care Act is fully operational, as a condition for receiving any Federal payments under section 1903(a) for calendar quarters occurring during such period, a State shall not have in effect eligibility standards, methodologies, or procedures under the State plan under this title or under any waiver of such plan that is in effect during that period, that are more restrictive than the eligibility standards, methodologies, or procedures, respectively, under the plan or waiver that are in effect on the date of enactment of the Patient Protection and Affordable Care Act.</p> <p>“(2) CONTINUATION OF ELIGIBILITY STANDARDS FOR CHILDREN UNTIL OCTOBER 1, 2019.—The requirement under paragraph (1) shall continue to apply to a State through September 30, 2019, with respect to the eligibility standards, methodologies, and procedures under the State plan under this title or under any waiver of such plan that are applicable to determining the eligibility for medical assistance of any child who is under 19 years of age (or such higher age as the State may have elected).</p> <p>“(3) NONAPPLICATION.—During the period that begins on January 1, 2011, and ends on December 31, 2013, the requirement under paragraph (1) shall not apply to a State with respect to nonpregnant, nondisabled adults who are eligible for medical assistance under the State plan or under a waiver of the</p>	<p>Amends Section 1902 of the Social Security Act, 42 U.S.C. 1396a, by adding a new subsection, gg.</p>

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>plan at the option of the State and whose income exceeds 133 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved if, on or after December 31, 2010, the State certifies to the Secretary that, with respect to the State fiscal year during which the certification is made, the State has a budget deficit, or with respect to the succeeding State fiscal year, the State is projected to have a budget deficit. Upon submission of such a certification to the Secretary, the requirement under paragraph (1) shall not apply to the State with respect to any remaining portion of the period described in the preceding sentence.</p> <p>“(4) DETERMINATION OF COMPLIANCE.—</p> <p>“(A) STATES SHALL APPLY MODIFIED GROSS INCOME.—</p> <p>A State’s determination of income in accordance with subsection (e)(14) shall not be considered to be eligibility standards, methodologies, or procedures that are more restrictive than the standards, methodologies, or procedures in effect under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act for purposes of determining compliance with the requirements of paragraph (1), (2), or (3).</p> <p>“(B) STATES MAY EXPAND ELIGIBILITY OR MOVE WAIVERED POPULATIONS INTO COVERAGE UNDER THE STATE PLAN.—With respect to any period applicable under paragraph (1), (2), or (3), a State that applies eligibility standards, methodologies, or procedures under the State plan under this title or under any waiver of the plan that are less restrictive than the eligibility standards, methodologies, or procedures, applied under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act, or that makes individuals who, on such date of enactment, are eligible for medical assistance under a waiver of the State plan, after such date of enactment eligible for medical assistance through a State plan amendment with an income eligibility level that is not less than the income eligibility level that applied under the waiver, or as a result of the application of subclause (VIII) of section 1902(a)(10)(A)(i), shall not be considered to have in effect eligibility standards, methodologies, or procedures that are more restrictive than the standards, methodologies, or procedures in effect under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act for purposes of determining compliance with the requirements of paragraph (1), (2), or (3).”.</p> <p>(c) MEDICAID BENCHMARK BENEFITS MUST CONSIST OF AT LEAST MINIMUM ESSENTIAL COVERAGE.—Section 1937(b) of such Act (42 U.S.C. 1396u-7(b)) is amended—</p> <p>(1) in paragraph (1), in the matter preceding subparagraph (A), by inserting “subject to paragraphs (5) and</p>	<p><u>Section 1937 of the Social Security Act (42 U.S.C. 1396u-7)</u></p> <p>...</p> <p>(b) Benchmark Benefit Packages.—</p> <p>(1) In general.—For purposes of subsection (a)(1), each of the following coverages shall be considered to be benchmark coverage:</p> <p>(A) FEHBP-equivalent health insurance coverage.—The standard Blue Cross/Blue Shield preferred provider option service benefit plan, described in and offered under section 8903(1) of title 5, United States Code.</p> <p>(B) State employee coverage.—A health benefits coverage plan that is offered and generally available to State employees in the State involved.</p> <p>(C) Coverage offered through HMO.—The health insurance coverage plan that—</p> <p>(i) is offered by a health maintenance organization (as defined in section 2791(b)(3) of the Public Health Service Act), and</p> <p>(ii) has the largest insured commercial, non-Medicaid enrollment of covered</p>

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(6),” before “each”;</p> <p>(2) in paragraph (2)—</p> <p>(A) in the matter preceding subparagraph (A), by inserting “subject to paragraphs (5) and (6)” after “subsection (a)(1),”;</p> <p>(B) in subparagraph (A)—</p> <p>(i) by redesignating clauses (iv) and (v) as clauses (vi) and (vii), respectively; and</p> <p>(ii) by inserting after clause (iii), the following:</p> <p>“(iv) Coverage of prescription drugs.</p> <p>“(v) Mental health services.”; and</p> <p>(C) in subparagraph (C)—</p> <p>(i) by striking clauses (i) and (ii); and</p> <p>(ii) by redesignating clauses (iii) and (iv) as clauses (i) and (ii), respectively; and</p> <p>(3) by adding at the end the following new paragraphs:</p> <p>“(5) MINIMUM STANDARDS.—Effective January 1, 2014, any benchmark benefit package under paragraph (1) or benchmark equivalent coverage under paragraph (2) must provide at least essential health benefits as described in section 1302(b) of the Patient Protection and Affordable Care Act.</p> <p align="center">...</p>	<p>lives of such coverage plans offered by such a health maintenance organization in the State involved.</p> <p>(D) Secretary-approved coverage.—Any other health benefits coverage that the Secretary determines, upon application by a State, provides appropriate coverage for the population proposed to be provided such coverage.</p> <p>(2) Benchmark-equivalent coverage.—For purposes of subsection (a)(1), coverage that meets the following requirement shall be considered to be benchmark-equivalent coverage:</p> <p>(A) Inclusion of basic services.—The coverage includes benefits for items and services within each of the following categories of basic services:</p> <p>(i) Inpatient and outpatient hospital services.</p> <p>(ii) Physicians' surgical and medical services.</p> <p>(iii) Laboratory and x-ray services.</p> <p>(iv) Well-baby and well-child care, including age-appropriate immunizations.</p> <p>(v) Other appropriate preventive services, as designated by the Secretary.</p> <p align="center">...</p> <p><u>Section 1902(a)(10)(A)(ii)(XX) of the Social Security Act (42 U.S.C.</u></p> <p><u>Section 1902 of the Social Security Act (42 USC 1396a(a)(10)(A)(ii)(XX))</u></p> <p>The provision allowing for the expansion of eligibility to 133 percent FPL for certain groups is a new addition to this section.</p>

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(e) STATE OPTION FOR COVERAGE FOR INDIVIDUALS WITH INCOME THAT EXCEEDS 133 PERCENT OF THE POVERTY LINE.—</p> <p>(1) COVERAGE AS OPTIONAL CATEGORICALLY NEEDY GROUP.— Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended—</p> <p>(A) in subsection (a)(10)(A)(ii)—</p> <p align="center">...</p> <p>(iii) by adding at the end the following new subclause: “(XX) beginning January 1, 2014, who are under 65 years of age and are not described in or enrolled under a previous subclause of this clause, and whose income (as determined under subsection (e)(14)) exceeds 133 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved but does not exceed the highest income eligibility level established under the State plan or under a waiver of the plan, subject to subsection (hh);” and</p> <p>(B) by adding at the end the following new subsection: “(hh)(1) A State may elect to phase-in the extension of eligibility for medical assistance to individuals described in subclause (XX) of subsection (a)(10)(A)(ii) based on the categorical group (including nonpregnant childless adults) or income, so long as the State does not extend such eligibility to individuals described in such subclause with higher income before making individuals described in such subclause with lower income eligible for medical assistance.</p> <p>“(2) If an individual described in subclause (XX) of subsection (a)(10)(A)(ii) is the parent of a child who is under 19 years of age (or such higher age as the State may have elected) who is eligible for medical assistance under the State plan or under a waiver of such plan, the individual may not be enrolled under the State plan unless the individual’s child is enrolled under the State plan or under a waiver of the plan or is enrolled in other health insurance coverage. For purposes of the preceding sentence, the term ‘parent’ includes an individual treated as a caretaker relative for purposes of carrying out section 1931.”</p> <p align="center">...</p>	

MEDICAID AND CHIP

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

Section 4106. Improving access to preventive services for eligible adults in Medicaid

Effective Date: January 1, 2013

Expands option to provide recommended adult immunizations and offers an increased FMAP (one-percentage point) for states that elect to do so without cost-sharing

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) CLARIFICATION OF INCLUSION OF SERVICES.—Section 1905(a)(13) of the Social Security Act (42 U.S.C. 1396d(a)(13)) is amended to read as follows: “(13) other diagnostic, screening, preventive, and rehabilitative services, including— “(A) any clinical preventive services that are assigned a grade of A or B by the United States Preventive Services Task Force; “(B) with respect to an adult individual, approved vaccines recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) and their administration; and “(C) any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level;”.</p> <p>(b) INCREASED FMAP.—Section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)), as amended by sections 2001(a)(3)(A) and 2004(c)(1), is amended in the first sentence—</p> <p>(2) by inserting before the period the following: “, and (5) in the case of a State that provides medical assistance for services and vaccines described in subparagraphs (A) and (B) of subsection (a)(13), and prohibits cost-sharing for such services and vaccines, the Federal medical assistance percentage, as determined under this subsection and subsection (y) (without regard to paragraph (1)(C) of such subsection), shall be increased by 1 percentage point with respect to medical assistance for such services and vaccines and for items and services described in subsection (a)(4)(D)”.</p> <p>(c) EFFECTIVE DATE.—The amendments made under this section shall take effect on January 1, 2013.</p>	<p><u>Section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a))</u> (13) other diagnostic, screening, preventive, and rehabilitative services, including any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level;</p> <p><u>Section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b))</u> (b) Subject to section 1933(d), the term “Federal medical assistance percentage” for any State shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum, (2) the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 50 per centum, (3) for purposes of this title and title XXI, the Federal medical assistance percentage for the District of Columbia shall be 70 percent and (4) the Federal medical assistance percentage shall be equal to the enhanced FMAP described in section 2105(b) with respect to medical assistance provided to individuals who are eligible for such assistance only on the basis of section 1902(a)(10)(A)(ii)(XVIII). The Federal medical assistance percentage for any State shall be determined and promulgated in accordance with the provisions of section 1101(a)(8)(B). Notwithstanding the first sentence of this section, the Federal medical assistance percentage shall be 100 per centum with respect to amounts expended as medical assistance for services which are received through an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization (as defined in section 4 of the Indian Health Care Improvement Act). Notwithstanding the first sentence of this subsection, in the case of a State plan that meets the condition described in subsection (u)(1), with respect to expenditures (other than expenditures under section 1923) described in subsection (u)(2)(A) or subsection (u)(3) for the State for a fiscal year, and that do not exceed the amount of the State's available allotment under section 2104, the Federal medical assistance percentage is equal to the enhanced FMAP described in section 2105(b),</p>

Medicare

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PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH
SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES
Section 4103. Medicare coverage of annual wellness visit providing a personalized prevention plan.

Effective Date: Services furnished on or after **January 1, 2011**

Provides cost-sharing free Medicare coverage for annual wellness visit and personalized prevention plan services, which includes a comprehensive health risk assessment

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) COVERAGE OF PERSONALIZED PREVENTION PLAN SERVICES.— (1) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended— . . . (C) by adding at the end the following new subparagraph: “(FF) personalized prevention plan services (as defined in subsection (hhh));”.</p> <p>(b) PERSONALIZED PREVENTION PLAN SERVICES DEFINED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection: “Annual Wellness Visit “(hhh)(1) The term ‘personalized prevention plan services’ means the creation of a plan for an individual— . . . “(E) The establishment of, or an update to, the following: “(i) A screening schedule for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual’s health status, screening history, and age-appropriate preventive services covered under this title. . . . “(F) The furnishing of personalized health advice and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition. “(G) Any other element determined appropriate by the Secretary. . . . “(E) The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment prior to or at the same time as receiving personalized prevention plan services. “(F) To the extent practicable, the Secretary shall encourage the use of, integration with, and coordination of health information technology (including use of technology that is compatible with electronic medical records and personal health records) and may experiment with the use of personalized technology to aid in the development of self-management skills and management of and adherence to provider</p>	<p><u>Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x)</u> (s) The term “medical and other health services” means any of the following items or services: (1) physicians’ services (2)(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician’s professional service, of kinds which are commonly furnished in physicians’ offices and are commonly either rendered without charge or included in the physicians’ bills (or would have been so included but for the application of section 1847B); (B) hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians’ services rendered to outpatients and partial hospitalization services incident to such services; . . . (E) rural health clinic services and Federally qualified health center services; . . . (K)(i) services which would be physicians’ services if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a physician assistant (as defined in subsection (aa)(5)) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician’s professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services, (ii) services which would be physicians’ services if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5)) working in collaboration (as defined in subsection (aa)(6)) with a physician (as defined in subsection (r)(1)) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

Section 4103. Medicare coverage of annual wellness visit providing a personalized prevention plan.

Effective Date: Services furnished on or after **January 1, 2011**

Provides cost-sharing free Medicare coverage for annual wellness visit and personalized prevention plan services, which includes a comprehensive health risk assessment

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>recommendations in order to improve the health status of beneficiaries.</p> <p>“(G)(i) A beneficiary shall only be eligible to receive an initial preventive physical examination (as defined under subsection (ww)(1)) at any time during the 12-month period after the date that the beneficiary’s coverage begins under part B and shall be eligible to receive personalized prevention plan services under this subsection provided that the beneficiary has not received such services within the preceding 12-month period.</p> <p>“(ii) The Secretary shall establish procedures to make beneficiaries aware of the option to select an initial preventive physical examination or personalized prevention plan services during the period of 12 months after the date that a beneficiary’s coverage begins under part B, which shall include information regarding any relevant differences between such services.</p> <p>“(H) The Secretary shall issue guidance that—</p> <p>“(i) identifies elements under paragraph (2) that are required to be provided to a beneficiary as part of their first visit for personalized prevention plan services; and “(ii) establishes a yearly schedule for appropriate provision of such elements thereafter.”.</p>	<p>a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

Section 4103. Medicare coverage of annual wellness visit providing a personalized prevention plan.

Effective Date: Services furnished on or after **January 1, 2011**

Provides cost-sharing free Medicare coverage for annual wellness visit and personalized prevention plan services, which includes a comprehensive health risk assessment

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(c) PAYMENT AND ELIMINATION OF COST-SHARING.—</p> <p>(1) PAYMENT AND ELIMINATION OF COINSURANCE.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—</p> <p>(A) in subparagraph (N), by inserting “other than personalized prevention plan services (as defined in section 1861(hhh)(1))” after “(as defined in section 1848(j)(3))”;</p> <p>(C) by inserting before the semicolon at the end the following: “, and (X) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848”.</p>	<p>(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;</p> <p>(BB) additional preventive services (described in subsection (ddd)(1));</p> <p>(10)(A) pneumococcal vaccine and its administration and, subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, influenza vaccine and its administration; and</p> <p>(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations);</p> <p><u>Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1))</u></p> <p>(a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—</p> <p>(1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that . . . (N) with respect to expenses incurred for physicians' services (as defined in section 1848(j)(3)), the amounts paid shall be 80 percent of the payment basis determined under section 1848(a)(1), . . .</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

Section 4103. Medicare coverage of annual wellness visit providing a personalized prevention plan.

Effective Date: Services furnished on or after **January 1, 2011**

Provides cost-sharing free Medicare coverage for annual wellness visit and personalized prevention plan services, which includes a comprehensive health risk assessment

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(2) PAYMENT UNDER PHYSICIAN FEE SCHEDULE.—Section 1848(j)(3) of the Social Security Act (42 U.S.C. 1395w–4(j)(3)) is amended by inserting “(2)(FF) (including administration of the health risk assessment),” after “(2)(EE),”.</p> <p align="center">...</p> <p>(e) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2011.</p>	<p><u>Section 1848(j)(3) of the Social Security Act (42 U.S.C. 1395w–4(j)(3))</u> (j) Definitions.—In this section:</p> <p align="center">...</p> <p>(3) Physicians' services.—The term “physicians' services” includes items and services described in paragraphs (1), (2)(A), (2)(D), (2)(G), (2)(P) (with respect to services described in subparagraphs (A) and (C) of section <u>1861(oo)(2)</u>, (2)(R) (with respect to services described in subparagraphs (B), (C), and (D) of section <u>1861(pp)(1)</u>, (2)(S), (2)(W), (2)(AA), (2)(DD), (2)(EE)^[140] (3), (4), (13) (14) (with respect to services described in section <u>1861(nn)(2)</u>, and (15) of section <u>1861(s)</u> (other than clinical diagnostic laboratory tests and, except for purposes of subsections (a)(3), (g), and (h) such other items and services as the Secretary may specify).</p>

MEDICARE

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH
SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES
Section 4104. Removal of barriers to preventive services in Medicare

Effective Date: Items and services furnished on or after **January 1, 2011**

Provides cost-sharing free Medicare coverage for annual wellness visit and personalized prevention plan services, which includes a comprehensive health risk assessment

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) DEFINITION OF PREVENTIVE SERVICES.—Section 1861(ddd) of the Social Security Act (42 U.S.C. 1395x(ddd)) is amended—</p> <p style="text-align: center;">. . .</p> <p>(3) by adding at the end the following new paragraph: “(3) The term ‘preventive services’ means the following: “(A) The screening and preventive services described in subsection (ww)(2) (other than the service described in subparagraph (M) of such subsection). “(B) An initial preventive physical examination (as defined in subsection (ww)). “(C) Personalized prevention plan services (as defined in subsection (hhh)(1)).”.</p> <p>(b) COINSURANCE.—</p> <p>(1) GENERAL APPLICATION.—</p> <p>(A) IN GENERAL.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)), as amended by section 4103(c)(1), is amended—</p> <p>(i) in subparagraph (T), by inserting “(or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual)” after “80 percent”;</p> <p style="text-align: center;">. . .</p> <p>(iv) by inserting before the semicolon at the end the following: “, and (Y) with respect to preventive services described in subparagraphs (A) and (B) of section 1861(ddd)(3) that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part”.</p> <p>(2) ELIMINATION OF COINSURANCE IN OUTPATIENT HOSPITAL SETTINGS.—</p> <p>(A) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) of the Social Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)), as amended by section 4103(c)(3)(A), is amended—</p> <p>(i) by striking “or” before “personalized prevention plan services”; and</p> <p>(ii) by inserting before the period the following:</p>	<p><u>Section 1861 of the Social Security Act (42 U.S.C. 1395x(ddd))</u> The provision allowing for Medicare to provide preventive care to enrollees is a new provision inserted into this section, as amended by other provisions in the Affordable Care Act.</p> <p><u>Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1))</u> (a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—</p> <p>(1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that . . . (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician, . . .</p> <p><u>Section 1833(t)(1)(B)(iv) of the Social Security Act (42 U.S.C. 1395l(t)(1)(B)(iv))</u> (t) Prospective Payment System for Hospital Outpatient Department Services.— (1) Amount of payment.—</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

Section 4104. Removal of barriers to preventive services in Medicare

Effective Date: Items and services furnished on or after **January 1, 2011**

Provides cost-sharing free Medicare coverage for annual wellness visit and personalized prevention plan services, which includes a comprehensive health risk assessment

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>‘, or preventive services described in subparagraphs (A) and (B) of section 1861(ddd)(3) that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population’.</p> <p>(B) CONFORMING AMENDMENTS.—Section 1833(a)(2) of the Social Security Act (42 U.S.C. 13951(a)(2)), as amended by section 4103(c)(3)(B), is amended—</p> <p align="center">...</p> <p>(iii) by inserting after subparagraph (H) the following new subparagraph: “(I) with respect to preventive services described in subparagraphs (A) and (B) of section 1861(ddd)(3) that are appropriate for the individual and are furnished by an outpatient department of a hospital and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount determined under paragraph (1)(W) or (1)(Y),”.</p> <p align="center">...</p> <p>(d) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after January 1, 2011.</p>	<p>(A) In general.—With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.</p> <p>(B) Definition of covered OPD services.—For purposes of this subsection, the term “covered OPD services”—</p> <p>(i) means hospital outpatient services designated by the Secretary;</p> <p>(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;</p> <p>(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1861(s); but</p> <p>(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1834(k) or section 1834(l) and does not include screening mammography (as defined in section 1861(jj)) and diagnostic mammography.</p>

MEDICARE

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH
SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES
Section 4105. Evidence-based coverage of preventive services in Medicare

Effective Date: January 1, 2010

Authorizes the Secretary (HHS) to modify coverage of currently covered preventive services under Medicare such that the services are consistent with recommendations from the United States Preventive Services Task Force and commissions a GAO study on the utilization of and payment for Medicare preventive services

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection: “(n) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Notwithstanding any other provision of this title, effective beginning on January 1, 2010, if the Secretary determines appropriate, the Secretary may— “(1) modify— “(A) the coverage of any preventive service described in subparagraph (A) of section 1861(ddd)(3) to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and “(B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and “(2) provide that no payment shall be made under this title for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.”.</p> <p>(b) CONSTRUCTION.—Nothing in the amendment made by paragraph (1) shall be construed to affect the coverage of diagnostic or treatment services under title XVIII of the Social Security Act.</p>	<p><u>Section 1834 of the Social Security Act (42 U.S.C. 1395m)</u> The provision allowing for the modification of Medicare’s covered, preventive services package is a new provision inserted at the end of this section, as amended by other provisions in the Affordable Care Act.</p>

MEDICARE

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE X – STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE D – PROVISIONS RELATING TO TITLE IV

Section 10406. Amendment relating to waiving coinsurance for preventive services

Effective Date: January 1, 2011

Allows for waiver of beneficiary coinsurance requirements for most preventive services, requiring Medicare to cover 100 percent of costs

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>Section 4104(b) of this Act is amended to read as follows: “(b) PAYMENT AND ELIMINATION OF COINSURANCE IN ALL SETTINGS.— Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)), as amended by section 4103(c)(1), is amended— “(1) in subparagraph (T), by inserting ‘(or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual)’ after ‘80 percent’; “(2) in subparagraph (W)— “(A) in clause (i), by inserting ‘(if such subparagraph were applied, by substituting ‘100 percent’ for ‘80 percent’)’ after ‘subparagraph (D)’; and “(B) in clause (ii), by striking ‘80 percent’ and inserting ‘100 percent’; “(3) by striking ‘and’ before ‘(X)’; and “(4) by inserting before the semicolon at the end the following: ‘, and (Y) with respect to preventive services described in subparagraphs (A) and (B) of section 1861(ddd)(3) that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t)’.”.</p>	<p><u>Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1))</u> The provision eliminating co-insurance in all settings is new language inserted at the end of the section.</p> <p>(a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to— (1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that . . . (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician, . . . (W) with respect to additional preventive services (as defined in section 1861(ddd)(1)), the amount paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D), and (ii) in the case of all other such services, 80 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph;</p>

Health Care Quality and Innovation

HEALTH CARE QUALITY AND INNOVATION

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE I—QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS	
SUBTITLE A—IMMEDIATE IMPROVEMENTS IN HEALTH CARE COVERAGE FOR ALL AMERICANS Section 1001. Amendments to the Public Health Service Act (PHSA)	
PHSA Section 2717. Ensuring the Quality of Care Effective Date: Plan years beginning on or after the date that is six (6) months after enactment (September 23, 2010) <i>Requires Secretary (HHS) to develop guidelines for use by health insurers to report on initiatives and programs that improve health outcomes</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(a) QUALITY REPORTING.—</p> <p>“(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary, in consultation with experts in health care quality and stakeholders, shall develop reporting requirements for use by a group health plan, and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures that—</p> <p>“(A) improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage;</p> <p>“(B) implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional;</p> <p>“(C) implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and</p> <p>“(D) implement wellness and health promotion activities.</p> <p>“(2) REPORTING REQUIREMENTS.—</p> <p>“(A) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall annually submit to the Secretary, and to enrollees under the plan or coverage, a report on whether the benefits under the plan or coverage satisfy the elements described in subparagraphs (A) through (D) of paragraph (1).</p> <p>“(B) TIMING OF REPORTS.—A report under subparagraph (A) shall be made available to an enrollee under the plan or coverage during each open enrollment period.</p> <p>“(C) AVAILABILITY OF REPORTS.—The Secretary shall make reports submitted under subparagraph (A) available to the public through an Internet website.</p> <p>“(D) PENALTIES.—In developing the reporting requirements under paragraph (1), the Secretary may develop and impose appropriate penalties for non-compliance with such requirements.</p> <p>“(E) EXCEPTIONS.—In developing the reporting requirements under paragraph (1), the Secretary may provide for exceptions to such requirements for group health plans and health insurance issuers that substantially meet the goals of this section.</p>	<p>Provision unique to PPACA; Section 1001 adds this new provision to the PHSA</p>

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE I—QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS**

SUBTITLE A—IMMEDIATE IMPROVEMENTS IN HEALTH CARE COVERAGE FOR ALL AMERICANS

Section 1001. Amendments to the Public Health Service Act (PHSA)

PHSA Section 2717. Ensuring the Quality of Care

Effective Date: Plan years beginning on or after the date that is six (6) months after enactment (**September 23, 2010**)

Requires Secretary (HHS) to develop guidelines for use by health insurers to report on initiatives and programs that improve health outcomes

AFFORDABLE CARE ACT LANGUAGE

LANGUAGE FROM EXISTING LAW

“(b) WELLNESS AND PREVENTION PROGRAMS.—For purposes of subsection (a)(1)(D), wellness and health promotion activities may include personalized wellness and prevention services, which are coordinated, maintained or delivered by a health care provider, a wellness and prevention plan manager, or a health, wellness or prevention services organization that conducts health risk assessments or offers ongoing face-to-face, telephonic or web-based intervention efforts for each of the program’s participants, and which may include the following wellness and prevention efforts:

- “(1) Smoking cessation.
- “(2) Weight management.
- “(3) Stress management.
- “(4) Physical fitness.
- “(5) Nutrition.
- “(6) Heart disease prevention.
- “(7) Healthy lifestyle support.
- “(8) Diabetes prevention.

“(c) REGULATIONS.—Not later than 2 years after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations that provide criteria for determining whether a reimbursement structure is described in subsection (a).

“(d) STUDY AND REPORT.—Not later than 180 days after the date on which regulations are promulgated under subsection (c), the Government Accountability Office shall review such regulations and conduct a study and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report regarding the impact the activities under this section have had on the quality and cost of health care.

HEALTH CARE QUALITY AND INNOVATION

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE III—IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE
SUBTITLE A – TRANSFORMING THE HEALTH CARE DELIVERY SYSTEM
PART II – NATIONAL STRATEGY TO IMPROVE HEALTH CARE QUALITY
Section 3011. National Strategy

Effective Date: March 23, 2010

Requires the Secretary to establish an annually update the national strategy to improve the delivery of health care services, patient health outcomes, and population health

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:</p> <p>“PART S—HEALTH CARE QUALITY PROGRAMS</p> <p>“Subpart I—National Strategy for Quality Improvement in Health Care</p> <p>“SEC. 399HH. NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE.</p> <p>“(a) ESTABLISHMENT OF NATIONAL STRATEGY AND PRIORITIES.—</p> <p>“(1) NATIONAL STRATEGY.—The Secretary, through a transparent collaborative process, shall establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health.</p> <p>“(2) IDENTIFICATION OF PRIORITIES.—</p> <p>“(A) IN GENERAL.—The Secretary shall identify national priorities for improvement in developing the strategy under paragraph (1).</p> <p>“(B) REQUIREMENTS.—The Secretary shall ensure that priorities identified under subparagraph (A) will—</p> <p>“(i) have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care for all populations, including children and vulnerable populations;</p> <p>“(ii) identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care;</p> <p>“(iii) address gaps in quality, efficiency, comparative effectiveness information, and health outcomes measures and data aggregation techniques;</p> <p>“(iv) improve Federal payment policy to emphasize quality and efficiency;</p> <p>“(v) enhance the use of health care data to improve quality, efficiency, transparency, and outcomes;</p> <p>“(vi) address the health care provided to patients with high-cost chronic diseases;</p> <p>“(vii) improve research and dissemination of strategies and best practices to improve patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections;</p> <p>“(viii) reduce health disparities across health disparity populations (as defined in section 485E) and geographic areas; and</p> <p>“(ix) address other areas as determined appropriate by the Secretary.</p> <p>“(C) CONSIDERATIONS.—In identifying priorities under subparagraph (A), the Secretary shall take into consideration the recommendations submitted by the entity with a contract under section 1890(a) of the Social Security Act and other stakeholders.</p> <p>“(D) COORDINATION WITH STATE AGENCIES.—The Secretary shall collaborate, coordinate, and consult with State agencies responsible for administering the Medicaid program under title XIX of the Social Security Act and the Children’s</p>	<p>Amends Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) by adding a new section, 399HH.</p>

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE III—IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE**

**SUBTITLE A – TRANSFORMING THE HEALTH CARE DELIVERY SYSTEM
PART II – NATIONAL STRATEGY TO IMPROVE HEALTH CARE QUALITY**

Section 3011. National Strategy

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>Health Insurance Program under title XXI of such Act with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities identified under subparagraph (A).</p> <p>“(b) STRATEGIC PLAN.—</p> <p>“(1) IN GENERAL.—The national strategy shall include a comprehensive strategic plan to achieve the priorities described in subsection (a).</p> <p>“(2) REQUIREMENTS.—The strategic plan shall include provisions for addressing, at a minimum, the following:</p> <p>“(A) Coordination among agencies within the Department, which shall include steps to minimize duplication of efforts and utilization of common quality measures, where available. Such common quality measures shall be measures identified by the Secretary under section 1139A or 1139B of the Social Security Act or endorsed under section 1890 of such Act.</p> <p>“(B) Agency-specific strategic plans to achieve national priorities.</p> <p>“(C) Establishment of annual benchmarks for each relevant agency to achieve national priorities.</p> <p>“(D) A process for regular reporting by the agencies to the Secretary on the implementation of the strategic plan.</p> <p>“(E) Strategies to align public and private payers with regard to quality and patient safety efforts.</p> <p>“(F) Incorporating quality improvement and measurement in the strategic plan for health information technology required by the American Recovery and Reinvestment Act of 2009 (Public Law 111–5).</p> <p>“(c) PERIODIC UPDATE OF NATIONAL STRATEGY.—The Secretary shall update the national strategy not less than annually. Any such update shall include a review of short- and long-term goals.</p> <p>“(d) SUBMISSION AND AVAILABILITY OF NATIONAL STRATEGY AND UPDATES.—</p> <p>“(1) DEADLINE FOR INITIAL SUBMISSION OF NATIONAL STRATEGY.—Not later than January 1, 2011, the Secretary shall submit to the relevant committees of Congress the national strategy described in subsection (a).</p> <p>“(2) UPDATES.—</p> <p>“(A) IN GENERAL.—The Secretary shall submit to the relevant committees of Congress an annual update to the strategy described in paragraph (1).</p> <p>“(B) INFORMATION SUBMITTED.—Each update submitted under subparagraph (A) shall include—</p> <p>“(i) a review of the short- and long-term goals of the national strategy and any gaps in such strategy;</p> <p>“(ii) an analysis of the progress, or lack of progress, in meeting such goals and any barriers to such progress;</p> <p>“(iii) the information reported under section 1139A of the Social Security Act, consistent with the reporting requirements of such section; and</p> <p>“(iv) in the case of an update required to be submitted on or after January 1, 2014, the information reported under section</p>	

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Section 3011. National Strategy

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<p>1139B(b)(4) of the Social Security Act, consistent with the reporting requirements of such section. “(C) SATISFACTION OF OTHER REPORTING REQUIREMENTS.— Compliance with the requirements of clauses (iii) and (iv) of subparagraph (B) shall satisfy the reporting requirements under sections 1139A(a)(6) and 1139B(b)(4), respectively, of the Social Security Act.</p> <p>“(e) HEALTH CARE QUALITY INTERNET WEBSITE.—Not later than January 1, 2011, the Secretary shall create an Internet website to make public information regarding— “(1) the national priorities for health care quality improvement established under subsection (a)(2); “(2) the agency-specific strategic plans for health care quality described in subsection (b)(2)(B); and “(3) other information, as the Secretary determines to be appropriate.”.</p>	

HEALTH CARE QUALITY AND INNOVATION

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE III—IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE
SUBTITLE A—TRANSFORMING THE HEALTH CARE DELIVERY SYSTEM
Section 3021. Establishment of Center for Medicare and Medicaid Innovation within CMS

Effective Date: January 1, 2011

Establishes the CMI Center to research, develop, test, and expand innovative payment and delivery arrangements to improve the quality and reduce the cost of care provided to individuals covered under Medicare and Medicaid

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) IN GENERAL.—Title XI of the Social Security Act is amended by inserting after section 1115 the following new section: “CENTER FOR MEDICARE AND MEDICAID INNOVATION “SEC. 1115A. (a) CENTER FOR MEDICARE AND MEDICAID INNOVATION ESTABLISHED.— “(1) IN GENERAL.—There is created within the Centers for Medicare & Medicaid Services a Center for Medicare and Medicaid Innovation (in this section referred to as the ‘CMI’) to carry out the duties described in this section. The purpose of the CMI is to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals defined in paragraph (4)(A).</p> <p>“(2) DEADLINE.—The Secretary shall ensure that the CMI is carrying out the duties described in this section by not later than January 1, 2011.</p> <p>“(3) CONSULTATION.—In carrying out the duties under this section, the CMI shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMI shall use open door forums or other mechanisms to seek input from interested parties.</p> <p>“(4) DEFINITIONS.—In this section: “(A) APPLICABLE INDIVIDUAL.—The term ‘applicable individual’ means— “(i) an individual who is entitled to, or enrolled for, benefits under part A of title XVIII or enrolled for benefits under part B of such title; “(ii) an individual who is eligible for medical assistance under title XIX, under a State plan or waiver; or “(iii) an individual who meets the criteria of both clauses (i) and (ii). “(B) APPLICABLE TITLE.—The term ‘applicable title’ means title XVIII, title XIX, or both.</p> <p>“(b) TESTING OF MODELS (PHASE I).— “(1) IN GENERAL.—The CMI shall test payment and service delivery models in accordance with selection criteria under paragraph (2) to determine the effect of applying such models under the applicable title (as defined in subsection (a)(4)(B)) on program expenditures under such titles and the quality of care received by individuals receiving benefits under such title.</p>	<p>Amends the Social Security Act by adding a new section 1115A</p>

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SUBTITLE A—TRANSFORMING THE HEALTH CARE DELIVERY SYSTEM

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Effective Date: January 1, 2011

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(2) SELECTION OF MODELS TO BE TESTED.—</p> <p>“(A) IN GENERAL.—The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The models selected under the preceding sentence may include the models described in subparagraph (B).</p> <p>“(B) OPPORTUNITIES.—The models described in this subparagraph are the following models:</p> <p>“(i) Promoting broad payment and practice reform in primary care, including patient-centered medical home models for high-need applicable individuals, medical homes that address women’s unique health care needs, and models that transition primary care practices away from fee-for-service based reimbursement and toward comprehensive payment or salary-based payment.</p> <p>“(ii) Contracting directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment.</p> <p>“(iii) Utilizing geriatric assessments and comprehensive care plans to coordinate the care (including through interdisciplinary teams) of applicable individuals with multiple chronic conditions and at least one of the following:</p> <p>“(I) An inability to perform 2 or more activities of daily living.</p> <p>“(II) Cognitive impairment, including dementia.</p> <p>“(iv) Promote care coordination between providers of services and suppliers that transition health care providers away from fee-for-service based reimbursement and toward salary-based payment.</p> <p>“(v) Supporting care coordination for chronically ill applicable individuals at high risk of hospitalization through a health information technology-enabled provider network that includes care coordinators, a chronic disease registry, and home telehealth technology.</p> <p>“(vi) Varying payment to physicians who order advanced diagnostic imaging services (as defined in section 1834(e)(1)(B)) according to the physician’s adherence to appropriateness criteria for the ordering of such services, as determined in consultation with physician specialty groups and other relevant stakeholders.</p> <p>“(vii) Utilizing medication therapy management services, such as those described in section 935 of the Public Health Service Act.</p> <p>“(viii) Establishing community-based health teams to support small-practice medical homes by assisting the primary care practitioner in chronic care management, including patient self-management, activities.</p> <p>“(ix) Assisting applicable individuals in making informed health care choices by paying providers of services and suppliers for using patient decision-support tools, including tools that meet the standards developed and identified under section 936(c)(2)(A) of the Public Health Service Act, that improve applicable individual and caregiver understanding of medical treatment options.</p>	

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<p>“(x) Allowing States to test and evaluate fully integrating care for dual eligible individuals in the State, including the management and oversight of all funds under the applicable titles with respect to such individuals.</p> <p>“(xi) Allowing States to test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual eligible individuals.</p> <p>“(xii) Aligning nationally recognized, evidence based guidelines of cancer care with payment incentives under title XVIII in the areas of treatment planning and follow-up care planning for applicable individuals described in clause (i) or (ii) of subsection (a)(4)(A) with cancer, including the identification of gaps in applicable quality measures.</p> <p>“(xiii) Improving post-acute care through continuing care hospitals that offer inpatient rehabilitation, long-term care hospitals, and home health or skilled nursing care during an inpatient stay and the 30 days immediately following discharge.</p> <p>“(xiv) Funding home health providers who offer chronic care management services to applicable individuals in cooperation with interdisciplinary teams.</p> <p>“(xv) Promoting improved quality and reduced cost by developing a collaborative of high-quality, low-cost health care institutions that is responsible for—</p> <p>“(I) developing, documenting, and disseminating best practices and proven care methods;</p> <p>“(II) implementing such best practices and proven care methods within such institutions to demonstrate further improvements in quality and efficiency; and</p> <p>“(III) providing assistance to other health care institutions on how best to employ such best practices and proven care methods to improve health care quality and lower costs.</p> <p>“(xvi) Facilitate inpatient care, including intensive care, of hospitalized applicable individuals at their local hospital through the use of electronic monitoring by specialists, including intensivists and critical care specialists, based at integrated health systems.</p> <p>“(xvii) Promoting greater efficiencies and timely access to outpatient services (such as outpatient physical therapy services) through models that do not require a physician or other health professional to refer the service or be involved in establishing the plan of care for the service, when such service is furnished by a health professional who has the authority to furnish the service under existing State law.</p> <p>“(xviii) Establishing comprehensive payments to Healthcare Innovation Zones, consisting of groups of providers that include a teaching hospital, physicians, and other clinical entities, that, through their structure, operations, and joint-activity deliver a full spectrum of integrated and comprehensive health care services to applicable individuals while also incorporating innovative methods for the clinical training of future health care professionals.</p> <p>“(C) ADDITIONAL FACTORS FOR CONSIDERATION.—In selecting models for testing under subparagraph (A), the CMI may consider the following additional factors:</p> <p>“(i) Whether the model includes a regular process for monitoring and updating patient care plans in a manner that is consistent</p>	

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<p>with the needs and preferences of applicable individuals.</p> <p>“(ii) Whether the model places the applicable individual, including family members and other informal caregivers of the applicable individual, at the center of the care team of the applicable individual.</p> <p>“(iii) Whether the model provides for in-person contact with applicable individuals.</p> <p>“(iv) Whether the model utilizes technology, such as electronic health records and patient-based remote monitoring systems, to coordinate care over time and across settings.</p> <p>“(v) Whether the model provides for the maintenance of a close relationship between care coordinators, primary care practitioners, specialist physicians, community-based organizations, and other providers of services and suppliers.</p> <p>“(vi) Whether the model relies on a team-based approach to interventions, such as comprehensive care assessments, care planning, and self-management coaching.</p> <p>“(vii) Whether, under the model, providers of services and suppliers are able to share information with patients, caregivers, and other providers of services and suppliers on a real time basis.</p> <p>“(3) BUDGET NEUTRALITY.—</p> <p>“(A) INITIAL PERIOD.—The Secretary shall not require, as a condition for testing a model under paragraph (1), that the design of such model ensure that such model is budget neutral initially with respect to expenditures under the applicable title.</p> <p>“(B) TERMINATION OR MODIFICATION.—The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services, with respect to program spending under the applicable title, certifies), after testing has begun, that the model is expected to—</p> <p>“(i) improve the quality of care (as determined by the Administrator of the Centers for Medicare & Medicaid Services) without increasing spending under the applicable title;</p> <p>“(ii) reduce spending under the applicable title without reducing the quality of care; or</p> <p>“(iii) improve the quality of care and reduce spending. Such termination may occur at any time after such testing has begun and before completion of the testing.</p> <p>“(4) EVALUATION.—</p> <p>“(A) IN GENERAL.—The Secretary shall conduct an evaluation of each model tested under this subsection. Such evaluation shall include an analysis of—</p> <p>“(i) the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary; and</p> <p>“(ii) the changes in spending under the applicable titles by reason of the model.</p> <p>“(B) INFORMATION.—The Secretary shall make the results of each evaluation under this paragraph available to the public in</p>	

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<p>a timely fashion and may establish requirements for States and other entities participating in the testing of models under this section to collect and report information that the Secretary determines is necessary to monitor and evaluate such models.</p> <p>“(c) EXPANSION OF MODELS (PHASE II).—Taking into account the evaluation under subsection (b)(4), the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under subsection (b) or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if—</p> <p>“(1) the Secretary determines that such expansion is expected to—</p> <p>“(A) reduce spending under applicable title without reducing the quality of care; or</p> <p>“(B) improve the quality of care and reduce spending; and</p> <p>“(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce program spending under applicable titles.</p> <p>“(d) IMPLEMENTATION.—</p> <p>“(1) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).</p> <p>“(2) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—</p> <p>“(A) the selection of models for testing or expansion under this section;</p> <p>“(B) the selection of organizations, sites, or participants to test those models selected;</p> <p>“(C) the elements, parameters, scope, and duration of such models for testing or dissemination;</p> <p>“(D) determinations regarding budget neutrality under subsection (b)(3);</p> <p>“(E) the termination or modification of the design and implementation of a model under subsection (b)(3)(B); and</p> <p>“(F) determinations about expansion of the duration and scope of a model under subsection (c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.</p> <p>“(3) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models or expansion of such models under this section.</p> <p>“(e) APPLICATION TO CHIP.—The Center may carry out activities under this section with respect to title XXI in the same manner as provided under this section with respect to the program under the applicable titles.</p>	

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<p>“(f) FUNDING.—</p> <p>“(1) IN GENERAL.—There are appropriated, from amounts in the Treasury not otherwise appropriated—</p> <p>“(A) \$5,000,000 for the design, implementation, and evaluation of models under subsection (b) for fiscal year 2010;</p> <p>“(B) \$10,000,000,000 for the activities initiated under this section for the period of fiscal years 2011 through 2019; and</p> <p>“(C) the amount described in subparagraph (B) for the activities initiated under this section for each subsequent 10-year fiscal period (beginning with the 10-year fiscal period beginning with fiscal year 2020). Amounts appropriated under the preceding sentence shall remain available until expended.</p> <p>“(2) USE OF CERTAIN FUNDS.—Out of amounts appropriated under subparagraphs (B) and (C) of paragraph (1), not less than \$25,000,000 shall be made available each such fiscal year to design, implement, and evaluate models under subsection (b).</p> <p>“(g) REPORT TO CONGRESS.—Beginning in 2012, and not less than once every other year thereafter, the Secretary shall submit to Congress a report on activities under this section. Each such report shall describe the models tested under subsection (b), including the number of individuals described in subsection (a)(4)(A)(i) and of individuals described in subsection (a)(4)(A)(ii) participating in such models and payments made under applicable titles for services on behalf of such individuals, any models chosen for expansion under subsection (c), and the results from evaluations under subsection (b)(4). In addition, each such report shall provide such recommendations as the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.”.</p> <p>(b) MEDICAID CONFORMING AMENDMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by section 8002(b), is amended—</p> <p>(1) in paragraph (81), by striking “and” at the end;</p> <p>(2) in paragraph (82), by striking the period at the end and inserting “; and”;</p> <p>(3) by inserting after paragraph (82) the following new paragraph:</p> <p>“(83) provide for implementation of the payment models specified by the Secretary under section 1115A(c) for implementation on a nationwide basis unless the State demonstrates to the satisfaction of the Secretary that implementation would not be administratively feasible or appropriate to the health care delivery system of the State.”.</p>	

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(c) REVISIONS TO HEALTH CARE QUALITY DEMONSTRATION PROGRAM.—
 Subsections (b) and (f) of section 1866C of the Social Security Act (42 U.S.C. 1395cc–3) are amended by striking “5-year” each place it appears.

HEALTH CARE QUALITY AND INNOVATION

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

TITLE VI—TRANSPARENCY AND PROGRAM INTEGRITY

SUBTITLE D – PATIENT-CENTERED OUTCOMES RESEARCH

Section 6301. Patient-Centered Outcomes Research

Effective Date: March 23, 2010

Establishes a private, nonprofit entity to be governed by a public-private sector board appointed by the Comptroller General

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<p>(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:</p> <p>‘PART D—COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH</p> <p>‘COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH</p> <p>‘SEC. 1181. (a) DEFINITIONS.—In this section:</p> <p>‘(1) BOARD.—The term ‘Board’ means the Board of Governors established under subsection (f).</p> <p>‘(2) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH; RESEARCH.—</p> <p>‘(A) IN GENERAL.—The terms ‘comparative clinical effectiveness research’ and ‘research’ mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).</p> <p>‘(B) MEDICAL TREATMENTS, SERVICES, AND ITEMS DESCRIBED.—The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.</p> <p style="text-align: center;">...</p> <p>‘(b) PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—</p> <p>‘(1) ESTABLISHMENT.—There is authorized to be established a nonprofit corporation, to be known as the ‘Patient-Centered Outcomes Research Institute’ (referred to in this section as the ‘Institute’) which is neither an agency nor establishment of the United States Government.</p> <p>‘(2) APPLICATION OF PROVISIONS.—The Institute shall be subject to the provisions of this section, and, to the extent consistent with this section, to the District of Columbia Nonprofit Corporation Act.</p> <p>‘(3) FUNDING OF COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.—For fiscal year 2010 and each subsequent fiscal year, amounts in the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the ‘PCORTF’) under section 9511 of the Internal Revenue Code of 1986 shall be available, without further appropriation, to the Institute to carry out this section.</p> <p>‘(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of</p>	<p>Amends Title XI of the Social Security Act, 42 U.S.C. 1301 et seq., by adding a new section, 1181.</p>

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE VI—TRANSPARENCY AND PROGRAM INTEGRITY**

SUBTITLE D – PATIENT-CENTERED OUTCOMES RESEARCH

Section 6301. Patient-Centered Outcomes Research

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<p>research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).</p> <p>“(d) DUTIES.—</p> <p>“(1) IDENTIFYING RESEARCH PRIORITIES AND ESTABLISHING RESEARCH PROJECT AGENDA.—</p> <p>“(A) IDENTIFYING RESEARCH PRIORITIES.—The Institute shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions, and priorities in the National Strategy for quality care established under section 399H of the Public Health Service Act that are consistent with this section.</p> <p>“(B) ESTABLISHING RESEARCH PROJECT AGENDA.—The Institute shall establish and update a research project agenda for research to address the priorities identified under subparagraph (A), taking into consideration the types of research that might address each priority and the relative value (determined based on the cost of conducting research compared to the potential usefulness of the information produced by research) associated with the different types of research, and such other factors as the Institute determines appropriate.</p> <p>“(2) CARRYING OUT RESEARCH PROJECT AGENDA.—</p> <p>“(A) RESEARCH.—The Institute shall carry out the research project agenda established under paragraph (1)(B) in accordance with the methodological standards adopted under paragraph (9) using methods, including the following:</p> <p>“(i) Systematic reviews and assessments of existing and future research and evidence including original research conducted subsequent to the date of the enactment of this section.</p> <p>“(ii) Primary research, such as randomized clinical trials, molecularly informed trials, and observational studies.</p> <p>“(iii) Any other methodologies recommended by the methodology committee established under paragraph (6) that are adopted by the Board under paragraph (9).</p> <p align="center">...</p> <p>“(iii) COVERAGE OF COPAYMENTS OR COINSURANCE.—</p> <p>A contract entered into under this subparagraph may allow for the coverage of copayments or coinsurance, or allow for other appropriate measures, to the extent that such coverage or other measures are necessary to preserve the validity of a research project, such as in the case where the research project must be blinded.</p> <p align="center">...</p> <p>“(C) REVIEW AND UPDATE OF EVIDENCE.—The Institute shall review and update evidence on a periodic basis as appropriate.</p>	

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“(D) TAKING INTO ACCOUNT POTENTIAL DIFFERENCES.— Research shall be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular sub-types, or quality of life preferences and include members of such subpopulations as subjects in the research as feasible and appropriate.

“(E) DIFFERENCES IN TREATMENT MODALITIES.—

Research shall be designed, as appropriate, to take into account different characteristics of treatment modalities that may affect research outcomes, such as the phase of the treatment modality in the innovation cycle and the impact of the skill of the operator of the treatment modality.

...

“(6) ESTABLISHING METHODOLOGY COMMITTEE.—

“(A) IN GENERAL.—The Institute shall establish a standing methodology committee to carry out the functions described in subparagraph (C).

“(B) APPOINTMENT AND COMPOSITION.—The methodology committee established under subparagraph (A) shall be composed of not more than 15 members appointed by the Comptroller General of the United States. Members appointed to the methodology committee shall be experts in their scientific field, such as health services research, clinical research, comparative clinical effectiveness research, biostatistics, genomics, and research methodologies. Stakeholders with such expertise may be appointed to the methodology committee. In addition to the members appointed under the first sentence, the Directors of the National Institutes of Health and the Agency for Healthcare Research and Quality (or their designees) shall each be included as members of the methodology committee.

“(C) FUNCTIONS.—Subject to subparagraph (D), the methodology committee shall work to develop and improve the science and methods of comparative clinical effectiveness research by, not later than 18 months after the establishment of the Institute, directly or through subcontract, developing and periodically updating the following:

“(i) Methodological standards for research. Such methodological standards shall provide specific criteria for internal validity, generalizability, feasibility, and timeliness of research and for health outcomes measures, risk adjustment, and other relevant aspects of research and assessment with respect to the design of research. Any methodological standards developed and updated under this subclause shall be scientifically based and include methods by which new information, data, or advances in technology are considered and incorporated into ongoing research projects by the Institute, as appropriate. The process for developing and updating such standards shall include input from relevant experts, stakeholders, and decision-makers, and shall provide opportunities for public comment. Such standards shall also include methods by which patient subpopulations can be accounted for and evaluated in different types of research. As appropriate, such standards shall build on existing work on methodological standards for defined categories of health interventions and for each of the major categories of comparative

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<p>clinical effectiveness research methods (determined as of the date of enactment of the Patient Protection and Affordable Care Act).</p> <p>“(ii) A translation table that is designed to provide guidance and act as a reference for the Board to determine research methods that are most likely to address each specific research question.</p> <p>“(D) CONSULTATION AND CONDUCT OF EXAMINATIONS.— The methodology committee may consult and contract with the Institute of Medicine of the National Academies and academic, nonprofit, or other private and governmental entities with relevant expertise to carry out activities described in subparagraph (C) and may consult with relevant stakeholders to carry out such activities.</p> <p>“(E) REPORTS.—The methodology committee shall submit reports to the Board on the committee’s performance of the functions described in subparagraph (C). Reports shall contain recommendations for the Institute to adopt methodological standards developed and updated by the methodology committee as well as other actions deemed necessary to comply with such methodological standards.</p> <p align="center">...</p> <p>“(8) RELEASE OF RESEARCH FINDINGS.— “(A) IN GENERAL.—The Institute shall, not later than 90 days after the conduct or receipt of research findings under this part, make such research findings available to clinicians, patients, and the general public. The Institute shall ensure that the research findings— “(i) convey the findings of research in a manner that is comprehensible and useful to patients and providers in making health care decisions; “(ii) fully convey findings and discuss considerations specific to certain subpopulations, risk factors, and comorbidities, as appropriate; “(iii) include limitations of the research and what further research may be needed as appropriate; “(iv) not be construed as mandates for practice guidelines, coverage recommendations, payment, or policy recommendations; and “(v) not include any data which would violate the privacy of research participants or any confidentiality agreements made with respect to the use of data under this section.</p> <p>“(B) DEFINITION OF RESEARCH FINDINGS.—In this paragraph, the term ‘research findings’ means the results of a study or assessment.</p> <p>“(9) ADOPTION.—Subject to subsection (h)(1), the Institute shall adopt the national priorities identified under paragraph (1)(A), the research project agenda established under paragraph (1)(B), the methodological standards developed and updated by the methodology committee under paragraph (6)(C)(i), and any peer-review process provided under paragraph (7) by majority vote. In the case where the Institute does not adopt such processes in accordance with the preceding sentence, the processes shall</p>	

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<p>be referred to the appropriate staff or entity within the Institute (or, in the case of the methodological standards, the methodology committee) for further review.</p> <p>“(10) ANNUAL REPORTS.—The Institute shall submit an annual report to Congress and the President, and shall make the annual report available to the public. Such report shall contain—</p> <p>“(A) a description of the activities conducted under this section, research priorities identified under paragraph (1)(A) and methodological standards developed and updated by the methodology committee under paragraph (6)(C)(i) that are adopted under paragraph (9) during the preceding year;</p> <p>“(B) the research project agenda and budget of the Institute for the following year;</p> <p>“(C) any administrative activities conducted by the Institute during the preceding year;</p> <p>“(D) the names of individuals contributing to any peer review process under paragraph (7), without identifying them with a particular research project; and</p> <p>“(E) any other relevant information (including information on the membership of the Board, expert advisory panels, methodology committee, and the executive staff of the Institute, any conflicts of interest with respect to these individuals, and any bylaws adopted by the Board during the preceding year).</p> <p align="center">...</p> <p>“(h) ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS.—The Institute shall establish procedures to ensure that the following requirements for ensuring transparency, credibility, and access are met:</p> <p>“(1) PUBLIC COMMENT PERIODS.—The Institute shall provide for a public comment period of not less than 45 days and not more than 60 days prior to the adoption under subsection (d)(9) of the national priorities identified under subsection (d)(1)(A), the research project agenda established under subsection (d)(1)(B), the methodological standards developed and updated by the methodology committee under subsection d)(6)(C)(i), and the peer-review process provided under paragraph (7), and after the release of draft findings with respect to systematic reviews of existing research and evidence.</p> <p>“(2) ADDITIONAL FORUMS.—The Institute shall support forums to increase public awareness and obtain and incorporate public input and feedback through media (such as an Internet website) on research priorities, research findings, and other duties, activities, or processes the Institute determines appropriate.</p> <p>“(3) PUBLIC AVAILABILITY.—The Institute shall make available to the public and disclose through the official public Internet website of the Institute the following:</p> <p>“(A) Information contained in research findings as specified in subsection (d)(9).</p> <p>“(B) The process and methods for the conduct of research, including the identity of the entity and the investigators conducting such research and any conflicts of interests of such parties, any direct or indirect links the entity has to industry, and research protocols, including measures taken, methods of research and analysis, research results, and such other information the Institute determines appropriate) concurrent with the release of research findings.</p>	

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“(C) Notice of public comment periods under paragraph (1), including deadlines for public comments.
 “(D) Subsequent comments received during each of the public comment periods.
 “(E) In accordance with applicable laws and processes and as the Institute determines appropriate, proceedings of the Institute.
 . . .

(b) DISSEMINATION AND BUILDING CAPACITY FOR RESEARCH.— Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), as amended by section 3606, is further amended by inserting after section 936 the following:
“SEC. 937. DISSEMINATION AND BUILDING CAPACITY FOR RESEARCH.
 “(a) IN GENERAL.—
 “(1) DISSEMINATION.—The Office of Communication and Knowledge Transfer (referred to in this section as the ‘Office’) at the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Research and Quality), in consultation with the National Institutes of Health, shall broadly disseminate the research findings that are published by the Patient Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act (referred to in this section as the ‘Institute’) and other government-funded research relevant to comparative clinical effectiveness research. The Office shall create informational tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers. The Office shall also develop a publicly available resource database that collects and contains government-funded evidence and research from public, private, not-for profit, and academic sources.
 “(2) REQUIREMENTS.—The Office shall provide for the dissemination of the Institute’s research findings and government-funded research relevant to comparative clinical effectiveness research to physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans. Materials, forums, and media used to disseminate the findings, informational tools, and resource databases shall—
 “(A) include a description of considerations for specific subpopulations, the research methodology, and the limitations of the research, and the names of the entities, agencies, instrumentalities, and individuals who conducted any research which was published by the Institute; and
 “(B) not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.
 “(b) INCORPORATION OF RESEARCH FINDINGS.—The Office, in consultation with relevant medical and clinical associations, shall assist users of health information technology focused on clinical decision support to promote the timely incorporation of research findings disseminated under subsection (a) into clinical practices and to promote the ease of use of such incorporation.
 “(c) FEEDBACK.—The Office shall establish a process to receive feedback from physicians, health care providers, patients, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans about the value of the information disseminated and the assistance provided under this section.

Amends Title IX of the Public Health Service Act, 42 U.S.C. 299 et seq., by adding a new section, 937.

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“(d) **RULE OF CONSTRUCTION.**—Nothing in this section shall preclude the Institute from making its research findings publicly available as required under section 1181(d)(8) of the Social Security Act.

“(e) **TRAINING OF RESEARCHERS.**—The Agency for Health Care Research and Quality, in consultation with the National Institutes of Health, shall build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews of existing research and primary research such as clinical trials. At a minimum, such training shall be in methods that meet the methodological standards adopted under section 1181(d)(9) of the Social Security Act.

“(f) **BUILDING DATA FOR RESEARCH.**—The Secretary shall provide for the coordination of relevant Federal health programs to build data capacity for comparative clinical effectiveness research, including the development and use of clinical registries and health outcomes research data networks, in order to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

“(g) **AUTHORITY TO CONTRACT WITH THE INSTITUTE.**—Agencies and instrumentalities of the Federal Government may enter into agreements with the Institute, and accept and retain funds, for the conduct and support of research described in this part, provided that the research to be conducted or supported under such agreements is authorized under the governing statutes of such agencies and instrumentalities.”.

(c) **IN GENERAL.**—Part D of title XI of the Social Security Act, as added by subsection (a), is amended by adding at the end the following new section:

“LIMITATIONS ON CERTAIN USES OF COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

“**SEC. 1182.** (a) The Secretary may only use evidence and findings from research conducted under section 1181 to make a determination regarding coverage under title XVIII if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.

“(b) Nothing in section 1181 shall be construed as—

“(1) superceding or modifying the coverage of items or services under title XVIII that the Secretary determines are reasonable and necessary under section 1862(l)(1); or

“(2) authorizing the Secretary to deny coverage of items or services under such title solely on the basis of comparative clinical effectiveness research.

“(c)(1) The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1181 in determining coverage, reimbursement, or incentive programs under title XVIII in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

“(2) Paragraph (1) shall not be construed as preventing the Secretary from using evidence or findings from such comparative

Amends Part D of Title XI of the Social Security Act, 42 U.S.C. 1101 et seq., by adding a new section, 1182.

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clinical effectiveness research in determining coverage, reimbursement, or incentive programs under title XVIII based upon a comparison of the difference in the effectiveness of alternative treatments in extending an individual’s life due to the individual’s age, disability, or terminal illness.

“(d)(1) The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1181 in determining coverage, reimbursement, or incentive programs under title XVIII in a manner that precludes, or with the intent to discourage, an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability.

“(2)(A) Paragraph (1) shall not be construed to—

“(i) limit the application of differential copayments under title XVIII based on factors such as cost or type of service; or

“(ii) prevent the Secretary from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under such title based upon a comparison of the difference in the effectiveness of alternative health care treatments in extending an individual’s life due to that individual’s age, disability, or terminal illness.

“(3) Nothing in the provisions of, or amendments made by the Patient Protection and Affordable Care Act, shall be construed to limit comparative clinical effectiveness research or any other research, evaluation, or dissemination of information concerning the likelihood that a health care treatment will result in disability.

“(e) The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollars-per- quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.”.

(d) IN GENERAL.—Part D of title XI of the Social Security Act, as added by subsection (a) and amended by subsection (c), is amended by adding at the end the following new section:

“TRUST FUND TRANSFERS TO PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND

“SEC. 1183. (a) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841, in proportion (as estimated by the Secretary) to the total expenditures during such fiscal year that are made under title XVIII from the respective trust fund, to the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the ‘PCORTF’) under section 9511 of the Internal Revenue Code of 1986, of the following:

“(1) For fiscal year 2013, an amount equal to \$1 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of title XVIII during such fiscal year.

“(2) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019, an amount equal to \$2 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of title XVIII during such fiscal year.

Amends Part D of Title XI of the Social Security Act, 42 U.S.C. 1101 et seq., by adding a new section, 1183.

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<p>“(b) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.— In the case of any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a)(2) for such fiscal year shall be equal to the sum of such dollar amount for the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of— “(1) such dollar amount for the previous fiscal year, multiplied by “(2) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.”.</p> <p>(e) PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND; FINANCING FOR TRUST FUND.— (1) ESTABLISHMENT OF TRUST FUND.— (A) IN GENERAL.—Subchapter A of chapter 98 of the Internal Revenue Code of 1986 (relating to establishment of trust funds) is amended by adding at the end the following new section: “SEC. 9511. PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND. “(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as the ‘Patient-Centered Outcomes Research Trust Fund’ (hereafter in this section referred to as the ‘PCORTF’), consisting of such amounts as may be appropriated or credited to such Trust Fund as provided in this section and section 9602(b). “(b) TRANSFERS TO FUND.— “(1) APPROPRIATION.—There are hereby appropriated to the Trust Fund the following: “(A) For fiscal year 2010, \$10,000,000. “(B) For fiscal year 2011, \$50,000,000. “(C) For fiscal year 2012, \$150,000,000. “(D) For fiscal year 2013— “(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and “(ii) \$150,000,000. “(E) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019— “(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and “(ii) \$150,000,000. The amounts appropriated under subparagraphs (A), (B), (C), (D)(ii), and (E)(ii) shall be transferred from the general fund of the Treasury, from funds not otherwise appropriated. “(2) TRUST FUND TRANSFERS.—In addition to the amounts appropriated under paragraph (1), there shall be credited to the PCORTF the amounts transferred under section 1183 of the Social Security Act.</p>	<p>Amends Subchapter A of Chapter 98 of the Internal Revenue Code of 1986 by adding a new section, 9511.</p>

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“(3) LIMITATION ON TRANSFERS TO PCORTF.—No amount may be appropriated or transferred to the PCORTF on and after the date of any expenditure from the PCORTF which is not an expenditure permitted under this section. The determination of whether an expenditure is so permitted shall be made without regard to—

“(A) any provision of law which is not contained or referenced in this chapter or in a revenue Act, and “(B) whether such provision of law is a subsequently enacted provision or directly or indirectly seeks to waive the application of this paragraph.

“(c) TRUSTEE.—The Secretary of the Treasury shall be a trustee of the PCORTF.

“(d) EXPENDITURES FROM FUND.—

“(1) AMOUNTS AVAILABLE TO THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—Subject to paragraph (2), amounts in the PCORTF are available, without further appropriation, to the Patient-Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act for carrying out part D of title XI of the Social Security Act (as in effect on the date of enactment of such Act).

“(2) TRANSFER OF FUNDS.—

“(A) IN GENERAL.—The trustee of the PCORTF shall provide for the transfer from the PCORTF of 20 percent of the amounts appropriated or credited to the PCORTF for each of fiscal years 2011 through 2019 to the Secretary of Health and Human Services to carry out section 937 of the Public Health Service Act.

“(B) AVAILABILITY.—Amounts transferred under subparagraph (A) shall remain available until expended.

“(C) REQUIREMENTS.—Of the amounts transferred under subparagraph (A) with respect to a fiscal year, the Secretary of Health and Human Services shall distribute—

“(i) 80 percent to the Office of Communication and Knowledge Transfer of the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Research and Quality) to carry out the activities described in section 937 of the Public Health Service Act; and

“(ii) 20 percent to the Secretary to carry out the activities described in such section 937.

“(e) NET REVENUES.—For purposes of this section, the term ‘net revenues’ means the amount estimated by the Secretary of the Treasury based on the excess of—

“(1) the fees received in the Treasury under subchapter B of chapter 34, over

“(2) the decrease in the tax imposed by chapter 1 resulting from the fees imposed by such subchapter.

“(f) TERMINATION.—No amounts shall be available for expenditure from the PCORTF after September 30, 2019, and any amounts in such Trust Fund after such date shall be transferred to the general fund of the Treasury.”.

(B) CLERICAL AMENDMENT.—The table of sections for subchapter A of chapter 98 of such Code is amended by adding at the end the following new item:

“Sec. 9511. Patient-centered outcomes research trust fund.”.

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<p>(2) FINANCING FOR FUND FROM FEES ON INSURED AND SELFINSURED HEALTH PLANS.— (A) GENERAL RULE.—Chapter 34 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subchapter: “Subchapter B—Insured and Self-Insured Health Plans “Sec. 4375. Health insurance. “Sec. 4376. Self-insured health plans. “Sec. 4377. Definitions and special rules.</p> <p>“SEC. 4375. HEALTH INSURANCE. “(a) IMPOSITION OF FEE.—There is hereby imposed on each specified health insurance policy for each policy year ending after September 30, 2012, a fee equal to the product of \$2 (\$1 in the case of policy years ending during fiscal year 2013) multiplied by the average number of lives covered under the policy. “(b) LIABILITY FOR FEE.—The fee imposed by subsection (a) shall be paid by the issuer of the policy. “(c) SPECIFIED HEALTH INSURANCE POLICY.—For purposes of this section: “(1) IN GENERAL.—Except as otherwise provided in this section, the term ‘specified health insurance policy’ means any accident or health insurance policy (including a policy under a group health plan) issued with respect to individuals residing in the United States. “(2) EXEMPTION FOR CERTAIN POLICIES.—The term ‘specified health insurance policy’ does not include any insurance if substantially all of its coverage is of excepted benefits described in section 9832(c). “(3) TREATMENT OF PREPAID HEALTH COVERAGE ARRANGEMENTS.— “(A) IN GENERAL.—In the case of any arrangement described in subparagraph (B), such arrangement shall be treated as a specified health insurance policy, and the person referred to in such subparagraph shall be treated as the issuer. “(B) DESCRIPTION OF ARRANGEMENTS.—An arrangement is described in this subparagraph if under such arrangement fixed payments or premiums are received as consideration for any person’s agreement to provide or arrange for the provision of accident or health coverage to residents of the United States, regardless of how such coverage is provided or arranged to be provided. “(d) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any policy year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a) for such policy year shall be equal to the sum of such dollar amount for policy years ending in the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of— “(1) such dollar amount for policy years ending in the previous fiscal year, multiplied by “(2) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.</p>	<p>Amends Chapter 34 of the Internal Revenue Code of 1986 by adding a new sections, 4375 through 4377.</p>

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“(e) TERMINATION.—This section shall not apply to policy years ending after September 30, 2019.

“**SEC. 4376. SELF-INSURED HEALTH PLANS.**

“(a) IMPOSITION OF FEE.—In the case of any applicable self-insured health plan for each plan year ending after September 30, 2012, there is hereby imposed a fee equal to \$2 (\$1 in the case of plan years ending during fiscal year 2013) multiplied by the average number of lives covered under the plan.

“(b) LIABILITY FOR FEE.—

“(1) IN GENERAL.—The fee imposed by subsection (a) shall be paid by the plan sponsor.

“(2) PLAN SPONSOR.—For purposes of paragraph (1) the term ‘plan sponsor’ means—

“(A) the employer in the case of a plan established or maintained by a single employer,

“(B) the employee organization in the case of a plan established or maintained by an employee organization,

“(C) in the case of—

“(i) a plan established or maintained by 2 or more employers or jointly by 1 or more employers and 1 or more employee organizations,

“(ii) a multiple employer welfare arrangement, or

“(iii) a voluntary employees’ beneficiary association described in section 501(c)(9), the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, or

“(D) the cooperative or association described in subsection (c)(2)(F) in the case of a plan established or maintained by such a cooperative or association.

“(c) APPLICABLE SELF-INSURED HEALTH PLAN.—For purposes of this section, the term ‘applicable self-insured health plan’ means any plan for providing accident or health coverage if—

“(1) any portion of such coverage is provided other than through an insurance policy, and

“(2) such plan is established or maintained—

“(A) by 1 or more employers for the benefit of their employees or former employees,

“(B) by 1 or more employee organizations for the benefit of their members or former members,

“(C) jointly by 1 or more employers and 1 or more employee organizations for the benefit of employees or former employees,

“(D) by a voluntary employees’ beneficiary association described in section 501(c)(9),

“(E) by any organization described in section 501(c)(6), or

“(F) in the case of a plan not described in the preceding subparagraphs, by a multiple employer welfare arrangement (as defined in section 3(40) of Employee Retirement Income Security Act of 1974), a rural electric cooperative (as defined in section 3(40)(B)(iv) of such Act), or a rural telephone cooperative association (as defined in section 3(40)(B)(v) of such Act).

“(d) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any plan year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a) for such plan year shall be equal to the

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE VI—TRANSPARENCY AND PROGRAM INTEGRITY**

**SUBTITLE D – PATIENT-CENTERED OUTCOMES RESEARCH
Section 6301. Patient-Centered Outcomes Research**

Effective Date: March 23, 2010

Establishes a private, nonprofit entity to be governed by a public-private sector board appointed by the Comptroller General

AFFORDABLE CARE ACT LANGUAGE

LANGUAGE FROM EXISTING LAW

sum of such dollar amount for plan years ending in the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—
 “(1) such dollar amount for plan years ending in the previous fiscal year, multiplied by “(2) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.
 “(e) TERMINATION.—This section shall not apply to plan years ending after September 30, 2019.

...

HEALTH CARE QUALITY AND INNOVATION

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE IX—STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE C—PROVISIONS RELATING TO TITLE III

Section 10306. Improvements under the Center for Medicare and Medicaid Innovation

Effective Date: January 1, 2011

Adds models for payment reform to the list of projects to be considered by CMI

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>Section 1115A of the Social Security Act, as added by section 3021, is amended—</p> <p>(1) in subsection (a), by inserting at the end the following new paragraph:</p> <p>“(5) TESTING WITHIN CERTAIN GEOGRAPHIC AREAS.—For purposes of testing payment and service delivery models under this section, the Secretary may elect to limit testing of a model to certain geographic areas.”;</p> <p>(2) in subsection (b)(2)—</p> <p>(A) in subparagraph (A)—</p> <p>(i) in the second sentence, by striking “the preceding sentence may include” and inserting “this subparagraph may include, but are not limited to,”; and</p> <p>(ii) by inserting after the first sentence the following new sentence: “The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title.”;</p> <p>(B) in subparagraph (B), by adding at the end the following new clauses:</p> <p>“(xix) Utilizing, in particular in entities located in medically underserved areas and facilities of the Indian Health Service (whether operated by such Service or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act)), telehealth services—</p> <p>“(I) in treating behavioral health issues (such as post-traumatic stress disorder) and stroke; and</p> <p>“(II) to improve the capacity of non-medical providers and non-specialized medical providers to provide health services for patients with chronic complex conditions.</p> <p>“(xx) Utilizing a diverse network of providers of services and suppliers to improve care coordination for applicable individuals described in subsection (a)(4)(A)(i) with 2 or more chronic conditions and a history of prior-year hospitalization through interventions developed under the Medicare Coordinated Care Demonstration Project under section 4016 of the Balanced Budget Act of 1997 (42 U.S.C. 1395b–1 note).”;</p> <p>(C) in subparagraph (C), by adding at the end the following new clause:</p> <p>“(viii) Whether the model demonstrates effective linkage with other public sector or private sector payers.”;</p> <p>(3) in subsection (b)(4), by adding at the end the following new subparagraph:</p> <p>“(C) MEASURE SELECTION.—To the extent feasible, the Secretary shall select measures under this paragraph that reflect national priorities for quality improvement and patient-centered care consistent with the measures described in 1890(b)(7)(B).”;</p> <p>and</p> <p>(4) in subsection (c)—</p>	<p>Amends section 1115A of the Social Security Act (as added by section 3021 of PPACA) by adding a new paragraph, (5).</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IX—STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE C—PROVISIONS RELATING TO TITLE III
Section 10306. Improvements under the Center for Medicare and Medicaid Innovation

Effective Date: January 1, 2011

Adds models for payment reform to the list of projects to be considered by CMI

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(A) in paragraph (1)(B), by striking “care and reduce spending; and” and inserting “patient care without increasing spending;”;</p> <p>(B) in paragraph (2), by striking “reduce program spending under applicable titles.” and inserting “reduce (or would not result in any increase in) net program spending under applicable titles; and”; and</p> <p>(C) by adding at the end the following:</p> <p>“(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals. In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.”.</p>	
<p align="center">***</p>	

Federal Funding for Vaccine Programs

FEDERAL FUNDING FOR VACCINE PROGRAMS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH
SUBTITLE C – CREATING HEALTHIER COMMUNITIES
Section 4204. Immunizations

Effective Date: March 23, 2010

Authorizes states to purchase adult vaccines under government-negotiated contracts (Centers for Disease Control and Prevention)

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) STATE AUTHORITY TO PURCHASE RECOMMENDED VACCINES FOR ADULTS.—Section 317 of the Public Health Service Act (42 U.S.C. 247b) is amended by adding at the end the following: “(1) AUTHORITY TO PURCHASE RECOMMENDED VACCINES FOR ADULTS.— “(1) IN GENERAL.—The Secretary may negotiate and enter into contracts with manufacturers of vaccines for the purchase and delivery of vaccines for adults as provided for under subsection (e). “(2) STATE PURCHASE.—A State may obtain additional quantities of such adult vaccines (subject to amounts specified to the Secretary by the State in advance of negotiations) through the purchase of vaccines from manufacturers at the applicable price negotiated by the Secretary under this subsection.”.</p> <p>(b) DEMONSTRATION PROGRAM TO IMPROVE IMMUNIZATION COVERAGE.— Section 317 of the Public Health Service Act (42 U.S.C. 247b), as amended by subsection (a), is further amended by adding at the end the following: “(m) DEMONSTRATION PROGRAM TO IMPROVE IMMUNIZATION COVERAGE.— “(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a demonstration program to award grants to States to improve the provision of recommended immunizations for children, adolescents, and adults through the use of evidence-based, population-based interventions for high-risk populations. “(2) STATE PLAN.—To be eligible for a grant under paragraph (1), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a State plan that describes the interventions to be implemented under the grant and how such interventions match with local needs and capabilities, as determined through consultation with local authorities. “(3) USE OF FUNDS.—Funds received under a grant under this subsection shall be used to implement interventions that are recommended by the Task Force on Community Preventive Services (as established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) or other evidence-based interventions, including— “(A) providing immunization reminders or recalls for target populations of clients, patients, and consumers; “(B) educating targeted populations and health care providers concerning immunizations in combination with one or more other interventions; “(C) reducing out-of-pocket costs for families for vaccines and their administration; “(D) carrying out immunization-promoting strategies for participants or clients of public programs, including</p>	<p><u>Section 317 of the Public Health Service Act (42 U.S.C. 247b)</u> The provisions authorizing states to purchase recommended vaccines for adults through the 317 program, allowing for demonstration programs, and grants represent new language inserted at the end of this section.</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE C – CREATING HEALTHIER COMMUNITIES

Section 4204. Immunizations

Effective Date: March 23, 2010

Authorizes states to purchase adult vaccines under government-negotiated contracts (Centers for Disease Control and Prevention)

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>assessments of immunization status, referrals to health care providers, education, provision of on-site immunizations, or incentives for immunization;</p> <p>“(E) providing for home visits that promote immunization through education, assessments of need, referrals, provision of immunizations, or other services;</p> <p>“(F) providing reminders or recalls for immunization providers;</p> <p>“(G) conducting assessments of, and providing feedback to, immunization providers;</p> <p>“(H) any combination of one or more interventions described in this paragraph; or</p> <p>“(I) immunization information systems to allow all States to have electronic databases for immunization records.</p> <p>“(4) CONSIDERATION.—In awarding grants under this subsection, the Secretary shall consider any reviews or recommendations of the Task Force on Community Preventive Services.</p> <p>“(5) EVALUATION.—Not later than 3 years after the date on which a State receives a grant under this subsection, the State shall submit to the Secretary an evaluation of progress made toward improving immunization coverage rates among high-risk populations within the State.</p> <p>“(6) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Affordable Health Choices Act, the Secretary shall submit to Congress a report concerning the effectiveness of the demonstration program established under this subsection together with recommendations on whether to continue and expand such program.</p> <p>“(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2010 through 2014.”.</p> <p>(c) REAUTHORIZATION OF IMMUNIZATION PROGRAM.—Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended—</p> <p>(1) in paragraph (1), by striking “for each of the fiscal years 1998 through 2005”; and</p> <p>(2) in paragraph (2), by striking “after October 1, 1997,”.</p> <p>(d) RULE OF CONSTRUCTION REGARDING ACCESS TO IMMUNIZATIONS.—</p> <p>Nothing in this section (including the amendments made by this section), or any other provision of this Act (including any amendments made by this Act) shall be construed to decrease children’s access to immunizations.</p> <p>(e) GAO STUDY AND REPORT ON MEDICARE BENEFICIARY ACCESS TO VACCINES.—</p> <p>(1) STUDY.—The Comptroller General of the United States (in this section referred to as the “Comptroller General”) shall conduct a study on the ability of Medicare beneficiaries who were 65 years of age or older to access routinely recommended vaccines covered under the prescription drug program under part D of title XVIII of the Social Security Act over the period since the establishment of such program. Such study shall include the following:</p>	<p><u>Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j))</u></p> <p>(j) Authorization of appropriations.</p> <p>(1) Except for grants for immunization programs the authorization of appropriations for which are established in paragraph (2), for grants under subsections (a) and (k)(1) for preventive health service programs to immunize without charge children, adolescents, and adults against vaccine-preventable diseases, there are authorized to be appropriated such sums as may be necessary. Not more than 10 percent of the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(1) for such fiscal year.</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE C – CREATING HEALTHIER COMMUNITIES

Section 4204. Immunizations

Effective Date: March 23, 2010

Authorizes states to purchase adult vaccines under government-negotiated contracts (Centers for Disease Control and Prevention)

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(A) An analysis and determination of—</p> <p>(i) the number of Medicare beneficiaries who were 65 years of age or older and were eligible for a routinely recommended vaccination that was covered under part D;</p> <p>(ii) the number of such beneficiaries who actually received a routinely recommended vaccination that was covered under part D; and</p> <p>(iii) any barriers to access by such beneficiaries to routinely recommended vaccinations that were covered under part D.</p> <p>(B) A summary of the findings and recommendations by government agencies, departments, and advisory bodies (as well as relevant professional organizations) on the impact of coverage under part D of routinely recommended adult immunizations for access to such immunizations by Medicare beneficiaries.</p> <p>(2) REPORT.—Not later than June 1, 2011, the Comptroller General shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.</p> <p>(3) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated \$1,000,000 for fiscal year 2010 to carry out this subsection.</p>	<p>(2) For grants under subsection (a) for preventive health service programs for the provision without charge of immunizations with vaccines approved for use, and recommended for routine use, there are authorized to be appropriated such sums as may be necessary.</p>

Population Health and Prevention Initiatives

POPULATION HEALTH AND PREVENTION INITIATIVES

<p>PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)</p> <p>TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH</p>	
<p>SUBTITLE A – MODERNIZING DISEASE PREVENTION AND PUBLIC HEALTH SYSTEMS</p> <p>Section 4001. National Prevention, Health Promotion and Public Health Council</p>	
<p>Effective Date: Report due not later than July 1, 2010, and annually thereafter through January 1, 2015 (March 23, 2010)</p>	
<p><i>Establishes an interagency council charged with promotion of Federal policies to improve health; the council shall include representatives from HHS, Agriculture, Education, Labor, Transportation, and other applicable agencies</i></p>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) ESTABLISHMENT.—The President shall establish, within the Department of Health and Human Services, a council to be known as the “National Prevention, Health Promotion and Public Health Council” (referred to in this section as the “Council”).</p> <p>(b) CHAIRPERSON.—The President shall appoint the Surgeon General to serve as the chairperson of the Council.</p> <p>(c) COMPOSITION.—The Council shall be composed of—</p> <ol style="list-style-type: none"> (1) the Secretary of Health and Human Services; (2) the Secretary of Agriculture; (3) the Secretary of Education; (4) the Chairman of the Federal Trade Commission; (5) the Secretary of Transportation; (6) the Secretary of Labor; (7) the Secretary of Homeland Security; (8) the Administrator of the Environmental Protection Agency; (9) the Director of the Office of National Drug Control Policy; (10) the Director of the Domestic Policy Council; (11) the Assistant Secretary for Indian Affairs; (12) the Chairman of the Corporation for National and Community Service; and (13) the head of any other Federal agency that the chairperson determines is appropriate. <p>(d) PURPOSES AND DUTIES.—The Council shall—</p> <ol style="list-style-type: none"> (1) provide coordination and leadership at the Federal level, and among all Federal departments and agencies, with respect to prevention, wellness and health promotion practices, the public health system, and integrative health care in the United States; (2) after obtaining input from relevant stakeholders, develop a national prevention, health promotion, public health, and integrative health care strategy that incorporates the most effective and achievable means of improving the health status of Americans and reducing the incidence of preventable illness and disability in the United States; (3) provide recommendations to the President and Congress concerning the most pressing health issues confronting the United States and changes in Federal policy to achieve national wellness, health promotion, and public health goals, including the reduction of tobacco use, sedentary behavior, and poor nutrition; (4) consider and propose evidence-based models, policies, and innovative approaches for the promotion of transformative models of prevention, integrative health, and public health on individual and community levels across the United States; 	<p>Provision unique to PPACA</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE A – MODERNIZING DISEASE PREVENTION AND PUBLIC HEALTH SYSTEMS

Section 4001. National Prevention, Health Promotion and Public Health Council

Effective Date: Report due not later than July 1, 2010, and annually thereafter through January 1, 2015 (**March 23, 2010**)

Establishes an interagency council charged with promotion of Federal policies to improve health; the council shall include representatives from HHS, Agriculture, Education, Labor, Transportation, and other applicable agencies

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(5) establish processes for continual public input, including input from State, regional, and local leadership communities and other relevant stakeholders, including Indian tribes and tribal organizations;</p> <p>(6) submit the reports required under subsection (g); and</p> <p>(7) carry out other activities determined appropriate by the President.</p> <p>(e) MEETINGS.—The Council shall meet at the call of the Chairperson.</p> <p>(f) ADVISORY GROUP.—</p> <p>(1) IN GENERAL.—The President shall establish an Advisory Group to the Council to be known as the “Advisory Group on Prevention, Health Promotion, and Integrative and Public Health” (hereafter referred to in this section as the “Advisory Group”). The Advisory Group shall be within the Department of Health and Human Services and report to the Surgeon General.</p> <p>(2) COMPOSITION.—</p> <p>(A) IN GENERAL.—The Advisory Group shall be composed of not more than 25 non-Federal members to be appointed by the President.</p> <p>(B) REPRESENTATION.—In appointing members under subparagraph (A), the President shall ensure that the Advisory Group includes a diverse group of licensed health professionals, including integrative health practitioners who have expertise in—</p> <p>(i) worksite health promotion;</p> <p>(ii) community services, including community health centers;</p> <p>(iii) preventive medicine;</p> <p>(iv) health coaching;</p> <p>(v) public health education;</p> <p>(vi) geriatrics; and</p> <p>(vii) rehabilitation medicine.</p> <p>(3) PURPOSES AND DUTIES.—The Advisory Group shall develop policy and program recommendations and advise the Council on lifestyle-based chronic disease prevention and management, integrative health care practices, and health promotion.</p> <p>(g) NATIONAL PREVENTION AND HEALTH PROMOTION STRATEGY.—Not later than 1 year after the date of enactment of this Act, the Chairperson, in consultation with the Council, shall develop and make public a national prevention, health promotion and public health strategy, and shall review and revise such strategy periodically. Such strategy shall—</p> <p>(1) set specific goals and objectives for improving the health of the United States through federally-supported prevention, health promotion, and public health programs, consistent with ongoing goal setting efforts conducted by specific agencies;</p> <p>(2) establish specific and measurable actions and timelines to carry out the strategy, and determine accountability for meeting those timelines, within and across Federal departments and agencies; and</p> <p>(3) make recommendations to improve Federal efforts relating to prevention, health promotion, public health, and integrative health care</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH
SUBTITLE A – MODERNIZING DISEASE PREVENTION AND PUBLIC HEALTH SYSTEMS
Section 4001. National Prevention, Health Promotion and Public Health Council

Effective Date: Report due not later than July 1, 2010, and annually thereafter through January 1, 2015 (**March 23, 2010**)

Establishes an interagency council charged with promotion of Federal policies to improve health; the council shall include representatives from HHS, Agriculture, Education, Labor, Transportation, and other applicable agencies

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>practices to ensure Federal efforts are consistent with available standards and evidence.</p> <p>(h) REPORT.—Not later than July 1, 2010, and annually thereafter through January 1, 2015, the Council shall submit to the President and the relevant committees of Congress, a report that—</p> <p>(1) describes the activities and efforts on prevention, health promotion, and public health and activities to develop a national strategy conducted by the Council during the period for which the report is prepared;</p> <p>(2) describes the national progress in meeting specific prevention, health promotion, and public health goals defined in the strategy and further describes corrective actions recommended by the Council and taken by relevant agencies and organizations to meet these goals;</p> <p>(3) contains a list of national priorities on health promotion and disease prevention to address lifestyle behavior modification (smoking cessation, proper nutrition, appropriate exercise, mental health, behavioral health, substance use disorder, and domestic violence screenings) and the prevention measures for the 5 leading disease killers in the United States;</p> <p>(4) contains specific science-based initiatives to achieve the measurable goals of Healthy People 2010 regarding nutrition, exercise, and smoking cessation, and targeting the 5 leading disease killers in the United States;</p> <p>(5) contains specific plans for consolidating Federal health programs and Centers that exist to promote healthy behavior and reduce disease risk (including eliminating programs and offices determined to be ineffective in meeting the priority goals of Healthy People 2010);</p> <p>(6) contains specific plans to ensure that all Federal health care programs are fully coordinated with science-based prevention recommendations by the Director of the Centers for Disease Control and Prevention; and</p> <p>(7) contains specific plans to ensure that all non-Department of Health and Human Services prevention programs are based on the science-based guidelines developed by the Centers for Disease Control and Prevention under paragraph (4).</p> <p>(i) PERIODIC REVIEWS.—The Secretary and the Comptroller General of the United States shall jointly conduct periodic reviews, not less than every 5 years, and evaluations of every Federal disease prevention and health promotion initiative, program, and agency. Such reviews shall be evaluated based on effectiveness in meeting metrics-based goals with an analysis posted on such agencies' public Internet websites.</p>	

POPULATION HEALTH AND PREVENTION INITIATIVES

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH SUBTITLE A – MODERNIZING DISEASE PREVENTION AND PUBLIC HEALTH SYSTEMS Section 4002. Prevention and Public Health Fund	
Effective Date: March 23, 2010	
<i>Establishes a Prevention and Public Health Investment Fund</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) PURPOSE.—It is the purpose of this section to establish a Prevention and Public Health Fund (referred to in this section as the ‘Fund’), to be administered through the Department of Health and Human Services, Office of the Secretary, to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs.</p> <p>(b) FUNDING.—There are hereby authorized to be appropriated, and appropriated, to the Fund, out of any monies in the Treasury not otherwise appropriated—</p> <ul style="list-style-type: none"> (1) for fiscal year 2010, \$500,000,000; (2) for fiscal year 2011, \$750,000,000; (3) for fiscal year 2012, \$1,000,000,000; (4) for fiscal year 2013, \$1,250,000,000; (5) for fiscal year 2014, \$1,500,000,000; and (6) for fiscal year 2015, and each fiscal year thereafter, \$2,000,000,000. <p>(c) USE OF FUND.—The Secretary shall transfer amounts in the Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for programs authorized by the Public Health Service Act, for prevention, wellness, and public health activities including prevention research and health screenings, such as the Community Transformation grant program, the Education and Outreach Campaign for Preventive Benefits, and immunization programs.</p> <p>(d) TRANSFER AUTHORITY.—The Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives may provide for the transfer of funds in the Fund to eligible activities under this section, subject to subsection (c).</p>	<p>Provision unique to PPACA</p>

POPULATION HEALTH AND PREVENTION INITIATIVES

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH
SUBTITLE A – MODERNIZING DISEASE PREVENTION AND PUBLIC HEALTH SYSTEMS
Section 4003. Clinical and Community Preventive Services

Effective Date: The report required under this section is due not later than **January 1, 2011 and every 3 years thereafter through January 1, 2017**

Expands efforts and increases coordination between task forces recommending preventive interventions

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) PREVENTIVE SERVICES TASK FORCE.—Section 915 of the Public Health Service Act (42 U.S.C. 299b–4) is amended by striking subsection (a) and inserting the following:</p> <p>“(a) PREVENTIVE SERVICES TASK FORCE.—</p> <p>“(1) ESTABLISHMENT AND PURPOSE.—The Director shall convene an independent Preventive Services Task Force (referred to in this subsection as the ‘Task Force’) to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services (referred to in this section as the ‘Guide’), for individuals and organizations delivering clinical services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, Congress and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives. Such recommendations shall consider clinical preventive best practice recommendations from the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies.</p> <p>“(2) DUTIES.—The duties of the Task Force shall include—</p> <p>“(A) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific sub-populations and age groups;</p> <p>“(B) at least once during every 5-year period, review interventions and update recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions;</p> <p>“(C) improved integration with Federal Government health objectives and related target setting for health improvement;</p> <p>“(D) the enhanced dissemination of recommendations;</p> <p>“(E) the provision of technical assistance to those health care professionals, agencies and organizations that request help in implementing the Guide recommendations; and</p> <p>“(F) the submission of yearly reports to Congress and related agencies identifying gaps in</p>	<p>Section 915 of the Public Health Service Act (42 U.S.C. 299b-4)</p> <p>Research supporting primary care and access in underserved areas</p> <p>(a) Preventive Services Task Force.</p> <p>—(1) Establishment and purpose. The Director shall convene an independent Preventive Services Task Force (referred to in this subsection as the “Task Force”) to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services (referred to in this section as the “Guide”), for individuals and organizations delivering clinical services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, Congress and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives. Such recommendations shall consider clinical preventive best practice recommendations from the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies.</p> <p>—(2) Duties. The duties of the Task Force shall include—</p> <p>—(A) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific sub-populations and age groups;</p> <p>—(B) at least once during every 5-year period, review interventions and update recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions;</p> <p>—(C) improved integration with Federal Government health objectives and related target setting for health improvement;</p> <p>—(D) the enhanced dissemination of recommendations;</p> <p>—(E) the provision of technical assistance to those health care professionals, agencies and organizations that request help in implementing the Guide recommendations; and</p> <p>—(F) the submission of yearly reports to Congress and related agencies identifying gaps in research, such as preventive services that receive an insufficient evidence statement, and recommending priority areas that deserve further examination, including areas related to</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

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Section 4003. Clinical and Community Preventive Services

Effective Date: The report required under this section is due not later than **January 1, 2011 and every 3 years thereafter through January 1, 2017**

Expands efforts and increases coordination between task forces recommending preventive interventions

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>research, such as preventive services that receive an insufficient evidence statement, and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.</p> <p>“(3) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the Guide’s recommendations.</p> <p>“(4) COORDINATION WITH COMMUNITY PREVENTIVE SERVICES TASK FORCE.—The Task Force shall take appropriate steps to coordinate its work with the Community Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force’s recommendations interact at the nexus of clinic and community.</p> <p>“(5) OPERATION.—Operation. In carrying out the duties under paragraph (2), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.</p> <p>“(6) INDEPENDENCE.—All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.</p> <p>“(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.”.</p>	<p>populations and age groups not adequately addressed by current recommendations.</p> <p>—(3) Role of Agency. The Agency shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the Guide’s recommendations.</p> <p>—(4) Coordination with Community Preventive Services Task Force. The Task Force shall take appropriate steps to coordinate its work with the Community Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force’s recommendations interact at the nexus of clinic and community.</p> <p>—(5) Operation. Operation. In carrying out the duties under paragraph (2), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.</p> <p>—(6) Independence. All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.</p> <p>—(7) Authorization of appropriations. There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.</p> <p>(b) Primary care research.</p> <p>(1) In general. There is established within the Agency a Center for Primary Care Research (referred to in this subsection as the "Center") that shall serve as the principal source of funding for primary care practice research in the Department of Health and Human Services. For purposes of this paragraph, primary care research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.</p> <p>(2) Research. In carrying out this section, the Center shall conduct and support research concerning--</p> <p>(A) the nature and characteristics of primary care practice;</p> <p>(B) the management of commonly occurring clinical problems;</p> <p>(C) the management of undifferentiated clinical problems; and</p> <p>(D) the continuity and coordination of health services.</p>

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Section 4003. Clinical and Community Preventive Services

Effective Date: The report required under this section is due not later than **January 1, 2011 and every 3 years thereafter through January 1, 2017**

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<p>(b) COMMUNITY PREVENTIVE SERVICES TASK FORCE.—</p> <p>(1) IN GENERAL.—Part P of title III of the Public Health Service Act, as amended by paragraph (2), is amended by adding at the end the following:</p> <p>“SEC. 399U. COMMUNITY PREVENTIVE SERVICES TASK FORCE.</p> <p>“(a) ESTABLISHMENT AND PURPOSE.—The Director of the Centers for Disease Control and Prevention shall convene an independent Community Preventive Services Task Force (referred to in this subsection as the ‘Task Force’) to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services (referred to in this section as the ‘Guide’), for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, Indian tribes, tribal organizations and urban Indian organizations, medical groups, Congress and other policymakers. Community preventive services include any policies, programs, processes or activities designed to affect or otherwise affecting health at the population level.</p> <p>“(b) DUTIES.—The duties of the Task Force shall include—</p> <p>“(1) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific populations and age groups, as well as the social, economic and physical environments that can have broad effects on the health and disease of populations and health disparities among sub-populations and age groups;</p> <p>“(2) at least once during every 5-year period, review interventions and update recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions, including health impact assessment and population health modeling;</p> <p>“(3) improved integration with Federal Government health objectives and related target setting for health improvement;</p> <p>“(4) the enhanced dissemination of recommendations;</p> <p>“(5) the provision of technical assistance to those health care professionals, agencies, and organizations that request help in implementing the Guide recommendations; and</p> <p>“(6) providing yearly reports to Congress and related agencies identifying gaps in research</p>	<p><u>Section 399U, part P, title III of the Public Health Service Act</u> Section 4003 adds this new provision to the PHSA</p>

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<p>and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.</p> <p>“(c) ROLE OF AGENCY.—The Director shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.</p> <p>“(d) COORDINATION WITH PREVENTIVE SERVICES TASK FORCE.— The Task Force shall take appropriate steps to coordinate its work with the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force’s recommendations interact at the nexus of clinic and community.</p> <p>“(e) OPERATION.—In carrying out the duties under subsection (b), the Task Force shall not be subject to the provisions of Appendix 2 of title 5, United States Code.</p> <p>“(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.”.</p> <p style="text-align: center;">. . .</p>	

POPULATION HEALTH AND PREVENTION INITIATIVES

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH SUBTITLE A – MODERNIZING DISEASE PREVENTION AND PUBLIC HEALTH SYSTEMS Section 4004. Education and outreach campaign regarding preventive benefits	
Effective Date: The report required under this section is due not later than January 1, 2011 and every 3 years thereafter through January 1, 2017	
<i>Instructs HHS Secretary to develop public/private partnership to develop and conduct a national prevention, health promotion outreach and education campaign</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall provide for the planning and implementation of a national public–private partnership for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement across the life span. Such campaign shall include the dissemination of information that—</p> <ol style="list-style-type: none"> (1) describes the importance of utilizing preventive services to promote wellness, reduce health disparities, and mitigate chronic disease; (2) promotes the use of preventive services recommended by the United States Preventive Services Task Force and the Community Preventive Services Task Force; (3) encourages healthy behaviors linked to the prevention of chronic diseases; (4) explains the preventive services covered under health plans offered through a Gateway; (5) describes additional preventive care supported by the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Advisory Committee on Immunization Practices, and other appropriate agencies; and (6) includes general health promotion information. <p>(b) CONSULTATION.—In coordinating the campaign under subsection (a), the Secretary shall consult with the Institute of Medicine to provide ongoing advice on evidence-based scientific information for policy, program development, and evaluation.</p> <p>(c) MEDIA CAMPAIGN.—</p> <ol style="list-style-type: none"> (1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish and implement a national science-based media campaign on health promotion and disease prevention. (2) REQUIREMENT OF CAMPAIGN.—The campaign implemented under paragraph (1)— <ol style="list-style-type: none"> (A) shall be designed to address proper nutrition, regular exercise, smoking cessation, obesity reduction, the 5 leading disease killers in the United States, and secondary prevention through disease screening promotion; (B) shall be carried out through competitively bid contracts awarded to entities providing for the professional production and design of such campaign; (C) may include the use of television, radio, Internet, and other commercial marketing venues and may be targeted to specific age groups based on peer-reviewed social research; 	<p>This reporting requirement provision is specific to PPACA and does not impact existing legal language</p>

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Section 4004. Education and outreach campaign regarding preventive benefits

Effective Date: The report required under this section is due not later than **January 1, 2011 and every 3 years thereafter through January 1, 2017**

Instructs HHS Secretary to develop public/private partnership to develop and conduct a national prevention, health promotion outreach and education campaign

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<p>(D) shall not be duplicative of any other Federal efforts relating to health promotion and disease prevention; and (E) may include the use of humor and nationally recognized positive role models. (3) EVALUATION.—The Secretary shall ensure that the campaign implemented under paragraph (1) is subject to an independent evaluation every 2 years and shall report every 2 years to Congress on the effectiveness of such campaigns towards meeting science-based metrics.</p> <p>(d) WEBSITE.—The Secretary, in consultation with private sector experts, shall maintain or enter into a contract to maintain an Internet website to provide science-based information on guidelines for nutrition, regular exercise, obesity reduction, smoking cessation, and specific chronic disease prevention. Such website shall be designed to provide information to health care providers and consumers.</p> <p>(e) DISSEMINATION OF INFORMATION THROUGH PROVIDERS.— The Secretary, acting through the Centers for Disease Control and Prevention, shall develop and implement a plan for the dissemination of health promotion and disease prevention information consistent with national priorities, to health care providers who participate in Federal programs, including programs administered by the Indian Health Service, the Department of Veterans Affairs, the Department of Defense, and the Health Resources and Services Administration, and Medicare and Medicaid.</p> <p>(f) PERSONALIZED PREVENTION PLANS.— (1) CONTRACT.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enter into a contract with a qualified entity for the development and operation of a Federal Internet website personalized prevention plan tool. (2) USE.—The website developed under paragraph (1) shall be designed to be used as a source of the most up-to-date scientific evidence relating to disease prevention for use by individuals. Such website shall contain a component that enables an individual to determine their disease risk (based on personal health and family history, BMI, and other relevant information) relating to the 5 leading diseases in the United States, and obtain personalized suggestions for preventing such diseases.</p> <p>(g) INTERNET PORTAL.—The Secretary shall establish an Internet portal for accessing risk-assessment tools developed and maintained by private and academic entities.</p> <p>(h) PRIORITY FUNDING.—Funding for the activities authorized under this section shall take priority over funding provided through the Centers for Disease Control and Prevention for grants to States and other entities for</p>	

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Section 4004. Education and outreach campaign regarding preventive benefits

Effective Date: The report required under this section is due not later than **January 1, 2011 and every 3 years thereafter through January 1, 2017**

Instructs HHS Secretary to develop public/private partnership to develop and conduct a national prevention, health promotion outreach and education campaign

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<p>similar purposes and goals as provided for in this section. Not to exceed \$500,000,000 shall be expended on the campaigns and activities required under this section.</p> <p>(i) PUBLIC AWARENESS OF PREVENTIVE AND OBESITY-RELATED SERVICES.—</p> <p>(1) INFORMATION TO STATES.—The Secretary of Health and Human Services shall provide guidance and relevant information to States and health care providers regarding preventive and obesity-related services that are available to Medicaid enrollees, including obesity screening and counseling for children and adults.</p> <p>(2) INFORMATION TO ENROLLEES.—Each State shall design a public awareness campaign to educate Medicaid enrollees regarding availability and coverage of such services, with the goal of reducing incidences of obesity.</p> <p>(3) REPORT.—Not later than January 1, 2011, and every 3 years thereafter through January 1, 2017, the Secretary of Health and Human Services shall report to Congress on the status and effectiveness of efforts under paragraphs (1) and (2), including summaries of the States’ efforts to increase awareness of coverage of obesity-related services.</p> <p>(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.</p>	<p align="center">***</p>

POPULATION HEALTH AND PREVENTION INITIATIVES

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH	
SUBTITLE E – MISCELLANEOUS PROVISIONS Section 4402. Effectiveness of Federal health and wellness initiatives	
Effective Date: March 23, 2010	
<i>Directs Secretary (HHS) to evaluate the effectiveness of Federal health and wellness initiatives</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>To determine whether existing Federal health and wellness initiatives are effective in achieving their stated goals, the Secretary of Health and Human Services shall—</p> <p>(1) conduct an evaluation of such programs as they relate to changes in health status of the American public and specifically on the health status of the Federal workforce, including absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees, and health conditions, including workplace fitness, healthy food and beverages, and incentives in the Federal Employee Health Benefits Program; and</p> <p>(2) submit to Congress a report concerning such evaluation, which shall include conclusions concerning the reasons that such existing programs have proven successful or not successful and what factors contributed to such conclusions.</p> <p style="text-align: center;">***</p>	<p>Provision unique to PPACA</p>

Research

RESEARCH

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE III – IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE

SUBTITLE D – MEDICARE PART D IMPROVEMENTS FOR PRESCRIPTION DRUG PLANS AND MA-PD PLANS

Section 3313. Office of Inspector General studies and reports.

Effective Date: March 23, 2010 (the report is due on or before **October 1, 2011**)

Requires the Office of Inspector General (HHS) to conduct a study comparing part D drug prices paid under Medicare Part D and under State Medicaid programs

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) STUDY AND ANNUAL REPORT ON PART D FORMULARIES' INCLUSION OF DRUGS COMMONLY USED BY DUAL ELIGIBLES.—</p> <p>(1) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study of the extent to which formularies used by prescription drug plans and MA–PD plans under part D include drugs commonly used by full benefit dual eligible individuals (as defined in section 1935(c)(6) of the Social Security Act (42 U.S.C. 1396u–5(c)(6))).</p> <p>(2) ANNUAL REPORTS.—Not later than July 1 of each year (beginning with 2011), the Inspector General shall submit to Congress a report on the study conducted under paragraph (1), together with such recommendations as the Inspector General determines appropriate.</p> <p>(b) STUDY AND REPORT ON PRESCRIPTION DRUG PRICES UNDER MEDICARE PART D AND MEDICAID.—</p> <p>(1) STUDY.—</p> <p>(A) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct a study on prices for covered part D drugs under the Medicare prescription drug program under part D of title XVIII of the Social Security Act and for covered outpatient drugs under title XIX. Such study shall include the following:</p> <p>(i) A comparison, with respect to the 200 most frequently dispensed covered part D drugs under such program and covered outpatient drugs under such title (as determined by the Inspector General based on volume and expenditures), of—</p> <p>(I) the prices paid for covered part D drugs by PDP sponsors of prescription drug plans and Medicare Advantage organizations offering MA–PD plans; and</p> <p>(II) the prices paid for covered outpatient drugs by a State plan under title XIX.</p> <p>(ii) An assessment of—</p> <p>(I) the financial impact of any discrepancies in such prices on the Federal Government; and</p> <p>(II) the financial impact of any such discrepancies on enrollees under part D or individuals eligible for medical assistance under a State plan under title XIX.</p> <p>(B) PRICE.—For purposes of subparagraph (A), the price of a covered part D drug or a covered outpatient drug shall include any rebate or discount under such program or such title, respectively, including any negotiated price concession described in section 1860D–2(d)(1)(B)</p>	<p>These provisions are PPACA specific; however, they do incorporate existing language, primarily cross-referencing current definitions—</p> <p><u>Section 1860D-2(e) of the Social Security Act (42 U.S.C. 1395w-102(e))</u></p> <p>(e) Covered Part D Drug Defined.—</p> <p>(1) In general.—Except as provided in this subsection, for purposes of this part, the term “covered part D drug” means—</p> <p style="text-align: center;">. . .</p> <p>(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary), and such term includes a vaccine licensed under section 351 of the Public Health Service Act (and, for vaccinations administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).</p> <p>(2) Exclusions.—</p> <p style="text-align: center;">. . .</p> <p>(B) Medicare covered drugs.—A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B for that individual.</p> <p>(3) Application of general exclusion provisions.—A prescription drug plan or an MA-PD plan may exclude from qualified prescription drug coverage any covered part D drug—</p> <p>(A) for which payment would not be made if section 1862(a) applied to this part; or</p> <p>(B) which is not prescribed in accordance with the plan or this part. Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1860D-4.</p> <p>(4) Medically accepted indication defined.—</p> <p>(A) In general.—For purposes of paragraph (1), the term “medically accepted indication” has the meaning given that term—</p>

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Section 3313. Office of Inspector General studies and reports.

Effective Date: March 23, 2010 (the report is due on or before **October 1, 2011**)

Requires the Office of Inspector General (HHS) to conduct a study comparing part D drug prices paid under Medicare Part D and under State Medicaid programs

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<p>of the Social Security Act (42 U.S.C. 1395w–102(d)(1)(B)) or rebate under an agreement under section 1927 of the Social Security Act (42 U.S.C. 1396r–8).</p> <p>(C) AUTHORITY TO COLLECT ANY NECESSARY INFORMATION.— Notwithstanding any other provision of law, the Inspector General of the Department of Health and Human Services shall be able to collect any information related to the prices of covered part D drugs under such program and covered outpatient drugs under such title XIX necessary to carry out the comparison under subparagraph (A).</p> <p>(2) REPORT.— (A) IN GENERAL.—Not later than October 1, 2011, subject to subparagraph (B), the Inspector General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Inspector General determines appropriate.</p> <p>(B) LIMITATION ON INFORMATION CONTAINED IN REPORT.—The report submitted under subparagraph (A) shall not include any information that the Inspector General determines is proprietary or is likely to negatively impact the ability of a PDP sponsor or a State plan under title XIX to negotiate prices for covered part D drugs or covered outpatient drugs, respectively.</p> <p>(3) DEFINITIONS.—In this section: (A) COVERED PART D DRUG.—The term “covered part D drug” has the meaning given such term in section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e)). (B) COVERED OUTPATIENT DRUG.—The term “covered outpatient drug” has the meaning given such term in section 1927(k) of such Act (42 U.S.C. 1396r(k)). (C) MA–PD PLAN.—The term “MA–PD plan” has the meaning given such term in section 1860D–41(a)(9) of such Act (42 U.S.C. 1395w–151(a)(9)). (D) MEDICARE ADVANTAGE ORGANIZATION.—The term “Medicare Advantage organization” has the meaning given such term in section 1859(a)(1) of such Act (42 U.S.C. 1395w–28(a)(1)). (E) PDP SPONSOR.—The term “PDP sponsor” has the meaning given such term in section 1860D–41(a)(13) of such Act (42 U.S.C. 1395w–151(a)(13)). (F) PRESCRIPTION DRUG PLAN.—The term “prescription drug plan” has the meaning given such term in section 1860D–41(a)(14) of such Act (42 U.S.C. 1395w–151(a)(14)).</p>	<p>(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1861(t)(2)(B), except that in applying such section— (I) “prescription drug plan or MA-PD plan” shall be substituted for “carrier” each place it appears; and (II) subject to subparagraph (B), the compendia described in section 1927(g)(1)(B)(i)(III) shall be included in the list of compendia described in clause (ii)(I) section 1861(t)(2)(B); and (ii) in the case of any other covered part D drug, in section 1927(k)(6).</p> <p>(B) Conflict of interest.—On and after January 1, 2010, subparagraph (A)(i)(II) shall not apply unless the compendia described in section 1927(g)(1)(B)(i)(III) meets the requirement in the third sentence of section 1861(t)(2)(B).</p> <p>(C) Update.—For purposes of applying subparagraph (A)(ii), the Secretary shall revise the list of compendia described in section 1927(g)(1)(B)(i) as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1861(t)(2)(B).</p> <p><u>Section 1927(k) of the Social Security Act (42 U.S.C. 1396r–8(k)(2))</u> (k) Definitions.—In the section— . . .</p> <p>(2) Covered outpatient drug.—Subject to the exceptions in paragraph (3), the term “covered outpatient drug” means— (A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and— (i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act; (ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a “new drug” (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act¹ or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to</p>

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
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SUBTITLE D – MEDICARE PART D IMPROVEMENTS FOR PRESCRIPTION DRUG PLANS AND MA-PD PLANS

Section 3313. Office of Inspector General studies and reports.

Effective Date: March 23, 2010 (the report is due on or before **October 1, 2011**)

Requires the Office of Inspector General (HHS) to conduct a study comparing part D drug prices paid under Medicare Part D and under State Medicaid programs

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	<p>enforce section 502(f) or 505(a) of such Act; or (iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and (B) a biological product, other than a vaccine which— (i) may only be dispensed upon prescription, (ii) is licensed under section 351 of the Public Health Service Act, and (iii) is produced at an establishment licensed under such section to produce such product; and (C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.</p>

RESEARCH

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE C – CREATING HEALTHIER COMMUNITIES

Section 4204. Immunizations

Effective Date: March 23, 2010

Authorizes states to purchase adult vaccines under government-negotiated contracts (Centers for Disease Control and Prevention)

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) STATE AUTHORITY TO PURCHASE RECOMMENDED VACCINES FOR ADULTS.—Section 317 of the Public Health Service Act (42 U.S.C. 247b) is amended by adding at the end the following: “(1) AUTHORITY TO PURCHASE RECOMMENDED VACCINES FOR ADULTS.— “(1) IN GENERAL.—The Secretary may negotiate and enter into contracts with manufacturers of vaccines for the purchase and delivery of vaccines for adults as provided for under subsection (e). “(2) STATE PURCHASE.—A State may obtain additional quantities of such adult vaccines (subject to amounts specified to the Secretary by the State in advance of negotiations) through the purchase of vaccines from manufacturers at the applicable price negotiated by the Secretary under this subsection.”.</p> <p>(b) DEMONSTRATION PROGRAM TO IMPROVE IMMUNIZATION COVERAGE.— Section 317 of the Public Health Service Act (42 U.S.C. 247b), as amended by subsection (a), is further amended by adding at the end the following: “(m) DEMONSTRATION PROGRAM TO IMPROVE IMMUNIZATION COVERAGE.— “(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a demonstration program to award grants to States to improve the provision of recommended immunizations for children, adolescents, and adults through the use of evidence-based, population-based interventions for high-risk populations. “(2) STATE PLAN.—To be eligible for a grant under paragraph (1), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a State plan that describes the interventions to be implemented under the grant and how such interventions match with local needs and capabilities, as determined through consultation with local authorities. “(3) USE OF FUNDS.—Funds received under a grant under this subsection shall be used to implement interventions that are recommended by the Task Force on Community Preventive Services (as established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) or other evidence-based interventions, including— “(A) providing immunization reminders or recalls for target populations of clients, patients, and consumers; “(B) educating targeted populations and health care providers concerning immunizations in combination with one or more other interventions; “(C) reducing out-of-pocket costs for families for vaccines and their administration;</p>	<p><u>Section 317 of the Public Health Service Act (42 U.S.C. 247b)</u> The provisions authorizing states to purchase recommended vaccines for adults through the 317 program, allowing for demonstration programs, and grants represent new language inserted at the end of this section.</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE C – CREATING HEALTHIER COMMUNITIES

Section 4204. Immunizations

Effective Date: March 23, 2010

Authorizes states to purchase adult vaccines under government-negotiated contracts (Centers for Disease Control and Prevention)

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(D) carrying out immunization-promoting strategies for participants or clients of public programs, including assessments of immunization status, referrals to health care providers, education, provision of on-site immunizations, or incentives for immunization;</p> <p>“(E) providing for home visits that promote immunization through education, assessments of need, referrals, provision of immunizations, or other services;</p> <p>“(F) providing reminders or recalls for immunization providers;</p> <p>“(G) conducting assessments of, and providing feedback to, immunization providers;</p> <p>“(H) any combination of one or more interventions described in this paragraph; or</p> <p>“(I) immunization information systems to allow all States to have electronic databases for immunization records.</p> <p>“(4) CONSIDERATION.—In awarding grants under this subsection, the Secretary shall consider any reviews or recommendations of the Task Force on Community Preventive Services.</p> <p>“(5) EVALUATION.—Not later than 3 years after the date on which a State receives a grant under this subsection, the State shall submit to the Secretary an evaluation of progress made toward improving immunization coverage rates among high-risk populations within the State.</p> <p>“(6) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Affordable Health Choices Act, the Secretary shall submit to Congress a report concerning the effectiveness of the demonstration program established under this subsection together with recommendations on whether to continue and expand such program.</p> <p>“(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2010 through 2014.’’.</p> <p>(c) REAUTHORIZATION OF IMMUNIZATION PROGRAM.—Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended—</p> <p>(1) in paragraph (1), by striking “for each of the fiscal years 1998 through 2005’’; and</p> <p>(2) in paragraph (2), by striking “after October 1, 1997.’’.</p> <p>(d) RULE OF CONSTRUCTION REGARDING ACCESS TO IMMUNIZATIONS.—</p> <p>Nothing in this section (including the amendments made by this section), or any other provision of this Act (including any amendments made by this Act) shall be construed to decrease children’s access to immunizations.</p> <p>(e) GAO STUDY AND REPORT ON MEDICARE BENEFICIARY ACCESS TO VACCINES.—</p> <p>(1) STUDY.—The Comptroller General of the United States (in this section referred to as the “Comptroller General’’) shall conduct a study on the ability of Medicare beneficiaries who were 65 years of age or older to access routinely recommended vaccines covered under the prescription drug program under part D of title XVIII of the Social Security</p>	<p><u>Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j))</u></p> <p>(j) Authorization of appropriations.</p> <p>(1) Except for grants for immunization programs the authorization of appropriations for which are established in paragraph (2), for grants under subsections (a) and (k)(1) for preventive health service programs to immunize without charge children, adolescents, and adults against vaccine-preventable diseases, there are authorized to be appropriated such sums as may be necessary. Not more than 10 percent of the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(1) for such fiscal year.</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE C – CREATING HEALTHIER COMMUNITIES

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>Act over the period since the establishment of such program. Such study shall include the following:</p> <p>(A) An analysis and determination of—</p> <p>(i) the number of Medicare beneficiaries who were 65 years of age or older and were eligible for a routinely recommended vaccination that was covered under part D;</p> <p>(ii) the number of such beneficiaries who actually received a routinely recommended vaccination that was covered under part D; and</p> <p>(iii) any barriers to access by such beneficiaries to routinely recommended vaccinations that were covered under part D.</p> <p>(B) A summary of the findings and recommendations by government agencies, departments, and advisory bodies (as well as relevant professional organizations) on the impact of coverage under part D of routinely recommended adult immunizations for access to such immunizations by Medicare beneficiaries.</p> <p>(2) REPORT.—Not later than June 1, 2011, the Comptroller General shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.</p> <p>(3) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated \$1,000,000 for fiscal year 2010 to carry out this subsection.</p>	<p>(2) For grants under subsection (a) for preventive health service programs for the provision without charge of immunizations with vaccines approved for use, and recommended for routine use, there are authorized to be appropriated such sums as may be necessary.</p>
<p align="center">***</p>	

RESEARCH

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH	
SUBTITLE D – SUUPPORT FOR PREVENTION AND PUBLIC HEALTH INNOVATION Section 4301. Research on optimizing the delivery of public health services	
Effective Date: March 23, 2010	
<i>Authorizes the Secretary (HHS) through CDC to issue funding for research in the area of public health services and systems (including best practices for prevention and identifying effective strategies for health services delivery)</i>	
AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ‘‘Secretary’’), acting through the Director of the Centers for Disease Control and Prevention, shall provide funding for research in the area of public health services and systems.</p> <p>(b) REQUIREMENTS OF RESEARCH.—Research supported under this section shall include—</p> <p>(1) examining evidence-based practices relating to prevention, with a particular focus on high priority areas as identified by the Secretary in the National Prevention Strategy or Healthy People 2020, and including comparing community-based public health interventions in terms of effectiveness and cost;</p> <p>(2) analyzing the translation of interventions from academic settings to real world settings; and</p> <p>(3) identifying effective strategies for organizing, financing, or delivering public health services in real world community settings, including comparing State and local health department structures and systems in terms of effectiveness and cost.</p> <p>(c) EXISTING PARTNERSHIPS.—Research supported under this section shall be coordinated with the Community Preventive Services Task Force and carried out by building on existing partnerships within the Federal Government while also considering initiatives at the State and local levels and in the private sector.</p> <p>(d) ANNUAL REPORT.—The Secretary shall, on an annual basis, submit to Congress a report concerning the activities and findings with respect to research supported under this section.</p>	<p>Provision unique to PPACA</p>

Community Health Centers

COMMUNITY HEALTH CENTERS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

TITLE V – HEALTH CARE WORKFORCE

SUBTITLE F – STRENGTHENING PRIMARY CARE AND OTHER WORKFORCE IMPROVEMENTS

Section 5508. Increasing Teaching Capacity

Effective Date: March 23, 2010

Establishes a grant program, administered by the Secretary, to support new or expanded primary care residency programs at teaching health centers

AFFORDABLE CARE ACT LANGUAGE

LANGUAGE FROM EXISTING LAW

(a) TEACHING HEALTH CENTERS TRAINING AND ENHANCEMENT.—
Part C of title VII of the Public Health Service Act (42 U.S.C. 293k et. seq.), as amended by section 5303, is further amended by inserting after section 749 the following:

“SEC. 749A. TEACHING HEALTH CENTERS DEVELOPMENT GRANTS.

“(a) PROGRAM AUTHORIZED.—The Secretary may award grants under this section to teaching health centers for the purpose of establishing new accredited or expanded primary care residency programs.

“(b) AMOUNT AND DURATION.—Grants awarded under this section shall be for a term of not more than 3 years and the maximum award may not be more than \$500,000.

“(c) USE OF FUNDS.—Amounts provided under a grant under this section shall be used to cover the costs of—

“(1) establishing or expanding a primary care residency training program described in subsection (a), including costs associated with—

“(A) curriculum development;

“(B) recruitment, training and retention of residents and faculty;

“(C) accreditation by the Accreditation Council for Graduate Medical Education (ACGME), the American Dental Association (ADA), or the American Osteopathic Association (AOA); and

“(D) faculty salaries during the development phase; and

“(2) technical assistance provided by an eligible entity.

“(d) APPLICATION.—A teaching health center seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

...

“(f) DEFINITIONS.—In this section:

“(1) ELIGIBLE ENTITY.—The term ‘eligible entity’ means an organization capable of providing technical assistance including an area health education center program as defined in sections 751 and 799B.

“(2) PRIMARY CARE RESIDENCY PROGRAM.—The term ‘primary care residency program’ means an approved graduate medical residency training program (as defined in section 340H) in family medicine, internal medicine, pediatrics, internal medicine- pediatrics, obstetrics and gynecology, psychiatry, general dentistry, pediatric dentistry, and geriatrics.

“(3) TEACHING HEALTH CENTER.—

“(A) IN GENERAL.—The term ‘teaching health center’ means an entity that—

“(i) is a community based, ambulatory patient care center; and

Amends the Public Health Service Act, Part C, title VII, by inserting a new section, 749A.

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE V – HEALTH CARE WORKFORCE**

SUBTITLE F – STRENGTHENING PRIMARY CARE AND OTHER WORKFORCE IMPROVEMENTS

Section 5508. Increasing Teaching Capacity

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(ii) operates a primary care residency program. “(B) INCLUSION OF CERTAIN ENTITIES.— Such term includes the following: “(i) A Federally qualified health center (as defined in section 1905(l)(2)(B), of the Social Security Act). “(ii) A community mental health center (as defined in section 1861(ff)(3)(B) of the Social Security Act). “(iii) A rural health clinic, as defined in section 1861(aa) of the Social Security Act. “(iv) A health center operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act). “(v) An entity receiving funds under title X of the Public Health Service Act. “(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, \$25,000,000 for fiscal year 2010, \$50,000,000 for fiscal year 2011, \$50,000,000 for fiscal year 2012, and such sums as may be necessary for each fiscal year thereafter to carry out this section. Not to exceed \$5,000,000 annually may be used for technical assistance program grants.”.</p> <p align="center">...</p> <p>(c) PAYMENTS TO QUALIFIED TEACHING HEALTH CENTERS.—Part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following: “Subpart XI—Support of Graduate Medical Education in Qualified Teaching Health Centers “SEC. 340H. PROGRAM OF PAYMENTS TO TEACHING HEALTH CENTERS THAT OPERATE GRADUATE MEDICAL EDUCATION PROGRAMS. “(a) PAYMENTS.—Subject to subsection (h)(2), the Secretary shall make payments under this section for direct expenses and for indirect expenses to qualified teaching health centers that are listed as sponsoring institutions by the relevant accrediting body for expansion of existing or establishment of new approved graduate medical residency training programs. “(b) AMOUNT OF PAYMENTS.— “(1) IN GENERAL.—Subject to paragraph (2), the amounts payable under this section to qualified teaching health centers for an approved graduate medical residency training program for a fiscal year are each of the following amounts: “(A) DIRECT EXPENSE AMOUNT.—The amount determined under subsection (c) for direct expenses associated with sponsoring approved graduate medical residency training programs. “(B) INDIRECT EXPENSE AMOUNT.—The amount determined under subsection (d) for indirect expenses associated with the additional costs relating to teaching residents in such programs.</p> <p align="center">...</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

TITLE V – HEALTH CARE WORKFORCE

SUBTITLE F – STRENGTHENING PRIMARY CARE AND OTHER WORKFORCE IMPROVEMENTS

Section 5508. Increasing Teaching Capacity

Effective Date: March 23, 2010

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(e) CLARIFICATION REGARDING RELATIONSHIP TO OTHER PAYMENTS FOR GRADUATE MEDICAL EDUCATION.—Payments under this section—</p> <p>“(1) shall be in addition to any payments—</p> <p>“(A) for the indirect costs of medical education under section 1886(d)(5)(B) of the Social Security Act;</p> <p>“(B) for direct graduate medical education costs under section 1886(h) of such Act; and</p> <p>“(C) for direct costs of medical education under section 1886(k) of such Act;</p> <p>...</p> <p>“(f) RECONCILIATION.—The Secretary shall determine any changes to the number of residents reported by a hospital in the application of the hospital for the current fiscal year to determine the final amount payable to the hospital for the current fiscal year for both direct expense and indirect expense amounts. Based on such determination, the Secretary shall recoup any overpayments made to pay any balance due to the extent possible. The final amount so determined shall be considered a final intermediary determination for the purposes of section 1878 of the Social Security Act and shall be subject to administrative and judicial review under that section in the same manner as the amount of payment under section 1186(d) of such Act is subject to review under such section.</p> <p>“(g) FUNDING.—To carry out this section, there are appropriated such sums as may be necessary, not to exceed \$230,000,000, for the period of fiscal years 2011 through 2015.</p> <p>“(h) ANNUAL REPORTING REQUIRED.—</p> <p>“(1) ANNUAL REPORT.—The report required under this paragraph for a qualified teaching health center for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic year completed immediately prior to such fiscal year:</p> <p>“(A) The types of primary care resident approved training programs that the qualified teaching health center provided for residents.</p> <p>“(B) The number of approved training positions for residents described in paragraph (4).</p> <p>“(C) The number of residents described in paragraph (4) who completed their residency training at the end of such residency academic year and care for vulnerable populations living in underserved areas.</p> <p>“(D) Other information as deemed appropriate by the Secretary.</p> <p>“(2) AUDIT AUTHORITY; LIMITATION ON PAYMENT.—</p> <p>“(A) AUDIT AUTHORITY.—The Secretary may audit a qualified teaching health center to ensure the accuracy and completeness of the information submitted in a report under paragraph (1).</p> <p>“(B) LIMITATION ON PAYMENT.—A teaching health center may only receive payment in a cost reporting period for a number of such resident positions that is greater than the base level of primary care resident positions, as determined by the Secretary. For purposes of this subparagraph, the ‘base level of primary care residents’ for a teaching health center is the level of such residents as of a base period.</p>	

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE V – HEALTH CARE WORKFORCE**

SUBTITLE F – STRENGTHENING PRIMARY CARE AND OTHER WORKFORCE IMPROVEMENTS

Section 5508. Increasing Teaching Capacity

Effective Date: March 23, 2010

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AFFORDABLE CARE ACT LANGUAGE

LANGUAGE FROM EXISTING LAW

“(3) REDUCTION IN PAYMENT FOR FAILURE TO REPORT.—
“(A) IN GENERAL.—The amount payable under this section to a qualified teaching health center for a fiscal year shall be reduced by at least 25 percent if the Secretary determines that—
“(i) the qualified teaching health center has failed to provide the Secretary, as an addendum to the qualified teaching health center’s application under this section for such fiscal year, the report required under paragraph (1) for the previous fiscal year; or
“(ii) such report fails to provide complete and accurate information required under any subparagraph of such paragraph.
“(B) NOTICE AND OPPORTUNITY TO PROVIDE ACCURATE AND MISSING INFORMATION.—Before imposing a reduction under subparagraph (A) on the basis of a qualified teaching health center’s failure to provide complete and accurate information described in subparagraph (A)(ii), the Secretary shall provide notice to the teaching health center of such failure and the Secretary’s intention to impose such education and shall provide the teaching health center with the opportunity to provide the required information within the period of 30 days beginning on the date of such notice. If the teaching health center provides such information within such period, no reduction shall be made under subparagraph (A) on the basis of the previous failure to provide such information.
“(4) RESIDENTS.—The residents described in this paragraph are those who are in part-time or full-time equivalent resident training positions at a qualified teaching health center in any approved graduate medical residency training program.
“(i) REGULATIONS.—The Secretary shall promulgate regulations to carry out this section.
“(j) DEFINITIONS.—In this section:
“(1) APPROVED GRADUATE MEDICAL RESIDENCY TRAINING PROGRAM.—The term ‘approved graduate medical residency training program’ means a residency or other postgraduate medical training program—
“(A) participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary; and
“(B) that meets criteria for accreditation (as established by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or the American Dental Association).
“(2) PRIMARY CARE RESIDENCY PROGRAM.—The term ‘primary care residency program’ has the meaning given that term in section 749A.
“(3) QUALIFIED TEACHING HEALTH CENTER.—The term ‘qualified teaching health center’ has the meaning given the term ‘teaching health center’ in section 749A.’”

COMMUNITY HEALTH CENTERS

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE X – STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE E – PROVISIONS RELATING TO TITLE V
Section 10503. Provisions Relating to Title V

Effective Date: March 23, 2010

Establishes a Community Health Centers and National Health Service Corps Fund to expand and sustain national investment in community health centers; mandatory appropriation of \$11 billion over five fiscal years

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) PURPOSE.—It is the purpose of this section to establish a Community Health Center Fund (referred to in this section as the “CHC Fund”), to be administered through the Office of the Secretary of the Department of Health and Human Services to provide for expanded and sustained national investment in community health centers under section 330 of the Public Health Service Act and the National Health Service Corps.</p> <p>(b) FUNDING.—There is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, to the CHC Fund—</p> <p>(1) to be transferred to the Secretary of Health and Human Services to provide enhanced funding for the community health center program under section 330 of the Public Health Service Act—</p> <p>(A) \$700,000,000 for fiscal year 2011;</p> <p>(B) \$800,000,000 for fiscal year 2012;</p> <p>(C) \$1,000,000,000 for fiscal year 2013;</p> <p>(D) \$1,600,000,000 for fiscal year 2014; and</p> <p>(E) \$2,900,000,000 for fiscal year 2015; and</p> <p>(2) to be transferred to the Secretary of Health and Human Services to provide enhanced funding for the National Health Service Corps—</p> <p>(A) \$290,000,000 for fiscal year 2011;</p> <p>(B) \$295,000,000 for fiscal year 2012;</p> <p>(C) \$300,000,000 for fiscal year 2013;</p> <p>(D) \$305,000,000 for fiscal year 2014; and</p> <p>(E) \$310,000,000 for fiscal year 2015.</p> <p>(c) CONSTRUCTION.—There is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, \$1,500,000,000 to be available for fiscal years 2011 through 2015 to be used by the Secretary of Health and Human Services for the construction and renovation of community health centers.</p> <p>(d) USE OF FUND.—The Secretary of Health and Human Services shall transfer amounts in the CHC Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for community health centers and the National Health Service Corps.</p>	<p>Amends the Public Health Service Act, Part C, title VII, by inserting a new section, 749A.</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE X – STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE E – PROVISIONS RELATING TO TITLE V
Section 10503. Provisions Relating to Title V

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
(e) AVAILABILITY.—Amounts appropriated under subsections (b) and (c) shall remain available until expended.	

School-Based Health Centers

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

Section 4101. School-based health centers

Effective Date: March 23, 2010

Authorizes grant program for development of school-based health clinics that can provide comprehensive, accessible preventive and primary health care services to medically underserved children and families

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>conditions, and referrals to, and follow-up for, specialty care and oral health services.</p> <p>“(B) MENTAL HEALTH.—Mental health and substance use disorder assessments, crisis intervention, counseling, treatment, and referral to a continuum of services including emergency psychiatric care, community support programs, inpatient care, and outpatient programs.</p> <p>“(2) MEDICALLY UNDERSERVED CHILDREN AND ADOLESCENTS.—</p> <p>“(A) IN GENERAL.—The term ‘medically underserved children and adolescents’ means a population of children and adolescents who are residents of an area designated as a medically underserved area or a health professional shortage area by the Secretary.</p> <p>“(B) CRITERIA.—The Secretary shall prescribe criteria for determining the specific shortages of personal health services for medically underserved children and adolescents under subparagraph (A) that shall—</p> <p>“(i) take into account any comments received by the Secretary from the chief executive officer of a State and local officials in a State; and</p> <p>“(ii) include factors indicative of the health status of such children and adolescents of an area, including the ability of the residents of such area to pay for health services, the accessibility of such services, the availability of health professionals to such children and adolescents, and other factors as determined appropriate by the Secretary.</p> <p>“(3) SCHOOL-BASED HEALTH CENTER.—The term ‘school based health center’ means a health clinic that—</p> <p>“(A) meets the definition of a school-based health center under section 2110(c)(9)(A) of the Social Security Act and is administered by a sponsoring facility (as defined in section 2110(c)(9)(B) of the Social Security Act);</p> <p>“(B) provides, at a minimum, comprehensive primary health services during school hours to children and adolescents by health professionals in accordance with established standards, community practice, reporting laws, and other State laws, including parental consent and notification laws that are not inconsistent with Federal law; and</p> <p>“(C) does not perform abortion services.</p> <p>“(b) AUTHORITY TO AWARD GRANTS.—The Secretary shall award grants for the costs of the operation of school-based health centers (referred to in this section as ‘SBHCs’) that meet the requirements of this section.</p> <p>“(c) APPLICATIONS.—To be eligible to receive a grant under this section, an entity shall—</p> <p>“(1) be an SBHC (as defined in subsection (a)(3)); and</p> <p>“(2) submit to the Secretary an application at such time, in such manner, and containing—</p> <p>“(A) evidence that the applicant meets all criteria necessary to be designated an SBHC;</p> <p>“(B) evidence of local need for the services to be provided by the SBHC;</p> <p>“(C) an assurance that—</p> <p>“(i) SBHC services will be provided to those children and adolescents for whom parental or guardian consent has been obtained in cooperation with Federal, State, and local laws governing health care service provision to children and</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>adolescents;</p> <p>“(ii) the SBHC has made and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the SBHC;</p> <p>“(iii) the SBHC will provide on-site access during the academic day when school is in session and 24- hour coverage through an on-call system and through its backup health providers to ensure access to services on a year-round basis when the school or the SBHC is closed;</p> <p>“(iv) the SBHC will be integrated into the school environment and will coordinate health services with school personnel, such as administrators, teachers, nurses, counselors, and support personnel, as well as with other community providers co-located at the school;</p> <p>“(v) the SBHC sponsoring facility assumes all responsibility for the SBHC administration, operations, and oversight; and</p> <p>“(vi) the SBHC will comply with Federal, State, and local laws concerning patient privacy and student records, including regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 and section 444 of the General Education Provisions Act; and</p> <p>“(D) such other information as the Secretary may require.</p> <p>“(d) PREFERENCES AND CONSIDERATION.—In reviewing applications:</p> <p>“(1) The Secretary may give preference to applicants who demonstrate an ability to serve the following:</p> <p>“(A) Communities that have evidenced barriers to primary health care and mental health and substance use disorder prevention services for children and adolescents.</p> <p>“(B) Communities with high per capita numbers of children and adolescents who are uninsured, underinsured, or enrolled in public health insurance programs.</p> <p>“(C) Populations of children and adolescents that have historically demonstrated difficulty in accessing health and mental health and substance use disorder prevention services.</p> <p>“(2) The Secretary may give consideration to whether an applicant has received a grant under subsection (a) of section 4101 of the Patient Protection and Affordable Care Act.</p> <p>“(e) WAIVER OF REQUIREMENTS.—The Secretary may—</p> <p>“(1) under appropriate circumstances, waive the application of all or part of the requirements of this subsection with respect to an SBHC for not to exceed 2 years; and</p> <p>“(2) upon a showing of good cause, waive the requirement that the SBHC provide all required comprehensive primary health services for a designated period of time to be determined by the Secretary.</p> <p>“(f) USE OF FUNDS.—</p> <p>“(1) FUNDS.—Funds awarded under a grant under this section—</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

Section 4101. School-based health centers

Effective Date: March 23, 2010

Authorizes grant program for development of school-based health clinics that can provide comprehensive, accessible preventive and primary health care services to medically underserved children and families

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(A) may be used for—</p> <p>“(i) acquiring and leasing equipment (including the costs of amortizing the principle of, and paying interest on, loans for such equipment);</p> <p>“(ii) providing training related to the provision of required comprehensive primary health services and additional health services;</p> <p>“(iii) the management and operation of health center programs;</p> <p>“(iv) the payment of salaries for physicians, nurses, and other personnel of the SBHC; and</p> <p>“(B) may not be used to provide abortions.</p> <p>“(2) CONSTRUCTION.—The Secretary may award grants which may be used to pay the costs associated with expanding and modernizing existing buildings for use as an SBHC, including the purchase of trailers or manufactured buildings to install on the school property.</p> <p>“(3) LIMITATIONS.—</p> <p>“(A) IN GENERAL.—Any provider of services that is determined by a State to be in violation of a State law described in subsection (a)(3)(B) with respect to activities carried out at a SBHC shall not be eligible to receive additional funding under this section.</p> <p>“(B) NO OVERLAPPING GRANT PERIOD.—No entity that has received funding under section 330 for a grant period shall be eligible for a grant under this section for with respect to the same grant period.</p> <p>“(g) MATCHING REQUIREMENT.—</p> <p>“(1) IN GENERAL.—Each eligible entity that receives a grant under this section shall provide, from non-Federal sources, an amount equal to 20 percent of the amount of the grant (which may be provided in cash or in-kind) to carry out the activities supported by the grant.</p> <p>“(2) WAIVER.—The Secretary may waive all or part of the matching requirement described in paragraph (1) for any fiscal year for the SBHC if the Secretary determines that applying the matching requirement to the SBHC would result in serious hardship or an inability to carry out the purposes of this section.</p> <p>“(h) SUPPLEMENT, NOT SUPPLANT.—Grant funds provided under this section shall be used to supplement, not supplant, other Federal or State funds.</p> <p>“(i) EVALUATION.—The Secretary shall develop and implement a plan for evaluating SBHCs and monitoring quality performance under the awards made under this section.</p> <p>“(j) AGE APPROPRIATE SERVICES.—An eligible entity receiving funds under this section shall only provide age appropriate services through a SBHC funded under this section to an individual.</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

SUBTITLE B – INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES

Section 4101. School-based health centers

Effective Date: March 23, 2010

Authorizes grant program for development of school-based health clinics that can provide comprehensive, accessible preventive and primary health care services to medically underserved children and families

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(k) PARENTAL CONSENT.—An eligible entity receiving funds under this section shall not provide services through a SBHC funded under this section to an individual without the consent of the parent or guardian of such individual if such individual is considered a minor under applicable State law.</p> <p>“(l) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.”.</p>	
<p align="center">***</p>	

Supporting the Health Workforce

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE IV – PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

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SUPPORTING THE HEALTH WORKFORCE

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

TITLE V – HEALTH CARE WORKFORCE

SUBTITLE F – SUPPORTING THE EXISTING HEALTH CARE WORKFORCE

Section 5405. Primary care extension program

Effective Date: March 23, 2010

Creates Primary Care Extension Program to educate and provide technical assistance to primary care providers about evidence based strategies, health promotion, chronic disease management, mental health, and preventive medical care

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.), as amended by section 5313, is further amended by adding at the end the following:</p> <p>“SEC. 399W. PRIMARY CARE EXTENSION PROGRAM.</p> <p>“(a) ESTABLISHMENT, PURPOSE AND DEFINITION.—</p> <p>“(1) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a Primary Care Extension Program.</p> <p>“(2) PURPOSE.—The Primary Care Extension Program shall provide support and assistance to primary care providers to educate providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services (including substance abuse prevention and treatment services), and evidence-based and evidence-informed therapies and techniques, in order to enable providers to incorporate such matters into their practice and to improve community health by working with community-based health connectors (referred to in this section as ‘Health Extension Agents’).</p> <p>“(3) DEFINITIONS.—In this section:</p> <p>“(A) HEALTH EXTENSION AGENT.—The term ‘Health Extension Agent’ means any local, community-based health worker who facilitates and provides assistance to primary care practices by implementing quality improvement or system redesign, incorporating the principles of the patient-centered medical home to provide high-quality, effective, efficient, and safe primary care and to provide guidance to patients in culturally and linguistically appropriate ways, and linking practices to diverse health system resources.</p> <p>“(B) PRIMARY CARE PROVIDER.—The term ‘primary care provider’ means a clinician who provides integrated, accessible health care services and who is accountable for addressing a large majority of personal health care needs, including providing preventive and health promotion services for men, women, and children of all ages, developing a sustained partnership with patients, and practicing in the context of family and community, as recognized by a State licensing or regulatory authority, unless otherwise specified in this section.</p> <p>“(b) GRANTS TO ESTABLISH STATE HUBS AND LOCAL PRIMARY CARE EXTENSION AGENCIES.—</p> <p>“(1) GRANTS.—The Secretary shall award competitive grants to States for the establishment of State- or multistate-level primary care Primary Care Extension Program State Hubs (referred to in this section as</p>	<p>Amends Part P, tit. III of the Public Health Service Act (42 U.S.C. 280g et seq.) by adding a new section, 399W.</p>

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE V – HEALTH CARE WORKFORCE**

SUBTITLE F – SUPPORTING THE EXISTING HEALTH CARE WORKFORCE

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>‘Hubs’).</p> <p>“(2) COMPOSITION OF HUBS.—A Hub established by a State pursuant to paragraph (1)—</p> <p>“(A) shall consist of, at a minimum, the State health department, the entity responsible for administering the State Medicaid program (if other than the State health department), the State-level entity administering the Medicare program, and the departments of 1 or more health professions schools in the State that train providers in primary care; and</p> <p>“(B) may include entities such as hospital associations, primary care practice-based research networks, health professional societies, State primary care associations, State licensing boards, organizations with a contract with the Secretary under section 1153 of the Social Security Act, consumer groups, and other appropriate entities.</p> <p>“(c) STATE AND LOCAL ACTIVITIES.—</p> <p>“(1) HUB ACTIVITIES.—Hubs established under a grant under subsection (b) shall—</p> <p>“(A) submit to the Secretary a plan to coordinate functions with quality improvement organizations and area health education centers if such entities are members of the Hub not described in subsection (b)(2)(A);</p> <p>“(B) contract with a county- or local-level entity that shall serve as the Primary Care Extension Agency to administer the services described in paragraph (2);</p> <p>“(C) organize and administer grant funds to county or local-level Primary Care Extension Agencies that serve a catchment area, as determined by the State; and</p> <p>“(D) organize State-wide or multistate networks of local-level Primary Care Extension Agencies to share and disseminate information and practices.</p> <p>“(2) LOCAL PRIMARY CARE EXTENSION AGENCY ACTIVITIES.—</p> <p>“(A) REQUIRED ACTIVITIES.—Primary Care Extension Agencies established by a Hub under paragraph (1) shall—</p> <p>“(i) assist primary care providers to implement a patient-centered medical home to improve the accessibility, quality, and efficiency of primary care services, including health homes;</p> <p>“(ii) develop and support primary care learning communities to enhance the dissemination of research findings for evidence-based practice, assess implementation of practice improvement, share best practices, and involve community clinicians in the generation of new knowledge and identification of important questions for research;</p> <p>“(iii) participate in a national network of Primary Care Extension Hubs and propose how the Primary Care Extension Agency will share and disseminate lessons learned and best practices; and</p> <p>“(iv) develop a plan for financial sustainability involving State, local, and private contributions, to provide</p>	

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

TITLE V – HEALTH CARE WORKFORCE

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Section 5405. Primary care extension program

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>for the reduction in Federal funds that is expected after an initial 6-year period of program establishment, infrastructure development, and planning.</p> <p>“(B) DISCRETIONARY ACTIVITIES.—Primary Care Extension Agencies established by a Hub under paragraph (1) may—</p> <p>“(i) provide technical assistance, training, and organizational support for community health teams established under section 3602 of the Patient Protection and Affordable Care Act;</p> <p>“(ii) collect data and provision of primary care provider feedback from standardized measurements of processes and outcomes to aid in continuous performance improvement;</p> <p>“(iii) collaborate with local health departments, community health centers, tribes and tribal entities, and other community agencies to identify community health priorities and local health workforce needs, and participate in community-based efforts to address the social and primary determinants of health, strengthen the local primary care workforce, and eliminate health disparities;</p> <p>“(iv) develop measures to monitor the impact of the proposed program on the health of practice enrollees and of the wider community served; and</p> <p>“(v) participate in other activities, as determined appropriate by the Secretary.</p> <p>“(d) FEDERAL PROGRAM ADMINISTRATION.—</p> <p>“(1) GRANTS; TYPES.—Grants awarded under subsection (b) shall be—</p> <p>“(A) program grants, that are awarded to State or multistate entities that submit fully-developed plans for the implementation of a Hub, for a period of 6 years; or</p> <p>“(B) planning grants, that are awarded to State or multistate entities with the goal of developing a plan for a Hub, for a period of 2 years.</p> <p>“(2) APPLICATIONS.—To be eligible for a grant under subsection (b), a State or multistate entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.</p> <p>“(3) EVALUATION.—A State that receives a grant under subsection (b) shall be evaluated at the end of the grant period by an evaluation panel appointed by the Secretary.</p> <p>“(4) CONTINUING SUPPORT.—After the sixth year in which assistance is provided to a State under a grant awarded under subsection (b), the State may receive additional support under this section if the State program has received satisfactory evaluations with respect to program performance and the merits of the State sustainability plan, as determined by the Secretary.</p> <p>“(5) LIMITATION.—A State shall not use in excess of 10 percent of the amount received under a grant to carry out administrative activities under this section. Funds awarded pursuant to this section shall not be used for funding direct patient care.</p>	

**PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE V – HEALTH CARE WORKFORCE**

SUBTITLE F – SUPPORTING THE EXISTING HEALTH CARE WORKFORCE

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>“(e) REQUIREMENTS ON THE SECRETARY.—In carrying out this section, the Secretary shall consult with the heads of other Federal agencies with demonstrated experience and expertise in health care and preventive medicine, such as the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Administration, the Health Resources and Services Administration, the National Institutes of Health, the Office of the National Coordinator for Health Information Technology, the Indian Health Service, the Agricultural Cooperative Extension Service of the Department of Agriculture, and other entities, as the Secretary determines appropriate.</p> <p>“(f) AUTHORIZATION OF APPROPRIATIONS.—To awards grants as provided in subsection (d), there are authorized to be appropriated \$120,000,000 for each of fiscal years 2011 and 2012, and such sums as may be necessary to carry out this section for each of fiscal years 2013 through 2014.”.</p> <p align="center">***</p>	

SUPPORTING THE HEALTH WORKFORCE

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) TITLE X – STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE E—PROVISIONS RELATING TO TITLE V

Section 10503. Community Health Centers and National Health Service Corps Fund

Effective Date: March 23, 2010

Establishes a Community Health Center Fund and authorizes mandatory appropriation over five years

AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
<p>(a) PURPOSE.—It is the purpose of this section to establish a Community Health Center Fund (referred to in this section as the “CHC Fund”), to be administered through the Office of the Secretary of the Department of Health and Human Services to provide for expanded and sustained national investment in community health centers under section 330 of the Public Health Service Act and the National Health Service Corps.</p> <p>(b) FUNDING.—There is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, to the CHC Fund—</p> <p>(1) to be transferred to the Secretary of Health and Human Services to provide enhanced funding for the community health center program under section 330 of the Public Health Service Act—</p> <p>(A) \$700,000,000 for fiscal year 2011;</p> <p>(B) \$800,000,000 for fiscal year 2012;</p> <p>(C) \$1,000,000,000 for fiscal year 2013;</p> <p>(D) \$1,600,000,000 for fiscal year 2014; and</p> <p>(E) \$2,900,000,000 for fiscal year 2015; and</p> <p>(2) to be transferred to the Secretary of Health and Human Services to provide enhanced funding for the National Health Service Corps—</p> <p>(A) \$290,000,000 for fiscal year 2011;</p> <p>(B) \$295,000,000 for fiscal year 2012;</p> <p>(C) \$300,000,000 for fiscal year 2013;</p> <p>(D) \$305,000,000 for fiscal year 2014; and</p> <p>(E) \$310,000,000 for fiscal year 2015.</p> <p>(c) CONSTRUCTION.—There is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, \$1,500,000,000 to be available for fiscal years 2011 through 2015 to be used by the Secretary of Health and Human Services for the construction and renovation of community health centers.</p> <p>(d) USE OF FUND.—The Secretary of Health and Human Services shall transfer amounts in the CHC Fund to accounts within the Department of Health and Human Services to increase funding, over the</p>	<p>Provision unique to PPACA</p>

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)
TITLE X – STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

SUBTITLE E—PROVISIONS RELATING TO TITLE V

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AFFORDABLE CARE ACT LANGUAGE	LANGUAGE FROM EXISTING LAW
fiscal year 2008 level, for community health centers and the National Health Service Corps. (e) AVAILABILITY.—Amounts appropriated under subsections (b) and (c) shall remain available until expended.	

Appendix II
Interim Final and Proposed Regulations

Dependent Coverage to Age 26 Interim Final Rule



Federal Register

**Thursday,
May 13, 2010**

Part II

Department of the Treasury
Internal Revenue Service
26 CFR Parts 54 and 602

Department of Labor
Employee Benefits Security
Administration
29 CFR Part 2590

**Department of Health and
Human Services**
45 CFR Parts 144, 146, and 147

**Group Health Plans and Health Insurance
Issuers Relating to Dependent Coverage
of Children to Age 26 Under the Patient
Protection and Affordable Care Act;
Interim Final Rule and Proposed Rule**

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Parts 54 and 602**

[TD 9482]

RIN 1545–BJ46

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210–AB41

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of the Secretary**

[OCIIO–4150–IFC]

45 CFR Parts 144, 146, and 147

RIN 0991–AB66

Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the requirements for group health plans and health insurance issuers in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding dependent coverage of children who have not attained age 26.

DATES: *Effective date.* These interim final regulations are effective on July 12, 2010.

Comment date. Comments are due on or before August 11, 2010.

Applicability date. These interim final regulations generally apply to group health plans and group health insurance issuers for plan years beginning on or after September 23, 2010. These interim final regulations generally apply to individual health insurance issuers for policy years beginning on or after September 23, 2010.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. *Warning:* Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210–AB41, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *E-mail:* E-OHPSCA.EBSA@dol.gov.
- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N–5653, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, Attention: RIN 1210–AB41.

Comments received by the Department of Labor will be posted without change to <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIIO–4150–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.

2. *By regular mail.* You may mail written comments to the following address only: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO–4150–IFC, P.O. Box 8016, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Office of Consumer Information and Insurance Oversight, Department of Health and

Human Services, Attention: OCIIO–4150–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201 (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document’s paperwork requirements by following the instructions at the end of the “Collection of Information Requirements” section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security

Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-114494-10, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* CC:PA:LPD:PR (REG-114494-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

- *Hand or courier delivery:* Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-114494-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT:

Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786-1565.

Customer Service Information:

Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp).

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in

the group and individual markets. The term "group health plan" includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of part A of title XXVII of the PHS Act applicable under ERISA and the Code to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if those provisions of the PHS Act were included in ERISA and the Code. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered with some, mostly minor, changes. Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act, specifies that certain plans or coverage existing as of the date of enactment (*i.e.*, grandfathered health plans) are subject to only certain provisions.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of the Affordable Care Act are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers stricter requirements than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

¹ The term "group health plan" is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term "health plan", as used in other provisions of title I of the Affordable Care Act. The term "health plan" does not include self-insured group health plans.

² Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) expect to issue regulations implementing the revised PHS Act sections 2701 through 2719A in several phases. The first publication in this series was a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the **Federal Register** on April 14, 2010 (75 FR 19297). These interim final regulations are being published to implement PHS Act section 2714 (requiring dependent coverage of children to age 26). PHS Act section 2714 generally is effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act.³ The implementation of other provisions of PHS Act sections 2701 through 2719A and section 1251 of the Affordable Care Act will be addressed in future regulations.

Because subtitles A and C of title I of the Affordable Care Act contain requirements that are applicable to both the group and individual health insurance markets, it would be duplicative to insert the requirements into both the existing 45 CFR part 146 (Requirements for the Group Health Insurance Market) and 45 CFR part 148 (Requirements for the Individual Health Insurance Market). Accordingly, these interim final regulations create a new part 147 in subchapter B of 45 CFR to implement the provisions of the Affordable Care Act. The provisions of the Affordable Care Act, to the extent that they apply to group health plans and group health insurance coverage, are also implemented under new regulations added to 29 CFR part 2590 and 26 CFR part 54.

II. Overview of the Regulations

A. PHS Act Section 2714, Continued Eligibility of Children Until Age 26 (26 CFR 54.9815-2714, 29 CFR 2590.715-2714, 45 CFR 147.120)

Section 2714 of the PHS Act, as added by the Affordable Care Act (and amended by the Reconciliation Act), and these interim final regulations provide that a plan or issuer that makes available dependent coverage⁴ of children must make such coverage available for children until attainment

³ See section 1004 of the Affordable Care Act.

⁴ For purposes of these interim final regulations, dependent coverage means coverage of any individual under the terms of a group health plan, or group or individual health insurance coverage, because of the relationship to a participant (in the individual market, primary subscriber).

of 26 years of age. The statute also requires the issuance of regulations to “define the dependents to which coverage shall be made available” under this rule.

Many group health plans that provide dependent coverage limit the coverage to health coverage excludible from employees’ gross income for income tax purposes. Thus, dependent coverage is limited to employees’ spouses and employees’ children that qualify as dependents for income tax purposes. Consequently, these plans often condition dependent coverage, in addition to the age of the child, on student status, residency, and financial support or other factors indicating dependent status. However, with the expansion of dependent coverage required by the Affordable Care Act to children until age 26, conditioning coverage on whether a child is a tax dependent or a student, or resides with or receives financial support from the parent, is no longer appropriate in light of the correlation between age and these factors. Therefore, these interim final regulations do not allow plans or coverage to use these requirements to deny dependent coverage to children. Because the statute does not distinguish between coverage for minor children and coverage for adult children under age 26, these factors also may not be used to determine eligibility for dependent coverage for minor children.

Accordingly, these interim final regulations clarify that, with respect to children who have not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of the relationship between the child and the participant (in the individual market, the primary subscriber). Examples of factors that cannot be used for defining dependent for purposes of eligibility (or continued eligibility) include financial dependency on the participant or primary subscriber (or any other person), residency with the participant or primary subscriber (or any other person), student status, employment, eligibility for other coverage, or any combination of these. These interim final regulations also provide that the terms of the plan or policy for dependent coverage cannot vary based on the age of a child, except for children age 26 or older. Examples illustrate that surcharges for coverage of children under age 26 are not allowed except where the surcharges apply regardless of the age of the child (up to age 26) and that, for children under age 26, the plan cannot vary benefits based on the age of the child. The Affordable Care Act, as

originally enacted, required plans and issuers to make dependent coverage available only to a child “who is not married.” This language was struck by section 2301(b) of the Reconciliation Act. Accordingly, under these interim final regulations, plans and issuers may not limit dependent coverage based on whether a child is married. (However, a plan or issuer is not required under these interim final regulations to cover the spouse of an eligible child).

The statute and these interim final regulations provide that nothing in PHS Act section 2714 requires a plan or issuer to make available coverage for a child of a child receiving dependent coverage.

Under section 1004(d) of the Reconciliation Act and IRS Notice 2010–38 (released to the public on April 27, 2010 and scheduled to be published in 2010–20 Internal Revenue Bulletin, May 17, 2010), employers may exclude from the employee’s income the value of any employer-provided health coverage for an employee’s child for the entire taxable year the child turns 26 if the coverage continues until the end of that taxable year. This means that if a child turns 26 in March, but stays on the plan past December 31st (the end of most people’s taxable year), the health benefits up to December 31st can be excluded for tax purposes.

Application to grandfathered health plans. Under the statute and these interim final regulations, the requirement to make available dependent coverage for children who have not attained age 26 generally applies to all group health plans and health insurance issuers offering group or individual health insurance coverage whether or not the plan or health insurance coverage qualifies as a grandfathered health plan⁵ under section 1251 of the Affordable Care Act, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. However, in accordance with section 2301(a) of the Reconciliation Act, for plan years beginning before January 1, 2014, these interim final regulations provide that a grandfathered health plan that is a group health plan that makes available dependent coverage of children may exclude an adult child who has not attained age 26 from coverage only if the child is eligible to enroll in an employer-sponsored health plan (as

⁵ Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act, specifies that certain plans or coverage existing as of the March 23, 2010 date of enactment (*i.e.*, grandfathered health plans) are subject to only certain provisions.

defined in section 5000A(f)(2) of the Code) other than a group health plan of a parent. In the case of an adult child who is eligible for coverage under the plans of the employers of both parents, neither plan may exclude the adult child from coverage based on the fact that the adult child is eligible to enroll in the plan of the other parent’s employer.

Regulations relating to grandfathered health plans under section 1251 of the Affordable Care Act are expected to be published in the very near future. The Departments anticipate that the regulations will make clear that changes to plan or policy terms to comply with PHS Act section 2714 and these interim final regulations, including voluntary compliance before plan years (in the individual market, policy years) beginning on or after September 23, 2010, will not cause a plan or health insurance coverage to lose grandfathered health plan status for any purpose under the Affordable Care Act, as amended.

Transitional Rule. Prior to the applicability date of PHS Act section 2714, a child who was covered under a group health plan or health insurance coverage as a dependent may have lost eligibility under the plan (or coverage) due to age prior to age 26. Moreover, if, when a parent first became eligible for coverage, a child was under age 26 but older than the age at which the plan (or coverage) stopped covering children, the child would not have become eligible for the plan (or coverage). When the provisions of section 2714 become applicable, a plan or issuer can no longer exclude coverage for the child prior to age 26 irrespective of whether or when that child was enrolled in the plan (or coverage). Also, a child of a primary subscriber with family coverage in the individual market may be entitled to an opportunity to enroll if the child previously lost coverage due to age while other family members retained the coverage.⁶

Accordingly, these interim final regulations provide transitional relief for a child whose coverage ended, or who was denied coverage (or was not

⁶ In the group market, section 9802(a) of the Code, section 702(a) of ERISA, and section 2705 of the PHS Act provide that a plan or issuer cannot impose any rule for eligibility for benefits (including any rule excluding coverage) based on a health factor, including a preexisting condition. These rules were added by HIPAA and generally became applicable for group health plans for plan years beginning on or after July 1, 1997. Similar guidance regarding re-enrollment rights for individuals previously denied coverage due to a health factor was issued by the Departments of the Treasury, Labor, and HHS on December 29, 1997, at 62 FR 67689 and on January 8, 2001 at 66 FR 1378, 1403, 1410, 1418.

eligible for coverage) under a group health plan or health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26.

These interim final regulations require a plan or issuer to give such a child an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll), regardless of whether the plan or coverage offers an open enrollment period and regardless of when any open enrollment period might otherwise occur. This enrollment opportunity (including the written notice) must be provided not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. Thus, many plans can use their existing annual enrollment periods (which commonly begin and end before the start of the plan year) to satisfy the enrollment opportunity requirement. If the child is enrolled, coverage must begin not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, even if the request for enrollment is made after the first day of the plan year. In subsequent years, dependent coverage may be elected for an eligible child in connection with normal enrollment opportunities under the plan or coverage.

Under these interim final regulations, the notice may be provided to an employee on behalf of the employee's child (in the individual market, to a primary subscriber on behalf of the primary subscriber's child). In addition, for a group health plan or group health insurance coverage, the notice may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For a group health plan or group health insurance coverage, if a notice satisfying these requirements is provided to an employee whose child is entitled to an enrollment opportunity, the obligation to provide the notice of enrollment opportunity with respect to that child is satisfied for both the plan and the issuer.

Any child enrolling in group health plan coverage pursuant to this enrollment right must be treated as a special enrollee, as provided under the regulations interpreting the HIPAA portability provisions.⁷ Accordingly, the child must be offered all the benefit

packages available to similarly situated individuals who did not lose coverage by reason of cessation of dependent status. The child also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of cessation of dependent status.

The Departments have been informed that many health insurance issuers have announced that they will allow continued coverage of adult children before such coverage is required by the Affordable Care Act. A plan or issuer that allows continued coverage of adult children before being required to do so by the Affordable Care Act is not required to provide the enrollment opportunity with respect to children who do not lose coverage.

Examples in these interim final regulations illustrate the application of these transitional rules. One example illustrates that, if a child qualifies for an enrollment opportunity under this section and the parent is not enrolled but is otherwise eligible for enrollment, the plan must provide an opportunity to enroll the parent, in addition to the child. Similarly, another example illustrates that, if a plan has more than one benefit package option, a child qualifies for enrollment under this section, and the parent is enrolled in one benefit package option, the plan must provide an opportunity to enroll the child in any benefit package option for which the child is otherwise eligible (thus allowing the parent to switch benefit package options). Another example illustrates that a child who qualifies for an enrollment opportunity under this section and who is covered under a COBRA continuation provision must be given the opportunity to enroll as a dependent of an active employee (*i.e.*, other than as a COBRA-qualified beneficiary). In this situation, if the child loses eligibility for coverage due to a qualifying event (including aging out of coverage at age 26), the child has another opportunity to elect COBRA continuation coverage. (If the qualifying event is aging out, the COBRA continuation coverage could last 36 months from the loss of eligibility that relates to turning age 26.) The final example in this section illustrates that an employee who joined a plan prior to the applicability date of PHS Act section 2714, and has a child who never enrolled because the child was too old under the terms of the plan but has not yet turned 26, must be provided an opportunity to enroll the child under this section even though the child was not previously covered under the plan. If the parent is no longer eligible for coverage under the plan (for example, if

the parent has ceased employment with the plan sponsor) as of the first date on which the enrollment opportunity would be required to be given, the plan would not be required to enroll the child.

B. Conforming Changes Under the PHS Act

1. References to the Public Health Service Act

Conforming changes to references to sections of title XXVII of the PHS Act are made throughout parts 144 and 146 of title 45 of the Code of Federal Regulations to reflect the renumbering of certain sections by the Affordable Care Act.

2. Definitions (45 CFR 144.103)

These interim final regulations define "policy year" as the 12-month period that is designated in the policy documents of individual health insurance coverage. If the policy document does not designate a policy year (or no such document is available), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year. The Affordable Care Act uses the term "plan year" in referring to the period of coverage in both the individual and group health insurance markets. The term "plan year", however, is generally used in the group health insurance market. Accordingly, these interim final regulations substitute the term "policy year" for "plan year" in defining the period of coverage in the individual health insurance market.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The

⁷ HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). Regulations regarding the treatment of HIPAA special enrollees are included at 26 CFR 54.9801-6(d), 29 CFR 2590.701-6(d), and 45 CFR 146.117(d).

provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA was applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process is completed. The statutory requirement implemented in these interim final regulations was enacted on March 23, 2010, and applies for plan years (in the individual market, policy years) beginning on or after September 23, 2010. Having a binding rule in effect is critical to ensuring that individuals entitled to the new protections being implemented have these protections uniformly applied.

Moreover, the provisions in these interim final regulations require lead time for implementation. These interim final regulations require that an enrollment period be provided no later than the first day the obligation to allow dependent children to enroll until attainment of age 26 takes effect. Preparations presumably would have to be made to put such an enrollment process in place. Group health plans and health insurance issuers also would have to take the cost associated with this new obligation into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits, and any such premiums and changes would have to receive necessary approvals in advance of the plan or policy year in question.

For the foregoing reasons, the Departments have determined that it is essential to provide certainty about what will be required of group health plans and health insurance issuers under the statutory requirements implemented in binding regulations as far in advance of September 23, 2010 as possible. This makes it impracticable to engage in full notice and comment rulemaking before putting regulations into effect, and in the public interest to do so through interim final regulations under which the public will have an opportunity for comment, but that opportunity will not delay putting rules in effect (a delay that could possibly last past September 23, 2010).

Issuance of proposed regulations would not be sufficient because the proposed regulations would not be binding, and different group health plans or health insurance issuers could interpret the statutory language in different ways. Had the Departments

published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. It therefore is in the public interest that these interim final regulations be in effect and apply when the statutory protections being implemented apply.

IV. Economic Impact and Paperwork Burden

A. Summary—Department of Labor and Department of Health and Human Services

As stated earlier in this preamble, these interim final regulations implement PHS Act section 2714, which requires plans or issuers that make dependent coverage available for children to continue to make such coverage available for an adult child until the attainment of age 26. The regulation also provides an enrollment opportunity to individuals who lost or were not eligible for dependent coverage before age 26.⁸ This provision generally is effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act.

The Departments have crafted these interim final regulations to secure the protections intended by Congress in the most economically efficient manner possible. The Departments have quantified costs where possible and provided a qualitative discussion of the economic benefits and some of the transfers and costs that may stem from these interim final regulations.

B. Executive Order 12866—Department of Labor and Department of Health and Human Services

Under Executive Order 12866 (58 FR 51735), this regulatory action has been determined “significant” and therefore subject to review by the Office of

⁸ The Affordable Care Act adds section 715 and Code section to make the provisions of part A of title XXVII of the PHS Act applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, under ERISA and the Code as if those provisions of the PHS Act were included in ERISA and the Code. The PHS Act sections incorporated by this reference are sections 2701 through 2728. Section 1251 of the Affordable Care Act provides rules for grandfathered health plans, and these rules are further clarified in section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act.

Management and Budget (OMB). Section 3(f) of the Executive Order defines a “significant regulatory action” as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. OMB has determined that this regulation is economically significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an annual effect on the economy of \$100 million in any one year. Accordingly, OMB has reviewed these rules pursuant to the Executive Order. The Departments provide an assessment of the potential costs, benefits, and transfers associated with the regulatory provision below. The Departments invite comments on this assessment and its conclusions.

1. Need for Regulatory Action

PHS Act section 2714, as added by the Affordable Care Act and amended by the Reconciliation Act requires group health plans and health insurance issuers offering group or individual health insurance coverage that make dependent coverage available for children to continue to make coverage available to such children until the attainment of age 26. With respect to a child receiving dependent coverage, coverage does not have to be extended to a child or children of the child or a spouse of the child. In addition, as provided by the Reconciliation Act, grandfathered group health plans are not required to offer dependent coverage to a child under 26 who is otherwise eligible for employer-sponsored insurance other than a group health plan of a parent for plan years beginning before January 1, 2014. PHS Act section 2714 generally is effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010. Thus, these interim final regulations are necessary to amend the Departments’ existing regulations to

implement these statutorily mandated changes.

2. Summary of Impacts

In this section, the Departments estimate the number of individuals affected by these interim final regulations, and the impact of the regulations on health insurance premiums in the group and individual markets. Beginning with the population of individuals age 19–25, the number of individuals potentially affected is

estimated by applying several criteria including whether their parents have existing employer-sponsored insurance (ESI) or an individual market policy; and whether the individuals are themselves uninsured, have ESI, individual market policies or other forms of coverage. A range of assumptions concerning the percentage of the potentially affected individuals that will accept the offer of new dependent coverage—“take-up” rates—

is then applied to estimate the number of newly covered individuals. The premium impact is calculated by using an estimated incremental insurance cost per newly-covered individual as a percent of average family premiums.

In accordance, with OMB Circular A–4,⁹ Table 1 below depicts an accounting statement showing the Departments’ assessment of the benefits, costs, and transfers associated with this regulatory action.

TABLE 1—ACCOUNTING TABLE

Costs ¹⁰	Low estimate	Mid-range estimate	High estimate	Year dollar	Discount rate percent	Period covered ¹¹
Benefits:						
Annualized Quantified: low estimate	0.19 million previously uninsured individuals gain coverage in 2011.					
mid-range estimate	0.65 million previously uninsured individuals gain coverage in 2011.					
high estimate	1.64 million previously uninsured individuals gain coverage in 2011.					
Qualitative: Expanding coverage options of the 19–25 population should decrease the number uninsured, which in turn should decrease the cost-shifting of uncompensated care onto those with insurance, increase the receipt of preventive health care and provide more timely access to high quality care, resulting in a healthier population. Allowing extended dependent coverage will also permit greater job mobility for this population as their insurance coverage will no longer be tied to their own jobs or student status. Dependents aged 19–25 that have chronic or other serious health conditions would still be able to continue their current coverage through a parent’s plan. To the extent there is an increase in beneficial utilization of healthcare, health could improve.						
Annualized Monetized (\$millions/year)	11.2 10.4	11.2 10.4	11.2 10.4	2010 2010	7 3	2011–2013 2011–2013
A one-time notice of right to enroll must be sent to those affected.						
Qualitative: To the extent additional coverage increases utilization of health care services, there will be additional costs incurred to achieve the health benefits.						
Transfer:¹²						
Annualized Monetized (\$millions/year)	3,459.3 3,482.5	5,250.2 5,274.5	6,893.9 6,895.4	2010 2010	7 3	2011–2013 2011–2013
Qualitative: If the rule causes family health insurance premiums to increase, there will be a transfer from individuals with family health insurance coverage who do not have dependents aged 19–25 to those individuals with family health insurance coverage that have dependents aged 19–25. To the extent that these higher premiums result in lower profits or higher prices for the employer’s product, then the higher premiums will result in a transfer either from stockholders or consumers.						

¹⁰ The cost estimates are annualize across the years 2011–2013, and reflects a single point estimate of the cost to send out a notice in the first year only.

¹¹ The Departments limited the period covered by the RIA to 2011–2013, because it only has reliable data to make projections over this period due to the fact that in 2014, things will change drastically when the subsidies and tax credits to offset premium increases and the exchanges are in effect.

¹² The estimates in this table reflect the annualized discounted value in 2010 of the additional premium costs for family policies calculated as the product of the newly covered dependents in each year from 2011–2013 (see below) and an incremental cost per newly-covered person in those years (see below).

3. Estimated Number of Affected Individuals

The Departments’ estimates in this section are based on the 2004–2006 Medical Expenditure Panel Survey Household Component (MEPS–HC) which was projected and calibrated to 2010 to be consistent with the National Health Accounts projections. The Departments estimate that in 2010, there are approximately 29.5 million

individuals aged 19–25 (young adults) in the United States. Of those individuals, 9.3 million young adults (of whom 3.1 million are uninsured) do not have a parent who has either ESI or non-group insurance, and thus they have no access to dependent coverage. As shown in Table 2, among the remaining 20.2 million young adults whose parents are covered either by ESI or by non-group insurance:

- 3.44 million are currently uninsured,
- 2.42 million are covered by their own non-group insurance,
- 5.55 million are covered by their own ESI,
- 5.73 million are already on their parent’s or spouse’s ESI, and
- 3.01 million have some other form of coverage such as Medicaid or TRICARE.

⁹ Available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

TABLE 2—YOUNG ADULTS AGED 19–25 BY INSURANCE STATUS

	Uninsured*	Non-group	Own ESI	ESI as a dependent	Other	Total
Total U.S. Population Aged 19–25	6.59	2.69	6.98	5.75	7.5	29.5
All Young Adults in U.S. with a Parent with a Policy by Young Adult Insurance Status						
Parents have ESI	3.28	2.03	5.32	5.73	2.91	19.27
Parents have non-group	0.16	0.40	0.23	0.10	0.88
Subtotal A	3.44	2.42	5.55	5.73	3.01	20.15

*The **bolded** numbers are potentially affected by the regulation.

Source: MEPS 2004–2006 HC Surveys, controlled to 2010 consistent with the National Health Accounts. Note: Total number of young adults, age 19–25 is 29.5 million; the 20.15 million in this Table are the subset whose parents have either ESI or non-group coverage.

Initially, the subset of this group of young adults that will be affected by these interim final regulations are those who are either uninsured (3.44 million) or covered by individual coverage (2.42 million). The statute does not require grandfathered group health plans to offer coverage to young adults who currently have their own ESI or an offer of an ESI. For the purposes of this analysis, it is assumed that all plans begin 2011 with grandfathered status. These impacts could change if plans lose their Grandfathered status.

Of these 5.86 million young adults, as shown in Table 3, 3.49 million are also unlikely to switch to their parents' coverage because:

- They are already allowed to enroll in extended dependent coverage for young adults through their State's existing laws, but have chosen not to

(2.61 million). Thirty-seven states already have requirements concerning dependent coverage in the group market, although most of these are substantially more restrictive than those contained in this regulation.¹³ Using information about State laws obtained from the Kaiser Family Foundation,¹⁴ a State by State profile of State required coverage based on a person's State of residence, age, student status, and living situation was developed. This profile was then overlaid on MEPS data to obtain an estimate of the number of individuals that would newly become eligible for coverage due to these interim final regulations.

- They have an offer of ESI and have parents who are covered by ESI (0.48 million). For the purposes of this regulatory impact statement, the Departments assume that the parents of

these young adults will be in grandfathered group health plans, and thus that these young adults will not be affected by the provisions of these interim final regulations. To the extent that some of the coverage in which these parents are enrolled is not grandfathered, the effect of these interim final regulations will be larger than the estimates provided here.

- Finally, there are 0.40 million young adults who have non-group coverage and whose parents have non-group coverage. Because the parents' non-group coverage is underwritten, there is not likely to be any financial benefit to the family in moving the young adult onto the parents' coverage, and the Departments assume that these young adults will not be affected by the regulation.

TABLE 3—“UNINSURED” AND “NON-GROUP” YOUNG ADULTS UNLIKELY TO BE AFFECTED BY EXTENDING DEPENDENT COVERAGE TO AGE 26

	Uninsured	Non-Group coverage	Total
(1) Young adults potentially covered by parent ESI due to state law	1.30	1.31	2.61
(2) Young adults with an offer of ESI whose parents have ESI	0.31	0.17	0.48
(3) Young adults with non-group coverage whose parents have non-group coverage	0.40	0.40
Subtotal B	1.61	1.88	3.49

As shown in Table 4, this leaves approximately 2.37 million young adults who might be affected by this provision, or approximately eight percent of the 29.5 million young adults

in the age group. Among the approximately 2.37 million young adults who are estimated to be potentially affected by this provision, approximately 1.83 million are

currently uninsured, and 0.55 million are currently covered by their own non-group coverage.

TABLE 4—YOUNG ADULTS POTENTIALLY AFFECTED BY EXTENDING DEPENDENT COVERAGE TO AGE 26

	Uninsured	Non-group coverage	Total
Parents have ESI	1.67	0.55	2.21
Parents have non-group	0.16	0.16

¹³ Restrictions include requirements for financial dependency, student status, and age limits.

¹⁴ As described in Kaiser Family Foundation, *Definition of Dependency by Age, 2010*, KFF State

Health Facts, at <http://www.statehealthfacts.org/comparetable.jsp?ind=601&cat=7>.

TABLE 4—YOUNG ADULTS POTENTIALLY AFFECTED BY EXTENDING DEPENDENT COVERAGE TO AGE 26—Continued

	Uninsured	Non-group coverage	Total
Total (Subtotal A—Subtotal B)*	1.83	0.55	2.37

Source: MEPS 2004–2006 HC Surveys, controlled to 2010 consistent with projections of the National Health Accounts.
*Subtotal A is in Table 2 and Subtotal B is in Table 3.

It is difficult to estimate precisely what fraction of the 2.37 million young adults who might potentially be affected by the provision will actually enroll on their parents' coverage. A study by Monheit and Cantor of the early experience in States that have extended coverage to dependents suggests that few uninsured children in these States shift to their parents' policy.¹⁵ However, data and methodological difficulties inevitably lead to substantial uncertainty about the finding.

The Departments considered two other points of reference to estimate take-up rates. One is the work that has analyzed take-up rates among people made newly eligible for public coverage by Medicaid expansions. These studies suggest take-up rates in the range of 10–34 percent.¹⁶ However, the populations eligible for these expansions have different socio-demographic compositions than those eligible for the dependent coverage provisions covered under these interim final regulations, and the decision to take-up Medicaid is clearly different than the decision to cover a child on a parent's private insurance policy. A second point of reference are estimates from the Kaiser/HRET Employer Health benefits Survey¹⁷ which suggest that, depending on the size of the worker contribution, between 77 percent and 90 percent of employees accept offers of family

policies. Again, these estimates would be based on a group that differs in characteristics from those eligible for new dependent coverage. These concerns notwithstanding, the analyses of Medicaid expansions and employee take-up of employer sponsored coverage provide useful points of reference.

Recognizing the uncertainty in the area, the Departments produced a range of assumptions concerning take-up rates. In developing the range of take-up rates, the Departments assume that these rates will vary by the following factors: (1) The young adult's current health coverage status (uninsured young adults are less likely to take advantage of the dependent coverage option than young adults already covered by non-group insurance, because young adults who have purchased non-group insurance have shown a strong preference for coverage, and can almost always save money and get better coverage by switching to their parents' policy); (2) the young adult's health status (young adults in fair or poor health are more likely to take advantage of the option than those in excellent, very good or good health), and (3) the young adult's living situation (those living with their parents are more likely to take up the option than those not living with their parents).

The almost fully covered or "high" take-up rate scenario assumes that

regardless of health or insurance status, 95 percent of young adults living at home and 85 percent of those not living at home would move to dependent coverage. For the mid-range scenario, the Departments assume that relative to the high take-up rate scenario, 90 percent of the uninsured whose health status was fair or poor health and 50 percent of those in good to excellent health would move to dependent coverage. In the low take-up rate scenario, the Departments adjusted the percentages to 80 percent and 10 percent of the high take-up rate scenario. In all three scenarios, the same assumptions apply to individuals with non-group policies whose parents have ESI—95 percent of those living at home and 85 percent of those living elsewhere would move to dependent coverage.

In the low take-up rate scenario, the assumptions lead to the result that approximately 30 percent of eligibles will enroll in dependent coverage. In the mid-range scenario, they result in an approximate 50 percent take-up rate, and in the high take-up scenario, they result in an approximate 90 percent take-up rate. The Departments are uncertain regarding which of these scenarios is most likely but are confident that they bracket the expected outcome.

TABLE 5—NUMBER OF INDIVIDUALS WITH NEW DEPENDENT COVERAGE AND IMPACT ON GROUP INSURANCE PREMIUMS, 2011–2013

	Low estimate			Mid-range estimate			High estimate		
	2011	2012	2013	2011	2012	2013	2011	2012	2013
Individuals with New Dependent Coverage (millions)	0.68	0.97	1.08	1.24	1.60	1.65	2.12	2.07	1.98
From Uninsured (millions)	0.19	0.29	0.33	0.65	0.94	0.91	1.64	1.42	1.21
Incremental Premium Cost Per Individual Coverage	\$3,670	\$3,800	\$4,000	\$3,380	\$3,500	\$3,690	\$3,220	\$3,340	\$3,510
Impact on Group Insurance Premiums (%)	0.5	0.7	0.7	0.7	1.0	1.0	1.2	1.2	1.1

¹⁵ Monheit, A., J. Cantor, *et al.*, "State Policies Expanding Dependent Coverage to Young Adults in Private Health Insurance Plans," presented at the Academy Health State Health Research and Policy Interest Group Meeting, Chicago IL, June 27, 2009.

¹⁶ Bansak, Cynthia and Steven Raphael. "The Effects of State Policy Design Features on Take-Up and Crowd-out Rates from the State Children's Health Insurance Program." *Journal of Policy Analysis and Management*, Vol. 26, No. 1, 149–175. 2006. Find that for the time period 1998–2002 take-up rates for SCHIP were about 10 percent.

Currie, Janet and Jonathan Gruber. "Saving babies: The Efficacy and Cost of Recent Changes in Medicaid Eligibility of Pregnant Women." *The Journal of Political Economy*, Vol. 104, No. 6, Dec. 1996, pp. 1263–1296. Find for Medicaid expansions during the 1979–1992 period the take-up rate for eligible pregnant women was 34 percent.

Cutler, David and Jonathan Gruber. "Does Public Insurance Crowd Out Private Insurance?" *The Quarterly Journal of Economics*, Vol. 111, No. 2, May 1996, pp. 391–430. Find that for the Medicaid expansions from 1987–1992 the take-up rate for the

uninsured is close to 30 percent, while for pregnant women it was seven percent.

Gruber, Jonathan and Kosali Simon. "Crowd-Out Ten years Later: Have Recent Public Insurance Expansions Crowded Out Private Health Insurance?" NBER Working Paper 12858. January 2007. Find that for the Medicaid expansions during 1996–2002 the take-up rate was 7 percent across all children, but nearly one-third for uninsured children.

¹⁷ Found at <http://www.kff.org/insurance/snapshot/chcm020707oth.cfm>.

These take-up rate assumptions are then applied to the number of potentially affected individuals displayed in Table 3. The resulting number of individuals with new dependent coverage is summarized in Table 5. Under the mid-range take-up rate assumption, the Departments estimate that in 2011, 1.24 million young adults will newly be covered by their parents' ESI or non-group market policies, of whom 0.65 million were previously uninsured, and 0.6 million were previously covered by non-group coverage. The number of individuals newly covered by their parents' plans would be 0.7 and 2.12 million under the high and low take-up rate assumptions respectively, with 0.2 and 1.64 million of these individuals being previously uninsured. Relative to the individuals covered under the high take-up rate assumption, higher proportions of the low- and mid-range assumption groups are accounted for by people who previously had non-group coverage (72 percent and 48 percent respectively in contrast to 23 percent for the high take-up rate group). This difference is a result of the Departments' assumption for the low- and mid-range take-up rates that people with non-group coverage will be more likely than healthy people who were uninsured to take advantage of the dependent coverage option.

Under the mid-range take-up rate assumptions, the estimated number of young adults covered by their parents' plans in 2012 increases somewhat over the 2011 estimate to 1.6 million in total, of whom approximately 0.9 million would have been uninsured. The increase in the estimate for 2012 results from the assumption that as children reach the age that would have caused them to be excluded from their parents' policy before the implementation of these interim final regulations, a large fraction of them now will remain on their parents' policy. Similarly, the estimated number of young adults enrolling in their parents' non-group policy increases from just under 75,000 in 2011 to approximately 100,000 in 2012, and 120,000 in 2013.

4. Benefits

The benefits of these interim final regulations are expected to outweigh the costs to the regulated community. In the mid-range take-up rate assumption, the Departments estimate that in 2011, 0.65 million previously uninsured individuals will now be covered on their parent's policies due to these interim final regulations and 1.24 million individuals total will now be covered on their parent's coverage. Expanding coverage options for the

19–25 population should decrease the number uninsured, which in turn should decrease the cost-shifting of uncompensated care onto those with coverage, increase the receipt of preventive health care and provide more timely access to high quality care, resulting in a healthier population. In particular, children with chronic conditions or other serious health issues will be able to continue coverage through a parent's plan until age 26. Allowing extended dependent coverage also will permit greater job mobility for this population as their health coverage will no longer be tied to their own jobs or student status.

5. Costs and Transfers Associated With the Rule

Estimates for the incremental annual premium costs for the newly covered individuals are developed based on expenditure data from MEPS and vary based on the take-up rate assumptions. These incremental costs are lowest for the high take-up rate assumption since the newly covered group would contain a relatively high percentage of individuals whose health status was good to excellent. Conversely, the low take-up rate assumption results in the highest incremental costs because a higher percentage of the newly covered individuals would be those whose health status was fair to poor. For those enrolling in their parents' ESI, the expected annual premium cost under the mid-range take-up rate assumption would be \$3,380 in 2011, \$3,500 in 2012 and \$3,690 in 2013. If these costs were distributed among all family ESI plans, family premiums would be expected to rise by 0.7 percent in 2011, 1.0 percent in 2012, and 1.0 percent in 2013 due to these interim final regulations.¹⁸ The comparable incremental costs and premium effects for the low and high take-up rate assumptions are summarized in Table 5. To the extent that these increases are passed on to workers in the form of higher premiums for all workers purchasing family policies or in the form of lower wages for all workers, there will be a transfer from workers who do not have newly covered dependents to those who do. To the extent that these higher premiums result in lower profits or higher prices for the employer's product, the higher premiums will result in a transfer either from stockholders or consumers.

In addition, to the extent that these interim final regulations result in a decrease in the number of uninsured,

¹⁸ For purposes of this regulatory impact analysis, the Departments assume that there would be no effect on premiums for employee-only policies.

the Departments expect a reduction in uncompensated care, and a reduction in liability for those who fund uncompensated care, including public programs (primarily Medicaid and State and local general revenue support for public hospitals), as well as the portion of uncompensated care that is paid for by the cost shift from private premium payers. Such effects would lead to lower premiums for the insured population, both with or without newly covered children.

For the small number of children (75,000 in 2011) enrolling in their parents' non-group insurance policy under the mid-range take-up assumption, the Departments expect estimated annual premium cost to be \$2,360 in 2011, \$2,400 in 2012 and \$2,480 in 2013. To a large extent, premiums in the non-group market are individually underwritten, and the Departments expect that most of the premium cost will be borne by the parents who are purchasing the policy to which their child is added. If, instead, these costs were distributed over the entire individual market (as would be the case in a pure community-rated market), then individual premiums would be expected to rise 0.7 percent in 2011, 1.0 percent in 2012, and 1.2 percent in 2013 due to these interim final regulations. However, the Departments expect the actual increase across the entire individual market, if any, will be much smaller than these estimates, because they expect that the costs largely will be borne by the subscribers who are directly affected rather than distributed across the entire individual market.

6. Enrollment Opportunity

These interim final regulations provide an enrollment opportunity for children excluded from coverage because of age before the effective date of the rule. The Departments estimate that this information collection request will result in approximately 105,000,000 notices being distributed with an hour burden of approximately 1,100,000 hours and cost burden of approximately \$2,010,500. For a discussion of this enrollment opportunity, see the Paperwork Reduction Act section later in this preamble.

7. Regulatory Alternatives

Section 6(a)(3)(C)(iii) of Executive Order 12866 requires an economically significant regulation to include an assessment of the costs and benefits of potentially effective and reasonable alternatives to the planned regulation, and an explanation of why the planned

regulatory action is preferable to the potential alternatives. The Departments carefully considered limiting the flexibility of plans and policies to define who is a child. However, the Departments concluded, as they have in other regulatory contexts, that plan sponsors and issuers should be free to determine whether to cover children or which children should be covered by their plans and policies (although they must comply with other applicable Federal or State law mandating coverage, such as ERISA section 609). Therefore, these interim final regulations have not limited a plan's or policy's flexibility to define who is a child for purposes of the determination of children to whom coverage must be made available.

C. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These interim final regulations are exempt from APA, because the Departments made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the regulations on small entities in connection with their assessment under Executive Order 12866. Consistent with the policy of the RFA, the Departments encourage the public to submit comments that suggest alternative rules that accomplish the stated purpose of PHS Act section 2714 and minimize the impact on small entities.

D. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department

of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the APA (5 U.S.C. chapter 5) does not apply to these interim final regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

E. Paperwork Reduction Act

1. Department of Labor and Department of the Treasury: Affordable Care Act Enrollment Opportunity Notice Relating to Extended Dependent Coverage

As part of their continuing efforts to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

As discussed earlier in this preamble, prior to the applicability date of PHS Act section 2714, a child who was covered under a group health plan (or group health insurance coverage) may have lost eligibility for coverage under the plan due to age before age 26. Moreover, if a child was under age 26 when a parent first became eligible for coverage, but older than the age at which the plan stopped covering children, the child would not have become eligible for coverage. When the provisions of PHS Act section 2714 become applicable to the plan (or coverage), the plan or coverage can no longer exclude coverage for the individual until age 26.

Accordingly, these interim final regulations require plans to provide a notice of an enrollment opportunity to individuals whose coverage ended, or who were denied coverage (or were not eligible for coverage) under a group health plan or health insurance coverage

because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26. The enrollment opportunity must continue for at least 30 days, regardless of whether the plan or coverage offers an open enrollment period and regardless of when any open enrollment period might otherwise occur. This enrollment opportunity must be presented not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010 (which is the applicability date of PHS Act section 2714). Coverage must begin not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.¹⁹

The Affordable Care Act dependent coverage enrollment opportunity notice is an information collection request (ICR) subject to the PRA. Currently, the Departments are soliciting public comments for 60 days concerning these disclosures. The Departments have submitted a copy of these interim final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of the information collections. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, for example, by permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer for the Employee Benefits Security

¹⁹ Any individual enrolling in coverage pursuant to this enrollment right must be treated as a special enrollee, as provided under HIPAA portability rules. Accordingly, the individual must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of cessation of dependent status. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of cessation of dependent status.

Administration either by fax to (202) 395-7285 or by e-mail to oir_submission@omb.eop.gov. A copy of the ICR may be obtained by contacting the PRA addressee: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Room N-5718, Washington, DC 20210. Telephone: (202) 693-8410; Fax: (202) 219-4745. These are not toll-free numbers. E-mail: ebbsa.opr@dol.gov. ICRs submitted to OMB also are available at <http://www.reginfo.gov/public/do/PRAMain>.

The Departments assume that 2,800,000 ERISA covered plans will send the enrollment opportunity notice to all 79,573,000 employees eligible for group health insurance coverage. The Departments estimate that preparing the enrollment notice will require 30 minutes of legal professional time at a labor rate of \$119 per hour²⁰ and one minute of clerical time at \$26 per hour per paper notice to distribute the notices.²¹ This results in an hour burden of nearly 822,000 hours and an associated equivalent cost of nearly \$21,513,000.

The Departments estimate that the cost burden associated with distributing the approximately 79,573,000 notices will be approximately \$2,467,000 based on one minute of clerical time, and \$.05 per page for material and printing costs. The Departments assumed that 38 percent of the notices would be sent electronically.²² In addition, plans can send these notices with other plan

²⁰ Hourly wage estimates are based on data from the Bureau of Labor Statistics Occupational Employment Survey (May 2008) and the Bureau of Labor Statistics Employment Cost Index (June 2009). All hourly wage rates include wages and benefits. Clerical wage and benefits estimates are based on metropolitan wage rates for executive secretaries and administrative assistants. Legal professional wage and benefits estimates are based on metropolitan wage rates for lawyers.

²¹ While plans could prepare their own notice, the Departments assume that the notices will be prepared by service providers. The Departments have previously estimated that there are 630 health insurers (460 providing coverage in the group market, and 490 providing coverage in the individual market.). These estimates are from NAIC 2007 financial statements data and the California Department of Managed Healthcare (2009), at <http://wpspo.dmhca.ca.gov/hpsearch/viewall.aspx>. Because the hour and cost burden is shared between the Departments of Labor/Treasury and the Department of Health and Human Services, the burden to prepare the notices is calculated using half the number of insurers (315).

²² For purposes of this burden estimate, the Departments assume that 38 percent of the disclosures will be provided through electronic means in accordance with the Department of Labor's standards for electronic communication of required information provided under 29 CFR 2520.104b-1(c).

documents, such as open enrollment materials. Therefore, the Departments have not included postage costs in this estimate. The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.²³

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Affordable Care Act Enrollment Opportunity Notice Relating to Extended Dependent Coverage.

OMB Number: 1210-0139; 1545-2172.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 2,800,000.

Total Responses: 79,573,000.

Frequency of Response: One-time.

Estimated Total Annual Burden Hours: 411,000 hours (Employee Benefits Security Administration); 411,000 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: \$1,233,500 (Employee Benefits Security Administration); \$1,233,500 (Internal Revenue Service).

2. Department of Health and Human Services: Affordable Care Act Enrollment Opportunity Notice Relating to Extended Dependent Coverage

We are soliciting public comment on the following sections of this document that contain information collection requirements (ICR) regarding the Affordable Care Act—ICR Relating to Enrollment Opportunity Notice—Dependent Coverage. As discussed earlier in this preamble, the Affordable Care Act and these interim final regulations require issuers in the individual market and group health plans sponsored by State and local governments to notify participants regarding an enrollment opportunity related to the extension of dependent coverage. Prior to the applicability date of PHS Act section 2714, a child who was covered under a group health plan (or group health insurance coverage) as a dependent may have lost eligibility for coverage under the plan due to age before age 26. Moreover, if, when a parent first became eligible for coverage, a child was under age 26 but older than the age at which the plan stopped covering children, the child would not have become eligible for coverage.

²³ 5 CFR 1320.1 through 1320.18.

When the provisions of PHS Act section 2714 become applicable to the plan (or coverage), the plan or coverage can no longer exclude coverage for the individual until age 26.

Accordingly, these interim final regulations require issuers in the individual insurance market and group health plans sponsored by State and local governments to provide a notice of an enrollment opportunity to individuals whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or group health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26. The enrollment opportunity must continue for at least 30 days, regardless of whether the plan or coverage offers an open enrollment period and regardless of when any open enrollment period might otherwise occur. This enrollment opportunity must be presented not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010 (which is the applicability date of PHS Act section 2714). Coverage must begin not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.²⁴

The Department estimates that 126,000 State and local governmental plans would have to send 19,627,000 notices to eligible employees and 490 insurers in the individual market would have to send approximately 5,444,000 notices to individuals with policies covering dependents.²⁵ For purposes of this estimate, the Department assumes that it will take a legal professional, on average, 30 minutes to prepare the notice at a labor rate of \$119 per hour,²⁶ and one minute, on average, of a clerical professional's time at \$26 per hour to copy and mail the notice.²⁷ While plans could prepare their own notice, the

²⁴ Any individual enrolling in coverage pursuant to this enrollment right must be treated as a special enrollee, as provided under HIPAA portability rules. Accordingly, the individual must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of cessation of dependent status. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of cessation of dependent status.

²⁵ The number of individual insurance notices was based on the number of individual policy holders with dependents on that policy according to the 2009 March Current Population Survey (CPS).

²⁶ Estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

Department assumes that the notices will be prepared by service providers. The Department has previously estimated that there are 630 health insurers²⁸ (460 providing coverage in the group market, and 490 providing coverage in the individual market). Because the hour and cost burden is shared among the Departments of Labor/Treasury and the Department of Health and Human Services, the burden to prepare the notices is calculated using half the number of insurers (315). The Department assumes that 38 percent of the notices would be sent electronically.²⁹ Notices that are sent electronically do not require any of the clerical worker's time to mail the notice. This results in an hour burden of approximately 259,000 hours and an associated equivalent cost of about \$6,791,000 to prepare and distribute 25,071,000 notices. The Department estimates that the cost burden associated with distributing the notices will be approximately \$777,000.³⁰ The Department assumes that 38 percent of the notices would be sent electronically.³¹ In addition, plans and issuers can send these notices with other plan documents (for example, during open enrollment for the government plans, or other communication at reenrollment in the individual market). Therefore, the Department did not include postage costs in this estimate. The Department notes that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.³²

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agency: Department of Health and Human Services.

Title: Notice of Special Enrollment Opportunity under the Affordable Care Act Relating to Dependent Coverage.

OMB Number: 0938–1089.

Affected Public: Business; State, Local, or Tribal Governments.

Respondents: 126,000.

²⁸ These estimates are from NAIC 2007 financial statements data and the California Department of Managed Healthcare (2009), at <http://wps0.dnhc.ca.gov/hpsearch/viewwall.aspx>.

²⁹ For purposes of this burden estimate, the Department assumes that 38 percent of the disclosures will be provided through electronic means.

³⁰ This estimate is based on an average document size of one page and \$.05 cents per page for material and printing costs.

³¹ For purposes of this burden estimate, the Department assumes that 38 percent of the disclosures will be provided through electronic means.

³² 5 CFR 1320.1 through 1320.18.

Responses: 25,071,000.
Frequency of Response: One-time.
Estimated Total Annual Burden Hours: 259,000 hours.
Estimated Total Annual Burden Cost: \$777,000.

If you comment on this information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,
Attention: CMS Desk Officer, 4140–IFC

Fax: (202) 395–6974; or

E-mail:
OIRA_submission@omb.eop.gov

F. Congressional Review Act

These interim final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare several analytic statements before proposing any rules that may result in annual expenditures of \$100 million (as adjusted for inflation) by State, local and tribal governments or the private sector. These interim final regulations are not subject to the Unfunded Mandates Reform Act, because they are being issued as an interim final regulation. However, consistent with the policy embodied in the Unfunded Mandates Reform Act, these interim final regulations have been designed to be the least burdensome alternative for State, local and tribal governments, and the private sector, while achieving the objectives of the Affordable Care Act.

H. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various

levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments' view, these interim final regulations have federalism implications, because they have direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. However, in the Departments' view, the federalism implications of these interim final regulations are substantially mitigated because, with respect to health insurance issuers, the Departments expect that the majority of States will enact laws or take other appropriate action resulting in their meeting or exceeding the Federal standard.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of ERISA section 731 and PHS Act section 2724 (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the HIPAA requirements (including those of the Affordable Care Act) are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of a federal standard. The conference report accompanying HIPAA indicates that this is intended to be the “narrowest” preemption of State laws. (See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.) States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to “prevent the application of” the Affordable Care Act, and be preempted. Accordingly, States have significant latitude to impose requirements on health

insurance issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected State and local officials, including attending conferences of the National Association of Insurance Commissioners and consulting with State insurance officials on an individual basis. It is expected that the Departments will act in a similar fashion in enforcing the Affordable Care Act requirements. Throughout the process of developing these interim final regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these regulations, the Departments certify that the Employee Benefits Security Administration and the Office of Consumer Information and Insurance Oversight have complied with the requirements of Executive Order 13132 for the attached regulation in a meaningful and timely manner.

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor's Order 6–2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42

USC 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Parts 144, 146, and 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: May 7, 2010.

Michael F. Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 6th day of May 2010.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Approved: May 4, 2010.

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Approved: May 7, 2010.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

Internal Revenue Service

26 CFR Chapter 1

■ Accordingly, 26 CFR Parts 54 and 602 are amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

■ **Par. 2.** Section 54.9815–2714T is added to read as follows:

§ 54.9815–2714T Eligibility of children until at least age 26 (temporary).

(a) *In general*—(1) A group health plan, or a health insurance issuer offering group health insurance coverage, that makes available dependent coverage of children must

make such coverage available for children until attainment of 26 years of age.

(2) The rule of this paragraph (a) is illustrated by the following example:

Example. (i) Facts. For the plan year beginning January 1, 2011, a group health plan provides health coverage for employees, employees' spouses, and employees' children until the child turns 26. On the birthday of a child of an employee, July 17, 2011, the child turns 26. The last day the plan covers the child is July 16, 2011.

(ii) *Conclusion.* In this *Example*, the plan satisfies the requirement of this paragraph (a) with respect to the child.

(b) *Restrictions on plan definition of dependent.* With respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant. Thus, for example, a plan or issuer may not deny or restrict coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency (upon the participant or any other person), residency with the participant or with any other person, student status, employment, or any combination of those factors. In addition, a plan or issuer may not deny or restrict coverage of a child based on eligibility for other coverage, except that paragraph (g) of this section provides a special rule for plan years beginning before January 1, 2014 for grandfathered health plans that are group health plans. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may mandate coverage of certain children.)

(c) *Coverage of grandchildren not required.* Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) *Uniformity irrespective of age.* The terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(e) *Examples.* The rules of paragraph (d) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) *Conclusion.* In this *Example 1*, the plan violates the requirement of paragraph (d) of this section because the plan varies the terms

for dependent coverage of children based on age.

Example 2. (i) Facts. A group health plan offers a choice among the following tiers of health coverage: self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage of children who have not attained age 26.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any child.

Example 3. (i) Facts. A group health plan offers two benefit packages—an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) *Conclusion.* In this *Example 3*, the plan violates the requirement of paragraph (d) of this section because the plan, by limiting children who are older than age 18 to the HMO option, varies the terms for dependent coverage of children based on age.

(f) *Transitional rules for individuals whose coverage ended by reason of reaching a dependent eligibility threshold—(1) In general.* The relief provided in the transitional rules of this paragraph (f) applies with respect to any child—

(i) Whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or group health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26 (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for coverage under a group health plan or group health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010 by reason of the application of this section.

(2) *Opportunity to enroll required.* (i) If a group health plan, or group health insurance coverage, in which a child described in paragraph (f)(1) of this section is eligible to enroll (or is required to become eligible to enroll) is the plan or coverage in which the child's coverage ended (or did not begin) for the reasons described in paragraph (f)(1)(i) of this section, and if the plan, or the issuer of such coverage, is subject to the requirements of this section, the plan and the issuer are required to give the child an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). This

opportunity (including the written notice) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The written notice must include a statement that children whose coverage ended, or who were denied coverage (or were not eligible for coverage), because the availability of dependent coverage of children ended before attainment of age 26 are eligible to enroll in the plan or coverage. The notice may be provided to an employee on behalf of the employee's child. In addition, the notice may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. If a notice satisfying the requirements of this paragraph (f)(2) is provided to an employee whose child is entitled to an enrollment opportunity under this paragraph (f), the obligation to provide the notice of enrollment opportunity under this paragraph (f)(2) with respect to that child is satisfied for both the plan and the issuer.

(3) *Effective date of coverage.* In the case of an individual who enrolls under paragraph (f)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) *Treatment of enrollees in a group health plan.* Any child enrolling in a group health plan pursuant to paragraph (f)(2) of this section must be treated as if the child were a special enrollee, as provided under the rules of § 54.9801–6(d). Accordingly, the child (and, if the child would not be a participant once enrolled in the plan, the participant through whom the child is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of cessation of dependent status. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The child also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of cessation of dependent status.

(5) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) Facts. Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan allows children of employees to be covered under the plan until age 19, or until age 23 for children who are full-time students. Individual B, an employee of Y, and Individual C, B's child and a full-time student, were enrolled in Y's group health

plan at the beginning of the 2010 plan year. On June 10, 2010, C turns 23 years old and loses dependent coverage under Y's plan. On or before January 1, 2011, Y's group health plan gives B written notice that individuals who lost coverage by reason of ceasing to be a dependent before attainment of age 26 are eligible to enroll in the plan, and that individuals may request enrollment for such children through February 14, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the plan has complied with the requirements of this paragraph (f) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) Facts. Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan allows children of employees to be covered under the plan until age 22. Individual D, an employee of Z, and Individual E, D's child, are enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E turns 22 years old and ceases to be eligible as a dependent under Z's plan and loses coverage. D drops coverage but remains an employee of Z.

(ii) *Conclusion.* In this *Example 2*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) Facts. Same facts as *Example 2*, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) *Conclusion.* In this *Example 3*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

Example 4. (i) Facts. Same facts as *Example 2*, except that E elected COBRA continuation coverage.

(ii) *Conclusion.* In this *Example 4*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll other than as a COBRA qualified beneficiary (and must provide, by that date, written notice of the opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 5. (i) Facts. Employer X maintains a group health plan with a calendar year plan year. Prior to 2011, the plan allows children of employees to be covered under the plan until the child attains age 22. During the 2009 plan year, an individual with a 22-year old child joins the plan; the child is denied coverage because the child is 22.

(ii) *Conclusion.* In this *Example 5*, notwithstanding that the child was not previously covered under the plan, the plan must provide the child, not later than January 1, 2011, an opportunity to enroll (including written notice to the employee of an opportunity to enroll the child) that continues for at least 30 days, with enrollment effective not later than January 1, 2011.

(g) *Special rule for grandfathered group health plans—(1) For plan years*

beginning before January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act and that makes available dependent coverage of children may exclude an adult child who has not attained age 26 from coverage only if the adult child is eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2)) other than a group health plan of a parent.

(2) For plan years beginning on or after January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act must comply with the requirements of paragraphs (a) through (f) of this section.

(h) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010.

(i) *Expiration date.* This section expires on or before May 13, 2013.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 5.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 6.** In § 602.101, paragraph (b) is amended by adding the following entry in numerical order to the table:

§ 602.101 OMB Control numbers.

CFR part or section where identified and described	Current OMB control No.
* * * * *	* * * * *
54.9815-2714T	1545-2172
* * * * *	* * * * *

Employee Benefits Security Administration

29 CFR Chapter XXV

■ 29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for Part 2590 is revised to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat.

645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

■ 2. Section 2590.715-2714 is added to Subpart C to read as follows:

§ 2590.715-2714 Eligibility of children until at least age 26.

(a) *In general*—(1) A group health plan, or a health insurance issuer offering group health insurance coverage, that makes available dependent coverage of children must make such coverage available for children until attainment of 26 years of age.

(2) The rule of this paragraph (a) is illustrated by the following example:

Example. (i) *Facts.* For the plan year beginning January 1, 2011, a group health plan provides health coverage for employees, employees' spouses, and employees' children until the child turns 26. On the birthday of a child of an employee, July 17, 2011, the child turns 26. The last day the plan covers the child is July 16, 2011.

(ii) *Conclusion.* In this *Example*, the plan satisfies the requirement of this paragraph (a) with respect to the child.

(b) *Restrictions on plan definition of dependent.* With respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant. Thus, for example, a plan or issuer may not deny or restrict coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency (upon the participant or any other person), residency with the participant or with any other person, student status, employment, or any combination of those factors. In addition, a plan or issuer may not deny or restrict coverage of a child based on eligibility for other coverage, except that paragraph (g) of this section provides a special rule for plan years beginning before January 1, 2014 for grandfathered health plans that are group health plans. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may mandate coverage of certain children.)

(c) *Coverage of grandchildren not required.* Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) *Uniformity irrespective of age.* The terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age

(except for children who are age 26 or older).

(e) *Examples.* The rules of paragraph (d) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) *Conclusion.* In this *Example 1*, the plan violates the requirement of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

Example 2. (i) *Facts.* A group health plan offers a choice among the following tiers of health coverage: self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage of children who have not attained age 26.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any child.

Example 3. (i) *Facts.* A group health plan offers two benefit packages—an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) *Conclusion.* In this *Example 3*, the plan violates the requirement of paragraph (d) of this section because the plan, by limiting children who are older than age 18 to the HMO option, varies the terms for dependent coverage of children based on age.

(f) *Transitional rules for individuals whose coverage ended by reason of reaching a dependent eligibility threshold*—(1) *In general.* The relief provided in the transitional rules of this paragraph (f) applies with respect to any child—

(i) Whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or group health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26 (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for coverage under a group health plan or group health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010 by reason of the application of this section.

(2) *Opportunity to enroll required*—(i) If a group health plan, or group health

insurance coverage, in which a child described in paragraph (f)(1) of this section is eligible to enroll (or is required to become eligible to enroll) is the plan or coverage in which the child's coverage ended (or did not begin) for the reasons described in paragraph (f)(1)(i) of this section, and if the plan, or the issuer of such coverage, is subject to the requirements of this section, the plan and the issuer are required to give the child an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). This opportunity (including the written notice) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The written notice must include a statement that children whose coverage ended, or who were denied coverage (or were not eligible for coverage), because the availability of dependent coverage of children ended before attainment of age 26 are eligible to enroll in the plan or coverage. The notice may be provided to an employee on behalf of the employee's child. In addition, the notice may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. If a notice satisfying the requirements of this paragraph (f)(2) is provided to an employee whose child is entitled to an enrollment opportunity under this paragraph (f), the obligation to provide the notice of enrollment opportunity under this paragraph (f)(2) with respect to that child is satisfied for both the plan and the issuer.

(3) *Effective date of coverage.* In the case of an individual who enrolls under paragraph (f)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) *Treatment of enrollees in a group health plan.* Any child enrolling in a group health plan pursuant to paragraph (f)(2) of this section must be treated as if the child were a special enrollee, as provided under the rules of § 2590.701-6(d) of this Part. Accordingly, the child (and, if the child would not be a participant once enrolled in the plan, the participant through whom the child is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of cessation of dependent status. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The child also cannot be required to pay more for coverage than similarly situated individuals who did not lose

coverage by reason of cessation of dependent status.

(5) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan allows children of employees to be covered under the plan until age 19, or until age 23 for children who are full-time students. Individual B, an employee of Y, and Individual C, B's child and a full-time student, were enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, C turns 23 years old and loses dependent coverage under Y's plan. On or before January 1, 2011, Y's group health plan gives B written notice that individuals who lost coverage by reason of ceasing to be a dependent before attainment of age 26 are eligible to enroll in the plan, and that individuals may request enrollment for such children through February 14, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the plan has complied with the requirements of this paragraph (f) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) *Facts.* Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan allows children of employees to be covered under the plan until age 22. Individual D, an employee of Z, and Individual E, D's child, are enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E turns 22 years old and ceases to be eligible as a dependent under Z's plan and loses coverage. D drops coverage but remains an employee of Z.

(ii) *Conclusion.* In this *Example 2*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) *Facts.* Same facts as *Example 2*, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) *Conclusion.* In this *Example 3*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

Example 4. (i) *Facts.* Same facts as *Example 2*, except that E elected COBRA continuation coverage.

(ii) *Conclusion.* In this *Example 4*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll other than as a COBRA qualified beneficiary (and must provide, by that date, written notice of the opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 5. (i) *Facts.* Employer X maintains a group health plan with a calendar year plan year. Prior to 2011, the plan allows children

of employees to be covered under the plan until the child attains age 22. During the 2009 plan year, an individual with a 22-year old child joins the plan; the child is denied coverage because the child is 22.

(ii) *Conclusion.* In this *Example 5*, notwithstanding that the child was not previously covered under the plan, the plan must provide the child, not later than January 1, 2011, an opportunity to enroll (including written notice to the employee of an opportunity to enroll the child) that continues for at least 30 days, with enrollment effective not later than January 1, 2011.

(g) *Special rule for grandfathered group health plans*—(1) For plan years beginning before January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act and that makes available dependent coverage of children may exclude an adult child who has not attained age 26 from coverage only if the adult child is eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a group health plan of a parent.

(2) For plan years beginning on or after January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act must comply with the requirements of paragraphs (a) through (f) of this section.

(h) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010.

Department of Health and Human Services

45 CFR Subtitle A

■ For reasons set forth in the preamble, the Department of Health and Human Services is amending 45 CFR Subtitle A, Subchapter B as follows:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

Subpart A—General Provisions

- 1. Section 144.101 is amended by—
- A. Revising paragraph (a).
- B. Redesignating paragraphs (b), (c) and (d) as paragraphs (c), (d) and (e), respectively.
- C. Adding a new paragraph (b).
- D. Revising the first sentence of newly redesignated paragraph (c).
- E. Amending newly redesignated paragraph (d) by removing “2722” and adding in its place “2723”.

The revisions and additions read as follows:

§ 144.101 Basis and purpose.

(a) Part 146 of this subchapter implements requirements of Title XXVII of the Public Health Service Act (PHS Act, 42 U.S.C. 300gg, *et seq.*) that apply to group health plans and group health insurance issuers.

(b) Part 147 of this subchapter implements the provisions of the Patient Protection and Affordable Care Act that apply to both group health plans and health insurance issuers in the Group and Individual Markets.

(c) Part 148 of this subchapter implements Individual Health Insurance Market requirements of the PHS Act.

* * *

■ 2. Section 144.103 is amended by adding the definition of “Policy Year” to read as follows:

§ 144.103 Definitions.

* * * * *

Policy Year means in the individual health insurance market the 12-month period that is designated as the policy year in the policy documents of the individual health insurance coverage. If there is no designation of a policy year in the policy document (or no such policy document is available), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year.

* * * * *

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 3. Section 146.101 is amended by—

- A. Revising the first sentence of paragraph (a).
- B. Revising paragraph (b)(4).

The revisions read as follows:

§ 146.101 Basis and Scope.

(a) Statutory basis. This part implements the Group Market requirements of the PHS Act. * * *

(b) * * *

(4) *Subpart E.* Subpart E of this part implements requirements relating to group health plans and issuers in the Group Health Insurance Market.

* * * * *

§ 146.115 [Amended]

■ 4. Section 146.115 is amended by removing “2721(b)” wherever it appears in paragraph (a)(6) and adding in its place “2722(a)”.

§ 146.130 [Amended]

■ 5. Section 146.130 is amended by—

- A. Removing “2704” wherever it appears in paragraphs (e) and (f),

including the examples in paragraph (e)(4), and adding in its place “2725”.

■ B. Removing “2723” wherever it appears in paragraph (e)(3), including the paragraph heading, and adding in its place “2724”.

■ 6. A new Part 147 is added to read as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

§ 147.100 Basis and scope.

Part 147 of this subchapter implements the requirements of the Patient Protection and Affordable Care Act that apply to group health plans and health insurance issuers in the Group and Individual markets.

§ 147.120 Eligibility of children until at least age 26.

(a) *In general*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, that makes available dependent coverage of children must make such coverage available for children until attainment of 26 years of age.

(2) The rule of this paragraph (a) is illustrated by the following example:

Example. (i) *Facts.* For the plan year beginning January 1, 2011, a group health plan provides health coverage for employees, employees’ spouses, and employees’ children until the child turns 26. On the birthday of a child of an employee, July 17, 2011, the child turns 26. The last day the plan covers the child is July 16, 2011.

(ii) *Conclusion.* In this *Example*, the plan satisfies the requirement of this paragraph (a) with respect to the child.

(b) *Restrictions on plan definition of dependent.* With respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant (in the individual market, the primary subscriber). Thus, for example, a plan or issuer may not deny or restrict coverage for a child who has not attained age 26 based on the presence or absence of the child’s financial dependency (upon the participant or primary subscriber, or any other person), residency with the participant (in the individual market, the primary subscriber) or with any other person, student status, employment, or any combination of

those factors. In addition, a plan or issuer may not deny or restrict coverage of a child based on eligibility for other coverage, except that paragraph (g) of this section provides a special rule for plan years beginning before January 1, 2014 for grandfathered health plans that are group health plans. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may mandate coverage of certain children.)

(c) *Coverage of grandchildren not required.* Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) *Uniformity irrespective of age.* The terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(e) *Examples.* The rules of paragraph (d) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) *Conclusion.* In this *Example 1*, the plan violates the requirement of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

Example 2. (i) *Facts.* A group health plan offers a choice among the following tiers of health coverage: Self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage of children who have not attained age 26.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any child.

Example 3. (i) *Facts.* A group health plan offers two benefit packages—an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) *Conclusion.* In this *Example 3*, the plan violates the requirement of paragraph (d) of this section because the plan, by limiting children who are older than age 18 to the HMO option, varies the terms for dependent coverage of children based on age.

(f) *Transitional rules for individuals whose coverage ended by reason of reaching a dependent eligibility*

threshold—(1) *In general.* The relief provided in the transitional rules of this paragraph (f) applies with respect to any child—

(i) Whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or group or individual health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26 (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for coverage under a group health plan or group or individual health insurance coverage on the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010 by reason of the application of this section.

(2) *Opportunity to enroll required*—(i) If a group health plan, or group or individual health insurance coverage, in which a child described in paragraph (f)(1) of this section is eligible to enroll (or is required to become eligible to enroll) is the plan or coverage in which the child's coverage ended (or did not begin) for the reasons described in paragraph (f)(1)(i) of this section, and if the plan, or the issuer of such coverage, is subject to the requirements of this section, the plan and the issuer are required to give the child an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). This opportunity (including the written notice) must be provided beginning not later than the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010.

(ii) The written notice must include a statement that children whose coverage ended, or who were denied coverage (or were not eligible for coverage), because the availability of dependent coverage of children ended before attainment of age 26 are eligible to enroll in the plan or coverage. The notice may be provided to an employee on behalf of the employee's child (in the individual market, to the primary subscriber on behalf of the primary subscriber's child). In addition, for a group health plan or group health insurance coverage, the notice may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (f)(2) is provided to an employee whose child is entitled to an enrollment opportunity

under this paragraph (f), the obligation to provide the notice of enrollment opportunity under this paragraph (f)(2) with respect to that child is satisfied for both the plan and the issuer.

(3) *Effective date of coverage.* In the case of an individual who enrolls under paragraph (f)(2) of this section, coverage must take effect not later than the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010.

(4) *Treatment of enrollees in a group health plan.* For purposes of this Part, any child enrolling in a group health plan pursuant to paragraph (f)(2) of this section must be treated as if the child were a special enrollee, as provided under the rules of 45 CFR 146.117(d). Accordingly, the child (and, if the child would not be a participant once enrolled in the plan, the participant through whom the child is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of cessation of dependent status. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The child also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of cessation of dependent status.

(5) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan allows children of employees to be covered under the plan until age 19, or until age 23 for children who are full-time students. Individual B, an employee of Y, and Individual C, B's child and a full-time student, were enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010, C turns 23 years old and loses dependent coverage under Y's plan. On or before January 1, 2011, Y's group health plan gives B written notice that individuals who lost coverage by reason of ceasing to be a dependent before attainment of age 26 are eligible to enroll in the plan, and that individuals may request enrollment for such children through February 14, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the plan has complied with the requirements of this paragraph (f) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) *Facts.* Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan allows children of employees to be

covered under the plan until age 22. Individual D, an employee of Z, and Individual E, D's child, are enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E turns 22 years old and ceases to be eligible as a dependent under Z's plan and loses coverage. D drops coverage but remains an employee of Z.

(ii) *Conclusion.* In this *Example 2*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) *Facts.* Same facts as *Example 2*, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) *Conclusion.* In this *Example 3*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

Example 4. (i) *Facts.* Same facts as *Example 2*, except that E elected COBRA continuation coverage.

(ii) *Conclusion.* In this *Example 4*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll other than as a COBRA qualified beneficiary (and must provide, by that date, written notice of the opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 5. (i) *Facts.* Employer X maintains a group health plan with a calendar year plan year. Prior to 2011, the plan allows children of employees to be covered under the plan until the child attains age 22. During the 2009 plan year, an individual with a 22-year old child joins the plan; the child is denied coverage because the child is 22.

(ii) *Conclusion.* In this *Example 5*, notwithstanding that the child was not previously covered under the plan, the plan must provide the child, not later than January 1, 2011, an opportunity to enroll (including written notice to the employee of an opportunity to enroll the child) that continues for at least 30 days, with enrollment effective not later than January 1, 2011.

(g) *Special rule for grandfathered group health plans*—(1) For plan years beginning before January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act and that makes available dependent coverage of children may exclude an adult child who has not attained age 26 from coverage only if the adult child is eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a group health plan of a parent.

(2) For plan years beginning on or after January 1, 2014, a group health plan that qualifies as a grandfathered

health plan under section 1251 of the Patient Protection and Affordable Care Act must comply with the requirements of paragraphs (a) through (f) of this section.

(h) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years)

beginning on or after September 23, 2010.

[FR Doc. 2010-11391 Filed 5-10-10; 4:15 pm]

BILLING CODE 4830-01-P; 4510-29-P; 4120-01-P

Grandfathered Health Plans Interim Final Rule



Federal Register

Thursday,
June 17, 2010

Part II

Department of the Treasury
Internal Revenue Service
26 CFR Parts 54 and 602

Department of Labor
Employee Benefits Security
Administration
29 CFR Part 2590

**Department of Health and
Human Services**
45 CFR Part 147

**Group Health Plans and Health Insurance
Coverage Relating to Status as a
Grandfathered Health Plan Under the
Patient Protection and Affordable Care
Act; Interim Final Rule and Proposed
Rule**

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Parts 54 and 602**

[TD 9489]

RIN 1545-BJ51

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AB42

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OCIO-9991-IFC]

45 CFR Part 147

RIN 0991-AB68

Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding status as a grandfathered health plan.

DATES: *Effective date.* These interim final regulations are effective on June 14, 2010, except that the amendments to 26 CFR 54.9815-2714T, 29 CFR 2590.715-2714, and 45 CFR 147.120 are effective July 12, 2010.

Comment date. Comments are due on or before August 16, 2010.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. *Warning:* Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want

publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB42, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* E-OHPSCA1251.EBSA@dol.gov.

- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, *Attention:* RIN 1210-AB42.

Comments received by the Department of Labor will be posted without change to <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIO-9991-IFC. Because of staff and resource limitations, the Departments cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-9991-IFC, P.O. Box 8016, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-9991-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

- a. For delivery in Washington, DC—Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

- b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. The Departments post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To

schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-118412-10, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* CC:PA:LPD:PR (REG-118412-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

- *Hand or courier delivery:* Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-118412-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT:

Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786-1565.

Customer Service Information:

Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (http://www.cms.hhs.gov/HealthInsReformforConsumer/01_Overview.asp) and information on health reform can be found at <http://www.healthreform.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions in part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The

term "group health plan" includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes. Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act, specifies that certain plans or coverage existing as of the date of enactment (that is, grandfathered health plans) are only subject to certain provisions.

The Affordable Care Act also adds section 715(a)(2) of ERISA, which provides that, to the extent that any provision of part 7 of ERISA conflicts with part A of title XXVII of the PHS Act with respect to group health plans or group health insurance coverage, the PHS Act provisions apply. Similarly, the Affordable Care Act adds section 9815(a)(2) of the Code, which provides that, to the extent that any provision of subchapter B of chapter 100 of the Code conflicts with part A of title XXVII of the PHS Act with respect to group health plans or group health insurance coverage, the PHS Act provisions apply. Therefore, although ERISA section 715(a)(1) and Code section 9815(a)(1) incorporate by reference new provisions, they do not affect preexisting sections of ERISA or the Code unless they cannot be read consistently with an incorporated provision of the PHS Act. For example, ERISA section 732(a) generally provides that part 7 of ERISA—and Code section 9831(a) generally provides that chapter 100 of the Code—does not apply to plans with less than two participants who are current employees (including retiree-only plans that cover less than two participants who are current employees). Prior to enactment of the

¹ The term "group health plan" is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term "health plan", as used in other provisions of title I of the Affordable Care Act. The term "health plan" does not include self-insured group health plans.

Affordable Care Act, the PHS Act had a parallel provision at section 2721(a). After the Affordable Care Act amended, reorganized, and renumbered most of title XXVII of the PHS Act, that exception no longer exists. Similarly, ERISA section 732(b) and (c) generally provides that the requirements of part 7 of ERISA—and Code section 9831(b) and (c) generally provides that the requirements of chapter 100 of the Code—do not apply to excepted benefits.² Prior to enactment of the Affordable Care Act, the PHS Act had a parallel section 2721(c) and (d) that indicated that the provisions of subparts 1 through 3 of part A of title XXVII of the PHS Act did not apply to excepted benefits. After the Affordable Care Act amended and renumbered PHS Act section 2721(c) and (d) as section 2722(b) and (c), that exception could be read to be narrowed so that it applies only with respect to subpart 2 of part A of title XXVII of the PHS Act, thus, in effect requiring excepted benefits to comply with subparts I and II of part A.

The absence of an express provision in part A of title XXVII of the PHS Act does not create a conflict with the relevant requirements of ERISA and the Code. Accordingly, the exceptions of ERISA section 732 and Code section 9831 for very small plans and certain retiree-only health plans, and for excepted benefits, remain in effect and, thus, ERISA section 715 and Code section 9815, as added by the Affordable Care Act, do not apply to such plans or excepted benefits.

Moreover, there is no express indication in the legislative history of an intent to treat issuers of group health insurance coverage or nonfederal governmental plans (that are subject to the PHS Act) any differently in this respect from plans subject to ERISA and the Code. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) operate under a Memorandum of Understanding (MOU)³ that implements section 104 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), enacted on August 21, 1996, and subsequent amendments, and provides that requirements over which two or more Secretaries have responsibility ("shared provisions") must be administered so as to have the same effect at all times. HIPAA section 104

² Excepted benefits generally include dental-only and vision-only plans, most health flexible spending arrangements, Medigap policies, and accidental death and dismemberment coverage. For more information on excepted benefits, see 26 CFR 54.9831-1, 29 CFR 2590.732, 45 CFR 146.145, and 45 CFR 148.220.

³ See 64 FR 70164 (December 15, 1999).

also requires the coordination of policies relating to enforcing the shared provisions in order to avoid duplication of enforcement efforts and to assign priorities in enforcement.

There is no express statement of intent that nonfederal governmental retiree-only plans should be treated differently from private sector plans or that excepted benefits offered by nonfederal governmental plans should be treated differently from excepted benefits offered by private sector plans. Because treating nonfederal governmental retiree-only plans and excepted benefits provided by nonfederal governmental plans differently would create confusion with respect to the obligations of issuers that do not distinguish whether a group health plan is subject to ERISA or the PHS Act, and in light of the MOU, the Department of Health and Human Services (HHS) does not intend to use its resources to enforce the requirements of HIPAA or the Affordable Care Act with respect to nonfederal governmental retiree-only plans or with respect to excepted benefits provided by nonfederal governmental plans.

PHS Act section 2723(a)(2) (formerly section 2722(a)(2)) gives the States primary authority to enforce the PHS Act group and individual market provisions over group and individual health insurance issuers. HHS enforces these provisions with respect to issuers only if it determines that the State has “failed to substantially enforce” one of the Federal provisions. Furthermore, the PHS Act preemption provisions allow States to impose requirements on issuers in the group and individual markets that are more protective than the Federal provisions. However, HHS is encouraging States not to apply the provisions of title XXVII of the PHS Act to issuers of retiree-only plans or of excepted benefits. HHS advises States that if they do not apply these provisions to the issuers of retiree-only plans or of excepted benefits, HHS will not cite a State for failing to substantially enforce the provisions of part A of title XXVII of the PHS Act in these situations.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724⁴ (implemented in 29 CFR 2590.731(a)

and 45 CFR 146.143(a)) apply so that the requirements of part 7 of ERISA and title XXVII of PHS Act, as amended by the Affordable Care Act, are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers requirements that are stricter than the requirements imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

The Departments are issuing regulations implementing the revised PHS Act sections 2701 through 2719A in several phases. The first publication in this series was a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the **Federal Register** on April 14, 2010 (75 FR 19297). The second publication was interim final regulations implementing PHS Act section 2714 (requiring dependent coverage of children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). This document contains interim final regulations implementing section 1251 of the Affordable Care Act (relating to grandfathered health plans), as well as adding a cross-reference to these interim final regulations in the regulations implementing PHS Act section 2714. The implementation of other provisions in PHS Act sections 2701 through 2719A will be addressed in future regulations.

II. Overview of the Regulations: Section 1251 of the Affordable Care Act, Preservation of Right To Maintain Existing Coverage (26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140)

A. Introduction

Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act, provides that certain group health plans and health insurance coverage existing as of March 23, 2010 (the date of enactment of the Affordable Care Act), are subject only to certain provisions of the Affordable Care Act. The statute and these interim final regulations refer to these plans and health insurance coverage as grandfathered health plans.

The Affordable Care Act balances the objective of preserving the ability of individuals to maintain their existing coverage with the goals of ensuring access to affordable essential coverage and improving the quality of coverage. Section 1251 provides that nothing in the Affordable Care Act requires an individual to terminate the coverage in which the individual was enrolled on March 23, 2010. It also generally provides that, with respect to group health plans or health insurance coverage in which an individual was enrolled on March 23, 2010, various requirements of the Act shall not apply to such plan or coverage, regardless of whether the individual renews such coverage after March 23, 2010. However, to ensure access to coverage with certain particularly significant protections, Congress required grandfathered health plans to comply with a subset of the Affordable Care Act’s health reform provisions. Thus, for example, grandfathered health plans must comply with the prohibition on rescissions of coverage except in the case of fraud or intentional misrepresentation and the elimination of lifetime limits (both of which apply for plan years, or in the individual market, policy years, beginning on or after September 23, 2010). On the other hand, grandfathered health plans are not required to comply with certain other requirements of the Affordable Care Act; for example, the requirement that preventive health services be covered without any cost sharing (which otherwise becomes generally applicable for plan years, or in the individual market, policy years, beginning on or after September 23, 2010).

A number of additional reforms apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014. As with the requirements effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, grandfathered health plans must then comply with some, but not all of these reforms. See Table 1 in section II.D of this preamble for a list of various requirements that apply to grandfathered health plans.

In making grandfathered health plans subject to some but not all of the health reforms contained in the Affordable Care Act, the statute balances its objective of preserving the ability to maintain existing coverage with the goals of expanding access to and improving the quality of health coverage. The statute does not, however, address at what point changes to a group health plan or health insurance coverage in which an individual was

⁴ Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

enrolled on March 23, 2010 are significant enough to cause the plan or health insurance coverage to cease to be a grandfathered health plan, leaving that question to be addressed by regulatory guidance.

These interim final regulations are designed to ease the transition of the healthcare industry into the reforms established by the Affordable Care Act by allowing for gradual implementation of reforms through a reasonable grandfathering rule. A more detailed description of the basis for these interim final regulations and other regulatory alternatives considered is included in section IV.B later in this preamble.

B. Definition of Grandfathered Health Plan Coverage in Paragraph (a) of 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 of These Interim Final Regulations

Under the statute and these interim final regulations, a group health plan or group or individual health insurance coverage is a grandfathered health plan with respect to individuals enrolled on March 23, 2010. Paragraph (a)(1) of 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 of these interim final regulations provides that a group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). The determination under the rules of these interim final regulations is made separately with respect to each benefit package made available under a group health plan or health insurance coverage.

Moreover, these interim final regulations provide that, subject to the rules of paragraph (f) of 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 for collectively bargained plans, if an employer or employee organization enters into a new policy, certificate, or contract of insurance after March 23, 2010 (because, for example, any previous policy, certificate, or contract of insurance is not being renewed), then that policy, certificate, or contract of insurance is not a grandfathered health plan with respect to the individuals in the group health plan. Any policies sold in the group and individual health insurance markets to new entities or individuals after March 23, 2010 will not be grandfathered health plans even if the health insurance products sold to

those subscribers were offered in the group or individual market before March 23, 2010.

To maintain status as a grandfathered health plan, a plan or health insurance coverage (1) must include a statement, in any plan materials provided to participants or beneficiaries (in the individual market, primary subscribers) describing the benefits provided under the plan or health insurance coverage, that the plan or health insurance coverage believes that it is a grandfathered health plan within the meaning of section 1251 of the Affordable Care Act and (2) must provide contact information for questions and complaints.

Model language is provided in these interim final regulations that can be used to satisfy this disclosure requirement. Comments are invited on possible improvements to the model language of grandfathered health plan status. Some have suggested, for example, that each grandfathered health plan be required to list and describe the various consumer protections that do not apply to the plan or health insurance coverage because it is grandfathered, together with their effective dates. The Departments intend to consider any comments regarding possible improvements to the model language in the near term; any changes to the model language that may result from such comments could be published in additional administrative guidance other than in the form of regulations.

Similarly, under these interim final regulations, to maintain status as a grandfathered health plan, a plan or issuer must also maintain records documenting the terms of the plan or health insurance coverage that were in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan. Such documents could include intervening and current plan documents, health insurance policies, certificates or contracts of insurance, summary plan descriptions, documentation of premiums or the cost of coverage, and documentation of required employee contribution rates. In addition, the plan or issuer must make such records available for examination. Accordingly, a participant, beneficiary, individual policy subscriber, or State or Federal agency official would be able to inspect such documents to verify the status of the plan or health insurance coverage as a grandfathered health plan. The plan or issuer must maintain such records and make them available for examination for as long as the plan or issuer takes the position that the plan or

health insurance coverage is a grandfathered health plan.

Under the statute and these interim final regulations, if family members of an individual who is enrolled in a grandfathered health plan as of March 23, 2010 enroll in the plan after March 23, 2010, the plan or health insurance coverage is also a grandfathered health plan with respect to the family members.

C. Adding New Employees in Paragraph (b) of 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 of These Interim Final Regulations

These interim final regulations at 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 provide that a group health plan that provided coverage on March 23, 2010 generally is also a grandfathered health plan with respect to new employees (whether newly hired or newly enrolled) and their families who enroll in the grandfathered health plan after March 23, 2010. These interim final regulations clarify that in such cases, any health insurance coverage provided under the group health plan in which an individual was enrolled on March 23, 2010 is also a grandfathered health plan. To prevent abuse, these interim final regulations provide that if the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan. The goal of this rule is to prevent grandfather status from being bought and sold as a commodity in commercial transactions. These interim final regulations also contain a second anti-abuse rule designed to prevent a plan or issuer from circumventing the limits on changes that cause a plan or health insurance coverage to cease to be a grandfathered health plan under paragraph (g) (described more fully in section II.F of this preamble). This rule in paragraph (b)(2)(ii) addresses a situation under which employees who previously were covered by a grandfathered health plan are transferred to another grandfathered health plan. This rule is intended to prevent efforts to retain grandfather status by indirectly making changes that would result in loss of that status if those changes were made directly.

D. Applicability of Part A of Title XXVII of the PHS Act to Grandfathered Health Plans Paragraphs (c), (d), and (e) of 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140 of These Interim Final Regulations

A grandfathered health plan generally is not subject to subtitles A and C of title I of the Affordable Care Act, except as specifically provided by the statute and these interim final regulations. The statute and these interim final regulations provide that some provisions of subtitles A and C of title I of the Affordable Care Act continue to

apply to all grandfathered health plans and some provisions continue to apply only to grandfathered health plans that are group health plans. These interim final regulations clarify that a grandfathered health plan must continue to comply with the requirements of the PHS Act, ERISA, and the Code that were applicable prior to the changes enacted by the Affordable Care Act, except to the extent supplanted by changes made by the Affordable Care Act. Therefore, the HIPAA portability and nondiscrimination requirements and the Genetic Information Nondiscrimination

Act requirements applicable prior to the effective date of the Affordable Care Act continue to apply to grandfathered health plans. In addition, the mental health parity provisions, the Newborns' and Mothers' Health Protection Act provisions, the Women's Health and Cancer Rights Act, and Michelle's Law continue to apply to grandfathered health plans. The following table lists the new health coverage reforms in part A of title XXVII of the PHS Act (as amended by the Affordable Care Act) that apply to grandfathered health plans:

TABLE 1—LIST OF THE NEW HEALTH REFORM PROVISIONS OF PART A OF TITLE XXVII OF THE PHS ACT THAT APPLY TO GRANDFATHERED HEALTH PLANS

PHS Act statutory provisions	Application to grandfathered health plans
§ 2704 Prohibition of preexisting condition exclusion or other discrimination based on health status.	Applicable to grandfathered group health plans and group health insurance coverage. Not applicable to grandfathered individual health insurance coverage.
§ 2708 Prohibition on excessive waiting periods	Applicable.
§ 2711 No lifetime or annual limits	Lifetime limits: Applicable. Annual limits: Applicable to grandfathered group health plans and group health insurance coverage; not applicable to grandfathered individual health insurance coverage.
§ 2712 Prohibition on rescissions	Applicable.
§ 2714 Extension of dependent coverage until age 26	Applicable ⁵ .
§ 2715 Development and utilization of uniform explanation of coverage documents and standardized definitions.	Applicable.
§ 2718 Bringing down cost of health care coverage (for insured coverage).	Applicable to insured grandfathered health plans.

⁵ For a group health plan or group health insurance coverage that is a grandfathered health plan for plan years beginning before January 1, 2014, PHS Act section 2714 is applicable in the case of an adult child only if the adult child is not eligible for other employer-sponsored health plan coverage. The interim final regulations relating to PHS Act section 2714, published in 75 FR 27122 (May 13, 2010), and these interim final regulations clarify that, in the case of an adult child who is eligible for coverage under the employer-sponsored plans of both parents, neither parent's plan may exclude the adult child from coverage based on the fact that the adult child is eligible to enroll in the other parent's employer-sponsored plan.

E. Health Insurance Coverage Maintained Pursuant to a Collective Bargaining Agreement of Paragraph (f) of 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140 of These Interim Final Regulations

In paragraph (f) of 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140, these interim final regulations provide that in the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements ratified before March 23, 2010, the coverage is a grandfathered health plan at least until the date on which the last agreement relating to the coverage that was in effect on March 23, 2010 terminates. Thus, before the last of the applicable collective bargaining agreement terminates, any health insurance coverage provided pursuant to the collective bargaining agreements is a grandfathered health plan, even if there is a change in issuers (or any other change described in paragraph (g)(1) of

26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140 of these interim final regulations) during the period of the agreement. The statutory language of the provision refers solely to “health insurance coverage” and does not refer to a group health plan; therefore, these interim final regulations apply this provision only to insured plans maintained pursuant to a collective bargaining agreement and not to self-insured plans. After the date on which the last of the collective bargaining agreements terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of paragraph (g). This determination is made by comparing the terms of the coverage on the date of determination with the terms of the coverage that were in effect on March 23, 2010. A change in issuers during the period of the agreement, by itself, would not cause the plan to cease to be a

grandfathered health plan at the termination of the agreement. However, for a change in issuers after the termination of the agreement, the rules of paragraph (a)(1)(ii) of 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140 of these interim final regulations apply.

Similar language to section 1251(d) in related bills that were not enacted would have provided a delayed effective date for collectively bargained plans with respect to the Affordable Care Act requirements. Questions have arisen as to whether section 1251(d) as enacted in the Affordable Care Act similarly operated to delay the application of the Affordable Care Act's requirements to collectively bargained plans—specifically, whether the provision of section 1251(d) that exempts collectively bargained plans from requirements for the duration of the agreement effectively provides the plans with a delayed effective date with respect to all new PHS Act requirements (in contrast to the rules for

grandfathered health plans which provide that specified PHS Act provisions apply to all plans, including grandfathered health plans). However, the statutory language that applies only to collectively bargained plans, as signed into law as part of the Affordable Care Act, provides that insured collectively bargained plans in which individuals were enrolled on the date of enactment are included in the definition of a grandfathered health plan. Therefore, collectively bargained plans (both insured and self-insured) that are grandfathered health plans are subject to the same requirements as other grandfathered health plans, and are not provided with a delayed effective date for PHS Act provisions with which other grandfathered health plans must comply. Thus, the provisions that apply to grandfathered health plans apply to collectively bargained plans before and after termination of the last of the applicable collective bargaining agreement.

F. Maintenance of Grandfather Status of Paragraph (g) of 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 of These Interim Final Regulations)

Questions have arisen regarding the extent to which changes can be made to a plan or health insurance coverage and still have the plan or coverage considered the same as that in existence on March 23, 2010, so as to maintain status as a grandfathered health plan. Some have suggested that any change would cause a plan or health insurance coverage to be considered different and thus cease to be a grandfathered health plan. Others have suggested that any degree of change, no matter how large, is irrelevant provided the plan or health insurance coverage can trace some continuous legal relationship to the plan or health insurance coverage that was in existence on March 23, 2010.

In paragraph (g)(1) of 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 of these interim final regulations, coordinated rules are set forth for determining when changes to the terms of a plan or health insurance coverage cause the plan or coverage to cease to be a grandfathered health plan. The first of those rules (in paragraph (g)(1)(i)) constrains the extent to which the scope of benefits can be reduced. It provides that the elimination of all or substantially all benefits to diagnose or treat a particular condition causes a plan or health insurance coverage to cease to be a grandfathered health plan. If, for example, a plan eliminates all benefits for cystic fibrosis, the plan ceases to be a grandfathered

health plan (even though this condition may affect relatively few individuals covered under the plan). Moreover, for purposes of paragraph (g)(1)(i), the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition. An example in these interim final regulations illustrates that if a plan provides benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs, and subsequently eliminates benefits for counseling, the plan is treated as having eliminated all or substantially all benefits for that mental health condition.

A second set of rules (in paragraphs (g)(1)(ii) through (g)(1)(iv)) limits the extent to which plans and issuers can increase the fixed-amount and the percentage cost-sharing requirements that are imposed with respect to individuals for covered items and services. Plans and issuers can choose to make larger increases to fixed-amount or percentage cost-sharing requirements than permissible under these interim final regulations, but at that point the individual's plan or health insurance coverage would cease to be grandfathered health plan coverage. A more detailed description of the basis for the cost-sharing requirements in these interim final regulations is included in section IV.B later in this preamble.

These interim final regulations provide different standards with respect to coinsurance and fixed-amount cost sharing. Coinsurance automatically rises with medical inflation. Therefore, changes to the level of coinsurance (such as moving from a requirement that the patient pay 20 percent to a requirement that the patient pay 30 percent of inpatient surgery costs) would significantly alter the level of benefits provided. On the other hand, fixed-amount cost-sharing requirements (such as copayments and deductibles) do not take into account medical inflation. Therefore, changes to fixed-amount cost-sharing requirements (for example, moving from a \$35 copayment to a \$40 copayment for outpatient doctor visits) may be reasonable to keep up with the rising cost of medical items and services. Accordingly, paragraph (g)(1)(ii) provides that any increase in a percentage cost-sharing requirement (such as coinsurance) causes a plan or health insurance coverage to cease to be a grandfathered health plan.

With respect to fixed-amount cost-sharing requirements, paragraph (g)(1)(iii) provides two rules: a rule for

cost-sharing requirements other than copayments and a rule for copayments. Fixed-amount cost-sharing requirements include, for example, a \$500 deductible, a \$30 copayment, or a \$2,500 out-of-pocket limit. With respect to fixed-amount cost-sharing requirements other than copayments, a plan or health insurance coverage ceases to be a grandfathered health plan if there is an increase, since March 23, 2010, in a fixed-amount cost-sharing requirement that is greater than the maximum percentage increase. The maximum percentage increase is defined as medical inflation (from March 23, 2010) plus 15 percentage points. For this purpose, medical inflation is defined in these interim final regulations by reference to the overall medical care component of the Consumer Price Index for All Urban Consumers, unadjusted (CPI), published by the Department of Labor. For fixed-amount copayments, a plan or health insurance coverage ceases to be a grandfathered health plan if there is an increase since March 23, 2010 in the copayment that exceeds the greater of (A) the maximum percentage increase or (B) five dollars increased by medical inflation. A more detailed description of the basis for these rules relating to cost-sharing requirements is included in section IV.B later in this preamble.

With respect to employer contributions, these interim final regulations include a standard for changes that would result in cessation of grandfather status. Specifically, paragraph (g)(1)(v) limits the ability of an employer or employee organization to decrease its contribution rate for coverage under a group health plan or group health insurance coverage. Two different situations are addressed. First, if the contribution rate is based on the cost of coverage, a group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate towards the cost of any tier of coverage for any class of similarly situated individuals⁶ by more than 5 percentage points below the contribution rate on March 23, 2010. For this purpose, contribution rate is defined as the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. These interim final regulations provide that total cost of coverage is determined in the same manner as the applicable

⁶ Similarly situated individuals are described in the HIPAA nondiscrimination regulations at 26 CFR 54.9802-1(d), 29 CFR 2590.702(d), and 45 CFR 146.121(d).

premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are calculated by subtracting the employee contributions towards the total cost of coverage from the total cost of coverage. Second, if the contribution rate is based on a formula, such as hours worked or tons of coal mined, a group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate towards the cost of any tier of coverage for any class of similarly situated individuals by more than 5 percent below the contribution rate on March 23, 2010.

Finally, paragraph (g)(1)(vi) addresses the imposition of a new or modified annual limit by a plan, or group or individual health insurance coverage.⁷ Three different situations are addressed:

- A plan or health insurance coverage that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits.
- A plan or health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010.
- A plan or health insurance coverage that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

Under these interim final regulations, changes other than the changes

⁷ Independent of these rules regarding the impact on grandfather status of newly adopted or reduced annual limits, group health plans and group or individual health insurance coverage (other than individual health insurance policies that are grandfathered health plans) are required to comply with PHS Act section 2711, which permits restricted annual limits (as defined in regulations) until 2014. The Departments expect to publish regulations regarding restricted annual limits in the very near future.

described in 26 CFR 54.9815–1251T(g)(1), 29 CFR 2590.715–1251(g)(1), and 45 CFR 147.140(g)(1) will not cause a plan or coverage to cease to be a grandfathered health plan. Examples include changes to premiums, changes to comply with Federal or State legal requirements, changes to voluntarily comply with provisions of the Affordable Care Act, and changing third party administrators, provided these changes are made without exceeding the standards established by paragraph (g)(1).

These interim final regulations provide transitional rules for plans and issuers that made changes after the enactment of the Affordable Care Act pursuant to a legally binding contract entered into prior to enactment, made changes to the terms of health insurance coverage pursuant to a filing before March 23, 2010 with a State insurance department, or made changes pursuant to written amendments to a plan that were adopted prior to March 23, 2010. If a plan or issuer makes changes in any of these situations, the changes are effectively considered part of the plan terms on March 23, 2010 even though they are not then effective. Therefore, such changes are not taken into account in considering whether the plan or health insurance coverage remains a grandfathered health plan.

Because status as a grandfathered health plan under section 1251 of the Affordable Care Act is determined in relation to coverage on March 23, 2010, the date of enactment of the Affordable Care Act, the Departments considered whether they should provide a good-faith compliance period from Departmental enforcement until guidance regarding the standards for maintaining grandfather status was made available to the public. Group health plans and health insurance issuers often make routine changes from year to year, and some plans and issuers may have needed to implement such changes prior to the issuance of these interim final regulations.

Accordingly, for purposes of enforcement, the Departments will take into account good-faith efforts to comply with a reasonable interpretation of the statutory requirements and may disregard changes to plan and policy terms that only modestly exceed those changes described in paragraph (g)(1) of 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140 and that are adopted before June 14, 2010, the date the regulations were made publicly available.

In addition, these interim final regulations provide employers and issuers with a grace period within

which to revoke or modify any changes adopted prior to June 14, 2010, where the changes might otherwise cause the plan or health insurance coverage to cease to be a grandfathered health plan. Under this rule, grandfather status is preserved if the changes are revoked, and the plan or health insurance coverage is modified, effective as of the first day of the first plan or policy year beginning on or after September 23, 2010 to bring the terms within the limits for retaining grandfather status in these interim final regulations. For this purpose, and for purposes of the reasonable good faith standard changes will be considered to have been adopted before these interim final regulations are publicly available if the changes are effective before that date, the changes are effective on or after that date pursuant to a legally binding contract entered into before that date, the changes are effective on or after that date pursuant to a filing before that date with a State insurance department, or the changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

While the Departments have determined that the changes identified in paragraph (g)(1) of these interim final regulations would cause a group health plan or health insurance coverage to cease to be a grandfathered health plan, the Departments invite comments from the public on whether this list of changes is appropriate and what other changes, if any, should be added to this list. Specifically, the Departments invite comments on whether the following changes should result in cessation of grandfathered health plan status for a plan or health insurance coverage: (1) Changes to plan structure (such as switching from a health reimbursement arrangement to major medical coverage or from an insured product to a self-insured product); (2) changes in a network plan's provider network, and if so, what magnitude of changes would have to be made; (3) changes to a prescription drug formulary, and if so, what magnitude of changes would have to be made; or (4) any other substantial change to the overall benefit design. In addition, the Departments invite comments on the specific standards included in these interim final regulations on benefits, cost sharing, and employer contributions. The Departments specifically invite comments on whether these standards should be drawn differently in light of the fact that changes made by the Affordable Care Act may alter plan or issuer practices in the next several

years. Any new standards published in the final regulations that are more restrictive than these interim final regulations would only apply prospectively to changes to plans or health insurance coverage after the publication of the final rules.

Moreover, the Departments may issue, as appropriate, additional administrative guidance other than in the form of regulations to clarify or interpret the rules contained in these interim final regulations for maintaining grandfathered health plan status prior to the issuance of final regulations. The ability to issue prompt, clarifying guidance is especially important given the uncertainty as to how plans or issuers will alter their plans or policies in response to these rules. This guidance can address unanticipated changes by plans and issuers to ensure that individuals benefit from the Affordable Care Act's new health care protections while preserving the ability to maintain the coverage individuals had on the date of enactment.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815. The rules set forth in these interim final regulations govern the applicability of the requirements in these sections and are therefore appropriate to carry them out. Therefore, the foregoing interim final rule authority applies to these interim final regulations.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public

interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, numerous provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Grandfathered health plans are exempt from many of these provisions while group health plans and group and individual health insurance coverage that are not grandfathered health plans must comply with them. The determination of whether a plan or health insurance coverage is a grandfathered health plan therefore could substantially affect the design of the plan or health insurance coverage.

The six-month period between the enactment of the Affordable Care Act and the applicability of many of the provisions affected by grandfather status would not allow sufficient time for the Departments to draft and publish proposed regulations, receive and consider comments, and draft and publish final regulations. Moreover, regulations are needed well in advance of the effective date of the requirements of the Affordable Care Act. Many group health plans and health insurance coverage that are not grandfathered health plans must make significant changes in their provisions to comply with the requirements of the Affordable Care Act. Moreover, plans and issuers considering other modifications to their terms need to know whether those modifications will affect their status as grandfathered health plans. Accordingly, in order to allow plans and health insurance coverage to be designed and implemented on a timely basis, regulations must be published and available to the public well in advance of the effective date of the requirements of the Affordable Care Act. It is not possible to have a full notice and comment process and to publish final regulations in the brief time between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the

interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these regulations into effect, and that it is in the public interest to promulgate interim final regulations.

IV. Economic Impact and Paperwork Burden

A. Overview—Department of Labor and Department of Health and Human Services

As stated earlier in this preamble, these interim final regulations implement section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act. Pursuant to section 1251, certain provisions of the Affordable Care Act do not apply to a group health plan or health insurance coverage in which an individual was enrolled on March 23, 2010 (a grandfathered health plan).⁸ The statute and these interim final regulations allow family members of individuals already enrolled in a grandfathered health plan to enroll in the plan after March 23, 2010; in such cases, the plan or coverage is also a grandfathered health plan with respect to the family members. New employees (whether newly hired or newly enrolled) and their families can enroll in a grandfathered group health plan after March 23, 2010 without affecting status as a grandfathered health plan.⁹

⁸The Affordable Care Act adds section 715(a)(1) to ERISA and section 9815(a)(1) to the Code to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes. Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act, specifies that certain plans or coverage existing as of the date of enactment (that is, grandfathered health plans) are only subject to certain provisions.

⁹For individuals who have coverage through an insured group health plans subject to a collective bargaining agreement ratified before March 23, 2010, an individual's coverage is grandfathered at least until the date on which the last agreement relating to the coverage that was in effect on March 23, 2010, terminates. These collectively bargained plans may make any permissible changes to the benefit structure before the agreement terminates and remain grandfathered. After the termination

Continued

As addressed earlier in this preamble, and further discussed below, these interim final regulations include rules for determining whether changes to the terms of a grandfathered health plan made by issuers and plan sponsors allow the plan or health insurance coverage to remain a grandfathered health plan. These rules are the primary focus of this regulatory impact analysis.

The Departments have quantified the effects where possible and provided a qualitative discussion of the economic effects and some of the transfers and costs that may result from these interim final regulations.

B. Executive Order 12866—Department of Labor and Department of Health and Human Services

Under Executive Order 12866 (58 FR 51735), “significant” regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a “significant regulatory action” as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. OMB has determined that this regulation is economically significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an annual effect on the economy of \$100 million in any one year. Accordingly, OMB has reviewed these rules pursuant to the Executive Order. The Departments provide an assessment of the potential costs, benefits, and transfers associated with these interim final regulations below. The Departments invite comments on this assessment and its conclusions.

date, grandfather status will be determined by comparing the plan, as it existed on March 23, 2010 to the changes that the plan made before termination under the rules established by these interim final regulations.

1. Need for Regulatory Action

As discussed earlier in this preamble, Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act, provides that grandfathered health plans are subject only to certain provisions of the Affordable Care Act. The statute, however, is silent regarding changes plan sponsors and issuers can make to plans and health insurance coverage while retaining grandfather status. These interim final regulations are necessary in order to provide rules that plan sponsors and issuers can use to determine which changes they can make to the terms of the plan or health insurance coverage while retaining their grandfather status, thus exempting them from certain provisions of the Affordable Care Act and fulfilling a goal of the legislation, which is to allow those that like their healthcare to keep it. These interim final regulations are designed to allow individuals who wish to maintain their current health insurance plan to do so, to reduce short term disruptions in the market, and to ease the transition to market reforms that phase in over time.

In drafting this rule, the Departments attempted to balance a number of competing interests. For example, the Departments sought to provide adequate flexibility to plan sponsors and issuers to ease transition and mitigate potential premium increases while avoiding excessive flexibility that would conflict with the goal of permitting individuals who like their healthcare to keep it and might lead to longer term market segmentation as the least costly plans remain grandfathered the longest. In addition, the Departments recognized that many plan sponsors and issuers make changes to the terms of plans or health insurance coverage on an annual basis: Premiums fluctuate, provider networks and drug formularies change, employer and employee contributions and cost-sharing change, and covered items and services may vary. Without some ability to make some adjustments while retaining grandfather status, the ability of individuals to maintain their current coverage would be frustrated, because most plans or health insurance coverage would quickly cease to be regarded as the same group health plan or health insurance coverage in existence on March 23, 2010. At the same time, allowing unfettered changes while retaining grandfather status would also be inconsistent with Congress’s intent to preserve coverage that was in effect on March 23, 2010.

Therefore, as further discussed below, these interim final regulations are designed, among other things, to take into account reasonable changes routinely made by plan sponsors or issuers without the plan or health insurance coverage relinquishing its grandfather status so that individuals can retain the ability to remain enrolled in the coverage in which they were enrolled on March 23, 2010. Thus, for example, these interim final regulations generally permit plan sponsors and issuers to make voluntary changes to increase benefits, to conform to required legal changes, and to adopt voluntarily other consumer protections in the Affordable Care Act.

2. Regulatory Alternatives

Section 6(a)(3)(C)(iii) of Executive Order 12866 requires an economically significant regulation to include an assessment of the costs and benefits of potentially effective and reasonable alternatives to the planned regulation, and an explanation of why the planned regulatory action is preferable to the potential alternatives. The alternatives considered by the Departments fall into two general categories: Permissible changes to cost sharing and benefits. The discussion below addresses the considered alternatives in each category.

The Departments considered allowing looser cost-sharing requirements, such as 25 percent plus medical inflation. However, the data analysis led the Departments to believe that the cost-sharing windows provided in these interim final regulations permit enough flexibility to enable a smooth transition in the group market over time, and further widening this window was not necessary and could conflict with the goal of allowing those who like their healthcare to keep it.

Another alternative the Departments considered was an annual allowance for cost-sharing increases above medical inflation, as opposed to the one-time allowance of 15 percent above medical inflation. An annual margin of 15 percent above medical inflation, for example, would permit plans to increase cost sharing by medical inflation plus 15 percent every year. The Departments concluded that the effect of the one-time allowance (15 percent of the original, date-of-enactment level plus medical inflation) would diminish over time insofar as it would represent a diminishing fraction of the total level of cost sharing with the cumulative effects of medical inflation over time. Accordingly, the one-time allowance would better reflect (i) the potential need of grandfathered health plans to make adjustments in the near term to

reflect the requirement that they comply with the market reforms that apply to grandfathered health plans in the near term as well as (ii) the prospect that, for many plans and health insurance coverage, the need to recover the costs of compliance in other ways will diminish in the medium term, in part because of the changes that will become effective in 2014 and in part because of the additional time plan sponsors and issuers will have to make gradual adjustments that take into account the market reforms that are due to take effect in later years.

The Departments considered establishing an overall prohibition against changes that, in the aggregate, or cumulatively over time, render the plan or coverage substantially different than the plan or coverage that existed on March 23, 2010, or further delineating other examples of changes that could cause a plan to relinquish grandfather status. This kind of “substantially different” standard would have captured significant changes not anticipated in the interim final regulation. However, it would rely on a “facts and circumstances” analysis in defining “substantially different” or “significant changes,” which would be less transparent and result in greater uncertainty about the status of a health plan. That, in turn, could hinder plan sponsor or issuer decisions as well as enrollee understanding of what protections apply to their coverage.

An actuarial equivalency standard was another considered option. Such a standard would allow a plan or health insurance coverage to retain status as a grandfathered health plan if the actuarial value of the coverage remains in approximately the same range as it was on March 23, 2010. However, under such a standard, a plan could make fundamental changes to the benefit design, potentially conflicting with the goal of allowing those who like their healthcare to keep it, and still retain grandfather status. Moreover, the complexity involved in defining and determining actuarial value for these purposes, the likelihood of varying methodologies for determining such value unless the Departments promulgated very detailed prescriptive rules, and the costs of administering and ensuring compliance with such rules led the Departments to reject that approach.

Another alternative was a requirement that employers continue to contribute the same dollar amount they were contributing for the period including March 23, 2010, plus an inflation component. However, the Departments were concerned that this approach would not provide enough flexibility to accommodate the year-to-year volatility in premiums that can result from changes in some plans’ covered populations or other factors.

The Departments also considered whether a change in third party administrator by a self-insured plan should cause the plan to relinquish grandfather status. The Departments decided that such a change would not necessarily cause the plan to be so different from the plan in effect on March 23, 2010 that it should be required to relinquish grandfather status.

After careful consideration, the Departments opted against rules that would require a plan sponsor or issuer to relinquish its grandfather status if only relatively small changes are made to the plan. The Departments concluded that plan sponsors and issuers of grandfathered health plans should be permitted to take steps within the boundaries of the grandfather definition to control costs, including limited increases in cost-sharing and other plan changes not prohibited by these interim final regulations. As noted earlier, deciding to relinquish grandfather status is a one-way sorting process: after some period of time, more plans will relinquish their grandfather status. These interim final regulations will likely influence plan sponsors’ decisions to relinquish grandfather status.

3. Discussion of Regulatory Provisions

As discussed earlier in this preamble, these interim final regulations provide that a group health plan or health insurance coverage no longer will be considered a grandfathered health plan if a plan sponsor or an issuer:

- Eliminates all or substantially all benefits to diagnose or treat a particular condition. The elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition;
- Increases a percentage cost-sharing requirement (such as coinsurance)

above the level at which it was on March 23, 2010;

- Increases fixed-amount cost-sharing requirements other than copayments, such as a \$500 deductible or a \$2,500 out-of-pocket limit, by a total percentage measured from March 23, 2010 that is more than the sum of medical inflation and 15 percentage points.¹⁰

- Increases copayments by an amount that exceeds the greater of: a total percentage measured from March 23, 2010 that is more than the sum of medical inflation plus 15 percentage points, or \$5 increased by medical inflation measured from March 23, 2010;

- For a group health plan or group health insurance coverage, an employer or employee organization decreases its contribution rate by more than five percentage points below the contribution rate on March 23, 2010; or

- With respect to annual limits (1) a group health plan, or group or individual health insurance coverage, that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits imposes an overall annual limit on the dollar value of benefits; (2) a group health plan, or group or individual health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010; or (3) a group health plan, or group or individual health insurance coverage, that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposes an overall lifetime limit on the dollar value of all benefits).

Table 1, in section II.D of this preamble, lists the relevant Affordable Care Act provisions that apply to grandfathered health plans.

In accordance with OMB Circular A-4,¹¹ Table 2 below depicts an accounting statement showing the Departments’ assessment of the benefits, costs, and transfers associated with this regulatory action. In accordance with Executive Order 12866, the Departments believe that the benefits of this regulatory action justify the costs.

¹⁰ Medical inflation is defined in these interim regulations by reference to the overall medical care component of the CPI.

¹¹ Available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

TABLE 2—ACCOUNTING TABLE

Benefits

Qualitative: These interim final regulations provide plans with guidance about the requirements for retaining grandfather status. Non-grandfathered plans are required to offer coverage with minimum benefit standards and patient protections as required by the Affordable Care Act, while grandfathered plans are required only to comply with certain provisions. The existence of grandfathered health plans will provide individuals with the benefits of plan continuity, which may have a high value to some. In addition, grandfathering could potentially slow the rate of premium growth, depending on the extent to which their current plan does not include the benefits and protections of the new law. It could also provide incentives to employers to continue coverage, potentially reducing new Medicaid enrollment and spending and lowering the number of uninsured individuals. These interim final regulations also provide greater certainty for plans and issuers about what changes they can make without affecting their grandfather status. As compared with alternative approaches, these regulations provide significant economic and noneconomic benefits to both issuers and beneficiaries, though these benefits cannot be quantified at this time.

Costs	Low-end estimate	Mid-range estimate	High-end estimate	Year dollar	Discount rate	Period covered
Annualized	22.0	25.6	27.9	2010	7%	2011–2013
Monetized (\$millions/year)	21.2	24.7	26.9	2010	3%	2011–2013

Monetized costs are due to a requirement to notify participants and beneficiaries of a plan’s grandfather status and maintain plan documents to verify compliance with these interim final regulation’s requirements to retain grandfather status.

Qualitative: Limitations on cost-sharing increases imposed by these interim final regulations could result in the cost of some grandfathered health plans increasing more (or decreasing less) than they otherwise would. This increased cost may encourage some sponsors and issuers to replace their grandfathered health plans with new, non-grandfathered ones. Market segmentation (adverse selection) due to the decision of higher risk plans to relinquish grandfathering could cause premiums in the exchanges to be higher than they would have been absent grandfathering.

Transfers

Qualitative: Limits on the changes to cost-sharing in grandfathered plans and the elimination of cost-sharing for some services in non-grandfathered plans, leads to transfers of wealth from premium payers overall to individuals using covered services. Once pre-existing conditions are fully prohibited and other insurance reforms take effect, the extent to which individuals are enrolled in grandfathered plans could affect adverse selection, as higher risk plans relinquish grandfather status to gain new protections while lower risk grandfathered plans retain their grandfather status. This could result in a transfer of wealth from non-grandfathered plans to grandfathered health plans.

4. Discussion of Economic Impacts of Retaining or Relinquishing Grandfather Status

The economic effects of these interim final regulations will depend on decisions by plan sponsors and issuers, as well as by those covered under these plans and health insurance coverage. The collective decisions of plan sponsors and issuers over time can be viewed as a one-way sorting process in which these parties decide whether, and when, to relinquish status as a grandfathered health plan.

Plan sponsors and issuers can decide to:

1. Continue offering the plan or coverage in effect on March 23, 2010 with limited changes, and thereby retain grandfather status;
2. Significantly change the terms of the plan or coverage and comply with Affordable Care Act provisions from which grandfathered health plans are excepted; or
3. In the case of a plan sponsor, cease to offer any plan.

For a plan sponsor or issuer, the potential economic impact of the application of the provisions in the Affordable Care Act may be one consideration in making its decisions. To determine the value of retaining the health plan’s grandfather status, each

plan sponsor or issuer must determine whether the rules applicable to grandfathered health plans are more or less favorable than the rules applicable to non-grandfathered health plans. This determination will depend on such factors as the respective prices of grandfathered and non-grandfathered health plans, as well as on the preferences of grandfathered health plans’ covered populations and their willingness to pay for benefits and patient protections available under non-grandfathered health plans. In making its decisions about grandfather status, a plan sponsor or issuer is also likely to consider the market segment (because different rules apply to the large and small group market segments), and the utilization pattern of its covered population.

In deciding whether to change a plan’s benefits or cost sharing, a plan sponsor or issuer will examine its short-run business requirements. These requirements are regularly altered by, among other things, rising costs that result from factors such as technological changes, changes in risk status of the enrolled population, and changes in utilization and provider prices. As shown below, changes in benefits and cost sharing are typical in insurance markets. Decisions about the extent of

changes will determine whether a plan retains its grandfather status. Ultimately, these decisions will involve a comparison by the plan sponsor or issuer of the long run value of grandfather status to the short-run need of that plan sponsor or issuer to adjust plan structure in order to control premium costs or achieve other business objectives.

Decisions by plan sponsors and issuers may be significantly affected by the preferences and behavior of the enrollees, especially a tendency among many towards inertia and resistance to change. There is limited research that has directly examined what drives this tendency—whether individuals remain with health plans because of simple inertia and procrastination, a lack of relevant information, or because they want to avoid risk associated with switching to new plans. One study that examined the extent to which premium changes influenced plan switching determined that younger low-risk employees were the most price-sensitive to premium changes; older, high-risk employees were the least price-sensitive. This finding suggests that, in particular, individuals with substantial health needs may be more apt to remain with a plan because of inertia as such or uncertainties associated with plan

switching rather than quality per se—a phenomenon some behavioral economists have called “status quo bias,”¹² which can be found when people stick with the status quo even though a change would have higher expected value.

Even when an enrollee could reap an economic or other advantage from changing plans, that enrollee may not make the change because of inertia, a lack of relevant information, or because of the cost and effort involved in examining new options and uncertainty about the alternatives. Consistent with well-known findings in behavioral economics, studies of private insurance demonstrate the substantial effect of inertia in the behavior of the insured. One survey found that approximately 83 percent of privately insured individuals stuck with their plans in the year prior to the survey.¹³ Among those who did change plans, well over half sought the same type of plan they had before. Those who switched plans also tended to do so for reasons other than preferring their new plans. For example, many switched because they changed jobs or their employer changed insurance offerings, compelling them to switch.

Medicare beneficiaries display similar plan loyalties. On average, only seven percent of the 17 million seniors on Medicare drug plans switch plans each year, according to the Centers for Medicare and Medicaid Services.¹⁴ Researchers have found this comparatively low rate of switching is maintained whether or not those insured have higher quality information about plan choices, and that switching has little effect on the satisfaction of the insured with their health plans.¹⁵

The incentives to change are different for people insured in the individual market than they are for those covered by group health plans or group health insurance coverage. The median length of coverage for people entering the individual market is eight months.¹⁶ In

part, this “churn” stems from the individual market’s function as a stopping place for people between jobs with employer-sponsored or other types of health insurance, but in part, the churn is due to the behavior of issuers. Evidence suggests that issuers often make policy changes such as raising deductibles as a means of attracting new, healthy enrollees who have few medical costs and so are little-concerned about such deductibles. There is also evidence that issuers use such changes to sort out high-cost enrollees from low-cost ones.¹⁷

Decisions about the value of retaining or relinquishing status as a grandfathered health plan are complex, and the wide array of factors affecting issuers, plan sponsors, and enrollees poses difficult challenges for the Departments as they try to estimate how large the presence of grandfathered health plans will be in the future and what the economic effects of their presence will be. As one example, these interim final regulations limit the extent to which plan sponsors and issuers can increase cost sharing and still remain grandfathered. The increases that are allowed provide plans and issuers with substantial flexibility in attempting to control expenditure increases. However, there are likely to be some plans and issuers that would, in the absence of these regulations, choose to make even larger increases in cost sharing than are specified here. Such plans will need to decide whether the benefits of maintaining grandfather status outweigh those expected from increasing cost sharing above the levels permitted in the interim final regulations.

A similar analysis applies to the provision that an employer’s or employee organization’s share of the total premium of a group health plan cannot be reduced by more than 5 percentage points from the share it was paying on March 23, 2010 without that plan or health insurance coverage relinquishing its grandfather status. Employers and employee organizations sponsoring group health plans or health insurance coverage may be faced with economic circumstances that would lead them to reduce their premium contributions. But reductions of greater than 5 percentage points would cause them to relinquish the grandfather status of their plans. These plan sponsors must decide whether the benefit of such premium reductions

outweigh those of retaining grandfather status.

Market dynamics affecting these decisions change in 2014, when the Affordable Care Act limits variation in premium rates for individual and small group policies. Small groups for this purpose include employers with up to 100 employees (States may limit this threshold to 50 employees until 2016). The Affordable Care Act rating rules will not apply to grandfathered health plans, but such plans will remain subject to State rating rules, which vary widely and typically apply to employers with up to 50 employees. Based on the current State rating rules, it is likely that, in many States, no rating rules will apply to group health insurance policies that are grandfathered health plans covering employers with 51 to 100 employees.¹⁸

The interaction of the Affordable Care Act and State rating rules implies that, beginning in 2014, premiums can vary more widely for grandfathered plans than for non-grandfathered plans for employers with up to 100 employees in many States. This could encourage both plan sponsors and issuers to continue grandfathered health plans that cover lower-risk groups, because these groups will be isolated from the larger, higher-risk, non-grandfathered risk pool. On the other hand, this scenario likely will encourage plan sponsors and issuers that cover higher-risk groups to end grandfathered health plans, because the group would be folded into the larger, lower-risk non-grandfathered pool. Depending on the size of the grandfathered health plan market, such adverse selection by grandfathered health plans against non-grandfathered plans could cause premiums in the exchanges to be higher than they would have been absent grandfathering. To accommodate these changes in market dynamics in 2014, the Departments have structured a cost-sharing rule whose parameters enable greater flexibility in early years and less over time. It is likely that few plans will delay for many years before making changes that exceed medical inflation. This is because the cumulative increase in copayments from March 23, 2010 is compared to a maximum percentage increase that includes a fixed amount—15 percentage points—that does not increase annually with any type of inflator. This should help mitigate adverse selection and require plans and issuers that seek to maintain grandfather status to find ways other than increased

¹² <http://www.nber.org/reporter/summer06/buchmueller.html>. “Consumer Demand for Health Insurance” The National Bureau of Economic Research (Buchmueller, 2006).

¹³ <http://content.healthaffairs.org/cgi/reprint/19/3/158.pdf>. “Health Plan Switching: Choice Or Circumstance?” (Cunningham and Kohn, 2000).

¹⁴ <http://www.kaiserhealthnews.org/Stories/2009/December/01/Medicare-Drug-Plan.aspx>. “Seniors Often Reluctant To Switch Medicare Drug Plans” (2009, Kaiser Health News/Washington Post).

¹⁵ <http://www.ncbi.nlm.nih.gov/pubmed/16704882>. “The effect of quality information on consumer health plan switching: evidence from the Buyers Health Care Action Group.” (Abraham, Feldman, Carlin, and Christianson, 2006).

¹⁶ Erika C. Ziller, Andrew F. Coburn, Timothy D. McBride, and Courtney Andrews. Patterns of

Individual Health Insurance Coverage, 1996–2000. *Health Affairs* Nov/Dec 2004; 210–221.

¹⁷ Melinda Beeuwkes Bustin, M. Susan Marquis, and Jill M. Yegian. The Role of the Individual Health Insurance Market and Prospects for Change. *Health Affairs* 2004; 23(6): 79–90.

¹⁸ Kaiser Family Foundation State Health Facts (2010), <http://www.statehealthfacts.org/comparetable.jsp?ind=351&cat=7>.

copayments to limit cost growth. As discussed in the preamble, the Departments are also soliciting comments to make any adjustments needed for the final rule prior to 2014. Therefore it is premature to estimate the economic effects described above in 2014 and beyond. In the following section, the Departments provide a range of estimates of how issuers and sponsors might respond to these interim final regulations, with the caveat that there is substantial uncertainty about actual outcomes, especially considering that available data are historical and so do not account for behavioral changes in plans and the insured as a result of enactment of the Affordable Care Act.

5. Estimates of Number of Plans and Employees Affected

The Affordable Care Act applies to group health plans and health insurance issuers in the group and individual markets. The large and small group markets will be discussed first, followed by a discussion of impacts on the individual market. The Departments have defined a large group health plan as a plan at an employer with 100 or more workers and a small group plan as a plan at an employer with less than 100 workers. Using data from the 2008 Medical Expenditure Survey—Insurance Component, the Departments estimated that there are approximately 72,000 large ERISA-covered health plans and 2.8 million small group health plans with an estimated 97.0 million participants and beneficiaries¹⁹ in large group plans and 40.9 million participants and beneficiaries in small group plans. The Departments estimate that there are 126,000 governmental plans²⁰ with 36.1 million participants in large plans and 2.3 million participants in small plans. The Departments estimate there are 16.7 million individuals under age 65 covered by individually purchased policies.

a. Methodology for Analyzing Plan Changes Over Time in the Group Market

For the large and small group markets, the Departments analyzed three years of Kaiser-HRET data to assess the changes that plans made between plan years 2007 to 2008 and 2008 to 2009. Specifically, the Departments examined changes made to deductibles, out-of-pocket maximums, copayments, coinsurance, and the employer's share of the premium or cost of coverage. The

Departments also estimated the number of fully-insured plans that changed issuers.²¹ The distribution of changes made within the two time periods were nearly identical and ultimately the 2008–2009 changes were used as a basis for the analyses.

As discussed previously, plans will need to make decisions that balance the value they (and their enrollees) place on maintaining grandfather status with the need to meet short run objectives by changing plan features including the various cost sharing requirements that are the subject of this rule. The 2008–2009 data reflect changes in plan benefit design that were made under very different market conditions and expectations than will exist in 2011 and beyond. Therefore, there is a significant degree of uncertainty associated with using the 2008–2009 data to project the number of plans whose grandfather status may be affected in the next few years. Because the level of uncertainty becomes substantially greater when trying to use this data to predict outcomes once the full range of reforms takes effect in 2014 and the exchanges begin operating, substantially changing market dynamics the Departments restrict our estimates to the 2011–2013 period and use the existing data and a range of assumptions to estimate possible outcomes based on a range of assumptions concerning how plans' behavior regarding cost sharing changes may change relative to what is reflected in the 2008–2009 data.

Deriving projections of the number of plans that could retain grandfather status under the requirements of these interim final regulations required several steps:

- Using Kaiser/HRET data for 2008–2009, estimates were generated of the number of plans in the large and small group markets that made changes in employer premium share or any of the cost-sharing parameters that were larger than permitted for a plan to retain grandfather status under these interim final regulations;
- In order to account for a range of uncertainty with regard to changes in plan behavior toward cost sharing changes, the Departments assumed that many plans will want to maintain grandfather status and will look for ways to achieve short run cost control and still maintain that status. One plausible assumption is that plans would look to a broader range of cost sharing strategies in order to achieve

cost containment and other objectives than they had in the past. In order to examine this possibility, the Departments carefully analyzed those plans that would have relinquished grandfather status based on a change they made from 2008–2009. The Departments then estimated the proportion of these plans that could have achieved similar cost control by using one or more other cost-sharing changes in addition to the one they made in a manner that would not have exceeded the limits set by these interim final regulations for qualifying as a grandfathered health plan. For example, if a plan was estimated to relinquish grandfather status because it increased its deductible by more than the allowed 15 percentage points plus medical inflation, the Departments analyze whether the plan could have achieved the same cost control objectives with a smaller change in deductible, but larger changes (within the limits set forth in these interim final regulations) in copayments, out-of-pocket maximums, and employer contributions to the premium or cost of coverage.

- Finally, the Departments examined the impact of alternative assumptions about sponsor behavior. For example, it is possible that some sponsors who made changes from 2008–2009 in plan parameters that were so large that they would have relinquished their grandfather status would not make similar changes in 2011–2013. It is also possible that even though a sponsor could make an equivalent change that conforms to the rules established in these interim final regulations to maintain grandfather status, it would decide not to.

The estimates in this example rely on several other assumptions. Among them: (1) The annual proportion of plans relinquishing grandfather status is the same throughout the period; (2) all group health plans existing at the beginning of 2010 qualify for grandfather status; (3) all changes during 2010 occur after March 23, 2010; (4) annual medical inflation is 4 percent (based on the average annual change in the medical CPI between 2000 and 2009); and (5) firms for which the Kaiser-HRET survey has data for both 2008 and 2009 are representative of all firms.²² The assumption used for

¹⁹ All participant counts and the estimates of individual policies are from the 2009 Current Population Survey (CPS).

²⁰ Estimate is from the 2007 Census of Government.

²¹ Under the Affordable Care Act and these interim final regulations, if a plan that is not a collectively bargained plan changes issuers after March 23, 2010, it is no longer a grandfathered health plan.

²² The analysis is limited to firms that responded to the Kaiser/HRET survey in both 2008 and 2009. Large firms are overrepresented in the analytic sample. New firms and firms that went out of business in 2008 or 2009 are underrepresented. The Departments present results separately for large firms and small firms, and weight the results to the number of employees in each firm-size category. Results are presented for PPO plans. The Kaiser/

estimating the effects of the limits on copayment increases does not take into account the greater flexibility in the near term than in the long term; the estimated increase in firms losing their grandfather status over time reflects cumulative effects of a constant policy. To the extent that the data reflect plans that are more likely to make frequent changes in cost sharing, the assumption that a constant share of plans relinquishing grandfather status throughout the period may underestimate the number of plans that will retain grandfather status through 2013. In addition, data on substantial benefit changes were not available and thus not included in the analysis. The survey data is limited, in that it covers only one year of changes in healthcare plans. The Departments' analysis employed data only on PPO plans, the predominant type of plan. In addition, the difficulties of forecasting behavior in response to this rule create uncertainties for quantitative evaluation. However, the analysis presented here is illustrative of the rule's goal of balancing flexibility with maintaining current coverage.

b. Impacts on the Group Market Resulting From Changes From 2008 to 2009

The Departments first estimated the percentage of plans that had a percent change in the dollar value of deductibles, copayments, or out-of-pocket maximums that exceeded 19 percent (the sum of medical inflation (assumed in these analyses to be four percent) plus 15 percentage points measured from March 23, 2010. Plans making copayment changes of five dollars or less were considered to have satisfied the copayment limit, even if that change exceeded 19 percent.²³ The Departments also estimated the number of plans for whom the percentage of

HRET survey gathers information about the PPO with the most enrollment in each year. If enrollment at a given employer shifted from one PPO to a different PPO between 2008 and 2009, then the PPO with the most enrollment in 2009 may be different than the PPO with the most enrollment in 2008. To the extent this occurred, the estimates presented here may overestimate the fraction of plans that will relinquish grandfather status. However, given the behavioral assumptions of the analysis and the need to present a range of results, the Departments believe that such overestimation will not have a noticeable effect on estimates presented here.

²³ The regulation allows plans to increase fixed-amount copayments by an amount that does not exceed \$5 increased by medical inflation. In this analysis, the Departments used a threshold of \$5, rather than the threshold of approximately \$5.20 that would be allowed by these interim final regulations. There would have been no difference in the results if the Departments had used \$5.20 rather than \$5 as the threshold.

total premium paid by the employer declined by more than 5 percentage points. For fully-insured plans only, estimates were made of the proportion that switched to a different issuer.²⁴ This estimate does not take into account collectively bargained plans, which can change issuers during the period of the collective bargaining agreement without a loss of grandfather status, because the Departments could not quantify this category of plans. Accordingly, this estimate represents an upper bound.

Using the Kaiser/HRET data, the Departments estimated that 55 percent of small employers and 36 percent of large employers made at least one change in cost-sharing parameters above the thresholds provided in these interim final regulations. Similarly, 33 percent of small employers and 21 percent of large employers decreased the employer's share of premium by more than five percentage points. In total, approximately 66 percent of small employers and 48 percent of large employers made a change in either cost sharing or premium contribution during 2009 that would require them to relinquish grandfather status if the same change were made in 2011.²⁵

The changes made by employers from 2008 to 2009 were possibly made in anticipation of the recession. As discussed previously, analysis of changes from 2007 to 2008 suggests that the 2007–08 changes were not much different from the 2008–09 changes. Nevertheless, as a result of improvements in economic conditions, it makes sense to think that the pressure on employers to reduce their contributions to health insurance will be smaller in 2011 than they were in 2009, and that the Department's analysis of changes in 2009 may overestimate the changes that should be expected in 2011.²⁶

As discussed previously, it is highly unlikely that plans would continue to exhibit the same behavior in 2011 to 2013 as in 2008 to 2009. In order to guide the choice of behavioral assumptions, the Departments

²⁴ In contrast, for self-insured plans, a change in third party administrator in and of itself does not cause a group health plan to cease to be a grandfathered health plan, provided changes do not exceed the limits of paragraph (g)(1) of these interim final regulations.

²⁵ Some employers made changes which exceeded at least one cost-sharing threshold and decreased the employer's share of contribution by more than five percent.

²⁶ Employers who offer plans on a calendar year basis generally make decisions about health plan offerings during the preceding summer. Thus, decisions for calendar 2009 were generally made during the summer of 2008. At that time, the depth of the coming recession was not yet clear to most observers.

conducted further analyses of the 2008–2009 data. Many employers who made changes between 2008 and 2009 that would have caused them to relinquish grandfather status did so based on exceeding one of the cost-sharing limits. Assuming that the sponsor's major objective in implementing these changes was to restrain employer costs or overall premiums, the Departments examined whether the sponsor could have achieved the same net effect on employer cost or premiums by spreading cost sharing over two or more changes without exceeding the limits on any of these changes. For example, an employer that increased its deductible by 30 percent would have relinquished grandfather status. However, it is possible that the employer could have achieved the same cost control objectives by limiting the deductible increase to 19 percent, and, also increasing the out-of-pocket maximum or copayments, or decreasing the employer share of the premium.

The Departments estimate that approximately two-thirds of the employers that made changes in 2009 that would have exceeded the threshold implemented by this rule could have achieved the same cost-control objective and remained grandfathered by making changes in other cost-sharing parameters or in the employer share of the premium. Only 24 percent of small employers and 16 percent of large employers could not have reconfigured the cost-sharing parameters or employer contributions in such a manner that would have allowed them to stay grandfathered. If benefit changes that are allowed within the grandfathered health plan definition were also taken into account (not possible with available data), these percentages would be even lower.

For fully insured group health plans, another change that would require a plan to relinquish grandfather status is a change in issuer. Between 2008 and 2009, 15 percent of small employers and four percent of large employers changed insurance carriers.²⁷ However, it is likely that the incentive to stay grandfathered would lead some of these employers to continue with the same issuer, making the actual share of firms relinquishing grandfather status as a result of an issuer change lower than the percentage that switched in 2009. There appears to be no empirical evidence to

²⁷ Among the 76 percent of small employers and 84 percent of large employers who could have accommodated the cost-sharing changes they desired to make within the parameters of these interim final regulations, 13 percent of the small employers and three percent of the large employers changed issuers.

provide guidance on the proportion of employers that would choose to remain with their issuer rather than relinquish grandfather status. That being so, an assumption was made that 50 percent of employers that changed issuers in 2009 would not have made a similar change in 2011 in order to retain grandfather status. It is likely that fewer employers will elect to change carriers than in recent years given that some will prefer to retain grandfather status. But it is also likely that many employers will prefer to switch carriers given a change in the issuer's network or other factors. Because there is little empirical evidence regarding the fraction of firms that would elect to switch in response to the change in regulations, we take the midpoint of the plausible range of no switching carriers at one extreme and all switching carriers at the other extreme. We therefore assume that 50 percent of employers that changed issuers in 2009 would not make a similar change in 2011 to retain grandfather status.

Combining the estimates of the percentage of employers that would relinquish grandfather status because they chose to make cost-sharing, benefit or employer contribution changes beyond the permitted parameters with the estimates of the percentage that would relinquish grandfather status because they change issuers, the Departments estimate that approximately 31 percent of small employers and 18 percent of large employers would make changes that would require them to relinquish grandfather status in 2011. The Departments use these estimates as our mid-range scenario.

c. Sensitivity Analysis: Assuming That Employers Will Be Willing To Absorb a Premium Increase in Order To Remain Grandfathered

To the extent that a large number of plans placed a high value on remaining grandfathered, it is reasonable to assume that some would consider other measures to maintain that status. In addition to the adjustments that employers could relatively easily make by simply adjusting the full set of cost-sharing parameters rather than focusing changes on a single parameter, the Departments expect that further behavioral changes in response to the incentives created by the Affordable Care Act and these interim final regulations is possible. For instance, plans could alter other benefits or could decide to accept a slight increase in plan premium or in premium contribution. All of these options would further lower the percentage of firms that would relinquish grandfather status. There is

substantial uncertainty, however, about how many firms would utilize these other avenues.

To examine the impact of this type of behavior on the estimates on the number of plans that would not maintain grandfather status, the Departments examined the magnitude of additional premium increases plans would need to implement if they were to modify their cost-sharing changes to stay within the allowable limits. Among the 24 percent of small firms that would have relinquished grandfather status based on the changes they made in 2009, 31 percent would have needed to increase premiums by 3 percent or less in order to maintain grandfather status. The analogous statistic for the 16 percent of large firms that would have relinquished grandfather status is 41 percent. It is reasonable to think that employers that are facing only a relatively small premium increase might choose to remain grandfathered.

Using these estimates, if employers value grandfathering enough that they are willing to allow premiums to increase by three percent more than their otherwise intended level (or can make changes to benefits other than cost-sharing that achieve a similar result), then 14 percent of small employers and 11 percent of large employers would relinquish grandfather status if they made the same changes in 2011 as they had in 2009. Adding in the employers who would relinquish grandfather status because they change issuers, the Departments' lower bound estimate is that approximately 21 percent of small employers and 13 percent of large employers will relinquish grandfather status in 2011.

d. Sensitivity Analysis: Incomplete Flexibility To Substitute One Cost-Sharing Mechanism for Another

Although economic conditions may cause more plans to remain grandfathered in 2011 than might be expected from analysis of the 2009 data, there are other factors that may cause the Departments' estimates of the fraction of plans retaining grandfather status to be overestimates of the fraction that will retain grandfather status. The estimates are based on the assumption that all plans that could accommodate the 2009 change they made in a single cost-sharing parameter by spreading out those changes over multiple parameters would actually do so. However, some plans and sponsors may be concerned about the labor relations consequences of reducing the employer contribution to premium. For example, if a plan increases its out-of-pocket maximum from \$3,000 to \$5,000 in 2009, it could

choose to remain grandfathered by limiting the out-of-pocket maximum to \$3,570, reducing the employer contribution and increasing the employee contribution to premium. It is not clear, however, that all plan sponsors would do so—some may see the costs in negative employee relations as larger than the benefits from remaining grandfathered. Moreover, because some plans may already nearly comply with all provisions of the Affordable Care Act, or because enrollees are of average to less favorable health status, some employers may place less value on retaining grandfather status.

With this in mind, the Departments replicated the analysis, but assumed that one-half of the employers who made a change in cost-sharing parameter that could not be accommodated without reducing the employer contribution will be unwilling to reduce the employer contribution as a share of premium. Under this assumption, the 24 percent and 16 percent estimates of the proportion of employers relinquishing grandfather status increases to approximately 37 percent and 28 percent among small and large employers, respectively. Adding in the number of employers that it is estimated will change issuers, the Departments' high-end estimate for the proportion that will relinquish grandfather status in 2011 is approximately 42 percent for small employers and 29 percent for large employers.

e. Estimates for 2011–2013

Estimates are provided above for the percentage of employers that will retain grandfather status in 2011. These estimates are extended through 2013 by assuming that the identical percentage of plan sponsors will relinquish grandfathering in each year. Again, to the extent that the 2008–2009 data reflect plans that are more likely to make frequent changes in cost sharing, this assumption will overestimate the number of plans relinquishing grandfather status in 2012 and 2013.

Under this assumption, the Departments' mid-range estimate is that 66 percent of small employer plans and 45 percent of large employer plans will relinquish their grandfather status by the end of 2013. The low-end estimates are for 49 percent and 34 percent of small and large employer plans, respectively, to have relinquished grandfather status, and the high-end estimates are 80 percent and 64 percent, respectively.

TABLE 3—ESTIMATES OF THE CUMULATIVE PERCENTAGE OF EMPLOYER PLANS RELINQUISHING THEIR GRANDFATHERED STATUS, 2011–2013

	2011	2012	2013
Low-end Estimate			
Small Employer Plans	20%	36%	49%
Large Employer Plans	13%	24%	34%
All Employer Plans	15%	28%	39%
Mid-range Estimate			
Small Employer Plans	30%	51%	66%
Large Employer Plans	18%	33%	45%
All Employer Plans	22%	38%	51%
High-end Estimate			
Small Employer Plans	42%	66%	80%
Large Employer Plans	29%	50%	64%
All Employer Plans	33%	55%	69%

Notes: Represents full-time employees. Small Employers=3 to 99 employees; Large Employers=100+ employees. All three scenarios assume that two percent of all large employer plans and six percent of small employer plans would relinquish grandfathered status due to a change in issuer. Estimates are based on enrollment in PPOs.

Source: Kaiser/RHET Employer Survey, 2008–2009

f. Impacts on the Individual Market

The market for individual insurance is significantly different than that for group coverage. This affects estimates of the proportion of plans that will remain grandfathered until 2014. As mentioned previously, the individual market is a residual market for those who need insurance but do not have group coverage available and do not qualify for public coverage. For many, the market is transitional, providing a bridge between other types of coverage. One study found a high percentage of individual insurance policies began and ended with employer-sponsored coverage.²⁸ More importantly, coverage on particular policies tends to be for short periods of time. Reliable data are scant, but a variety of studies indicate that between 40 percent and 67 percent of policies are in effect for less than one year.²⁹ Although data on changes in benefit packages comparable to that for the group market is not readily available, the high turnover rates described here would dominate benefit changes as the chief source of changes in grandfather status.

While a substantial fraction of individual policies are in force for less than one year, a small group of individuals maintain their policies over longer time periods. One study found that 17 percent of individuals maintained their policies for more than two years,³⁰ while another found that

nearly 30 percent maintained policies for more than three years.³¹

Using these turnover estimates, a reasonable range for the percentage of individual policies that would terminate, and therefore relinquish their grandfather status, is 40 percent to 67 percent. These estimates assume that the policies that terminate are replaced by new individual policies, and that these new policies are not, by definition, grandfathered. In addition, the coverage that some individuals maintain for long periods might lose its grandfather status because the cost-sharing parameters in policies change by more than the limits specified in these interim final regulations. The frequency of this outcome cannot be gauged due to lack of data, but as a result of it, the Departments estimate that the percentage of individual market policies losing grandfather status in a given year exceeds the 40 percent to 67 percent range that is estimated based on the fraction of individual policies that turn over from one year to the next.

g. Application to Extension of Dependent Coverage to Age 26

One way to assess the impact of these interim final regulations is to assess how they interact with other Affordable Care Act provisions. One such provision is the requirement that, in plan years on or after September 23, 2010, but prior to January 1, 2014, grandfathered group health plans are required to offer dependent coverage to a child under the age of 26 who is not eligible for employer-sponsored insurance. In the Regulatory Impact Assessment (RIA) for the regulation that was issued on May

13, 2010 (75 FR 27122), the Departments estimated that there were 5.3 million young adults age 19–25 who were covered by employer-sponsored coverage (ESI) and whose parents were covered by employer-sponsored insurance, and an additional 480,000 young adults who were uninsured, were offered ESI, and whose parents were covered by ESI. In that impact assessment, the Departments assumed that all parents with employer-sponsored insurance would be in grandfathered health plans, and that none of their 19–25 year old dependents with their own offer of employer-sponsored insurance would gain coverage as a result of that regulation.

As estimated here, approximately 80 percent of the parents with ESI are likely to be in grandfathered health plans in 2011, leaving approximately 20 percent of these parents in non-grandfathered health plans. Young adults under 26 with employer-sponsored insurance or with an offer of such coverage whose parents are in non-grandfathered plans potentially could enroll in their parents' coverage. The Departments assume that a large percentage of the young adults who are uninsured will enroll in their parents' coverage when given the opportunity. It is more difficult to model the choices of young adults with an offer of employer-sponsored insurance whose parents also have group coverage. One assumes these young adults will compare the amount that they must pay for their own employer's coverage with the amount that they (or their parents) would pay if they were covered under their parents' policies. Such a decision will incorporate the type of plan that the parent has, since if the parent already has a family plan whose premium does not vary by number of dependents, the

²⁸ Adele M. Kirk. *The Individual Insurance Market: A Building Block for Health Care Reform? Health Care Financing Organization Research Synthesis*. May 2008.

²⁹ *Ibid.*

³⁰ <http://content.healthaffairs.org/cgi/content/full/23/6/210#R14>. "Patterns of Individual Health Insurance Coverage" *Health Affairs* (Ziller et al, 2004).

³¹ <http://content.healthaffairs.org/cgi/content/full/hlthaff.25.w226v1/DC1>. "Consumer Decision Making in the Individual Health Insurance Market" *Health Affairs* (Marquis et al., 2006).

adult child could switch at no additional cost to the parents. A very rough estimate therefore is that approximately 25 percent of young adults with ESI will switch to their parents' coverage when their parents' coverage is not grandfathered. The Departments assume that 15 percent of young adults who are offered ESI but are uninsured and whose parents have non-grandfathered health plans will switch to their parents' plan. This latter estimate roughly corresponds to the assumption made in the low-take up rate scenario in the RIA for dependent coverage for young adults who are uninsured.

These assumptions imply that an additional approximately 414,000 young adults whose parents have non-grandfathered ESI will be covered by their parents' health coverage in 2011, of whom 14,000 would have been uninsured, compared with the dependent coverage regulation impact analysis that assumed that all existing plans would have remained grandfathered and none of these adult children would have been eligible for coverage under their parents' plans. By 2013, an estimated 698,000 additional young adults with ESI or an offer of ESI will be covered by their parent's non-grandfathered health policy, of which 36,000 would have been uninsured.

6. Grandfathered Health Plan Document Retention and Disclosure Requirements

To maintain grandfathered health plan status under these interim final regulations, a plan or issuer must maintain records that document the plan or policy terms in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain or clarify its status as a grandfathered health plan. The records must be made available for examination by participants, beneficiaries, individual policy subscribers, or a State or Federal agency official.

Plans or health insurance coverage that intend to be a grandfathered health plan, also must include a statement, in any plan materials provided to participants or beneficiaries (in the individual market, primary subscriber) describing the benefits provided under the plan or health insurance coverage, and that the plan or coverage is intended to be a grandfathered health plan within the meaning of section 1251 of the Affordable Care Act. In these interim final regulations, the Departments provide a model statement plans and issuers may use to satisfy the disclosure requirement. The Department's estimate that the one time

cost to plans and insurance issuers of preparing and distributing the grandfathered health plan disclosure is \$39.6 million in 2011. The one time cost to plans and insurance issuers for the record retention requirement is estimated to be \$32.2 million in 2011. For a discussion of the grandfathered health plan document retention and disclosure requirements, see the Paperwork Reduction Act section later in this preamble.

C. Regulatory Flexibility Act— Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These interim final regulations are exempt from the APA, because the Departments made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the regulations on small entities in connection with their assessment under Executive Order 12866. Consistent with the policy of the RFA, the Departments encourage the public to submit comments that suggest alternative rules that accomplish the stated purpose of section 1251 of the Affordable Care Act and minimize the impact on small entities.

D. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative

Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

E. Paperwork Reduction Act

1. Department of Labor and Department of Treasury: Affordable Care Act Grandfathered Plan Disclosure and Record Retention Requirements

As part of their continuing efforts to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection requirements on respondents can be properly assessed.

As discussed earlier in this preamble, if a plan or health insurance coverage intends to be a grandfathered health plan, it must include a statement in any plan materials provided to participants or beneficiaries (in the individual market, primary subscriber) describing the benefits provided under the plan or health insurance coverage, and that the plan or coverage is intended to be grandfathered health plan within the meaning of section 1251 of the Affordable Care Act ("grandfathered health plan disclosure"). Model language has been provided in these interim final regulations, the use of which will satisfy this disclosure requirement.

To maintain status as a grandfathered health plan under these interim final regulations, a plan or issuer must maintain records documenting the plan or policy terms in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan ("recordkeeping requirement"). In addition, the plan or issuer must make such records available for examination. Accordingly, a participant, beneficiary, individual policy subscriber, or State or Federal agency official would be able to

inspect such documents to verify the status of the plan or health insurance coverage as a grandfathered health plan.

As discussed earlier in this preamble, grandfathered health plans are not required to comply with certain Affordable Care Act provisions. These interim regulations define for plans and issuers the scope of changes that they can make to their grandfathered health plans and policies under the Affordable Care Act while retaining their grandfathered health plan status.

The Affordable Care Act grandfathered health plan disclosure and recordkeeping requirements are information collection requests (ICR) subject to the PRA. Currently, the Departments are soliciting public comments for 60 days concerning these disclosures. The Departments have submitted a copy of these interim final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of the information collections. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, for example, by permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer for the Employee Benefits Security Administration either by fax to (202) 395-7285 or by e-mail to oir_submission@omb.eop.gov. A copy of the ICR may be obtained by contacting the PRA addressee: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Room N-5718, Washington, DC 20210. Telephone: (202) 693-8410; Fax: (202) 219-2745. These are not toll-free numbers. E-mail: ebbsa.opr@dol.gov. ICRs submitted to OMB also are available at [reginfo.gov](http://www.reginfo.gov)

(<http://www.reginfo.gov/public/do/PRAMain>).

a. Grandfathered Health Plan Disclosure

In order to satisfy the interim final regulations' grandfathered health plan disclosure requirement, the Departments estimate that 2.2 million ERISA-covered plans will need to notify an estimated 56.3 million policy holders of their plans' grandfathered health plan status.³² The following estimates, except where noted, are based on the mid-range estimates of the percent of plans retaining grandfather status. Because the interim final regulations provide model language for this purpose, the Departments estimate that five minutes of clerical time (with a labor rate of \$26.14/hour) will be required to incorporate the required language into the plan document and ten minutes of an human resource professional's time (with a labor rate of \$89.12/hour) will be required to review the modified language.³³ After plans first satisfy the grandfathered health plan disclosure requirement in 2011, any additional burden should be de minimis if a plan wants to maintain its grandfather status in future years. The Departments also expect the cost of removing the notice from plan documents as plans relinquish their grandfather status to be de minimis and therefore is not estimated. Therefore, the Departments estimate that plans will incur a one-time hour burden of 538,000 hours with an equivalent cost of \$36.6 million to meet the disclosure requirement.

The Departments assume that only printing and material costs are associated with the disclosure requirement, because the interim final regulations provide model language that can be incorporated into existing plan documents, such as a summary plan description (SPD). The Departments estimate that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically. This results in a cost burden of \$873,000 (\$0.05 per page*1/2 pages per notice * 34.9 million notices*0.62).

³² The Departments' estimate of the number of ERISA-covered health plans was obtained from the 2008 Medical Expenditure Panel Survey's Insurance component. The estimate of the number of policy holders was obtained from the 2009 Current Population Survey. The methodology used to estimate the percentage of plans that will retain their grandfathered plans was discussed above.

³³ EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

b. Record-Keeping Requirement

The Departments assume that most of the documents required to be retained to satisfy recordkeeping requirement of these interim final regulations already are retained by plans for tax purposes, to satisfy ERISA's record retention and statute of limitations requirements, and for other business reasons. Therefore, the Departments estimate that the recordkeeping burden imposed by this ICR will require five minutes of a legal professional's time (with a rate of \$119.03/hour) to determine the relevant plan documents that must be retained and ten minutes of clerical staff time (with a labor rate of \$26.14/hour) to organize and file the required documents to ensure that they are accessible to participants, beneficiaries, and Federal and State governmental agency officials.

With an estimated 2.2 million grandfathered plans in 2011, the Departments estimate an hour burden of approximately 538,000 hours with equivalent costs of \$30.7 million. The Departments have estimated this as a one-time cost incurred in 2011, because after the first year, the Departments anticipate that any future costs will be *de minimis*.

Overall, for both the grandfathering notice and the recordkeeping requirement, the Departments expect there to be a total hour burden of 1.1 million hours and a cost burden of \$291,000.

The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.

These paperwork burden estimates are summarized as follows:

Type of Review: New Collection.
Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of Treasury.

Title: Disclosure and Recordkeeping Requirements for Grandfathered Health Plans under the Affordable Care Act.

OMB Number: 1210-0140; 1545-2178.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 2,151,000.

Total Responses: 56,347,000.

Frequency of Response: One time.

Estimated Total Annual Burden

Hours: 538,000 (Employee Benefits Security Administration); 538,000 (Internal Revenue Service).

Estimated Total Annual Burden Cost: \$437,000 (Employee Benefits Security Administration); \$437,000 (Internal Revenue Service).

2. Department of Health and Human Services: Affordable Care Act Grandfathered Plan Disclosure and Record Retention Requirements

As discussed above in the Department of Labor and Department of the Treasury PRA section, these interim final regulations contain a record retention and disclosure requirement for grandfathered health plans. These requirements are information collection requirements under the PRA.

a. Grandfathered Health Plan Disclosure

In order to satisfy the interim final regulations' grandfathered health plan disclosure requirement, the Department estimates that 98,000 state and local governmental plans will need to notify approximately 16.2 million policy holders of their plans' status as a grandfathered health plan. The following estimates except where noted are based on the mid-range estimates of the percent of plans retaining grandfather status. An estimated 490 insurers providing coverage in the individual market will need to notify an estimated 4.3 million policy holders of their policies' status as a grandfathered health plan.³⁴

Because the interim final regulations provide model language for this purpose, the Department estimates that five minute of clerical time (with a labor rate of \$26.14/hour) will be required to incorporate the required language into the plan document and ten minutes of a human resource professional's time (with a labor rate of \$89.12/hour) will be required to review the modified language.³⁵ After plans first satisfy the grandfathered health plan disclosure requirement in 2011, any additional burden should be *de minimis* if a plan wants to maintain its grandfather status in future years. The Department also expects the cost of removing the notice from plan documents as plans relinquish their grandfather status to be *de minimis* and therefore is not estimated. Therefore, the Department estimates that plans and insurers will incur a one-time hour burden of 26,000 hours with an equivalent cost of \$1.8

³⁴ The Department's estimate of the number of state and local governmental health plans was obtained from the 2007 Census of Governments. The estimate of the number of policy holders in the individual market were obtained from the 2009 Current Population Survey. The methodology used to estimate the percentage of state and local governmental plans and individual market policies that will retain their grandfathered health plan status was discussed above.

³⁵ EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

million to meet the disclosure requirement.

The Department assumes that only printing and material costs are associated with the disclosure requirement, because the interim final regulations provide model language that can be incorporated into existing plan documents, such as an SPD. The Department estimates that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically. This results in a cost burden of \$318,000 (\$0.05 per page*1/2 pages per notice * 12.7 million notices*0.62).

b. Record-Keeping Requirement

The Department assumes that most of the documents required to be retained to satisfy the Affordable Care Act's recordkeeping requirement already are retained by plans for tax purposes, to satisfy ERISA's record retention and statute of limitations requirements, and for other business reasons. Therefore, the Department estimates that the recordkeeping burden imposed by this ICR will require five minutes of a legal professional's time (with a rate of \$119.03/hour) to determine the relevant plan documents that must be retained and ten minutes of clerical staff time (with a labor rate of \$26.14/hour) to organize and file the required documents to ensure that they are accessible to participants, beneficiaries, and Federal and State governmental agency officials.

With an estimated 98,000 grandfathered plans and 7,400 grandfathered individual insurance products³⁶ in 2011, the Department estimates an hour burden of approximately 26,000 hours with equivalent costs of \$1.5 million. The Department's have estimated this as a one-time cost incurred in 2011, because after the first year, the Department assumes any future costs will be *de minimis*.

Overall, for both the grandfathering notice and the recordkeeping requirement, the Department expects there to be a total hour burden of 53,000 hours and a cost burden of \$318,000.

The Department notes that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless

³⁶ The Department is not certain on the number of products offered in the individual market and requests comments. After reviewing the number of products offered by various insurers in the individual market the Department used an estimate of 15 which it believes is a high estimate.

the ICR has a valid OMB control number.

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.
Agency: Department of Health and Human Services.
Title: Disclosure and Recordkeeping Requirements for Grandfathered Health Plans under the Affordable Care Act.
OMB Number: 0938-1093.
Affected Public: Business; State, Local, or Tribal Governments.
Respondents: 105,000.
Responses: 20,508,000.
Frequency of Response: One-time.
Estimated Total Annual Burden Hours: 53,000 hours.
Estimated Total Annual Burden Cost: \$318,000.

If you comment on this information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: OCIO Desk Officer, OCIO-9991-IFC.

Fax: (202) 395-6974; or

E-mail:

OIRA_submission@omb.eop.gov.

F. Congressional Review Act

These interim final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires agencies to prepare several analytic statements before proposing any rules that may result in annual expenditures of \$100 million (as adjusted for inflation) by State, local and tribal governments or the private sector. These interim final regulations are not subject to the Unfunded Mandates Reform Act, because they are being issued as an interim final regulation. However, consistent with the policy embodied in the Unfunded Mandates Reform Act, these interim final regulations have been designed to be the least burdensome alternative for State, local and tribal governments, and the private sector, while achieving the objectives of the Affordable Care Act.

H. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments’ view, this regulation has federalism implications, because it has direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. However, in the Departments’ view, the federalism implications of the regulation is substantially mitigated because, with respect to health insurance issuers, the Departments expect that the majority of States will enact laws or take other appropriate action resulting in their meeting or exceeding the Federal standard.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of ERISA section 731 and PHS Act section 2724 (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the HIPAA requirements (including those of the Affordable Care Act) are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of a Federal standard. The conference report accompanying HIPAA indicates that this is intended to be the “narrowest” preemption of State laws. (See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code

Cong. & Admin. News 2018.) States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the federal requirements are unlikely to “prevent the application of” the Affordable Care Act, and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected State and local officials, including attending conferences of the National Association of Insurance Commissioners and consulting with State insurance officials on an individual basis. It is expected that the Departments will act in a similar fashion in enforcing the Affordable Care Act requirements. Throughout the process of developing these regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Departments have attempted to balance the States’ interests in regulating health insurance issuers, and Congress’ intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments’ view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these regulations, the Departments certify that the Employee Benefits Security Administration and the Office of Consumer Information and Insurance Oversight have complied with the requirements of Executive Order 13132 for the attached regulation in a meaningful and timely manner.

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; section 101(g), Public Law 104–191, 110 Stat. 1936; section 401(b), Public Law 105–

200, 112 Stat. 645 (42 U.S.C. 651 note); section 512(d), Public Law 110–343, 122 Stat. 3881; section 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor’s Order 6–2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: June 10, 2010.

Michael F. Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 4th day of June, 2010.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Approved: June 8, 2010.

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Approved: June 9, 2010.

Kathleen Sebelius,

Secretary.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

■ Accordingly, 26 CFR parts 54 and 602 are amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 is amended by adding entries for §§ 54.9815–1251T and 54.9815–2714T in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Section 54.9815–1251T also issued under 26 U.S.C. 9833.

Section 54.9815–2714T also issued under 26 U.S.C. 9833. * * *

■ 2. Section 54.9815–1251T is added to read as follows:

§ 54.9815–1251T Preservation of right to maintain existing coverage (temporary).

(a) *Definition of grandfathered health plan coverage—(1) In general—(i) Grandfathered health plan coverage* means coverage provided by a group health plan, or a health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage.

(ii) Subject to the rules of paragraph (f) of this section for collectively bargained plans, if an employer or employee organization enters into a new policy, certificate, or contract of insurance after March 23, 2010 (because, for example, any previous policy, certificate, or contract of insurance is not being renewed), then that policy, certificate, or contract of insurance is not a grandfathered health plan with respect to the individuals in the group health plan.

(2) *Disclosure of grandfather status—*

(i) To maintain status as a grandfathered health plan, a plan or health insurance coverage must include a statement, in any plan materials provided to a participant or beneficiary describing the benefits provided under the plan or health insurance coverage, that the plan or coverage believes it is a grandfathered health plan within the meaning of

section 1251 of the Patient Protection and Affordable Care Act and must provide contact information for questions and complaints.

(ii) The following model language can be used to satisfy this disclosure requirement:

This [group health plan or health insurance issuer] believes this [plan or coverage] is a “grandfathered health plan” under the Patient Protection and Affordable Care Act (the Affordable Care Act). As permitted by the Affordable Care Act, a grandfathered health plan can preserve certain basic health coverage that was already in effect when that law was enacted. Being a grandfathered health plan means that your [plan or policy] may not include certain consumer protections of the Affordable Care Act that apply to other plans, for example, the requirement for the provision of preventive health services without any cost sharing. However, grandfathered health plans must comply with certain other consumer protections in the Affordable Care Act, for example, the elimination of lifetime limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to the plan administrator at [insert contact information]. [For ERISA plans, insert: You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1–866–444–3272 or www.dol.gov/ebsa/healthreform. This website has a table summarizing which protections do and do not apply to grandfathered health plans.] [For individual market policies and nonfederal governmental plans, insert: You may also contact the U.S. Department of Health and Human Services at www.healthreform.gov.]

(3) *Documentation of plan or policy terms on March 23, 2010.* To maintain status as a grandfathered health plan, a group health plan, or group health insurance coverage, must, for as long as the plan or health insurance coverage takes the position that it is a grandfathered health plan—

(i) Maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(ii) Make such records available for examination upon request.

(4) *Family members enrolling after March 23, 2010.* With respect to an individual who is enrolled in a group health plan or health insurance coverage on March 23, 2010, grandfathered health plan coverage includes coverage of family members of the individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(5) *Examples.* The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement provides coverage through a group health insurance policy from Issuer X on March 23, 2010. For the plan year beginning January 1, 2012, the plan enters into a new policy with Issuer Z.

(ii) *Conclusion.* In this *Example 1*, for the plan year beginning January 1, 2012, the group health insurance coverage issued by Z is not a grandfathered health plan under the rules of paragraph (a)(1)(ii) of this section because the policy issued by Z did not provide coverage on March 23, 2010.

Example 2. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option F is a self-insured option. Options G and H are insured options. Beginning July 1, 2013, the plan replaces the issuer for Option H with a new issuer.

(ii) *Conclusion.* In this *Example 2*, the coverage under Option H is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (a)(1)(ii) of this section. Whether the coverage under Options F and G is grandfathered health plan coverage is determined under the rules of this section, including paragraph (g) of this section. If the plan enters into a new policy, certificate, or contract of insurance for Option G, Option G’s status as a grandfathered health plan would cease under paragraph (a)(1)(ii) of this section.

(b) *Allowance for new employees to join current plan—(1) In general.* Subject to paragraph (b)(2) of this section, a group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of this section, including paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010.

(2) *Anti-abuse rules—(i) Mergers and acquisitions.* If the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan.

(ii) *Change in plan eligibility.* A group health plan or health insurance coverage (including a benefit package under a group health plan) ceases to be a grandfathered health plan if—

(A) Employees are transferred into the plan or health insurance coverage (the transferee plan) from a plan or health insurance coverage under which the employees were covered on March 23, 2010 (the transferor plan);

(B) Comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the transferor plan would cause a loss of grandfather status under the provisions of paragraph (g)(1) of this section; and

(C) There was no bona fide employment-based reason to transfer the employees into the transferee plan. For this purpose, changing the terms or cost of coverage is not a bona fide employment-based reason.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options F and G. During a subsequent open enrollment period, some of the employees enrolled in Option F on March 23, 2010 switch to Option G.

(ii) *Conclusion.* In this *Example 1*, the group health coverage provided under Option G remains a grandfathered health plan under the rules of paragraph (b)(1) of this section because employees previously enrolled in Option F are allowed to enroll in Option G as new employees.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that the plan sponsor eliminates Option F because of its high cost and transfers employees covered under Option F to Option G. If instead of transferring employees from Option F to Option G, Option F was amended to match the terms of Option G, then Option F would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 2*, the plan did not have a bona fide employment-based reason to transfer employees from Option F to Option G. Therefore, Option G ceases to be a grandfathered health plan with respect to all employees. (However, any other benefit package maintained by the plan sponsor is analyzed separately under the rules of this section.)

Example 3. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options H and I. On March 23, 2010, Option H provides coverage only for employees in one manufacturing plant. Subsequently, the plant is closed, and some employees in the closed plant are moved to another plant. The employer eliminates Option H and the employees that are moved are transferred to Option I. If instead of transferring employees from Option H to Option I, Option H was amended to match the terms of Option I, then Option H would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 3*, the plan has a bona fide employment-based reason to transfer employees from Option H to Option I. Therefore, Option I does not cease to be a grandfathered health plan.

(c) *General grandfathering rule*—(1) Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles,

and the incorporation of those amendments into section 9815 and ERISA section 715) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709 (relating to coverage for individuals participating in approved clinical trials, as added by section 10103 of the Patient Protection and Affordable Care Act), 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. (In addition, *see* 45 CFR 147.140(c), which provides that the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it relates to annual limits, do not apply to grandfathered health plans that are individual health insurance coverage.)

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the Code, the PHS Act, and ERISA applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) *Provisions applicable to all grandfathered health plans.* The provisions of PHS Act section 2711 insofar as it relates to lifetime limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage*—(1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as

defined in section 5000A(f)(2)) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans*—(1) *In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into section 9815 and ERISA section 715) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010) and, for any changes in insurance coverage after the termination of the collective bargaining agreement, under the rules of paragraph (a)(1)(ii) of this section.

(2) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan maintained pursuant to a collective bargaining agreement provides coverage through a group health insurance policy from Issuer W on March 23, 2010. The collective bargaining agreement has not been amended and will not expire before December 31, 2011. The group health plan enters into a new group health insurance policy with Issuer Y for the plan year starting on January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the group health plan, and the group health

insurance policy provided by Y, remains a grandfathered health plan with respect to existing employees and new employees and their families because the coverage is maintained pursuant to a collective bargaining agreement ratified prior to March 23, 2010 that has not terminated.

Example 2. (i) *Facts.* Same facts as *Example 1*, except the coverage with Y is renewed under a new collective bargaining agreement effective January 1, 2012, with the only changes since March 23, 2010 being changes that do not cause the plan to cease to be a grandfathered health plan under the rules of this section, including paragraph (g) of this section.

(ii) *Conclusion.* In this *Example 2*, the group health plan remains a grandfathered health plan pursuant to the rules of this section. Moreover, the group health insurance policy provided by Y remains a grandfathered health plan under the rules of this section, including paragraph (g) of this section.

(g) *Maintenance of grandfather status—(1) Changes causing cessation of grandfather status.* Subject to paragraph (g)(2) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan.

(i) *Elimination of benefits.* The elimination of all or substantially all benefits to diagnose or treat a particular condition causes a group health plan or health insurance coverage to cease to be a grandfathered health plan. For this purpose, the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition.

(ii) *Increase in percentage cost-sharing requirement.* Any increase, measured from March 23, 2010, in a percentage cost-sharing requirement (such as an individual's coinsurance requirement) causes a group health plan or health insurance coverage to cease to be a grandfathered health plan.

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, causes

a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total increase in the copayment measured from March 23, 2010 exceeds the greater of:

(A) An amount equal to \$5 increased by medical inflation, as defined in paragraph (g)(3)(i) of this section (that is, \$5 times medical inflation, plus \$5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations—(A) Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(3)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 54.9802-1(d)) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 54.9802-1(d)) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(vi) *Changes in annual limits—(A) Addition of an annual limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits.

(B) *Decrease in limit for a plan or coverage with only a lifetime limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010.

(C) *Decrease in limit for a plan or coverage with an annual limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

(2) *Transitional rules—(i) Changes made prior to March 23, 2010.* If a group health plan or health insurance issuer makes the following changes to the terms of the plan or health insurance coverage, the changes are considered part of the terms of the plan or health insurance coverage on March 23, 2010 even though they were not effective at that time and such changes do not cause a plan or health insurance coverage to cease to be a grandfathered health plan:

(A) Changes effective after March 23, 2010 pursuant to a legally binding contract entered into on or before March 23, 2010;

(B) Changes effective after March 23, 2010 pursuant to a filing on or before March 23, 2010 with a State insurance department; or

(C) Changes effective after March 23, 2010 pursuant to written amendments to a plan that were adopted on or before March 23, 2010.

(ii) *Changes made after March 23, 2010 and adopted prior to issuance of regulations.* If, after March 23, 2010, a group health plan or health insurance issuer makes changes to the terms of the plan or health insurance coverage and the changes are adopted prior to June 14, 2010, the changes will not cause the plan or health insurance coverage to cease to be a grandfathered health plan if the changes are revoked or modified effective as of the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, and the terms of the plan or health insurance coverage on that date, as modified, would not cause the plan or coverage to cease to be a grandfathered health plan under the rules of this section, including paragraph (g)(1) of this section. For this purpose, changes will be considered to have been adopted prior to June 14, 2010 if:

(A) The changes are effective before that date;

(B) The changes are effective on or after that date pursuant to a legally binding contract entered into before that date;

(C) The changes are effective on or after that date pursuant to a filing before

that date with a State insurance department; or

(D) The changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

(3) *Definitions*—(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI-U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI-U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means medical inflation (as defined in paragraph (g)(3)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined.* For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage.* The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 4980B(f)(4), section 604 of ERISA, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula.* The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

(4) *Examples.* The rules of this paragraph (g) are illustrated by the following examples:

Example 1. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended

to increase the coinsurance requirement to 25%.

(ii) *Conclusion.* In this *Example 1*, the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts.* Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2*, the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment requirement of \$30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to \$40. Within the 12-month period before the \$40 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3*, the increase in the copayment from \$30 to \$40, expressed as a percentage, is 33.33% ($40 - 30 = 10$; $10 \div 30 = 0.3333$; $0.3333 = 33.33\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 ($475 - 387.142 = 87.858$; $87.858 \div 387.142 = 0.2269$). The maximum percentage increase permitted is 37.69% ($0.2269 = 22.69\%$; $22.69\% + 15\% = 37.69\%$). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3*, except the grandfathered health plan subsequently increases the \$40 copayment requirement to \$45 for a later plan year. Within the 12-month period before the \$45 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4*, the increase in the copayment from \$30 (the copayment that was in effect on March 23, 2010) to \$45, expressed as a percentage, is 50% ($45 - 30 = 15$; $15 \div 30 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2527 ($485 - 387.142 = 97.858$; $97.858 \div 387.142 = 0.2527$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% ($0.2527 = 25.27\%$; $25.27\% + 15\% = 40.27\%$), or \$6.26 ($\$5 \times 0.2527 = \1.26 ; $\$1.26 + \$5 = \$6.26$). Because 50% exceeds 40.27% and \$15 exceeds \$6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment of \$10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$15. Within the 12-month period before the

\$15 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 5*, the increase in the copayment, expressed as a percentage, is 50% ($15 - 10 = 5$; $5 \div 10 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3) of this section) from March 2010 is 0.0720 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% ($0.0720 = 7.20\%$; $7.20\% + 15\% = 22.20\%$), or \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 5* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to \$5.36.

Example 6. (i) *Facts.* The same facts as *Example 5*, except on March 23, 2010, the grandfathered health plan has no copayment (\$0) for office visits for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$5.

(ii) *Conclusion.* In this *Example 6*, medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.0720 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 6* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of \$5.36. Thus, the \$5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 7. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 7*, the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of \$5000 for self-only coverage and \$12,000 for family coverage. The required employee contribution for the coverage is \$1000 for self-only coverage and \$4000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ($(5000 - 1000)/5000$) for self-only coverage and 67% ($(12,000 - 4000)/12,000$) for family coverage. For a subsequent plan year, the COBRA premium is \$6000 for self-only coverage and \$15,000 for family coverage. The employee contributions for that plan year are \$1200 for self-only coverage and \$5000 for family coverage. Thus, the contribution rate based on cost of coverage is

80% ((6000 - 1200)/6000) for self-only coverage and 67% ((15,000 - 5000)/15,000) for family coverage.

(ii) *Conclusion.* In this *Example 8*, because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 9. (i) *Facts.* Before March 23, 2010, Employer W and Individual B enter into a legally binding employment contract that promises B lifetime health coverage upon termination. Prior to termination, B is covered by W's self-insured grandfathered group health plan. B is terminated after March 23, 2010 and W purchases a new health insurance policy providing coverage to B, consistent with the terms of the employment contract.

(ii) *Conclusion.* In this *Example 9*, because no individual is enrolled in the health insurance policy on March 23, 2010, it is not a grandfathered health plan.

(h) *Expiration date.* This section expires on or before June 14, 2013.

■ 3. Section 54.9815-2714T is amended by revising paragraphs (h) and (i) to read as follows:

* * * * *

(h) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 54.9815-1251T for determining the application of this section to grandfathered health plans.

(i) *Expiration date.* This section expires on or before May 10, 2013.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ 4. The authority citation for part 602 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

■ 5. Section 602.101(b) is amended by adding the following entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	* * * * *
54.9815-1251T	1545-2178
* * * * *	* * * * *

**DEPARTMENT OF LABOR
Employee Benefits Security Administration**

29 CFR Chapter XXV

■ 29 CFR part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

■ 2. Section 2590.715-1251 is added to subpart C to read as follows:

§ 2590.715-1251 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage—*(1) *In general—*(i) *Grandfathered health plan coverage* means coverage provided by a group health plan, or a health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage.

(ii) Subject to the rules of paragraph (f) of this section for collectively bargained plans, if an employer or employee organization enters into a new policy, certificate, or contract of insurance after March 23, 2010 (because, for example, any previous policy, certificate, or contract of insurance is not being renewed), then that policy, certificate, or contract of insurance is not a grandfathered health plan with respect to the individuals in the group health plan.

(2) *Disclosure of grandfather status—*(i) To maintain status as a grandfathered health plan, a plan or health insurance coverage must include a statement, in any plan materials provided to a participant or beneficiary describing the

benefits provided under the plan or health insurance coverage, that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Patient Protection and Affordable Care Act and must provide contact information for questions and complaints.

(ii) The following model language can be used to satisfy this disclosure requirement:

This [group health plan or health insurance issuer] believes this [plan or coverage] is a "grandfathered health plan" under the Patient Protection and Affordable Care Act (the Affordable Care Act). As permitted by the Affordable Care Act, a grandfathered health plan can preserve certain basic health coverage that was already in effect when that law was enacted. Being a grandfathered health plan means that your [plan or policy] may not include certain consumer protections of the Affordable Care Act that apply to other plans, for example, the requirement for the provision of preventive health services without any cost sharing. However, grandfathered health plans must comply with certain other consumer protections in the Affordable Care Act, for example, the elimination of lifetime limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to the plan administrator at [insert contact information]. [For ERISA plans, insert: You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1-866-444-3272 or www.dol.gov/ebsa/healthreform. This Web site has a table summarizing which protections do and do not apply to grandfathered health plans.] [For individual market policies and nonfederal governmental plans, insert: You may also contact the U.S. Department of Health and Human Services at www.healthreform.gov.]

(3) *Documentation of plan or policy terms on March 23, 2010.* To maintain status as a grandfathered health plan, a group health plan, or group health insurance coverage, must, for as long as the plan or health insurance coverage takes the position that it is a grandfathered health plan—

(i) Maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(ii) Make such records available for examination upon request.

(4) *Family members enrolling after March 23, 2010.* With respect to an individual who is enrolled in a group health plan or health insurance coverage on March 23, 2010, grandfathered health plan coverage includes coverage of family members of the individual who

enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(5) *Examples.* The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement provides coverage through a group health insurance policy from Issuer X on March 23, 2010. For the plan year beginning January 1, 2012, the plan enters into a new policy with Issuer Z.

(ii) *Conclusion.* In this *Example 1*, for the plan year beginning January 1, 2012, the group health insurance coverage issued by Z is not a grandfathered health plan under the rules of paragraph (a)(1)(ii) of this section because the policy issued by Z did not provide coverage on March 23, 2010.

Example 2. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option F is a self-insured option. Options G and H are insured options. Beginning July 1, 2013, the plan replaces the issuer for Option H with a new issuer.

(ii) *Conclusion.* In this *Example 2*, the coverage under Option H is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (a)(1)(ii) of this section. Whether the coverage under Options F and G is grandfathered health plan coverage is determined under the rules of this section, including paragraph (g) of this section. If the plan enters into a new policy, certificate, or contract of insurance for Option G, Option G's status as a grandfathered health plan would cease under paragraph (a)(1)(ii) of this section.

(b) *Allowance for new employees to join current plan—(1) In general.* Subject to paragraph (b)(2) of this section, a group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of this section, including paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010.

(2) *Anti-abuse rules—(i) Mergers and acquisitions.* If the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan.

(ii) *Change in plan eligibility.* A group health plan or health insurance coverage (including a benefit package under a group health plan) ceases to be a grandfathered health plan if—

(A) Employees are transferred into the plan or health insurance coverage (the

transferee plan) from a plan or health insurance coverage under which the employees were covered on March 23, 2010 (the transferor plan);

(B) Comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the transferor plan would cause a loss of grandfather status under the provisions of paragraph (g)(1) of this section; and

(C) There was no bona fide employment-based reason to transfer the employees into the transferee plan. For this purpose, changing the terms or cost of coverage is not a bona fide employment-based reason.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options F and G. During a subsequent open enrollment period, some of the employees enrolled in Option F on March 23, 2010 switch to Option G.

(ii) *Conclusion.* In this *Example 1*, the group health coverage provided under Option G remains a grandfathered health plan under the rules of paragraph (b)(1) of this section because employees previously enrolled in Option F are allowed to enroll in Option G as new employees.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that the plan sponsor eliminates Option F because of its high cost and transfers employees covered under Option F to Option G. If instead of transferring employees from Option F to Option G, Option F was amended to match the terms of Option G, then Option F would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 2*, the plan did not have a bona fide employment-based reason to transfer employees from Option F to Option G. Therefore, Option G ceases to be a grandfathered health plan with respect to all employees. (However, any other benefit package maintained by the plan sponsor is analyzed separately under the rules of this section.)

Example 3. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options H and I. On March 23, 2010, Option H provides coverage only for employees in one manufacturing plant. Subsequently, the plant is closed, and some employees in the closed plant are moved to another plant. The employer eliminates Option H and the employees that are moved are transferred to Option I. If instead of transferring employees from Option H to Option I, Option H was amended to match the terms of Option I, then Option H would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 3*, the plan has a bona fide employment-based reason to transfer employees from Option H to Option I. Therefore, Option I does not cease to be a grandfathered health plan.

(c) *General grandfathering rule—(1)* Except as provided in paragraphs (d)

and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709 (relating to coverage for individuals participating in approved clinical trials, as added by section 10103 of the Patient Protection and Affordable Care Act), 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. (In addition, *see* 45 CFR 147.140(c), which provides that the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it relates to annual limits, do not apply to grandfathered health plans that are individual health insurance coverage.)

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) *Provisions applicable to all grandfathered health plans.* The provisions of PHS Act section 2711 insofar as it relates to lifetime limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage—(1)* The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an

adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans*—(1) *In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010) and, for any changes in insurance coverage after the termination of the collective bargaining agreement, under the rules of paragraph (a)(1)(ii) of this section.

(2) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan maintained pursuant to a collective bargaining agreement provides coverage through a group health insurance policy from Issuer W on March 23, 2010. The collective

bargaining agreement has not been amended and will not expire before December 31, 2011. The group health plan enters into a new group health insurance policy with Issuer Y for the plan year starting on January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the group health plan, and the group health insurance policy provided by Y, remains a grandfathered health plan with respect to existing employees and new employees and their families because the coverage is maintained pursuant to a collective bargaining agreement ratified prior to March 23, 2010 that has not terminated.

Example 2. (i) *Facts.* Same facts as *Example 1*, except the coverage with Y is renewed under a new collective bargaining agreement effective January 1, 2012, with the only changes since March 23, 2010 being changes that do not cause the plan to cease to be a grandfathered health plan under the rules of this section, including paragraph (g) of this section.

(ii) *Conclusion.* In this *Example 2*, the group health plan remains a grandfathered health plan pursuant to the rules of this section. Moreover, the group health insurance policy provided by Y remains a grandfathered health plan under the rules of this section, including paragraph (g) of this section.

(g) *Maintenance of grandfather status*—(1) *Changes causing cessation of grandfather status.* Subject to paragraph (g)(2) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan.

(i) *Elimination of benefits.* The elimination of all or substantially all benefits to diagnose or treat a particular condition causes a group health plan or health insurance coverage to cease to be a grandfathered health plan. For this purpose, the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition.

(ii) *Increase in percentage cost-sharing requirement.* Any increase, measured from March 23, 2010, in a percentage cost-sharing requirement (such as an individual's coinsurance requirement) causes a group health plan or health insurance coverage to cease to be a grandfathered health plan.

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing

requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total increase in the copayment measured from March 23, 2010 exceeds the greater of:

(A) An amount equal to \$5 increased by medical inflation, as defined in paragraph (g)(3)(i) of this section (that is, \$5 times medical inflation, plus \$5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(3)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 2590.702(d) of this part) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in section 2590.702(d) of this part) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(vi) *Changes in annual limits*—(A) *Addition of an annual limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits.

(B) *Decrease in limit for a plan or coverage with only a lifetime limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit

on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010.

(C) *Decrease in limit for a plan or coverage with an annual limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

(2) *Transitional rules*—(i) *Changes made prior to March 23, 2010.* If a group health plan or health insurance issuer makes the following changes to the terms of the plan or health insurance coverage, the changes are considered part of the terms of the plan or health insurance coverage on March 23, 2010 even though they were not effective at that time and such changes do not cause a plan or health insurance coverage to cease to be a grandfathered health plan:

(A) Changes effective after March 23, 2010 pursuant to a legally binding contract entered into on or before March 23, 2010;

(B) Changes effective after March 23, 2010 pursuant to a filing on or before March 23, 2010 with a State insurance department; or

(C) Changes effective after March 23, 2010 pursuant to written amendments to a plan that were adopted on or before March 23, 2010.

(ii) *Changes made after March 23, 2010 and adopted prior to issuance of regulations.* If, after March 23, 2010, a group health plan or health insurance issuer makes changes to the terms of the plan or health insurance coverage and the changes are adopted prior to June 14, 2010, the changes will not cause the plan or health insurance coverage to cease to be a grandfathered health plan if the changes are revoked or modified effective as of the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, and the terms of the plan or health insurance coverage on that date, as modified, would not cause the plan or coverage to cease to be a grandfathered health plan under the rules of this section, including paragraph (g)(1) of this section. For this purpose, changes will be considered to have been adopted prior to June 14, 2010 if:

(A) The changes are effective before that date;

(B) The changes are effective on or after that date pursuant to a legally binding contract entered into before that date;

(C) The changes are effective on or after that date pursuant to a filing before that date with a State insurance department; or

(D) The changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

(3) *Definitions*—(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI-U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI-U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means medical inflation (as defined in paragraph (g)(3)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined.* For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage.* The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula.* The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such

as hours worked or tons of coal mined), the formula.

(4) *Examples.* The rules of this paragraph (g) are illustrated by the following examples:

Example 1. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion.* In this *Example 1*, the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts.* Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2*, the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment requirement of \$30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to \$40. Within the 12-month period before the \$40 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3*, the increase in the copayment from \$30 to \$40, expressed as a percentage, is 33.33% ($40 - 30 = 10$; $10 \div 30 = 0.3333$; $0.3333 = 33.33\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 ($475 - 387.142 = 87.858$; $87.858 \div 387.142 = 0.2269$). The maximum percentage increase permitted is 37.69% ($0.2269 = 22.69\%$; $22.69\% + 15\% = 37.69\%$). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3*, except the grandfathered health plan subsequently increases the \$40 copayment requirement to \$45 for a later plan year. Within the 12-month period before the \$45 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4*, the increase in the copayment from \$30 (the copayment that was in effect on March 23, 2010) to \$45, expressed as a percentage, is 50% ($45 - 30 = 15$; $15 \div 30 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2527 ($485 - 387.142 = 97.858$; $97.858 \div 387.142 = 0.2527$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% ($0.2527 = 25.27\%$; $25.27\% + 15\% = 40.27\%$), or \$6.26 ($\$5 \times 0.2527 = \1.26 ; $\$1.26 + \$5 = \$6.26$).

Because 50% exceeds 40.27% and \$15 exceeds \$6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment of \$10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$15. Within the 12-month period before the \$15 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 5*, the increase in the copayment, expressed as a percentage, is 50% ($15 - 10 = 5$; $5 \div 10 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3) of this section) from March 2010 is 0.0720 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% ($0.0720 = 7.20\%$; $7.20\% + 15\% = 22.20\%$), or \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 5* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to \$5.36.

Example 6. (i) *Facts.* The same facts as *Example 5*, except on March 23, 2010, the grandfathered health plan has no copayment (\$0) for office visits for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$5.

(ii) *Conclusion.* In this *Example 6*, medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.0720 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 6* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of \$5.36. Thus, the \$5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 7. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 7*, the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of \$5000 for self-only coverage and \$12,000 for family coverage. The required employee contribution for the coverage is \$1000 for self-only coverage and \$4000 for family coverage. Thus, the contribution rate based

on cost of coverage for 2010 is 80% ($(5000 - 1000)/5000$) for self-only coverage and 67% ($(12,000 - 4000)/12,000$) for family coverage. For a subsequent plan year, the COBRA premium is \$6000 for self-only coverage and \$15,000 for family coverage. The employee contributions for that plan year are \$1200 for self-only coverage and \$5000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ($(6000 - 1200)/6000$) for self-only coverage and 67% ($(15,000 - 5000)/15,000$) for family coverage.

(ii) *Conclusion.* In this *Example 8*, because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 9. (i) *Facts.* Before March 23, 2010, Employer W and Individual B enter into a legally binding employment contract that promises B lifetime health coverage upon termination. Prior to termination, B is covered by W's self-insured grandfathered group health plan. B is terminated after March 23, 2010 and W purchases a new health insurance policy providing coverage to B, consistent with the terms of the employment contract.

(ii) *Conclusion.* In this *Example 9*, because no individual is enrolled in the health insurance policy on March 23, 2010, it is not a grandfathered health plan.

■ 3. Section 2590.715–2714 is amended by revising paragraph (h) to read as follows:

§ 2590.715–2714 Eligibility of children until at least age 26.

* * * * *

(h) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715–1251 of this Part for determining the application of this section to grandfathered health plans.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Chapter I

■ For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Section 147.120 is amended by revising paragraph (h) to read as follows:

(h) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See § 147.140 of this part for determining the application of this section to grandfathered health plans.

■ 3. Section 147.140 is added to read as follows:

§ 147.140 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage—(1) In general—(i) Grandfathered health plan coverage* means coverage provided by a group health plan, or a group or individual health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage.

(ii) Subject to the rules of paragraph (f) of this section for collectively bargained plans, if an employer or employee organization enters into a new policy, certificate, or contract of insurance after March 23, 2010 (because, for example, any previous policy, certificate, or contract of insurance is not being renewed), then that policy, certificate, or contract of insurance is not a grandfathered health plan with respect to the individuals in the group health plan.

(2) *Disclosure of grandfather status—*

(i) To maintain status as a grandfathered health plan, a plan or health insurance coverage must include a statement, in any plan materials provided to a participant or beneficiary (in the individual market, primary subscriber) describing the benefits provided under the plan or health insurance coverage, that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Patient Protection and Affordable Care Act and must provide contact information for questions and complaints.

(ii) The following model language can be used to satisfy this disclosure requirement:

This [group health plan or health insurance issuer] believes this [plan or coverage] is a “grandfathered health plan” under the Patient Protection and Affordable Care Act (the Affordable Care Act). As permitted by the Affordable Care Act, a grandfathered health plan can preserve certain basic health coverage that was already in effect when that law was enacted. Being a grandfathered health plan means that your [plan or policy] may not include certain consumer protections of the Affordable Care Act that apply to other plans, for example, the requirement for the provision of preventive health services without any cost sharing. However, grandfathered health plans must comply with certain other consumer protections in the Affordable Care Act, for example, the elimination of lifetime limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to the plan administrator at [insert contact information]. [For ERISA plans, insert: You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1-866-444-3272 or www.dol.gov/ebsa/healthreform. This Web site has a table summarizing which protections do and do not apply to grandfathered health plans.] [For individual market policies and nonfederal governmental plans, insert: You may also contact the U.S. Department of Health and Human Services at www.healthreform.gov.]

(3) *Documentation of plan or policy terms on March 23, 2010.* To maintain status as a grandfathered health plan, a group health plan, or group or individual health insurance coverage, must, for as long as the plan or health insurance coverage takes the position that it is a grandfathered health plan—

(i) Maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(ii) Make such records available for examination upon request.

(4) *Family members enrolling after March 23, 2010.* With respect to an individual who is enrolled in a group health plan or health insurance coverage on March 23, 2010, grandfathered health plan coverage includes coverage of family members of the individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(5) *Examples.* The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement provides coverage

through a group health insurance policy from Issuer X on March 23, 2010. For the plan year beginning January 1, 2012, the plan enters into a new policy with Issuer Z.

(ii) *Conclusion.* In this *Example 1*, for the plan year beginning January 1, 2012, the group health insurance coverage issued by Z is not a grandfathered health plan under the rules of paragraph (a)(1)(ii) of this section because the policy issued by Z did not provide coverage on March 23, 2010.

Example 2. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option F is a self-insured option. Options G and H are insured options. Beginning July 1, 2013, the plan replaces the issuer for Option H with a new issuer.

(ii) *Conclusion.* In this *Example 2*, the coverage under Option H is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (a)(1)(ii) of this section. Whether the coverage under Options F and G is grandfathered health plan coverage is determined under the rules of this section, including paragraph (g) of this section. If the plan enters into a new policy, certificate, or contract of insurance for Option G, Option G’s status as a grandfathered health plan would cease under paragraph (a)(1)(ii) of this section.

(b) *Allowance for new employees to join current plan—(1) In general.* Subject to paragraph (b)(2) of this section, a group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of this section, including paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010.

(2) *Anti-abuse rules—(i) Mergers and acquisitions.* If the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan.

(ii) *Change in plan eligibility.* A group health plan or health insurance coverage (including a benefit package under a group health plan) ceases to be a grandfathered health plan if—

(A) Employees are transferred into the plan or health insurance coverage (the transferee plan) from a plan or health insurance coverage under which the employees were covered on March 23, 2010 (the transferor plan);

(B) Comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the

transferor plan would cause a loss of grandfather status under the provisions of paragraph (g)(1) of this section; and

(C) There was no bona fide employment-based reason to transfer the employees into the transferee plan. For this purpose, changing the terms or cost of coverage is not a bona fide employment-based reason.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options F and G. During a subsequent open enrollment period, some of the employees enrolled in Option F on March 23, 2010 switch to Option G.

(ii) *Conclusion.* In this *Example 1*, the group health coverage provided under Option G remains a grandfathered health plan under the rules of paragraph (b)(1) of this section because employees previously enrolled in Option F are allowed to enroll in Option G as new employees.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that the plan sponsor eliminates Option F because of its high cost and transfers employees covered under Option F to Option G. If instead of transferring employees from Option F to Option G, Option F was amended to match the terms of Option G, then Option F would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 2*, the plan did not have a bona fide employment-based reason to transfer employees from Option F to Option G. Therefore, Option G ceases to be a grandfathered health plan with respect to all employees. (However, any other benefit package maintained by the plan sponsor is analyzed separately under the rules of this section.)

Example 3. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options H and I. On March 23, 2010, Option H provides coverage only for employees in one manufacturing plant. Subsequently, the plant is closed, and some employees in the closed plant are moved to another plant. The employer eliminates Option H and the employees that are moved are transferred to Option I. If instead of transferring employees from Option H to Option I, Option H was amended to match the terms of Option I, then Option H would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 3*, the plan has a bona fide employment-based reason to transfer employees from Option H to Option I. Therefore, Option I does not cease to be a grandfathered health plan.

(c) *General grandfathering rule—(1)* Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the

provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709 (relating to coverage for individuals participating in approved clinical trials, as added by section 10103 of the Patient Protection and Affordable Care Act), 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. In addition, the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it relates to annual limits, do not apply to grandfathered health plans that are individual health insurance coverage.

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) *Provisions applicable to all grandfathered health plans.* The provisions of PHS Act section 2711 insofar as it relates to lifetime limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage—*(1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent.

For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans—*(1) *In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010) and, for any changes in insurance coverage after the termination of the collective bargaining agreement, under the rules of paragraph (a)(1)(ii) of this section.

(2) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan maintained pursuant to a collective bargaining agreement provides coverage through a group health insurance policy from Issuer *W* on March 23, 2010. The collective bargaining agreement has not been amended and will not expire before December 31, 2011. The group health plan enters into a new group health insurance policy with Issuer *Y* for the plan year starting on January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the group health plan, and the group health insurance policy provided by *Y*, remains a

grandfathered health plan with respect to existing employees and new employees and their families because the coverage is maintained pursuant to a collective bargaining agreement ratified prior to March 23, 2010 that has not terminated.

Example 2. (i) *Facts.* Same facts as *Example 1*, except the coverage with *Y* is renewed under a new collective bargaining agreement effective January 1, 2012, with the only changes since March 23, 2010 being changes that do not cause the plan to cease to be a grandfathered health plan under the rules of this section, including paragraph (g) of this section.

(ii) *Conclusion.* In this *Example 2*, the group health plan remains a grandfathered health plan pursuant to the rules of this section. Moreover, the group health insurance policy provided by *Y* remains a grandfathered health plan under the rules of this section, including paragraph (g) of this section.

(g) *Maintenance of grandfather status—*(1) *Changes causing cessation of grandfather status.* Subject to paragraph (g)(2) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan.

(i) *Elimination of benefits.* The elimination of all or substantially all benefits to diagnose or treat a particular condition causes a group health plan or health insurance coverage to cease to be a grandfathered health plan. For this purpose, the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition.

(ii) *Increase in percentage cost-sharing requirement.* Any increase, measured from March 23, 2010, in a percentage cost-sharing requirement (such as an individual's coinsurance requirement) causes a group health plan or health insurance coverage to cease to be a grandfathered health plan.

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, causes a group health plan or health insurance

coverage to cease to be a grandfathered health plan, if the total increase in the copayment measured from March 23, 2010 exceeds the greater of:

(A) An amount equal to \$5 increased by medical inflation, as defined in paragraph (g)(3)(i) of this section (that is, \$5 times medical inflation, plus \$5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage*. A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(3)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in section 146.121(d) of this subchapter) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula*. A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in section 146.121(d) of this subchapter) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(vi) *Changes in annual limits*—(A) *Addition of an annual limit*. A group health plan, or group or individual health insurance coverage, that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits.

(B) *Decrease in limit for a plan or coverage with only a lifetime limit*. A group health plan, or group or individual health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar

value of the lifetime limit on March 23, 2010.

(C) *Decrease in limit for a plan or coverage with an annual limit*. A group health plan, or group or individual health insurance coverage, that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

(2) *Transitional rules*—(i) *Changes made prior to March 23, 2010*. If a group health plan or health insurance issuer makes the following changes to the terms of the plan or health insurance coverage, the changes are considered part of the terms of the plan or health insurance coverage on March 23, 2010 even though they were not effective at that time and such changes do not cause a plan or health insurance coverage to cease to be a grandfathered health plan:

(A) Changes effective after March 23, 2010 pursuant to a legally binding contract entered into on or before March 23, 2010;

(B) Changes effective after March 23, 2010 pursuant to a filing on or before March 23, 2010 with a State insurance department; or

(C) Changes effective after March 23, 2010 pursuant to written amendments to a plan that were adopted on or before March 23, 2010.

(ii) *Changes made after March 23, 2010 and adopted prior to issuance of regulations*. If, after March 23, 2010, a group health plan or health insurance issuer makes changes to the terms of the plan or health insurance coverage and the changes are adopted prior to June 14, 2010, the changes will not cause the plan or health insurance coverage to cease to be a grandfathered health plan if the changes are revoked or modified effective as of the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, and the terms of the plan or health insurance coverage on that date, as modified, would not cause the plan or coverage to cease to be a grandfathered health plan under the rules of this section, including paragraph (g)(1) of this section. For this purpose, changes will be considered to have been adopted prior to June 14, 2010 if:

(A) The changes are effective before that date;

(B) The changes are effective on or after that date pursuant to a legally

binding contract entered into before that date;

(C) The changes are effective on or after that date pursuant to a filing before that date with a State insurance department; or

(D) The changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

(3) *Definitions*—(i) *Medical inflation defined*. For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI-U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI-U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined*. For purposes of this paragraph (g), the term *maximum percentage increase* means medical inflation (as defined in paragraph (g)(3)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined*. For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage*. The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula*. The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

(4) *Examples*. The rules of this paragraph (g) are illustrated by the following examples:

Example 1. (i) Facts. On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion.* In this *Example 1*, the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) Facts. Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2*, the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) Facts. On March 23, 2010, a grandfathered health plan has a copayment requirement of \$30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to \$40. Within the 12-month period before the \$40 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3*, the increase in the copayment from \$30 to \$40, expressed as a percentage, is 33.33% ($40 - 30 = 10$; $10 \div 30 = 0.3333$; $0.3333 = 33.33\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 ($475 - 387.142 = 87.858$; $87.858 \div 387.142 = 0.2269$). The maximum percentage increase permitted is 37.69% ($0.2269 = 22.69\%$; $22.69\% + 15\% = 37.69\%$). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) Facts. Same facts as *Example 3*, except the grandfathered health plan subsequently increases the \$40 copayment requirement to \$45 for a later plan year. Within the 12-month period before the \$45 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4*, the increase in the copayment from \$30 (the copayment that was in effect on March 23, 2010) to \$45, expressed as a percentage, is 50% ($45 - 30 = 15$; $15 \div 30 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is

0.2527 ($485 - 387.142 = 97.858$; $97.858 \div 387.142 = 0.2527$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% ($0.2527 = 25.27\%$; $25.27\% + 15\% = 40.27\%$), or \$6.26 ($\$5 \times 0.2527 = \1.26 ; $\$1.26 + \$5 = \$6.26$). Because 50% exceeds 40.27% and \$15 exceeds \$6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) Facts. On March 23, 2010, a grandfathered health plan has a copayment of \$10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$15. Within the 12-month period before the \$15 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 5*, the increase in the copayment, expressed as a percentage, is 50% ($15 - 10 = 5$; $5 \div 10 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3) of this section) from March 2010 is 0.0720 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% ($0.0720 = 7.20\%$; $7.20\% + 15\% = 22.20\%$), or \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 5* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to \$5.36.

Example 6. (i) Facts. The same facts as *Example 5*, except on March 23, 2010, the grandfathered health plan has no copayment (\$0) for office visits for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$5.

(ii) *Conclusion.* In this *Example 6*, medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.0720 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 6* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of \$5.36. Thus, the \$5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 7. (i) Facts. On March 23, 2010, a self-insured group health plan provides two

tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 7*, the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 8. (i) Facts. On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of \$5000 for self-only coverage and \$12,000 for family coverage. The required employee contribution for the coverage is \$1000 for self-only coverage and \$4000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ($(5000 - 1000)/5000$) for self-only coverage and 67% ($(12,000 - 4000)/12,000$) for family coverage. For a subsequent plan year, the COBRA premium is \$6000 for self-only coverage and \$15,000 for family coverage. The employee contributions for that plan year are \$1200 for self-only coverage and \$5000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ($(6000 - 1200)/6000$) for self-only coverage and 67% ($(15,000 - 5000)/15,000$) for family coverage.

(ii) *Conclusion.* In this *Example 8*, because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 9. (i) Facts. Before March 23, 2010, Employer *W* and Individual *B* enter into a legally binding employment contract that promises *B* lifetime health coverage upon termination. Prior to termination, *B* is covered by *W*'s self-insured grandfathered group health plan. *B* is terminated after March 23, 2010 and *W* purchases a new health insurance policy providing coverage to *B*, consistent with the terms of the employment contract.

(ii) *Conclusion.* In this *Example 9*, because no individual is enrolled in the health insurance policy on March 23, 2010, it is not a grandfathered health plan.

[FR Doc. 2010-14488 Filed 6-14-10; 11:15 am]

BILLING CODE 4830-01-P, 4510-29-P, 4120-01-P

Preventive Services Interim Final Rules

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 1.2 percent of the complete feed.

(c) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use including a statement that ammonium formate must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing ammonium formate.

(d) To assure safe use of the additive, in addition to the other information required by the act and paragraph (c) of this section, the label and labeling shall contain:

(1) Appropriate warnings and safety precautions concerning ammonium formate (37 percent ammonium salt of formic acid and 62 percent formic acid).

(2) Statements identifying ammonium formate in formic acid (37 percent ammonium salt of formic acid and 62 percent formic acid) as a corrosive and possible severe irritant.

(3) Information about emergency aid in case of accidental exposure as follows:

(i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

Dated: July 14, 2010.

Tracey H. Forfa,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2010-17565 Filed 7-16-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9493]

RIN 1545-BJ60

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB44

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OCIO-9992-IFC]

45 CFR Part 147

RIN 0938-AQ07

Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preventive health services.

DATES: *Effective date.* These interim final regulations are effective on September 17, 2010.

Comment date. Comments are due on or before September 17, 2010.

Applicability dates. These interim final regulations generally apply to group health plans and group health insurance issuers for plan years beginning on or after September 23, 2010. These interim final regulations generally apply to individual health insurance issuers for policy years beginning on or after September 23, 2010.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be

shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB44, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* [E-MAIL: E-OHPSA2713.EBSA@dol.gov](mailto:EHPSA2713.EBSA@dol.gov).

- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, *Attention:* RIN 1210-AB44.

Comments received by the Department of Labor will be posted without change to <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIO-9992-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-9992-IFC, P.O. Box 8016, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the

following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-9992-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments. All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the

headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-120391-10, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* CC:PA:LPD:PR (REG-120391-10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

- *Hand or courier delivery:* Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-120391-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786-1565.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.as) and information on health reform can be found at <http://www.healthreform.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend,

and add to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term "group health plan" includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of part 7 of ERISA and title XXVII of the PHS Act, as amended by the Affordable Care Act, are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers requirements that are stricter than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

¹ The term "group health plan" is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term "health plan," as used in other provisions of title I of the Affordable Care Act. The term "health plan" does not include self-insured group health plans.

² Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing regulations in several phases implementing the revised PHS Act sections 2701 through 2719A and related provisions of the Affordable Care Act. The first phase in this series was the publication of a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the **Federal Register** on April 14, 2010 (75 FR 19297). The second phase was interim final regulations implementing PHS Act section 2714 (requiring dependent coverage of children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). The third phase was interim final regulations implementing section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan), published in the **Federal Register** on June 17, 2010 (75 FR 34538). The fourth phase was interim final regulations implementing PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), and 2719A (regarding patient protections), published in the **Federal Register** on June 28, 2010 (75 FR 37188). These interim final regulations are being published to implement PHS Act section 2713 (relating to coverage for preventive services). PHS Act section 2713 is generally effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act. The implementation of other provisions of PHS Act sections 2701 through 2719A will be addressed in future regulations.

II. Overview of the Regulations: PHS Act Section 2713, Coverage of Preventive Health Services (26 CFR 54.9815–2713T, 29 CFR 2590.715–2713, 45 CFR 147.130)

Section 2713 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations require that a group health plan and a health insurance issuer offering group or individual health insurance coverage provide benefits for and prohibit the imposition of cost-sharing requirements with respect to:

- Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task

Force (Task Force) with respect to the individual involved.³

- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (Advisory Committee) with respect to the individual involved. A recommendation of the Advisory Committee is considered to be “in effect” after it has been adopted by the Director of the Centers for Disease Control and Prevention. A recommendation is considered to be for routine use if it appears on the Immunization Schedules of the Centers for Disease Control and Prevention.

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).

- With respect to women, evidence-informed preventive care and screening guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force). The Department of HHS is developing these guidelines and expects to issue them no later than August 1, 2011.

The complete list of recommendations and guidelines that are required to be covered under these interim final regulations can be found at <http://www.HealthCare.gov/center/regulations/prevention.html>. Together, the items and services described in these recommendations and guidelines are referred to in this preamble as “recommended preventive services.”

These interim final regulations clarify the cost-sharing requirements when a recommended preventive service is provided during an office visit. First, if a recommended preventive service is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit. Second, if a recommended preventive service is

not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit. Finally, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit. The reference to tracking individual encounter data was included to provide guidance with respect to plans and issuers that use capitation or similar payment arrangements that do not bill individually for items and services.

Examples in these interim final regulations illustrate these provisions. In one example, an individual receives a cholesterol screening test, a recommended preventive service, during a routine office visit. The plan or issuer may impose cost-sharing requirements for the office visit because the recommended preventive service is billed as a separate charge. A second example illustrates that treatment resulting from a preventive screening can be subject to cost-sharing requirements if the treatment is not itself a recommended preventive service. In another example, an individual receives a recommended preventive service that is not billed as a separate charge. In this example, the primary purpose for the office visit is recurring abdominal pain and not the delivery of a recommended preventive service; therefore the plan or issuer may impose cost-sharing requirements for the office visit. In the final example, an individual receives a recommended preventive service that is not billed as a separate charge, and the delivery of that service is the primary purpose of the office visit. Therefore, the plan or issuer may not impose cost-sharing requirements for the office visit.

With respect to a plan or health insurance coverage that has a network of providers, these interim final regulations make clear that a plan or issuer is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. Such a plan or issuer may also impose cost-sharing requirements for recommended preventive services delivered by an out-of-network provider.

These interim final regulations provide that if a recommendation or

³ Under PHS Act section 2713(a)(5), the Task Force recommendations regarding breast cancer screening, mammography, and prevention issued in or around November of 2009 are not to be considered current recommendations on this subject for purposes of any law. Thus, the recommendations regarding breast cancer screening, mammography, and prevention issued by the Task Force prior to those issued in or around November of 2009 (*i.e.*, those issued in 2002) will be considered current until new recommendations in this area are issued by the Task Force or appear in comprehensive guidelines supported by the Health Resources and Services Administration concerning preventive care and screenings for women.

guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations. The use of reasonable medical management techniques allows plans and issuers to adapt these recommendations and guidelines to coverage of specific items and services where cost sharing must be waived. Thus, under these interim final regulations, a plan or issuer may rely on established techniques and the relevant evidence base to determine the frequency, method, treatment, or setting for which a recommended preventive service will be available without cost-sharing requirements to the extent not specified in a recommendation or guideline.

The statute and these interim final regulations clarify that a plan or issuer continues to have the option to cover preventive services in addition to those required to be covered by PHS Act section 2713. For such additional preventive services, a plan or issuer may impose cost-sharing requirements at its discretion. Moreover, a plan or issuer may impose cost-sharing requirements for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.

The statute requires the Departments to establish an interval of not less than one year between when recommendations or guidelines under PHS Act section 2713(a)⁴ are issued, and the plan year (in the individual market, policy year) for which coverage of the services addressed in such recommendations or guidelines must be in effect. These interim final regulations provide that such coverage must be provided for plan years (in the

⁴ Section 2713(b)(1) refers to an interval between “the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.” While the first part of this statement does not mention guidelines under subsection (a)(4), it would make no sense to treat the services covered under (a)(4) any differently than those in (a)(1), (a)(2), and (a)(3). First, the same sentence refers to “the requirement described in subsection (a),” which would include a requirement under (a)(4). Secondly, the guidelines under (a)(4) are from the same source as those under (a)(3), except with respect to women rather than infants, children and adolescents; and other preventive services involving women are addressed in (a)(1), so there is no plausible policy rationale for treating them differently. Third, without this clarification, it would be unclear when such services would have to be covered. These interim final regulations accordingly apply the intervals established therein to services under section 2713(a)(4).

individual market, policy years) beginning on or after the later of September 23, 2010, or one year after the date the recommendation or guideline is issued. Thus, recommendations and guidelines issued prior to September 23, 2009 must be provided for plan years (in the individual market, policy years) beginning on or after September 23, 2010. For the purpose of these interim final regulations, a recommendation or guideline of the Task Force is considered to be issued on the last day of the month on which the Task Force publishes or otherwise releases the recommendation; a recommendation or guideline of the Advisory Committee is considered to be issued on the date on which it is adopted by the Director of the Centers for Disease Control and Prevention; and a recommendation or guideline in the comprehensive guidelines supported by HRSA is considered to be issued on the date on which it is accepted by the Administrator of HRSA or, if applicable, adopted by the Secretary of HHS. For recommendations and guidelines adopted after September 23, 2009, information at <http://www.HealthCare.gov/center/regulations/prevention.html> will be updated on an ongoing basis and will include the date on which the recommendation or guideline was accepted or adopted.

Finally, these interim final regulations make clear that a plan or issuer is not required to provide coverage or waive cost-sharing requirements for any item or service that has ceased to be a recommended preventive service.⁵ Other requirements of Federal or State law may apply in connection with ceasing to provide coverage or changing cost-sharing requirements for any such item or service. For example, PHS Act section 2715(d)(4) requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

Recommendations or guidelines in effect as of July 13, 2010 are described in section V later in this preamble. Any change to a recommendation or guideline that has—at any point since September 23, 2009—been included in the recommended preventive services will be noted at <http://www.HealthCare.gov/center/regulations/prevention.html>. As described above, new recommendations and guidelines will also be noted at this

⁵ For example, if a recommendation of the United States Preventive Services Task Force is downgraded from a rating of A or B to a rating of C or D, or if a recommendation or guideline no longer includes a particular item or service.

site and plans and issuers need not make changes to coverage and cost-sharing requirements based on a new recommendation or guideline until the first plan year (in the individual market, policy year) beginning on or after the date that is one year after the new recommendation or guideline went into effect. Therefore, by visiting this site once per year, plans or issuers will have straightforward access to all the information necessary to determine any additional items or services that must be covered without cost-sharing requirements, or to determine any items or services that are no longer required to be covered.

The Affordable Care Act gives authority to the Departments to develop guidelines for group health plans and health insurance issuers offering group or individual health insurance coverage to utilize value-based insurance designs as part of their offering of preventive health services. Value-based insurance designs include the provision of information and incentives for consumers that promote access to and use of higher value providers, treatments, and services. The Departments recognize the important role that value-based insurance design can play in promoting the use of appropriate preventive services. These interim final regulations, for example, permit plans and issuers to implement designs that seek to foster better quality and efficiency by allowing cost-sharing for recommended preventive services delivered on an out-of-network basis while eliminating cost-sharing for recommended preventive health services delivered on an in-network basis. The Departments are developing additional guidelines regarding the utilization of value-based insurance designs by group health plans and health insurance issuers with respect to preventive benefits. The Departments are seeking comments related to the development of such guidelines for value-based insurance designs that promote consumer choice of providers or services that offer the best value and quality, while ensuring access to critical, evidence-based preventive services.

The requirements to cover recommended preventive services without any cost-sharing requirements do not apply to grandfathered health plans. See 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 (75 FR 34538, June 17, 2010).

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS

Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, the preventive health service provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Moreover, the requirements in these interim final

regulations require significant lead time in order to implement. These interim final regulations require plans and issuers to provide coverage for preventive services listed in certain recommendations and guidelines without imposing any cost-sharing requirements. Preparations presumably would have to be made to identify these preventive services. With respect to the changes that would be required to be made under these interim final regulations, group health plans and health insurance issuers subject to these provisions have to be able to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits, and these premiums and plan or policy changes would have to receive necessary approvals in advance of the plan or policy year in question.

Accordingly, in order to allow plans and health insurance coverage to be designed and implemented on a timely basis, regulations must be published and available to the public well in advance of the effective date of the requirements of the Affordable Care Act. It is not possible to have a full notice and comment process and to publish final regulations in the brief time between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the interim final regulations provide the public with an opportunity for

comment, but without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final regulations into effect, and that it is in the public interest to promulgate interim final regulations.

IV. Economic Impact

Under Executive Order 12866 (58 FR 51735), a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a “significant regulatory action” as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. OMB has determined that this regulation is economically significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an annual effect on the economy of \$100 million in any one year. Accordingly, OMB has reviewed these rules pursuant to the Executive Order. The Departments provide an assessment of the potential costs, benefits, and transfers associated with these interim final regulations, summarized in the following table.

TABLE 1—ACCOUNTING TABLE (2011–2013)

Benefits:

Qualitative: By expanding coverage and eliminating cost sharing for the recommended preventive services, the Departments expect access and utilization of these services to increase. To the extent that individuals increase their use of these services the Departments anticipate several benefits: (1) prevention and reduction in transmission of illnesses as a result of immunization and screening of transmissible diseases; (2) delayed onset, earlier treatment, and reduction in morbidity and mortality as a result of early detection, screening, and counseling; (3) increased productivity and fewer sick days; and (4) savings from lower health care costs. Another benefit of these interim final regulations will be to distribute the cost of preventive services more equitably across the broad insured population.

Costs:

Qualitative: New costs to the health care system result when beneficiaries increase their use of preventive services in response to the changes in coverage and cost-sharing requirements of preventive services. The magnitude of this effect on utilization depends on the price elasticity of demand and the percentage change in prices facing those with reduced cost sharing or newly gaining coverage.

Transfers:

TABLE 1—ACCOUNTING TABLE (2011–2013)—Continued

Qualitative: Transfers will occur to the extent that costs that were previously paid out-of-pocket for certain preventive services will now be covered by group health plans and issuers under these interim final regulations. Risk pooling in the group market will result in sharing expected cost increases across an entire plan or employee group as higher average premiums for all enrollees. However, not all of those covered will utilize preventive services to an equivalent extent. As a result, these interim final regulations create a small transfer from those paying premiums in the group market utilizing less than the average volume of preventive services in their risk pool to those whose utilization is greater than average. To the extent there is risk pooling in the individual market, a similar transfer will occur.

A. The Need for Federal Regulatory Action

As discussed later in this preamble, there is current underutilization of preventive services, which stems from three main factors. First, due to turnover in the health insurance market, health insurance issuers do not currently have incentives to cover preventive services, whose benefits may only be realized in the future when an individual may no longer be enrolled. Second, many preventive services generate benefits that do not accrue immediately to the individual that receives the services, making the individual less likely to take-up, especially in the face of direct, immediate costs. Third, some of the benefits of preventive services accrue to society as a whole, and thus do not get factored into an individual's decision-making over whether to obtain such services.

These interim final regulations address these market failures through two avenues. First, they require coverage of recommended preventive services by non-grandfathered group health plans and health insurance issuers in the group and individual markets, thereby overcoming plans' lack of incentive to invest in these services. Second, they eliminate cost-sharing requirements, thereby removing a barrier that could otherwise lead an individual to not obtain such services, given the long-term and partially external nature of benefits.

These interim final regulations are necessary in order to provide rules that plan sponsors and issuers can use to determine how to provide coverage for certain preventive health care services without the imposition of cost sharing in connection with these services.

B. PHS Act Section 2713, Coverage of Preventive Health Services (26 CFR 54.9815–2713T, 29 CFR 2590.715–2713, 45 CFR 147.130)

1. Summary

As discussed earlier in this preamble, PHS Act section 2713, as added by the Affordable Care Act, and these interim final regulations require a group health plan and a health insurance issuer offering group or individual health insurance coverage to provide benefits

for and prohibit the imposition of cost-sharing requirements with respect to the following preventive health services:

- Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (Task Force). While these guidelines will change over time, for the purposes of this impact analysis, the Departments utilized currently available guidelines, which include blood pressure and cholesterol screening, diabetes screening for hypertensive patients, various cancer and sexually transmitted infection screenings, and counseling related to aspirin use, tobacco cessation, obesity, and other topics.

- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (Advisory Committee) with respect to the individual involved.

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).

- With respect to women, evidence-informed preventive care and screening provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force). The Department of HHS is developing these guidelines and expects to issue them no later than August 1, 2011.

2. Preventive Services

For the purposes of this analysis, the Departments used the relevant recommendations of the Task Force and Advisory Committee and current HRSA guidelines as described in section V later in this preamble. In addition to covering immunizations, these lists include such services as blood pressure and cholesterol screening, diabetes screening for hypertensive patients, various cancer and sexually transmitted infection screenings, genetic testing for the BRCA gene, adolescent depression screening, lead testing, autism testing, and oral health screening and

counseling related to aspirin use, tobacco cessation, and obesity.

3. Estimated Number of Affected Entities

For purposes of the new requirements in the Affordable Care Act that apply to group health plans and health insurance issuers in the group and individual markets, the Departments have defined a large group health plan as an employer plan with 100 or more workers and a small group plan as an employer plan with less than 100 workers. The Departments estimated that there are approximately 72,000 large and 2.8 million small ERISA-covered group health plans with an estimated 97.0 million participants in large group plans and 40.9 million participants in small group plans.⁶ The Departments estimate that there are 126,000 governmental plans with 36.1 million participants in large plans and 2.3 million participants in small plans.⁷ The Departments estimate there are 16.7 million individuals under age 65 covered by individual health insurance policies.⁸

As described in the Departments' interim final regulations relating to status as a grandfathered health plan,⁹ the Affordable Care Act preserves the ability of individuals to retain coverage under a group health plan or health insurance coverage in which the individual was enrolled on March 23, 2010 (a grandfathered health plan). Group health plans, and group and individual health insurance coverage, that are grandfathered health plans do not have to meet the requirements of these interim final regulations. Therefore, only plans and issuers offering group and individual health insurance coverage that are not grandfathered health plans will be affected by these interim final regulations.

⁶ All participant counts and the estimates of individual policies are from the U.S. Department of Labor, EBSA calculations using the March 2008 Current Population Survey Annual Social and Economic Supplement and the 2008 Medical Expenditure Panel Survey.

⁷ Estimate is from the 2007 Census of Government.

⁸ US Census Bureau, Current Population Survey, March 2009.

⁹ 75 FR 34538 (June 17, 2010).

Plans can choose to relinquish their grandfather status in order to make certain otherwise permissible changes to their plans.¹⁰ The Affordable Care Act provides plans with the ability to maintain grandfathered status in order to promote stability for consumers while allowing plans and sponsors to make reasonable adjustments to lower costs and encourage the efficient use of services. Based on an analysis of the changes plans have made over the past few years, the Departments expect that more plans will choose to make these changes over time and therefore the number of grandfathered health plans is expected to decrease. Correspondingly, the number of plans and policies affected by these interim final regulations is likely to increase over time. In addition, the number of individuals receiving the benefits of the Affordable Care Act is likely to increase over time. The Departments' mid-range estimate is that 18 percent of large employer plans and 30 percent of small employer plans would relinquish grandfather status in 2011, increasing over time to 45 percent and 66 percent respectively by 2013, although there is substantial uncertainty surrounding these estimates.¹¹

Using the mid-range assumptions, the Departments estimate that in 2011, roughly 31 million people will be enrolled in group health plans subject to the prevention provisions in these interim final regulations, growing to approximately 78 million in 2013.¹² The mid-range estimates suggest that approximately 98 million individuals

will be enrolled in grandfathered group health plans in 2013, many of which already cover preventive services (see discussion of the extent of preventive services coverage in employer-sponsored plans later in this preamble).

In the individual market, one study estimated that 40 percent to 67 percent of individual policies terminate each year. Because all newly purchased individual policies are not grandfathered, the Departments expect that a large proportion of individual policies will not be grandfathered, covering up to and perhaps exceeding 10 million individuals.¹³

However, not all of the individuals potentially affected by these interim final regulations will directly benefit given the prevalence and variation in insurance coverage today. State laws will affect the number of entities affected by all or some provision of these interim final regulations, since plans, policies, and enrollees in States that already have certain requirements will be affected to different degrees.¹⁴ For instance, 29 States require that health insurance issuers cover most or all recommended immunizations for children.¹⁵ Of these 29 States, 18 States require first-dollar coverage of immunizations so that the insurers pay for immunizations without a deductible and 12 States exempt immunizations from copayments (e.g., \$5, \$10, or \$20 per vaccine) or coinsurance (e.g., 10 percent or 20 percent of charges). State laws also require coverage of certain other preventive health services. Every State except Utah mandates coverage for some type of breast cancer screening for women. Twenty-eight States mandate coverage for some cervical cancer screening and 13 States mandate coverage for osteoporosis screening.¹⁶

Estimation of the number of entities immediately affected by some or all provisions of these interim final regulations is further complicated by the fact that, although not all States require insurance coverage for certain preventive services, many health plans

have already chosen to cover these services. For example, most health plans cover most childhood and some adult immunizations contained in the recommendations from the Advisory Committee. A survey of small, medium and large employers showed that 78 percent to 80 percent of their point of service, preferred provider organization (PPO), and health maintenance organization (HMO) health plans covered childhood immunizations and 57 percent to 66 percent covered influenza vaccines in 2001.¹⁷ All 61 health plans (HMOs and PPOs) responding to a 2005 America's Health Insurance Plans (AHIP) survey covered childhood immunizations¹⁸ in their best-selling products and almost all health plans (60 out of 61) covered diphtheria-tetanus-pertussis vaccines and influenza vaccines for adults.¹⁹ A survey of private and public employer health plans found that 84 percent covered influenza vaccines in 2002–2003.²⁰

Similarly, many health plans already cover preventive services today, but there are differences in the coverage of these services in the group and individual markets. According to a 2009 survey of employer health benefits, over 85 percent of employer-sponsored health insurance plans covered preventive services without having to meet a deductible.²¹ Coverage of preventive services does vary slightly by employer size, with large employers being more likely to cover such services than small employers.²² In contrast, coverage of preventive services is less prevalent and varies more significantly in the individual market.²³ For PPOs,

¹⁰ See 75 FR 34538 (June 17, 2010).

¹¹ See 75 FR 34538 (June 17, 2010) for a detailed description of the derivation of the estimates for the percentages of grandfathered health plans. In brief, the Departments used data from the 2008 and 2009 Kaiser Family Foundations/Health Research and Educational Trust survey of employers to estimate the proportion of plans that made changes in cost-sharing requirements that would have caused them to relinquish grandfather status if those same changes were made in 2011, and then applied a set of assumptions about how employer behavior might change in response to the incentives created by the grandfather regulations to estimate the proportion of plans likely to relinquish grandfather status. The estimates of changes in 2012 and 2013 were calculated by using the 2011 calculations and assuming that an identical percentage of plan sponsors will relinquish grandfather status in each year.

¹² To estimate the number of individuals covered in grandfathered health plans, the Departments extended the analysis described in 75 FR 34538, and estimated a weighted average of the number of employees in grandfathered health plans in the large employer and small employer markets separately, weighting by the number of employees in each employer's plan. Estimates for the large employer and small employer markets were then combined, using the estimates supplied above that there are 133.1 million covered lives in the large group market, and 43.2 million in the small group market.

¹³ Adele M. Kirk. *The Individual Insurance Market: A Building Block for Health Care Reform? Health Care Financing Organization Research Synthesis*. May 2008.

¹⁴ Of note, State insurance requirements do not apply to self-insured group health plans, whose participants and beneficiaries make up 57 percent of covered employees (in firms with 3 or more employees) in 2009 according to a major annual survey of employers due to ERISA preemption of State insurance laws. See e.g., Kaiser Family Foundation and Health Research and Education Trust, *Employer Health Benefits 2009 Annual Survey* (2009).

¹⁵ See e.g., American Academy of Pediatrics, *State Legislative Report* (2009).

¹⁶ See Kaiser Family Foundation, www.statehealthfacts.org.

¹⁷ See e.g., Mary Ann Bondi et al., "Employer Coverage of Clinical Preventive Services in the United States," *American Journal of Health Promotion*, 20(3), pp. 214–222 (2006).

¹⁸ The specific immunizations include: DTaP (diphtheria and tetanus toxoids and acellular Pertussis), Hib (*Haemophilus influenzae* type b), Hepatitis B, inactivated polio, influenza, MMR (measles, mumps, and rubella), pneumococcal, and varicella vaccine.

¹⁹ McPhillips-Tangum C., Rehm B., Hilton O. "Immunization practices and policies: A survey of health insurance plans." *AHIP Coverage*. 47(1), 32–7 (2006).

²⁰ See e.g., Matthew M. Davis et al., "Benefits Coverage for Adult Vaccines in Employer-Sponsored Health Plans," University of Michigan for the CDC National Immunizations Program (2003).

²¹ See e.g., Kaiser Family Foundation and Health Research and Education Trust, *Employer Health Benefits 2009 Annual Survey* (2009) available at <http://ehbs.kff.org/pdf/2009/7936.pdf>.

²² See e.g., Mary Ann Bondi et al., "Employer Coverage of Clinical Preventive Services in the United States," *American Journal of Health Promotion*, 20(3), pp. 214–222 (2006).

²³ See e.g., Matthew M. Davis et al., "Benefits Coverage for Adult Vaccines in Employer-Sponsored Health Plans," University of Michigan

only 66.2 percent of single policies purchased covered adult physicals, while 94.1 percent covered cancer screenings.²⁴

In summary, the number of affected entities depends on several factors, such as whether a health plan retains its grandfather status, the number of new health plans, whether State benefit requirements for preventive services apply, and whether plans or issuers voluntarily offer coverage and/or no cost sharing for recommended preventive services. In addition, participants, beneficiaries, and enrollees in such plans or health insurance coverage will be affected in different ways: Some will newly gain coverage for recommended preventive services, while others will have the cost sharing that they now pay for such services eliminated. As such, there is considerable uncertainty surrounding estimation of the number of entities affected by these interim final regulations.

4. Benefits

The Departments anticipate that four types of benefits will result from these interim final regulations. First, individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease. Second, healthier workers and children will be more productive with fewer missed days of work or school. Third, some of the recommended preventive services will result in savings due to lower health care costs. Fourth, the cost of preventive services will be distributed more equitably.

By expanding coverage and eliminating cost sharing for

recommended preventive services, these interim final regulations could be expected to increase access to and utilization of these services, which are not used at optimal levels today. Nationwide, almost 38 percent of adult residents over 50 have never had a colorectal cancer screening (such as a sigmoidoscopy or a colonoscopy)²⁵ and almost 18 percent of women over age 18 have not been screened for cervical cancer in the past three years.²⁶ Vaccination rates for childhood vaccines are generally high due to State laws requiring certain vaccinations for children to enter school, but recommended childhood vaccines that are not subject to State laws and adult vaccines have lower vaccination rates (e.g., the meningococcal vaccination rate among teenagers is 42 percent).²⁷ Studies have shown that improved coverage of preventive services leads to expanded utilization of these services,²⁸ which would lead to substantial benefits as discussed further below.

In addition, these interim final regulations limit preventive service coverage under this provision to services recommended by the Task Force, Advisory Committee, and HRSA. The preventive services given a grade of A or B by the Task Force have been determined by the Task Force to have at least fair or good²⁹ evidence that the preventive service improves important health outcomes and that benefits outweigh harms in the judgment of an independent panel of private sector experts in primary care and prevention.³⁰ Similarly, the mission of the Advisory Committee is to provide advice that will lead to a reduction in the incidence of vaccine preventable

diseases in the United States, and an increase in the safe use of vaccines and related biological products. The comprehensive guidelines for infants, children, and adolescents supported by HRSA are developed by multidisciplinary professionals in the relevant fields to provide a framework for improving children's health and reducing morbidity and mortality based on a review of the relevant evidence. The statute and interim final regulations limit the preventive services covered to those recommended by the Task Force, Advisory Committee, and HRSA because the benefits of these preventive services will be higher than others that may be popular but unproven.

Research suggests significant health benefits from a number of the preventive services that would be newly covered with no cost sharing by plans and issuers under the statute and these interim final regulations. A recent article in *JAMA* stated, "By one account, increasing delivery of just five clinical preventive services would avert 100,000 deaths per year."³¹ These five services are all items and services recommended by the Task Force, Advisory Committee, and/or the comprehensive guidelines supported by HRSA. The National Council on Prevention Priorities (NCP) estimated that almost 150,000 lives could potentially be saved by increasing the 2005 rate of utilization to 90 percent for eight of the preventive services recommended by the Task Force or Advisory Committee.³² Table 2 shows eight of the services and the number of lives potentially saved if utilization of preventive services were to increase to 90 percent.

for the CDC National Immunizations Program (2003).

²⁴ See Individual Health Insurance 2006–2007: A Comprehensive Survey of Premiums, Availability, and Benefits. Available at http://www.ahipresearch.org/pdfs/Individual_Market_Survey_December_2007.pdf.

²⁵ This differs from the Task Force recommendation that individuals aged 50–75 receive fecal occult blood testing, sigmoidoscopy, or colonoscopy screening for colorectal cancer.

²⁶ For Behavioral Risk Factor Surveillance System Numbers see e.g., Centers for Disease Control and Prevention (CDC). *Behavioral Risk Factor Surveillance System Survey Data*. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, (2008) at <http://apps.nccd.cdc.gov/BRFSS/page.asp?cat=CC&yr=2008&state=UB#CC>.

²⁷ See <http://www.cdc.gov/vaccines/stats-surv/imm-coverage.htm#nis> for vaccination rates.

²⁸ See e.g., Jonathan Gruber, *The Role of Consumer Copayments for Health Care: Lessons from the RAND Health Insurance Experiment and Beyond*, Kaiser Family Foundation (Oct. 2006). This paper examines an experiment in which copays randomly vary across several thousand individuals.

The author finds that individuals are sensitive to prices for health services—i.e. as copays decline, more services are demanded. See e.g., Sharon Long, "On the Road to Universal Coverage: Impacts of Reform in Massachusetts At One Year," *Health Affairs*, Volume 27, Number 4 (June 2008). The author investigated the case of Massachusetts, where coverage of preventive services became a requirement in 2007, and found that for individuals under 300 percent of the poverty line, doctor visits for preventive care increased by 6.1 percentage points in the year after adoption, even after controlling for observable characteristics. Additionally, the incidence of individuals citing cost as the reason for not receiving preventive screenings declined by 2.8 percentage points from 2006 to 2007. In the Massachusetts case, these preventive care services were not necessarily free; therefore, economists would expect a higher differential under these interim final rules because of the price sensitivity of health care usage.

²⁹ The Task Force defines good and fair evidence as follows. Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality or consistency of the individual studies, generalizability to routine practice or indirect nature of the evidence on health outcomes. See <http://www.ahrq.gov/clinic/uspstf/gradespre.htm#drec>.

³⁰ See <http://www.ahrq.gov/clinic/uspstf/gradespre.htm#drec> for details of the Task Force grading.

³¹ Woolf, Steven. A Closer Look at the Economic Argument for Disease Prevention. *JAMA* 2009;301(5):536–538.

³² See National Commission on Prevention Priorities. *Preventive Care: A National Profile on Use, Disparities, and Health Benefits*. Partnership for Prevention, August 2007 at <http://www.prevent.org/content/view/full/129/72/#citations> accessed on 6/22/2010. Lives saved were estimated using models previously developed to rank clinical preventive services. See Maciosek MV, Edwards NM, Coffield AB, Flottesmesch TJ, Nelson WW, Goodman MJ, Riecke DA, Butani AB, Solberg LI. Priorities among effective clinical preventive services: methods. *Am J Prev Med* 2006; 31(1):90–96.

TABLE 2.—LIVES SAVED FROM INCREASING UTILIZATION OF SELECTED PREVENTIVE SERVICES TO 90 PERCENT

Preventive service	Population group	Percent utilizing preventive service in 2005	Lives saved annually if percent utilizing preventive service increased to 90 percent
Regular aspirin use	Men 40+ and women 50+	40	45,000
Smoking cessation advice and help to quit	All adult smokers	28	42,000
Colorectal cancer screening	Adults 50+	48	14,000
Influenza vaccination	Adults 50+	37	12,000
Cervical cancer screening in the past 3 years	Women 18–64	83	620
Cholesterol screening	Men 35+ and women 45+	79	2,450
Breast cancer screening in the past 2 years	Women 40+	67	3,700
Chlamydia screening	Women 16–25	40	30,000

Source: National Commission on Prevention Priorities, 2007.

Since financial barriers are not the only reason for sub-optimal utilization rates, population-wide utilization of preventive services is unlikely to increase to the 90 percent level assumed in Table 2 as a result of these interim final regulations. Current utilization of preventive services among insured populations varies widely, but the Departments expect that utilization will increase among those individuals in plans affected by the regulation because the provisions eliminate cost sharing and require coverage for these services.

These interim final regulations are expected to increase the take-up rate of preventive services and are likely, over time, to lead physicians to increase their use of these services knowing that they will be covered, and covered with zero copayment. In the absence of data on the elasticity of demand for these specific services, it is difficult to know precisely how many more patients will use these services. Evidence from studies comparing the utilization of preventive services such as blood pressure and cholesterol screening between insured and uninsured individuals with relatively high incomes suggests that coverage increases usage rates in a wide range between three and 30 percentage points, even among those likely to be able to afford basic preventive services out-of-pocket.³³ A reasonable assumption is that the average increase in utilization of these services will be modest, perhaps on the order of 5 to 10 percentage points for some of them. For services that are generally covered without cost sharing in the current market, the Departments would expect minimal change in utilization.

³³ The Commonwealth Fund. "Insurance Coverage and the Receipt of Preventive Care." 2005. <http://www.commonwealthfund.org/Content/Performance-Snapshots/Financial-and-Structural-Access-to-Care/Insurance-Coverage-and-Receipt-of-Preventive-Care.aspx>.

Preventive services' benefits have also been evaluated individually. Effective cancer screening, early treatment, and sustained risk reduction could reduce the death rate due to cancer by 29 percent.³⁴ Improved blood sugar control could reduce the risk for eye disease, kidney disease and nerve disease by 40 percent in people with Type 1 or Type 2 diabetes.³⁵

Some recommended preventive services have both individual and public health value. Vaccines have reduced or eliminated serious diseases that, prior to vaccination, routinely caused serious illnesses or deaths. Maintaining high levels of immunization in the general population protects the un-immunized from exposure to the vaccine-preventable disease, so that individuals who cannot receive the vaccine or who do not have a sufficient immune response to the vaccine to protect against the disease are indirectly protected.³⁶

A second type of benefit from these interim final regulations is improved workplace productivity and decreased absenteeism for school children. Numerous studies confirm that ill health compromises worker output and that health prevention efforts can improve worker productivity. For example, one study found that 69 million workers reported missing days due to illness and 55 million workers reported a time when they were unable to concentrate at work because of their own illness or a family member's

³⁴ Curry, Susan J., Byers, Tim, and Hewitt, Maria, eds. 2003. *Fulfilling the Potential of Cancer Prevention and Early Detection*. Washington, DC: National Academies Press.

³⁵ Centers for Disease Control and Prevention. 2010. *Diabetes at a Glance*. See http://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2010/diabetes_aag.pdf.

³⁶ See Modern Infectious Disease Epidemiology by Johan Giesecke 1994. Chapter 18, *The Epidemiology of Vaccination*.

illness.³⁷ Together, labor time lost due to health reasons represents lost economic output totaling \$260 billion per year.³⁸ Prevention efforts can help prevent these types of losses. Studies have also shown that reduced cost-sharing for medical services results in fewer restricted-activity days at work,³⁹ and increased access to health insurance coverage improves labor market outcomes by improving worker health.⁴⁰ Thus, the expansion of benefits and the elimination of cost sharing for preventive services as provided in these

³⁷ Health and Productivity Among U.S. Workers, Karen Davis, Ph.D., Sara R. Collins, Ph.D., Michelle M. Doty, Ph.D., Alice Ho, and Alyssa L. Holmgren, The Commonwealth Fund, August 2005 <http://www.commonwealthfund.org/Content/Publications/Issue-Briefs/2005/Aug/Health-and-Productivity-Among-U-S-Workers.aspx>.

³⁸ *Ibid.*

³⁹ See e.g., RAND, *The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate*, Rand Research Brief, Number 9174 (2006), at http://www.rand.org/pubs/research_briefs/2006/RAND_RB9174.pdf and Janet Currie et al., "Has Public Health Insurance for Older Children Reduced Disparities in Access to Care and Health Outcomes?" *Journal of Health Economics*, Volume 27, Issue 6, pages 1567–1581 (Dec. 2008). With early childhood interventions, there appear to be improved health outcomes in later childhood. Analogously, health interventions in early adulthood could have benefits for future productivity.

⁴⁰ In a RAND policy brief, the authors cite results from the RAND Health Insurance Experiment in which cost-sharing is found to correspond with workers having fewer restricted-activity days—evidence that free care for certain services may be productivity enhancing. See e.g., RAND, *The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate*, Rand Research Brief, Number 9174 (2006), at http://www.rand.org/pubs/research_briefs/2006/RAND_RB9174.pdf. See e.g., Janet Currie et al., "Has Public Health Insurance for Older Children Reduced Disparities in Access to Care and Health Outcomes?" *Journal of Health Economics*, Volume 27, Issue 6, pages 1567–1581 (Dec. 2008). With early childhood interventions, there appears to be improved health outcomes in later childhood. Analogously, health interventions in early adulthood could have benefits for future productivity. Council of Economic Advisers. "The Economic Case for Health Reform." (2009).

interim final regulations can be expected to have substantial productivity benefits in the labor market.

Illnesses also contribute to increased absenteeism among school children, which could be avoided with recommended preventive services. In 2006, 56 percent of students missed between one and five days of school due to illness, 10 percent missed between six and ten days and five percent missed 11 or more days.⁴¹ Obesity in particular contributes to missed school days: One study from the University of Pennsylvania found that overweight children were absent on average 20 percent more than their normal-weight peers.⁴² Studies also show that influenza contributes to school absenteeism, and vaccination can reduce missed school days and indirectly improve community health.⁴³ These interim final regulations will ensure that children have access to preventive services, thus decreasing the number of days missed due to illness.⁴⁴ Similarly, regular pediatric care, including care by physicians specializing in pediatrics, can improve child health outcomes and avert preventable health care costs. For example, one study of Medicaid enrolled children found that when children were up to date for their age on their schedule of well-child visits, they were less likely to have an avoidable hospitalization at a later time.⁴⁵

A third type of benefit from some preventive services is cost savings. Increasing the provision of preventive services is expected to reduce the incidence or severity of illness, and, as a result, reduce expenditures on treatment of illness. For example, childhood vaccinations have generally been found to reduce such expenditures by more than the cost of the vaccinations themselves and generate considerable benefits to society. Researchers at the Centers for Disease

⁴¹ Bloom B, Cohen RA. Summary health statistics for U.S. children: National Health Interview Survey, 2006. *Vital Health Stat* 2007;10(234). Available at <http://www.cdc.gov/nchs/nhis.htm>.

⁴² University of Pennsylvania 2007: <http://www.upenn.edu/pennnews/news/childhood-obesity-indicates-greater-risk-school-absenteeism-university-pennsylvania-study-revea>.

⁴³ Davis, Mollie M., James S. King, Ginny Cummings, and Laurence S. Madger. "Countywide School-Based Influenza Immunization: Direct and Indirect Impact on Student Absenteeism." *Pediatrics* 122.1 (2008).

⁴⁴ Moonie, Sheniz, David A. Sterling, Larry Figgis, and Mario Castro. "Asthma Status and Severity Affects Missed School Days." *Journal of School Health* 76.1 (2006): 18–24.

⁴⁵ Bye, "Effectiveness of Compliance with Pediatric Preventative Care Guidelines Among Medicaid Beneficiaries."

Control and Prevention (CDC) studying the economic impact of DTaP (diphtheria and tetanus toxoids and acellular Pertussis), Td (tetanus and diphtheria toxoids), Hib (*Haemophilus influenzae* type b), IPV (inactivated poliovirus), MMR (measles, mumps and rubella), Hepatitis B and varicella routine childhood vaccines found that every dollar spent on immunizations in 2001 was estimated to save \$5.30 on direct health care costs and \$16.50 on total societal costs of the diseases as they are prevented or reduced (direct health care associated with the diseases averted were \$12.1 billion and total societal costs averted were \$33.9 billion).⁴⁶

A review of preventive services by the National Committee on Prevention Priorities found that, in addition to childhood immunizations, two of the recommended preventive services—discussing aspirin use with high-risk adults and tobacco use screening and brief intervention—are cost-saving on net.⁴⁷ By itself, tobacco use screening with a brief intervention was found to save more than \$500 per smoker.⁴⁸

Another area where prevention could achieve savings is obesity prevention and reduction. Obesity is widely recognized as an important driver of higher health care expenditures.⁴⁹ The Task Force recommends children over age six and adults be screened for obesity and be offered or referred to counseling to improve weight status or promote weight loss. Increasing obesity screening and referrals to counseling should decrease obesity and its related costs. If providers are able to proactively identify and monitor obesity in child patients, they may reduce the incidence of adult health conditions that can be expensive to treat, such as diabetes,

⁴⁶ Fangjun Zhou, Jeanne Santoli, Mark L. Messonnier, Hussain R. Yusuf, Abigail Shefer, Susan Y. Chu, Lance Rodewald, Rafael Harpaz. Economic Evaluation of the 7-Vaccine Routine Childhood Immunization Schedule in the United States. *Archives of Pediatric and Adolescent Medicine* 2005; 159(12): 1136–1144. The estimates of the cost savings are based on current immunization levels. The incremental impact of increasing immunization rates is likely to be smaller, but still significant and positive.

⁴⁷ Maciosek MV, Coffield AB, Edwards NM, Coffield AB, Flottemesch TJ, Goodman MJ, Solberg LI. Priorities among effective clinical preventive services: Results of a Systematic Review and Analysis. *Am J Prev Med* 2006; 31(1):52–61.

⁴⁸ Solberg LI, Maciosek, MV, Edwards NM, Khanchandani HS, and Goodman MJ. Repeated tobacco-use screening and intervention in clinical practice: Health impact and cost effectiveness. *American Journal of Preventive Medicine*. 2006;31(1).

⁴⁹ Congressional Budget Office. "Technological Change and the Growth of Health Care Spending." January 2008. Box 1, pdf p. 18. <http://www.cbo.gov/ftpdocs/89xx/doc8947/01-31-TechHealth.pdf>.

hypertension, and adult obesity.⁵⁰ One recent study estimated that a one-percentage-point reduction in obesity among twelve-year-olds would save \$260.4 million in total medical expenditures.⁵¹

A full quantification of the cost savings from the extension of coverage of preventive services in these interim final regulations is not possible, but to illustrate the potential savings, an assessment of savings from obesity reduction was conducted. According to the CDC, in 2008, 34.2 percent of U.S. adults and 16.9 percent of children were obese (defined as having a body mass index (BMI) of 30.0 or greater).⁵² Obesity is associated with increased risk for coronary heart disease, hypertension, stroke, type 2 diabetes, several types of cancer, diminished mobility, and social stigmatization.⁵³ As a result, obesity is widely recognized as an important driver of higher health care expenditures on an individual⁵⁴ and national level.⁵⁵

As described below, the Departments' analysis assumes that the utilization of preventive services will increase when they are covered with zero copayment, and these interim final regulations are expected to increase utilization of dietary counseling services both among people who currently have the service covered with a copayment and among people for whom the service is not currently covered at all.

Data from the 2009 Kaiser Family Foundation Employer Health Benefits Survey shows that 73 percent of employees with employer-sponsored insurance from a small (< 200 employees) employer do not currently have coverage for weight loss programs,

⁵⁰ "Working Group Report on Future Research Directions in Childhood Obesity Prevention and Treatment." National Heart, Lung and Blood Institute, National Institutes of Health, U.S. Department of Health and Human Services (2007), available at <http://www.nhlbi.nih.gov/meetings/workshops/child-obesity/index.htm>.

⁵¹ *Ibid.*

⁵² Centers for Disease Control and Prevention. "Obesity and Overweight." 2010. <http://www.cdc.gov/nchs/fastats/overwt.htm>.

⁵³ Agency for Healthcare Research and Quality (AHRQ). "Screening for Obesity in Adults." December 2003. <http://www.ahrq.gov/clinic/3rduspstf/obesity/obesrr.pdf>.

⁵⁴ Thorpe, Kenneth E. "The Future Costs of Obesity: National and State Estimates of the Impact of Obesity on Direct Health Care Expenses." November 2009; McKinsey Global Institute. "Sample data suggest that obese adults can incur nearly twice the annual health care costs of normal-weight adults." 2007.

⁵⁵ Congressional Budget Office. "Technological Change and the Growth of Health Care Spending." January 2008. Box 1, pdf p. 18. <http://www.cbo.gov/ftpdocs/89xx/doc8947/01-31-TechHealth.pdf>.

compared to 38 percent at large firms.⁵⁶ In the illustrative analysis below, the share of individuals without weight loss coverage in the individual market is assumed to be equal to the share in the small group market.

The size of the increase in the number of individuals receiving dietary counseling or other weight loss services will be limited by current physician practice patterns, in which relatively few individuals who are obese receive physician recommendations for dietary counseling. In one study of patients at an internal medicine clinic in the Bronx, NY, approximately 15 percent of obese patients received a recommendation for dietary counseling.⁵⁷ Similarly, among overweight and obese patients enrolled in the Cholesterol Education and Research Trial, approximately 15 to 20 percent were referred to nutrition counseling.⁵⁸

These interim final regulations are expected to increase the take-up rate of counseling among patients who are referred to it, and may, over time, lead physicians to increase their referral to such counseling, knowing that it will be covered, and covered without cost sharing. The effect of these interim final regulations is expected to be magnified because of the many other public and private sector initiatives dedicated to combating the obesity epidemic.

In the absence of data on take-up of counseling among patients who are referred by their physicians, it is difficult to know what fraction of the estimated 15 percent to 20 percent of patients who are currently referred to counseling follow through on that referral, or how that fraction will change after coverage of these services is expanded. A reasonable assumption is that utilization of dietary counseling among patients who are obese might increase by five to 10 percentage points as a result of these interim final regulations. If physicians change their behavior and increase the rate at which they refer to counseling, the effect might be substantially larger.

The share of obese individuals without weight loss coverage is

⁵⁶ Kaiser Family Foundation. 2009 Employer Health Benefits Annual Survey. Public Use File provided to CEA; documentation of statistical analysis available upon request. See <http://ehbs.kff.org>.

⁵⁷ Davis NJ, Emerenini A, Wylie-Rosett J. "Obesity management: physician practice patterns and patient preference." *Diabetes Education*. 2006 Jul-Aug; 32(4):557-61.

⁵⁸ Molly E. Waring, PhD, Mary B. Roberts, MS, Donna R. Parker, ScD and Charles B. Eaton, MD, MS. "Documentation and Management of Overweight and Obesity in Primary Care." *The Journal of the American Board of Family Medicine* 22 (5): 544-552 (2009).

estimated to be 29 percent.⁵⁹ It is assumed that obese individuals have health care costs 39 percent above average, based on a McKinsey Global Institute analysis.⁶⁰ The Task Force noted that counseling interventions led to sustained weight loss ranging from four percent to eight percent of body weight, although there is substantial heterogeneity in results across interventions, with many interventions having little long-term effect.⁶¹ Assuming midpoint reduction of six percent of body weight, the BMI for an individual taking up such an intervention would fall by six percent as well, as height would remain constant. Based on the aforementioned McKinsey Global Institute analysis, a six percent reduction in BMI for an obese individual (from 32 to around 30, for example) would result in a reduction in health care costs of approximately five percent. This parameter for cost reduction is subject to considerable uncertainty, given the wide range of potential weight loss strategies with varying degrees of impact on BMI, and their interconnectedness with changes in individual health care costs.

Multiplying the percentage reduction in health care costs by the total premiums of obese individuals newly gaining obesity prevention coverage allows for an illustrative calculation of the total dollar reduction in premiums, and dividing by total premiums for the affected population allows for an estimate of the reduction in average premiums across the entire affected population. Doing so results in a potential private premium reduction of 0.05 percent to 0.1 percent from lower health care costs due to a reduction in obesity for enrollees in non-grandfathered plans. This does not account for potential savings in Medicaid, Medicare, or other health programs.

A fourth benefit of these interim final regulations will be to distribute the cost of preventive services more equitably across the broad insured population. Some Americans in plans affected by

⁵⁹ This estimate is constructed using a weighted average obesity rate taking into account the share of the population aged 0 to 19 and 20 to 74 and their respective obesity rates, derived from Census Bureau and Centers for Disease Control and Prevention data. U.S. Census Bureau. "Current Population Survey (CPS) Table Creator." 2010. http://www.census.gov/hhes/www/cpstc/cps_table_creator.html. Centers for Disease Control and Prevention. "Obesity and Overweight." 2010. <http://www.cdc.gov/nchs/fastats/overwt.htm>.

⁶⁰ McKinsey Global Institute Analysis provided to CEA.

⁶¹ Agency for Healthcare Research and Quality (AHRQ). "Screening for Obesity in Adults." December 2003. p. 4. <http://www.ahrq.gov/clinic/3rduspstf/obesity/obesrr.pdf>.

these regulations currently have no coverage of certain recommended preventive services, and pay for them entirely out-of-pocket. For some individuals who currently have no coverage of certain recommended preventive services, these interim final regulations will result in a large savings in out-of-pocket payments, and only a small increase in premiums. Many other Americans have limited coverage of certain recommended preventive services, with large coinsurance or deductibles, and also make substantial out-of-pocket payments to obtain preventive services. Some with limited coverage of preventive services will also experience large savings as a result of these interim final regulations. Reductions in out-of-pocket costs are expected to be largest among people in age groups in which relatively expensive preventive services are most likely to be recommended.

5. Costs and Transfers

The changes in how plans and issuers cover the recommended preventive services resulting from these interim final regulations will result in changes in covered benefits and premiums for individuals in plans and health insurance coverage subject to these interim final regulations. New costs to the health system result when beneficiaries increase their use of preventive services in response to the changes in coverage of preventive services. Cost sharing, including coinsurance, deductibles, and copayments, divides the costs of health services between the insurer and the beneficiaries. The removal of cost sharing increases the quantity of services demanded by lowering the direct cost of the service to consumers. Therefore, the Departments expect that the statute and these interim final regulations will increase utilization of the covered preventive services. The magnitude of this effect on utilization depends on the price elasticity of demand.

Several studies have found that individuals are sensitive to prices for health services.⁶² Evidence that consumers change their utilization of preventive services is available from CDC researchers who studied out-of-pocket costs of immunizations for

⁶² See e.g., Jonathan Gruber, *The Role of Consumer Copayments for Health Care: Lessons from the RAND Health Insurance Experiment and Beyond*, Kaiser Family Foundation (Oct. 2006). This paper examines an experiment in which copays randomly vary across several thousand individuals. The author finds that individuals are sensitive to prices for health services—i.e., as copays decline, more services are demanded.

privately insured children up to age 5 in families in Georgia in 2003, to find that a one percent increase in out-of-pocket costs for routine immunizations (DTaP, IPV, MMR, Hib, and Hep B) was associated with a 0.07 percent decrease in utilization.⁶³

Along with new costs of induced utilization, there are transfers associated with these interim final regulations. A transfer is a change in who pays for the services, where there is not an actual change in the level of resources used. For example, costs that were previously paid out-of-pocket for certain preventive services will now be covered by plans and issuers under these interim final regulations. Such a transfer of costs could be expected to lead to an increase in premiums.

a. Estimate of Average Changes in Health Insurance Premiums

The Departments assessed the impact of eliminating cost sharing, increases in services covered, and induced utilization on the average insurance premium using a model to evaluate private health insurance plans against a nationally representative population. The model is based on the Medical Expenditure Panel Survey data from 2004, 2005, and 2006 on household spending on health care, which are scaled to levels consistent with the CMS projections of the National Health Expenditure Accounts.⁶⁴ This data is combined with data from the Employer Health Benefits Surveys conducted by the Kaiser Family Foundation and Health Research and Education Trust to model a “typical PPO coverage” plan. The model then allows the user to assess changes in covered expenses, benefits, premiums, and induced utilization of services resulting from changes in the characteristics of the plan. The analysis of changes in coverage is based on the average per-person covered expenses and insurance benefits. The average covered expense is the total charge for covered services; insurance benefits are the part of the covered expenses covered by the insurer. The effect on the average premium is then estimated based on the percentage changes in the insurance benefits and the distribution of the individuals across individual and group markets in non-grandfathered plans.

⁶³ See e.g., Noelle-Angelique Molinari *et al.*, “Out-of-Pocket Costs of Childhood Immunizations: A Comparison by Type of Insurance Plan,” *Pediatrics*, 120(5) pp. 148–156 (2006).

⁶⁴ The National Health Expenditure Accounts (NHEA) are the official estimates of total health care spending in the United States. See http://www.cms.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp.

The Departments assume that the percent increase for insurance benefits and premiums will be the same. This is based on two assumptions: (1) That administrative costs included in the premium will increase proportionally with the increase in insurance benefits; and (2) that the increases in insurance benefits will be directly passed on to the consumer in the form of higher premiums. These assumptions bias the estimates of premium changes upward. Using this model, the Departments assessed: (1) Changes in cost-sharing for currently covered and utilized services, (2) changes in services covered, and (3) induced utilization of preventive services. There are several additional sources of uncertainty concerning these estimates. First, there is no accurate, granular data on exactly what baseline coverage is for the particular preventive services addressed in these interim final regulations. Second, there is uncertainty over behavioral assumptions related to additional utilization that results from reduced cost-sharing. Therefore, after providing initial estimates, the Departments provide a sensitivity analysis to capture the potential range of impacts of these interim final regulations.

From the Departments’ analysis of the Medical Expenditure Panel Survey (MEPS) data, controlled to be consistent with projections of the National Health Expenditure Accounts, the average person with employer-sponsored insurance (ESI) has \$264 in covered expenses for preventive services, of which \$240 is paid by insurance, and \$24 is paid out-of-pocket.⁶⁵ When preventive services are covered with zero copayment, the Departments expect the average preventive benefit (holding utilization constant) will increase by \$24. This is a 0.6 percent increase in insurance benefits and premiums for plans that have relinquished their grandfather status. A similar, but larger effect is expected in the individual market because existing evidence suggests that individual health insurance policies generally have less generous benefits for preventive services than group health plans. However, the evidence base for current coverage and cost sharing for preventive services in individual health insurance policies is weaker than for group health plans, making estimation of the increase in average benefits and premiums in the individual market highly uncertain.

⁶⁵ The model does not distinguish between recommended and non-recommended preventive services, and so this likely represents an overestimate of the insurance benefits for preventive services.

For analyses of changes in covered services, the Departments used the Blue Cross/Blue Shield Standard (BC/BS) plan offered through the Federal Employees Health Benefits Program as an average plan.⁶⁶ Other analyses have used the BC/BS standard option as an average plan as it was designed to reflect standard practice within employer-sponsored health insurance plans.⁶⁷ BC/BS covers most of the preventive services listed in the Task Force and Advisory Committee recommendations, and most of the preventive services listed in the comprehensive guidelines for infants, children, and adolescents supported by HRSA. Not covered by the BC/BS Standard plan are the recommendations for genetic testing for the BRCA gene, adolescent depression screening,⁶⁸ lead testing, autism testing, and oral health screening.⁶⁹

The Departments estimated the increase in benefits from newly covered services by estimating the number of new services that would be provided times the cost of providing the services, and then spread these new costs across the total insured population. The Departments estimated that adding coverage for genetic screening and depression screening would increase insurance benefits an estimated 0.10 percent. Adding lead testing, autism testing, and oral health screening would increase insurance benefits by an estimated 0.02 percent. This results in a total average increase in insurance benefits on these services of 0.12 percent, or just over \$4 per insured person. This increase represents a mixture of new costs and transfers, dependent on whether beneficiaries previously would have purchased these services on their own. It is also important to remember that actual plan

⁶⁶ The Blue Cross Blue Shield standard option plan documentation is available online at <http://jepblue.org/benefitplans/standard-option/index.html>.

⁶⁷ Frey A, Mika S, Nuzum R, and Schoen C. “Setting a National Minimum Standard for Health Benefits: How do State Benefit Mandates Compare with Benefits in Large-Group Plans?” Issue Brief. Commonwealth Fund June 2009 available at <http://www.commonwealthfund.org/Content/Publications/Issue-Briefs/2009/Jun/Setting-a-National-Minimum-Standard-for-Health-Benefits.aspx>.

⁶⁸ The Task Force recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for BRCA testing and screening of adolescents (12–18 years of age) for major depressive disorder (MDD) when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.

⁶⁹ Lead, autism, and oral health screening are from the HRSA comprehensive guidelines.

impacts will vary depending on baseline benefit levels, and that grandfathered health plans will not experience any impact from these interim final regulations. The Departments expect the increase to be larger in the individual market because coverage of preventive services in the individual market is less complete than coverage in the group market, but as noted previously, the evidence base for the individual market is weaker than that of the group market, making detailed estimates of the size of this effect difficult and highly uncertain.

Actuaries use an “induction formula” to estimate the behavioral change in response to changes in the relative levels of coverage for health services. For this analysis, the Departments used the model to estimate the induced demand (the increased use of preventive services). The model uses a standard actuarial formula for induction $1/(1+\alpha \cdot P)$, where α is the “induction parameter” and P is the average fraction of the cost of services paid by the consumer. The induction parameter for physician services is 0.7, derived by the standard actuarial formula that is generally consistent with the estimates of price elasticity of demand from the RAND Health Insurance Experiment and other economic studies.⁷⁰ Removing cost sharing for preventive services lowers the direct cost to consumers of using preventive services, which induces additional utilization, estimated with the model above to increase covered expenses and benefits by approximately \$17, or 0.44 percent in insurance benefits in group health plans. The Departments expect a similar but larger effect in the individual market, although these estimates are highly uncertain.

The Departments calculated an estimate of the average impact using the information from the analyses described above, using estimates of the number of individuals in non-grandfathered health plans in the group and individual markets in 2011. The Departments estimate that premiums will increase by approximately 1.5 percent on average for enrollees in non-grandfathered plans. This estimate assumes that any changes in insurance benefits will be directly passed on to the consumer in the form of changes in premiums. As mentioned earlier, this assumption biases the estimates of premium change upward.

⁷⁰ Standard formula best described in “Quantity-Price Relationships in Health Insurance”, Charles L. Trowbridge, Chief Actuary, Social Security Administration (DHEW Publication No. (SSA)73-11507, November 1972).

b. Sensitivity analysis

As discussed previously, there is substantial uncertainty associated with the estimates presented above. To address the uncertainty in the group market, the Departments first varied the estimated change to underlying benefits, to address the particular uncertainty behind the estimate of baseline coverage of preventive services in the group market. The estimate for the per person annual increase in insurance benefits from adding coverage for new services is approximately \$4. The Departments considered the impact of a smaller and larger addition in benefits of approximately \$2 and \$6 per person. To consider the impact of uncertainty around the size of the behavioral change (that is, the utilization of more services when cost sharing is eliminated), the Departments analyzed the impact on insurance benefits if the behavioral change were 15 percent smaller and 15 percent larger.

In the individual market, to accommodate the greater uncertainty relative to the group market, the Departments considered the impact of varying the increase in benefits resulting from cost shifting due to the elimination of cost sharing, in addition to varying the cost of newly covered services and behavioral change.

Combining results in the group and individual markets for enrollees in non-grandfathered plans, the Departments’ low-end is a few tenths of a percent lower than the mid-range estimate of approximately 1.5 percent, and the high-end estimate is a few tenths of a percent higher. Grandfathered health plans are not subject to these interim final regulations and therefore would not experience this premium change.

6. Alternatives Considered

Several provisions in these interim final regulations involved policy choices. One was whether to allow a plan or issuer to impose cost sharing for an office visit when a recommended preventive service is provided in that visit. Sometimes a recommended preventive service is billed separately from the office visit; sometimes it is not. The Departments decided that the cost sharing prohibition of these interim final regulations applies to the specific preventive service as recommended by the guidelines. Therefore, if the preventive service is billed separately from the office visit, it is the preventive service that has cost sharing waived, not the entire office visit.

A second policy choice was if the preventive service is not billed separately from the office visit, whether

these interim final regulations should prohibit cost sharing for any office visit in which any recommended preventive service was administered, or whether cost sharing should be prohibited only when the preventive service is the primary purpose of the office visit. Prohibiting cost sharing for office visits when any recommended preventive service is provided, regardless of the primary purpose of the visit, could lead to an overly broad application of these interim final regulations; for example, a person who sees a specialist for a particular condition could end up with a zero copayment simply because his or her blood pressure was taken as part of the office visit. This could create financial incentives for consumers to request preventive services at office visits that are intended for other purposes in order to avoid copayments and deductibles. The increased prevalence of the application of zero cost sharing would lead to increased premiums compared with the chosen option, without a meaningful additional gain in access to preventive services.

A third issue involves health plans that have differential cost sharing for services provided by providers who are in and out of their networks. These interim final regulations provide that a plan or issuer is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. The plan or issuer may also impose cost sharing for recommended preventive services delivered by an out-of-network provider. The Departments considered that requiring coverage by out-of-network providers at no cost sharing would result in higher premiums for these interim final regulations. Plans and issuers negotiate allowed charges with in-network providers as a way to promote effective, efficient health care, and allowing differences in cost sharing in- and out-of-network enables plans to encourage use of in-network providers. Allowing zero cost sharing for out of network providers could reduce providers’ incentives to participate in insurer networks. The Departments decided that permitting cost sharing for recommended preventive services provided by out-of-network providers is the appropriate option to preserve choice of providers for individuals, while avoiding potentially larger increases in costs and transfers as well as potentially lower quality care.

C. Regulatory Flexibility Act— Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes

certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B or title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

Moreover, under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These interim final regulations are exempt from APA, because the Departments made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. Consistent with the policy of the RFA, the Departments encourage the public to submit comments that suggest alternative rules that accomplish the stated purpose of the Affordable Care Act and minimize the impact on small entities.

D. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the APA (5 U.S.C. chapter 5) does not apply to these interim final regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published

elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

E. Paperwork Reduction Act: Department of Labor, Department of the Treasury, and Department of Health and Human Services

These interim final regulations are not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) because it does not contain a “collection of information” as defined in 44 U.S.C. 3502 (11).

F. Congressional Review Act

These interim final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare several analytic statements before proposing any rules that may result in annual expenditures of \$100 million (as adjusted for inflation) by State, local and tribal governments or the private sector. These interim final regulations are not subject to the Unfunded Mandates Reform Act because they are being issued as interim final regulations. However, consistent with the policy embodied in the Unfunded Mandates Reform Act, these interim final regulations have been designed to be the least burdensome alternative for State, local and tribal governments, and the private sector, while achieving the objectives of the Affordable Care Act.

H. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their

consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments’ view, these interim final regulations have federalism implications, because they have direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. However, in the Departments’ view, the federalism implications of these interim final regulations are substantially mitigated because, with respect to health insurance issuers, the Departments expect that the majority of States will enact laws or take other appropriate action resulting in their meeting or exceeding the Federal standards.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the HIPAA requirements (including those of the Affordable Care Act) are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of a Federal standard. The conference report accompanying HIPAA indicates that this is intended to be the “narrowest” preemption of State laws. (*See* House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.) States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to “prevent the application of” the Affordable Care Act, and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit

the policy making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected State and local officials, including attending conferences of the National Association of Insurance Commissioners and consulting with State insurance officials on an individual basis. It is expected that the Departments will act in a similar fashion in enforcing the Affordable Care Act requirements. Throughout the process of developing these interim final regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these interim final regulations, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached regulations in a meaningful and timely manner.

V. Recommended Preventive Services as of July 14, 2010

The materials that follow list recommended preventive services, current as of July 14, 2010, that will have to be covered without cost-sharing

when delivered by an in-network provider. In many cases, the recommendations or guidelines went into effect before September 23, 2009; therefore the recommended services must be covered under these interim final regulations in plan years (in the individual market, policy years) that begin on or after September 23, 2010. However, there are some services that appear in the figure that are based on recommendations or guidelines that went into effect at some point later than September 23, 2009. Those services do not have to be covered under these interim final regulations until plan years (in the individual market, policy years) that begin at some point later than September 23, 2010. In addition, there are a few recommendations and guidelines that went into effect after September 23, 2009 and are not included in the figure. In both cases, information at <http://www.HealthCare.gov/center/regulations/prevention.html> specifically identifies those services and the relevant dates. The materials at <http://www.HealthCare.gov/center/regulations/prevention.html> will be updated on an ongoing basis, and will contain the most current recommended preventive services.

A. Recommendations of the United States Preventive Services Task Force (Task Force)

Recommendations of the Task Force appear in a chart that follows. This chart includes a description of the topic, the text of the Task Force recommendation, the grade the recommendation received

(A or B), and the date that the recommendation went into effect.

B. Recommendations of the Advisory Committee On Immunization Practices (Advisory Committee) That Have Been Adopted by the Director of the Centers for Disease Control and Prevention

Recommendations of the Advisory Committee appear in four immunization schedules that follow: A schedule for children age 0 to 6 years, a schedule for children age 7 to 18 years, a "catch-up" schedule for children, and a schedule for adults. Immunization schedules are issued every year, and the schedules that appear here are the 2010 schedules. The schedules contain graphics that provide information about the recommended age for vaccination, number of doses needed, interval between the doses, and (for adults) recommendations associated with particular health conditions. In addition to the graphics, the schedules contain detailed footnotes that provide further information on each immunization in the schedule.

C. Comprehensive Guidelines Supported by the Health Resources and Services Administration (HRSA) for Infants, Children, and Adolescents

Comprehensive guidelines for infants, children, and adolescents supported by HRSA appear in two charts that follow: The Periodicity Schedule of the Bright Futures Recommendations for Pediatric Preventive Health Care, and the Uniform Panel of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

BILLING CODE 4830-01-P; 4510-29-P; 4210-01-P

Grade A and B Recommendations of the United States Preventive Services Task Force - July 13, 2010

Topic	Text	Grade	Date in Effect
Screening for abdominal aortic aneurysm	The USPSTF recommends one-time screening for abdominal aortic aneurysm (AAA) by ultrasonography in men aged 65 to 75 who have ever smoked.	B	February 28, 2005
Counseling for alcohol misuse	The U.S. Preventive Services Task Force (USPSTF) recommends screening and behavioral counseling interventions to reduce alcohol misuse (go to Clinical Considerations) by adults, including pregnant women, in primary care settings.	B	April 30, 2004
Screening for anemia	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B	May 31, 2006
Aspirin to prevent CVD: men	The USPSTF recommends the use of aspirin for men age 45 to 79 years when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage.	A	March 30, 2009
Aspirin to prevent CVD: women	The USPSTF recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.	A	March 30, 2009
Screening for bacteriuria	The USPSTF recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit, if later.	A	July 31, 2008
Screening for blood pressure	The U.S. Preventive Services Task Force (USPSTF) recommends screening for high blood pressure in adults aged 18 and older.	A	December 31, 2007
Counseling for BRCA screening	The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing.	B	September 30, 2005
Screening for breast cancer (mammography)	The USPSTF recommends screening mammography for women with or without clinical breast examination (CBE), every 1-2 years for women aged 40 and older.	B	September 30, 2002
Chemoprevention of breast cancer	The USPSTF recommends that clinicians discuss chemoprevention with women at high risk for breast cancer and at low risk for adverse effects of chemoprevention. Clinicians should inform patients of the potential benefits and harms of chemoprevention.	B	July 31, 2002
Counseling for breast feeding	The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.	B	October 31, 2008
Screening for cervical cancer	The USPSTF strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix.	B	January 31, 2003
Screening for chlamydia infection, non-pregnant women	The U.S. Preventive Services Task Force (USPSTF) recommends screening for chlamydia infection for all sexually active non-pregnant young women aged 24 and younger and for older non-pregnant women who are at increased risk.	A	June 30, 2007
Screening for chlamydia infection, pregnant women	The USPSTF recommends screening for chlamydia infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk.	B	June 30, 2007

Screening for cholesterol abnormalities: men 35 and older	The U.S. Preventive Services Task Force (USPSTF) strongly recommends screening men aged 35 and older for lipid disorders.	A	June 30, 2008
Screening for cholesterol abnormalities: men younger than 35	The USPSTF recommends screening men aged 20 to 35 for lipid disorders if they are at increased risk for coronary heart disease.	B	June 30, 2008
Screening for cholesterol abnormalities: women 45 and older	The USPSTF strongly recommends screening women aged 45 and older for lipid disorders if they are at increased risk for coronary heart disease.	A	June 30, 2008
Screening for cholesterol abnormalities: women younger than 45	The USPSTF recommends screening women aged 20 to 45 for lipid disorders if they are at increased risk for coronary heart disease.	B	June 30, 2008
Screening for colorectal cancer	The USPSTF recommends screening for colorectal cancer (CRC) using fecal occult blood testing, sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.	A	October 31, 2008
Chemoprevention of dental caries	The USPSTF recommends that primary care clinicians prescribe oral fluoride supplementation at currently recommended doses to preschool children older than 6 months of age whose primary water source is deficient in fluoride.	B	April 30, 2004
Screening for depression: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.	B	December 31, 2009, identical to a 2002 recommendation
Screening for depression: adolescents	The USPSTF recommends screening of adolescents (12-18 years of age) for major depressive disorder (MDD) when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive behavioral or interpersonal), and follow-up.	B	March 30, 2009
Screening for diabetes	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.	B	June 30, 2008
Counseling for diet	The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians.	B	January 30, 2003
Supplementation with folic acid	The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.	A	May 31, 2009
Screening for gonorrhea: women	The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors, go to Clinical Considerations for further discussion of risk factors).	B	May 31, 2005
Prophylactic medication for gonorrhea: newborns	The USPSTF strongly recommends prophylactic ocular topical medication for all newborns against gonococcal ophthalmia neonatorum.	A	May 31, 2005

		B	July 31, 2008
Screening for hearing loss	The USPSTF recommends screening for hearing loss in all newborn infants.	A	September 30, 2007
Screening for hemoglobinopathies	The U. S. Preventive Services Task Force (USPSTF) recommends screening for sickle cell disease in newborns.	A	June 30, 2009
Screening for hepatitis B	The U.S. Preventive Services Task Force (USPSTF) strongly recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit.	A	July 31, 2005
Screening for HIV	The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen for human immunodeficiency virus (HIV) all adolescents and adults at increased risk for HIV infection. (Go to Clinical Considerations for discussion of risk factors).	A	March 31, 2008
Screening for congenital hypothyroidism	The USPSTF recommends screening for congenital hypothyroidism (CH) in newborns.	B	May 30, 2006
Iron supplementation in children	The U.S. Preventive Services Task Force (USPSTF) recommends routine iron supplementation for asymptomatic children aged 6 to 12 months who are at increased risk for iron deficiency anemia (go to Clinical Considerations for a discussion of increased risk).	B	December 31, 2003
Screening and counseling for obesity: adults	The USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.	B	January 31, 2010
Screening and counseling for obesity: children	The USPSTF recommends that clinicians screen children aged 6 years and older for obesity and offer them or refer them to comprehensive, intensive behavioral interventions to promote improvement in weight status.	B	September 30, 2002
Screening for osteoporosis	The U.S. Preventive Services Task Force (USPSTF) recommends that women aged 65 and older be screened routinely for osteoporosis. The USPSTF recommends that routine screening begin at age 60 for women at increased risk for osteoporotic fractures. (Go to Clinical Considerations for discussion of women at increased risk).	A	March 31, 2008
Screening for PKU	The USPSTF recommends screening for phenylketonuria (PKU) in newborns.	A	February 29, 2004
Screening for Rh incompatibility:	The U.S. Preventive Services Task Force (USPSTF) strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.	B	February 29, 2004
Screening for Rh incompatibility: 24-28 weeks' gestation	The USPSTF recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative women at 24-28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.	B	October 31, 2008
Counseling for STIs	The USPSTF recommends high-intensity behavioral counseling to prevent sexually transmitted infections (STIs) for all sexually active adolescents and for adults at increased risk for STIs.	A	April 30, 2009
Counseling for tobacco use: adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.	A	April 30, 2009
Counseling for tobacco use: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke.	A	April 30, 2009

Screening for syphilis: non-pregnant persons	The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen persons at increased risk for syphilis infection.	A	July 31, 2004
Screening for syphilis: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for syphilis infection.	A	July 31, 2004
Screening for visual acuity in children	The USPSTF recommends screening to detect amblyopia, strabismus, and defects in visual acuity in children younger than age 5 years.	B	May 31, 2004

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2010

For those who fall behind or start late, see the catch-up schedule

Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B ¹	HepB	HepB	HepB				HepB					
Rotavirus ²				RV	RV	RV ²						
Diphtheria, Tetanus, Pertussis ³				DTaP	DTaP	DTaP	see footnote ³	DTaP				DTaP
<i>Haemophilus influenzae</i> type b ⁴				Hib	Hib	Hib ⁴		Hib				
Pneumococcal ⁵				PCV	PCV	PCV		PCV			PPSV	
Inactivated Poliovirus ⁶				IPV	IPV							IPV
Influenza ⁷							Influenza (Yearly)					
Measles, Mumps, Rubella ⁸							MMR		see footnote ⁸			MMR
Varicella ⁹							Varicella		see footnote ⁹			Varicella
Hepatitis A ¹⁰							HepA (2 doses)				HepA Series	
Meningococcal ¹¹												MCV

Range of recommended ages for all children except certain high-risk groups

Range of recommended ages for certain high-risk groups

This schedule includes recommendations in effect as of December 15, 2009. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory

Committee on Immunization Practices statement for detailed recommendations: <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

1. Hepatitis B vaccine (HepB). (Minimum age: birth)

At birth:

- Administer monovalent HepB to all newborns before hospital discharge.
- If mother is hepatitis B surface antigen (HBsAg)-positive, administer HepB and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth.
- If mother's HBsAg status is unknown, administer HepB within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if HBsAg-positive, administer HBIG (no later than age 1 week).

After the birth dose:

- The HepB series should be completed with either monovalent HepB or a combination vaccine containing HepB. The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks. The final dose should be administered no earlier than age 24 weeks.
- Infants born to HBsAg-positive mothers should be tested for HBsAg and antibody to HBsAg 1 to 2 months after completion of at least 3 doses of the HepB series, at age 9 through 18 months (generally at the next well-child visit).
- Administration of 4 doses of HepB to infants is permissible when a combination vaccine containing HepB is administered after the birth dose. The fourth dose should be administered no earlier than age 24 weeks.

2. Rotavirus vaccine (RV). (Minimum age: 6 weeks)

- Administer the first dose at age 6 through 14 weeks (maximum age: 14 weeks 6 days). Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
- The maximum age for the final dose in the series is 8 months 0 days
- If Rotarix is administered at ages 2 and 4 months, a dose at 6 months is not indicated.

3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). (Minimum age: 6 weeks)

- The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.
- Administer the final dose in the series at age 4 through 6 years.

4. *Haemophilus influenzae* type b conjugate vaccine (Hib).

- (Minimum age: 6 weeks)
- If PRP-OMP (PedvaxHib or Comvax [HepB-Hib]) is administered at ages 2 and 4 months, a dose at age 6 months is not indicated.
- TriHibit (DTaP/Hib) and Hiberix (PRP-T) should not be used for doses at ages 2, 4, or 6 months for the primary series but can be used as the final dose in children aged 12 months through 4 years.

5. Pneumococcal vaccine. (Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPSV])

- PCV is recommended for all children aged younger than 5 years. Administer 1 dose of PCV to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
- Administer PPSV 2 or more months after last dose of PCV to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant. See *MMWR* 1997;46(No. RR-8).

6. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)

- The final dose in the series should be administered on or after the fourth birthday and at least 6 months following the previous dose.
- If 4 doses are administered prior to age 4 years a fifth dose should be administered at age 4 through 6 years. See *MMWR* 2009;58(30):829–30.

7. Influenza vaccine (seasonal). (Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 2 years for live, attenuated influenza vaccine [LAIV])

- Administer annually to children aged 6 months through 18 years.
- For healthy children aged 2 through 6 years (i.e., those who do not have underlying medical conditions that predispose them to influenza complications), either LAIV or TIV may be used, except LAIV should not be given to children aged 2 through 4 years who have had wheezing in the past 12 months.
- Children receiving TIV should receive 0.25 mL if aged 6 through 35 months or 0.5 mL if aged 3 years or older.
- Administer 2 doses (separated by at least 4 weeks) to children aged younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time during the previous influenza season but only received 1 dose.
- For recommendations for use of influenza A (H1N1) 2009 monovalent vaccine see *MMWR* 2009;58(No. RR-10).

8. Measles, mumps, and rubella vaccine (MMR). (Minimum age: 12 months)

- Administer the second dose routinely at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 28 days have elapsed since the first dose.

9. Varicella vaccine. (Minimum age: 12 months)

- Administer the second dose routinely at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 3 months have elapsed since the first dose.
- For children aged 12 months through 12 years the minimum interval between doses is 3 months. However, if the second dose was administered at least 28 days after the first dose, it can be accepted as valid.

10. Hepatitis A vaccine (HepA). (Minimum age: 12 months)

- Administer to all children aged 1 year (i.e., aged 12 through 23 months). Administer 2 doses at least 6 months apart.
- Children not fully vaccinated by age 2 years can be vaccinated at subsequent visits
- HepA also is recommended for older children who live in areas where vaccination programs target older children, who are at increased risk for infection, or for whom immunity against hepatitis A is desired.

11. Meningococcal vaccine. (Minimum age: 2 years for meningococcal conjugate vaccine [MCV4] and for meningococcal polysaccharide vaccine [MPSV4])

- Administer MCV4 to children aged 2 through 10 years with persistent complement component deficiency, anatomic or functional asplenia, and certain other conditions placing them at high risk.
- Administer MCV4 to children previously vaccinated with MCV4 or MPSV4 after 3 years if first dose administered at age 2 through 6 years. See *MMWR* 2009;58:1042–3.

The Recommended Immunization Schedules for Persons Aged 0 through 18 Years are approved by the Advisory Committee on Immunization Practices (<http://www.cdc.gov/vaccines/recs/acip>), the American Academy of Pediatrics (<http://www.aap.org>), and the American Academy of Family Physicians (<http://www.aafp.org>). Department of Health and Human Services • Centers for Disease Control and Prevention

Recommended Immunization Schedule for Persons Aged 7 Through 18 Years—United States • 2010

For those who fall behind or start late, see the schedule below and the catch-up schedule

Vaccine ▼	Age ►	7–10 years	11–12 years	13–18 years
Tetanus, Diphtheria, Pertussis ¹			Tdap	Tdap
Human Papillomavirus ²		see footnote 2	HPV (3 doses)	HPV series
Meningococcal ³		MCV	MCV	MCV
Influenza ⁴		Influenza (Yearly)		
Pneumococcal ⁵		PPSV		
Hepatitis A ⁶		HepA Series		
Hepatitis B ⁷		Hep B Series		
Inactivated Poliovirus ⁸		IPV Series		
Measles, Mumps, Rubella ⁹		MMR Series		
Varicella ¹⁰		Varicella Series		

Range of recommended ages for all children except certain high-risk groups

Range of recommended ages for catch-up immunization

Range of recommended ages for certain high-risk groups

This schedule includes recommendations in effect as of December 15, 2009. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory

Committee on Immunization Practices statement for detailed recommendations: <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967.

1. **Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).** (Minimum age: 10 years for Boostrix and 11 years for Adacel)
 - Administer at age 11 or 12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a tetanus and diphtheria toxoid (Td) booster dose.
 - Persons aged 13 through 18 years who have not received Tdap should receive a dose.
 - A 5-year interval from the last Td dose is encouraged when Tdap is used as a booster dose; however, a shorter interval may be used if pertussis immunity is needed.
2. **Human papillomavirus vaccine (HPV).** (Minimum age: 9 years)
 - Two HPV vaccines are licensed: a quadrivalent vaccine (HPV4) for the prevention of cervical, vaginal and vulvar cancers (in females) and genital warts (in females and males), and a bivalent vaccine (HPV2) for the prevention of cervical cancers in females.
 - HPV vaccines are most effective for both males and females when given before exposure to HPV through sexual contact.
 - HPV4 or HPV2 is recommended for the prevention of cervical precancers and cancers in females.
 - HPV4 is recommended for the prevention of cervical, vaginal and vulvar precancers and cancers and genital warts in females.
 - Administer the first dose to females at age 11 or 12 years.
 - Administer the second dose 1 to 2 months after the first dose and the third dose 6 months after the first dose (at least 24 weeks after the first dose).
 - Administer the series to females at age 13 through 18 years if not previously vaccinated.
 - HPV4 may be administered in a 3-dose series to males aged 9 through 18 years to reduce their likelihood of acquiring genital warts.
3. **Meningococcal conjugate vaccine (MCV4).**
 - Administer at age 11 or 12 years, or at age 13 through 18 years if not previously vaccinated.
 - Administer to previously unvaccinated college freshmen living in a dormitory.
 - Administer MCV4 to children aged 2 through 10 years with persistent complement component deficiency, anatomic or functional asplenia, or certain other conditions placing them at high risk.
 - Administer to children previously vaccinated with MCV4 or MPSV4 who remain at increased risk after 3 years (if first dose administered at age 2 through 6 years) or after 5 years (if first dose administered at age 7 years or older). Persons whose only risk factor is living in on-campus housing are not recommended to receive an additional dose. See *MMWR* 2009;58:1042–3.
4. **Influenza vaccine (seasonal).**
 - Administer annually to children aged 6 months through 18 years.
 - For healthy nonpregnant persons aged 7 through 18 years (i.e., those who do not have underlying medical conditions that predispose them to influenza complications), either LAIV or TIV may be used.
 - Administer 2 doses (separated by at least 4 weeks) to children aged younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time during the previous influenza season but only received 1 dose.
 - For recommendations for use of influenza A (H1N1) 2009 monovalent vaccine. See *MMWR* 2009;58(No. RR-10).
5. **Pneumococcal polysaccharide vaccine (PPSV).**
 - Administer to children with certain underlying medical conditions, including a cochlear implant. A single revaccination should be administered after 5 years to children with functional or anatomic asplenia or an immunocompromising condition. See *MMWR* 1997;46(No. RR-8).
6. **Hepatitis A vaccine (HepA).**
 - Administer 2 doses at least 6 months apart.
 - HepA is recommended for children aged older than 23 months who live in areas where vaccination programs target older children, who are at increased risk for infection, or for whom immunity against hepatitis A is desired.
7. **Hepatitis B vaccine (HepB).**
 - Administer the 3-dose series to those not previously vaccinated.
 - A 2-dose series (separated by at least 4 months) of adult formulation Recombivax HB is licensed for children aged 11 through 15 years.
8. **Inactivated poliovirus vaccine (IPV).**
 - The final dose in the series should be administered on or after the fourth birthday and at least 6 months following the previous dose.
 - If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
9. **Measles, mumps, and rubella vaccine (MMR).**
 - If not previously vaccinated, administer 2 doses or the second dose for those who have received only 1 dose, with at least 28 days between doses.
10. **Varicella vaccine.**
 - For persons aged 7 through 18 years without evidence of immunity (see *MMWR* 2007;56(No. RR-4)), administer 2 doses if not previously vaccinated or the second dose if only 1 dose has been administered.
 - For persons aged 7 through 12 years, the minimum interval between doses is 3 months. However, if the second dose was administered at least 28 days after the first dose, it can be accepted as valid.
 - For persons aged 13 years and older, the minimum interval between doses is 28 days.

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The Recommended Immunization Schedules for Persons Aged 0 through 18 Years are approved by the Advisory Committee on Immunization Practices (<http://www.cdc.gov/vaccines/recs/acip>), the American Academy of Pediatrics (<http://www.aap.org>), and the American Academy of Family Physicians (<http://www.aafp.org>). Department of Health and Human Services • Centers for Disease Control and Prevention

Catch-up Immunization Schedule for Persons Aged 4 Months Through 18 Years Who Start Late or Who Are More Than 1 Month Behind—United States • 2010

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age.

PERSONS AGED 4 MONTHS THROUGH 6 YEARS					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Hepatitis B ¹	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Rotavirus ²	6 wks	4 weeks	4 weeks ²		
Diphtheria, Tetanus, Pertussis ³	6 wks	4 weeks	4 weeks	6 months	6 months ³
<i>Haemophilus influenzae</i> type b ⁴	6 wks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose) if first dose administered at age 12–14 months No further doses needed if first dose administered at age 15 months or older	4 weeks ⁴ if current age is younger than 12 months 8 weeks (as final dose) ⁴ if current age is 12 months or older and first dose administered at younger than age 12 months and second dose administered at younger than 15 months No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months through 59 months who received 3 doses before age 12 months	
Pneumococcal ⁵	6 wks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older or current age 24 through 59 months No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 months through 59 months who received 3 doses before age 12 months or for high-risk children who received 3 doses at any age	
Inactivated Poliovirus ⁶	6 wks	4 weeks	4 weeks	6 months	
Measles, Mumps, Rubella ⁷	12 mos	4 weeks			
Varicella ⁸	12 mos	3 months			
Hepatitis A ⁹	12 mos	6 months			
PERSONS AGED 7 THROUGH 18 YEARS					
Tetanus, Diphtheria/ Tetanus, Diphtheria, Pertussis ³	7 yrs ¹⁰	4 weeks	4 weeks if first dose administered at younger than age 12 months 6 months if first dose administered at 12 months or older	6 months if first dose administered at younger than age 12 months	
Human Papillomavirus ¹¹	9 yrs	Routine dosing intervals are recommended ¹¹			
Hepatitis A ⁹	12 mos	6 months			
Hepatitis B ¹	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated Poliovirus ⁶	6 wks	4 weeks	4 weeks	6 months	
Measles, Mumps, Rubella ⁷	12 mos	4 weeks			
Varicella ⁸	12 mos	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

- Hepatitis B vaccine (HepB).**
 - Administer the 3-dose series to those not previously vaccinated.
 - A 2-dose series (separated by at least 4 months) of adult formulation Recombivax HB is licensed for children aged 11 through 15 years.
- Rotavirus vaccine (RV).**
 - The maximum age for the first dose is 14 weeks 6 days. Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
 - The maximum age for the final dose in the series is 8 months 0 days.
 - If Rotarix was administered for the first and second doses, a third dose is not indicated.
- Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP).**
 - The fifth dose is not necessary if the fourth dose was administered at age 4 years or older.
- Haemophilus influenzae* type b conjugate vaccine (Hib).**
 - Hib vaccine is not generally recommended for persons aged 5 years or older. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults. However, studies suggest good immunogenicity in persons who have sickle cell disease, leukemia, or HIV infection, or who have had a splenectomy; administering 1 dose of Hib vaccine to these persons who have not previously received Hib vaccine is not contraindicated.
 - If the first 2 doses were PRP-OMP (PedvaxHIB or Comvax), and administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
 - If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months.
- Pneumococcal vaccine.**
 - Administer 1 dose of pneumococcal conjugate vaccine (PCV) to all healthy children aged 24 through 59 months who have not received at least 1 dose of PCV on or after age 12 months.
 - For children aged 24 through 59 months with underlying medical conditions, administer 1 dose of PCV if 3 doses were received previously or administer 2 doses of PCV at least 8 weeks apart if fewer than 3 doses were received previously.
 - Administer pneumococcal polysaccharide vaccine (PPSV) to children aged 2 years or older with certain underlying medical conditions, including a cochlear implant, at least 8 weeks after the last dose of PCV. See *MMWR* 1997;46(No. RR-8).
- Inactivated poliovirus vaccine (IPV).**
 - The final dose in the series should be administered on or after the fourth birthday and at least 6 months following the previous dose.
 - A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months following the previous dose.
 - In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
- Measles, mumps, and rubella vaccine (MMR).**
 - Administer the second dose routinely at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 28 days have elapsed since the first dose.
 - If not previously vaccinated, administer 2 doses with at least 28 days between doses.
- Varicella vaccine.**
 - Administer the second dose routinely at age 4 through 6 years. However, the second dose may be administered before age 4, provided at least 3 months have elapsed since the first dose.
 - For persons aged 12 months through 12 years, the minimum interval between doses is 3 months. However, if the second dose was administered at least 28 days after the first dose, it can be accepted as valid.
 - For persons aged 13 years and older, the minimum interval between doses is 28 days.
- Hepatitis A vaccine (HepA).**
 - HepA is recommended for children aged older than 23 months who live in areas where vaccination programs target older children, who are at increased risk for infection, or for whom immunity against hepatitis A is desired.
- Tetanus and diphtheria toxoids vaccine (Td) and tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).**
 - Doses of DTaP are counted as part of the Td/Tdap series.
 - Tdap should be substituted for a single dose of Td in the catch-up series or as a booster for children aged 10 through 18 years; use Td for other doses.
- Human papillomavirus vaccine (HPV).**
 - Administer the series to females at age 13 through 18 years if not previously vaccinated.
 - Use recommended routine dosing intervals for series catch-up (i.e., the second and third doses should be administered at 1 to 2 and 6 months after the first dose). The minimum interval between the first and second doses is 4 weeks. The minimum interval between the second and third doses is 12 weeks, and the third dose should be administered at least 24 weeks after the first dose.

Information about reporting reactions after immunization is available online at <http://www.vaers.hhs.gov> or by telephone, 800-822-7967. Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for immunization, is available from the National Center for Immunization and Respiratory Diseases at <http://www.cdc.gov/vaccines> or telephone, 800-CDC-INFO (800-232-4636).

Recommended Adult Immunization Schedule UNITED STATES • 2010

Note: These recommendations *must* be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group

VACCINE ▼	AGE GROUP ▶	19–26 years	27–49 years	50–59 years	60–64 years	≥65 years
Tetanus, diphtheria, pertussis (Td/Tdap) ^{1*}		Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs				Td booster every 10 yrs
Human papillomavirus (HPV) ^{2*}		3 doses (females)				
Varicella ^{3*}		2 doses				
Zoster ⁴					1 dose	
Measles, mumps, rubella (MMR) ^{5*}		1 or 2 doses		1 dose		
Influenza ^{6*}		1 dose annually				
Pneumococcal (polysaccharide) ^{7*}		1 or 2 doses				1 dose
Hepatitis A ^{8*}		2 doses				
Hepatitis B ^{9*}		3 doses				
Meningococcal ^{10*}		1 or more doses				

*Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

No recommendation

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 24 hours a day, 7 days a week.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

CDC/10R14

Figure 2. Vaccines that might be indicated for adults based on medical and other indications

VACCINE	Pregnancy	Immune-compromising conditions (excluding human immunodeficiency virus (HIV)) ^{a,c}	HIV infection ^{a,c,d} CD4+ T lymphocyte count <200 cells/µL	Diabetes, heart disease, chronic lung disease, chronic alcoholism	Asplenia ^e (including elective splenectomy and persistent complement component deficiencies)	Chronic liver disease	Kidney failure, end-stage renal disease, receipt of hemodialysis	Health-care personnel
Tetanus, diphtheria, pertussis (Td/Tdap)^f	Td							
Human papillomavirus (HPV)^g								
Varicella^h	Contraindicated ⁱ					2 doses		
Zoster^h	Contraindicated ⁱ					1 dose		
Measles, mumps, rubella (MMR)^h	Contraindicated ⁱ					1 or 2 doses		
Influenza^h			1 dose TIV annually					1 dose TIV or LAIV annually
Pneumococcal (polysaccharide)^h				1 or 2 doses				
Hepatitis A^h				2 doses				
Hepatitis B^h				3 doses				
Meningococcal^h				1 or more doses				

^a Covered by the Vaccine Injury Compensation Program.

^b For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

^c Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

^d No recommendation

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of January 1, 2010. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.htm)

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), and the American College of Physicians (ACP).



Footnotes

Recommended Adult Immunization Schedule—UNITED STATES - 2010

For complete statements by the Advisory Committee on Immunization Practices (ACIP), visit www.cdc.gov/vaccines/pubs/ACIP-list.htm.

1. **Tetanus, diphtheria, and acellular pertussis (Tdap)** vaccination
 Tdap should replace a single dose of Td for adults aged 19 through 64 years who have not received a dose of Tdap previously.
 Adults with uncertain or incomplete history of primary vaccination series with tetanus and diphtheria toxoid-containing vaccines should begin or complete a primary vaccination series. A primary series for adults is 3 doses of tetanus and diphtheria toxoid-containing vaccines, administered the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second; Tdap can substitute for any one of the doses of Td in the 3-dose primary series. The booster dose of tetanus and diphtheria toxoid-containing vaccine should be administered to adults who have completed a primary series and if the last vaccination was received ≥ 10 years previously. Tdap or Td vaccine may be used, as indicated.
 If a woman is pregnant and received the last Td vaccination ≥ 10 years previously, administer Td during the second or third trimester. If the woman received the last Td vaccination < 10 years previously, administer Tdap during the immediate postpartum period. A dose of Tdap is recommended for postpartum women, close contacts of infants aged < 12 months, and all health-care personnel with direct patient contact if they have not previously received Tdap. An interval as short as 2 years from the last Td is suggested; shorter intervals can be used. Td may be deferred during pregnancy and Tdap substituted in the immediate postpartum period, or Tdap can be administered instead of Td to a pregnant woman. Consult the ACIP statement for recommendations for giving Td as prophylaxis in wound management.
2. **Human papillomavirus (HPV) vaccination**
 HPV vaccination is recommended at age 11 or 12 years with catch-up vaccination at ages 13 through 26 years.
 Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, females who are sexually active should still be vaccinated consistent with age-based recommendations. Sexually active females who have not been infected with any of the four HPV vaccine types (types 6, 11, 16, 18) all of which HPV2 prevents) or any of the two HPV vaccine types (types 16 and 18) both of which HPV2 prevents) receive the full benefit of the vaccination. Vaccination is less beneficial for females who have already been infected with one or more of the HPV vaccine types. HPV4 or HPV2 can be administered to persons with a history of genital warts, abnormal Papanicolaou test, or positive HPV DNA test, because these conditions are not evidence of prior infection with all vaccine HPV types.
 HPV4 may be administered to males aged 9 through 26 years to reduce their likelihood of acquiring genital warts. HPV4 would be most effective when administered before exposure to HPV through sexual contact.
 A complete series for either HPV4 or HPV2 consists of 3 doses. The second dose should be administered 1–2 months after the first dose; the third dose should be administered 6 months after the first dose.
 Although HPV vaccination is not specifically recommended for persons with the medical indications described in Figure 2, “Vaccines that might be indicated for adults based on medical and other indications.” It may be administered to these persons because the HPV vaccine is not a live-virus vaccine. However, the immune response and vaccine efficacy might be less for persons with the medical indications described in Figure 2 than in persons who do not have the medical indications described or who are immunocompetent. Health-care personnel are not at increased risk because of occupational exposure, and should be vaccinated consistent with age-based recommendations.
3. **Varicella vaccination**
 All adults without evidence of immunity to varicella should receive 2 doses of single antigen varicella vaccine if not previously vaccinated or the second dose if they have received only 1 dose, unless they have a medical contraindication. Special consideration should be given to those who: 1) have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of persons with immunocompromising conditions) or 2) are at high risk for exposure or transmission (e.g., teachers, child-care employees, residents and staff members of institutional settings, including correctional institutions, college students, military personnel, adolescents and adults living in households with children, nonpregnant women of childbearing age, and international travelers).
 Evidence of immunity to varicella in adults includes any of the following: 1) documentation of 2 doses of varicella vaccine at least 4 weeks apart; 2) U.S. born before 1980 (although for health-care personnel and pregnant women, birth before 1980 should not be considered evidence of immunity); 3) history of varicella based on diagnosis or verification of varicella by a health-care provider (or a patient reporting a history of or presenting with an atypical case, a milder case, or both); health-care providers should seek either an epidemiologic link with a typical varicella case or to a laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease; 4) history of herpes zoster based on diagnosis or verification of herpes zoster by a health-care provider; or 5) laboratory evidence of immunity of laboratory confirmation of disease.
 Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.
4. **Herpes zoster vaccination**
 A single dose of zoster vaccine is recommended for adults aged ≥ 60 years regardless of whether they report a prior episode of herpes zoster. Persons with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication.
5. **Measles, mumps, rubella (MMR) vaccination**
 Adults born before 1957 generally are considered immune to measles and mumps.
Measles component: Adults born during or after 1957 should receive 1 or more doses of MMR vaccine unless they have 1) a medical contraindication; 2) documentation of vaccination with 1 or more doses of MMR vaccine; 3) laboratory evidence of immunity; or 4) documentation of physician-diagnosed measles.
 A second dose of MMR vaccine, administered 4 weeks after the first dose, is recommended for adults who 1) have been recently exposed to measles or are in an outbreak setting; 2) have been vaccinated previously with killed measles vaccine; 3) have been vaccinated with an unknown type of measles vaccine during 1963–1967; 4) are students in postsecondary educational institutions; 5) work in a health-care facility; or 6) plan to travel internationally.
Mumps component: Adults born during or after 1957 should receive 1 dose of MMR vaccine unless they have 1) a medical contraindication; 2) documentation of vaccination with 1 or more doses of MMR vaccine; 3) laboratory evidence of immunity; or 4) documentation of physician-diagnosed mumps.
 A second dose of MMR vaccine, administered 4 weeks after the first dose, is recommended for adults who 1) live in a community experiencing a mumps outbreak and are in an affected age group; 2) are students in postsecondary educational institutions; 3) work in a health-care facility; or 4) plan to travel internationally.
Rubella component: 1) dose of MMR vaccine is recommended for women who do not have documentation of rubella vaccination, or who lack laboratory evidence of immunity, for women of childbearing age, regardless of birth year, rubella immunity should be determined and women should be counseled regarding congenital rubella syndrome. Women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health-care facility.
Health-care personnel born before 1957: For unvaccinated health-care personnel born before 1957, who lack laboratory evidence of measles, mumps, and/or rubella immunity (or laboratory confirmation of disease, health-care facilities should consider vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval (for measles and mumps) and 1 dose of MMR vaccine (for rubella), respectively.

During outbreaks, health care facilities should recommend that unvaccinated health-care personnel born before 1957, who lack laboratory evidence of measles, mumps, and/or rubella immunity or laboratory confirmation of disease, receive 2 doses of MMR vaccine during an outbreak of measles or mumps, and 1 dose during an outbreak of rubella.

Complete information about evidence of immunity is available at www.cdc.gov/vaccines/imz/iinfo/faq/imm.htm.

6. Seasonal Influenza Vaccination

Vaccinate all persons aged ≥ 50 years and any younger persons who would like to decrease their risk of getting influenza. Vaccinate persons aged 19 through 49 years with any of the following indications.

Medical: Chronic disorders of the cardiovascular or pulmonary systems, including asthma; chronic metabolic diseases, including diabetes mellitus; renal or hepatic dysfunction, hemoglobinopathies, or immunocompromising conditions (including immunocompromising conditions caused by medications or HIV); cognitive, neurologic or neuromuscular disorders; and pregnancy during the influenza season. No data exist on the risk for severe or complicated influenza disease among persons with asplenia, however, influenza is a risk factor for secondary bacterial infections that can cause severe disease among persons with asplenia.

Occupational: All health-care personnel, including those employed by long-term care and assisted living facilities, and caregivers of children aged ≤ 5 years.

Other: Residents of nursing homes and other long-term care and assisted living facilities; persons likely to transmit influenza to persons at high risk (e.g., in-home household contacts and caregivers of children aged ≤ 5 years, persons aged ≥ 60 years, and persons of all ages with high-risk conditions).

Healthy, nonpregnant adults aged ≤ 60 years without high-risk medical conditions who are not contacts of severely immunocompromised persons in special-care units may receive either intranasally administered live, attenuated influenza vaccine (FluMist) or inactivated vaccine. Other persons should receive the inactivated vaccine.

7. Pneumococcal polysaccharide (PPSV) vaccination

Vaccinate all persons with the following indications.

Medical: Chronic lung disease (including asthma), chronic cardiovascular diseases; diabetes mellitus; chronic liver diseases, cirrhosis; chronic alcoholism; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]); immunocompromising conditions including chronic renal failure or nephrotic syndrome; and cochlear implants and cerebrospinal fluid leaks. Vaccinate as close to HIV diagnosis as possible.

Other: Residents of nursing homes or long-term care facilities and persons who smoke cigarettes. Routine use of PPSV is not recommended for American Indians/Alaska Natives or persons aged ≤ 65 years unless they have underlying medical conditions that are PPSV indications. However, public health authorities may consider recommending PPSV for American Indians/Alaska Natives and persons aged 50 through 64 years who are living in areas where the risk for invasive pneumococcal disease is increased.

8. Revaccination with PPSV

One-time revaccination after 5 years is recommended for persons with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); and for persons with immunocompromising conditions. For persons aged ≥ 65 years, one-time revaccination is recommended if they were vaccinated ≥ 5 years previously and were younger than aged ≤ 65 years at the time of primary vaccination.

9. Hepatitis A Vaccination

Vaccinate persons with any of the following indications and any person seeking protection from hepatitis A virus (HAV) infection.

Behavioral: Men who have sex with men and persons who use injection drugs.

Occupational: Persons working with HAV-infected primates or with HAV in a research laboratory setting.

Medical: Persons with chronic liver disease and persons who receive clotting factor concentrates.

Other: Persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (a list of countries is available at www.cdc.gov/travel/consult/diseases.aspx).

Unvaccinated persons who anticipate close personal contact (e.g., household contact or regular babysitting) with an international adoptee from a country of high or intermediate endemicity during the first 60 days after arrival of the adoptee in the United States should consider vaccination. The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally 22 weeks before the arrival of the adoptee.

Single-antigen vaccine formulations should be administered in a 2-dose schedule at either 0 and 6–12 months (Havrix) or 0 and 4–18 months (Votiva). If the combined hepatitis A and hepatitis B vaccine (Votivax) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule, administered on days 0, 7, and 21–30, followed by a booster dose at month 12, may be used.

10. Hepatitis B Vaccination

Vaccinate persons with any of the following indications and any person seeking protection from hepatitis B virus (HBV) infection.

Behavioral: Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months); persons seeking evaluation or treatment for a sexually transmitted disease (STD); current or recent injection-drug users; and men who have sex with men.

Occupational: Health care personnel and public safety workers who are exposed to blood or other potentially infectious body fluids.

Medical: Persons with end-stage renal disease, including patients receiving hemodialysis; persons with HIV infection; clients and staff members of institutions for persons with developmental disabilities; and international travelers to countries with high or intermediate prevalence of chronic HBV infection (a list of countries is available at www.cdc.gov/travel/consult/diseases.aspx).

Other: Household contacts and sex partners of persons with chronic HBV infection; clients and staff members of institutions for persons with chronic liver disease.

Hepatitis B vaccination is recommended for all adults in the following settings: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug abuse treatment and prevention services; health care settings, including services to injection-drug users or men who have sex with men; coronal facilities, end-stage renal disease programs and facilities for chronic hemodialysis patients, and institutions and nonresidential day-care facilities for persons with developmental disabilities.

Administer or complete a 3-dose series of HepB to those persons not previously vaccinated. The second dose should be administered 1 month after the first dose; the third dose should be administered at least 2 months after the second dose (and at least 4 months after the first dose). If the combined hepatitis A and hepatitis B vaccine (Votivax) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule, administered on days 0, 7, and 21–30, followed by a booster dose at month 12, may be used.

Adult patients receiving hemodialysis or with other immunocompromising conditions should receive 1 dose of 40 µg/ml (Recombivax HB) administered on a 3-dose schedule or 2 doses of 20 µg/ml (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2 and 6 months.

11. Meningococcal vaccination

Meningococcal vaccine should be administered to persons with the following indications:

Meningi/Adults with anatomic or functional splenoma, or persistent complement component deficiencies.

Other: First-year college students living in university dormitories; meniscococcal disease routinely exposed to states of *Neisseria meningitidis*, military recruits; and persons who travel to, or live in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the meningitis belt of sub-Saharan Africa during the dry season [December through June]), particularly if their contact with local populations will be prolonged. Vaccination is required by the government of Saudi Arabia for all travelers to that country during the Hajj season.

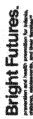
Adults for all travelers to Saudi Arabia during the Hajj season. Meningococcal polysaccharide vaccine (MPSV4) is preferred for adults aged >56 years. Re-vaccination with MPSV4 after 5 years is recommended for adults previously vaccinated with MPSV4 or MPSV4 who remain at increased risk for infection (e.g., adults with anatomic or functional splenoma). Persons whose only risk factor is living in on-campus housing are not recommended to receive an additional dose.

12. Selected conditions for which Haemophilus influenzae type b (Hib) vaccine may be used

Hib vaccine generally is not recommended for persons aged >5 years. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults. However, studies suggest good immunogenicity in patients who have sickle cell disease, leukemia, or HIV infection or who have had a splenectomy. Administering 1 dose of Hib vaccine to these high-risk persons who have not previously received Hib vaccine is not contraindicated.

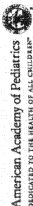
13. Immunocompromising conditions

Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, influenza [inactivated influenza vaccine]) and live vaccines generally are avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at www.cdc.gov/vaccines/pubs/ocp-1st.htm.



Recommendations for Preventive Pediatric Health Care

Bright Futures/American Academy of Pediatrics



Each child and family is unique; therefore, these Recommendations for Preventive Pediatric Health Care are designed for the care of children who are receiving comprehensive preventive care. Additional services may be necessary if circumstances suggest variations from normal.

Developmental, psychosocial, and chronic disease issues for children and adolescents may require frequent counseling and treatment; visits separate from preventive care may be necessary. These guidelines represent a consensus by the American Academy of Pediatrics (AAP) and Bright Futures. The AAP continues to emphasize the great importance of comprehensive preventive health supervision and the need to avoid fragmentation of care.

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	INFANCY		EARLY CHILDHOOD					MIDDLE CHILDHOOD					ADOLESCENCE																		
	PRENATAL	NEWBORN ¹	2 mo	4 mo	8 mo	12 mo	15 mo	18 mo	24 mo	30 mo	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	18 yr	19 yr	20 yr	21 yr		
HISTORY																															
Initial/Interval	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
MEASUREMENTS																															
Length	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
Head Circumference	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
Weight for Length	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
Body Mass Index	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
Blood Pressure	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
SENSORY SCREENING																															
Vision	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Hearing	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
DEVELOPMENTAL/BEHAVIORAL ASSESSMENT																															
Developmental Screening ²	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Autism Screening ³	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Developmental Surveillance ⁴	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Psychosocial Assessment ⁵	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Alcohol and Drug Use Assessment ⁶	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
PHYSICAL EXAMINATION⁷																															
Newborn Metabolic/Hemoglobin Screening ⁸	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Immunization ⁹	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Lead Screening ¹⁰	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Hemoglobin or Hematocrit ¹¹	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Tuberculin Test ¹²	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Dyslipidemia Screening ¹³	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Cervical Dysplasia Screening ¹⁴	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
ORAL HEALTH¹⁵																															
Anticipatory Guidance ¹⁶	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*

1. If a child cannot hear for the first time in any part of the world, or if any team are not accomplished at the age of 3 months, a hearing evaluation should be performed. For children who are not hearing, or for whom the hearing is not normal, a hearing evaluation should be performed. For children who are not hearing, or for whom the hearing is not normal, a hearing evaluation should be performed. For children who are not hearing, or for whom the hearing is not normal, a hearing evaluation should be performed.

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KEY: * = to be performed; - = not recommended; -/ = to be performed, with appropriate action to follow; † = optional; †† = single testing which is optional; ††† = optional (including the preferred age)

SACHDNC Recommended Uniform Screening Panel¹
CORE² CONDITIONS³
 (as of February 2010)

ACMG Code	Core Condition	Metabolic Disorder			Endocrine Disorder	Hemoglobin Disorder	Other Disorder
		Organic acid condition	Fatty acid oxidation disorders	Amino acid disorders			
PROP	Propionic academia						
MUT	Methylmalonic acidemia (methylmalonyl-CoA mutase)						
Cbl A,B	Methylmalonic acidemia (cobalamin disorders)						
IVA	Isovaleric acidemia						
3-MCC	3-Methylcrotonyl-CoA carboxylase deficiency						
HMG	3-Hydroxy-3-methylglutaric aciduria						
MCD	Holocarboxylase synthase deficiency						
βKT	β-Ketothiolase deficiency						
GA1	Glutaric acidemia type I						
CUD	Carnitine uptake defect/carnitine transport defect						
MCAD	Medium-chain acyl-CoA dehydrogenase deficiency						
VLCAD	Very long-chain acyl-CoA dehydrogenase deficiency						
LCHAD	Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency						
TFP	Trifunctional protein deficiency						
ASA	Argininosuccinic aciduria						
CIT	Citrullinemia, type I						
MSUD	Maple syrup urine disease						
HCY	Homocystinuria						
PKU	Classic phenylketonuria						
TYR I	Tyrosinemia, type I						
CH	Primary congenital hypothyroidism						
CAH	Congenital adrenal hyperplasia						
Hb SS	S,S disease (Sickle cell anemia)						
Hb S/βTh	S, β-thalassemia						
Hb S/C	S,C disease						
BIOT	Biotinidase deficiency						
GALT	Classic galactosemia						
SCID	Severe Combined Immunodeficiencies						
CF	Cystic fibrosis						
HEAR	Hearing loss						

1. The selection of these conditions is based on the report "Newborn Screening: Towards a Uniform Screening Panel and System. Genet Med. 2006; 8(5) Suppl: S12-S252" as authored by the American College of Medical Genetics (ACMG) and commissioned by the Health Resources and Services Administration (HRSA).
2. Disorders that should be included in every Newborn Screening Program
3. The Nomenclature for Conditions is based on the report "Naming and Counting Disorders (Conditions) Included in Newborn Screening Panels" Pediatrics 2006; 117 (5) Suppl: S308-S314

SACHDNC Recommended Uniform Screening Panel¹
SECONDARY² CONDITIONS³
(as of February 2010)

ACMG Code	Secondary Condition	Metabolic Disorder			Hemoglobin Disorder	Other Disorder
		Organic acid condition	Fatty acid oxidation disorders	Amino acid disorders		
Cbl C,D	Methylmalonic acidemia with homocystinuria					
MAL	Malonic acidemia					
IBG	Isobutyrylglycinuria					
2MBG	2-Methylbutyrylglycinuria					
3MGA	3-Methylglutaconic aciduria					
2M3HBA	2-Methyl-3-hydroxybutyric aciduria					
SCAD	Short-chain acyl-CoA dehydrogenase deficiency					
M/SCHAD	Medium/short-chain L-3-hydroxyacyl-CoA dehydrogenase deficiency					
GA2	Glutaric acidemia type II					
MCAT	Medium-chain ketoacyl-CoA thiolase deficiency					
DE RED	2,4 Dienoyl-CoA reductase deficiency					
CPT IA	Camitine palmitoyltransferase type I deficiency					
CPT II	Camitine palmitoyltransferase type II deficiency					
CACT	Camitine acylcamitine translocase deficiency					
ARG	Argininemia					
CIT II	Citrullinemia, type II					
MET	Hypermethioninemia					
H-PHE	Benign hyperphenylalaninemia					
BIOPT (BS)	Biopterin defect in cofactor biosynthesis					
BIOPT (REG)	Biopterin defect in cofactor regeneration					
TYR II	Tyrosinemia, type II					
TRY III	Tyrosinemia, type III					
Var Hb	Various other hemoglobinopathies					
GALE	Galactosepimerase deficiency					
GALK	Galactokinase deficiency					
	T-cell related lymphocyte deficiencies					

1. The selection of these conditions is based on the report "Newborn Screening: Towards a Uniform Screening Panel and System. Genet Med. 2006; 8(5) Suppl: S12-S252" as authored by the American College of Medical Genetics (ACMG) and commissioned by the Health Resources and Services Administration (HRSA).
2. Disorders that can be detected in the differential diagnosis of a core disorder
3. The Nomenclature for Conditions is based on the report "Naming and Counting Disorders (Conditions) Included in Newborn Screening Panels" Pediatrics 2006; 117 (5) Suppl: S308-S314

BILLING CODE 4830-01-C; 4510-29-C; 4210-01-C

VI. Statutory Authority

The Department of the Treasury temporary regulations are adopted

pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor's Order 6–2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: July 8, 2010

Michael F. Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 9th day of July, 2010.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: July 9, 2010

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Dated: July 9, 2010.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter 1

■ Accordingly, 26 CFR Part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by adding an entry for § 54.9815–2713T in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Section 54.9815–2713T also issued under 26 U.S.C. 9833. * * *

■ **Par. 2.** Section 54.9815–2713T is added to read as follows:

§ 54.9815–2713T Coverage of preventive health services (temporary).

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) with respect to those items or services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration.

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1*, the plan may not impose any cost-sharing requirements with respect to the separately-

billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as

Example 1. As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2*, because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3*, the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4*, the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement with respect to the office visit.

(3) *Out-of-network providers.* Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management

techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the recommendation or guideline.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing—(1) In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Effective/applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 54.9815-1251T for determining the application of this section to grandfathered health plans (providing that these rules regarding

coverage of preventive health services do not apply to grandfathered health plans).

(e) *Expiration date.* This section expires on July 12, 2013 or on such earlier date as may be provided in final regulations or other action published in the **Federal Register**.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

■ 29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for Part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

Subpart C—Other Requirements

■ 2. Section 2590.715-2713 is added to subpart C to read as follows:

§ 2590.715-2713 Coverage of preventive health services.

(a) *Services—(1) In general.* Beginning at the time described in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) with respect to those items or services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been

adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration.

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) Facts. An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1*, the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) Facts. Same facts as *Example 1*. As the result of the screening, the

individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2*, because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) Facts. An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3*, the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) Facts. A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4*, the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement with respect to the office visit.

(3) *Out-of-network providers.* Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the recommendation or guideline.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer

from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715–1251 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

■ For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 147, added May 13, 2010, at 75 FR 27138, effective July 12, 2010, as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: Sections 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Add § 147.130 to read as follows:

§ 147.130 Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) with respect to those items or services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, to the extent not described in paragraph

(a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration.

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) Facts. An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1*, the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) Facts. Same facts as *Example 1*. As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2*, because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) Facts. An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure

screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3*, the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) Facts. A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4*, the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement for the office visit charge.

(3) *Out-of-network providers.* Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the recommendation or guideline.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A

plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *In general*. A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines*. A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) *Recommendations not current*. For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date*. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

[FR Doc. 2010-17242 Filed 7-14-10; 11:15 am]

BILLING CODE 4830-01-P; 4510-29-P; 4210-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2010-0646]

RIN 1625-AA00

Safety Zone; Transformers 3 Movie Filming, Chicago River, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Chicago River near Chicago, Illinois. This zone is intended to restrict vessels from a portion of the Chicago River due to the filming of a major motion picture. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with the different types of stunts that will be performed during the filming of this movie.

DATES: *Effective Date:* this rule is effective in the CFR from July 19, 2010 until 9 p.m. on July 19, 2010. This rule is effective with actual notice for purposes of enforcement beginning 7 a.m. on July 16, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2010-0646 and are available online by going to <http://www.regulations.gov>, inserting USCG-2010-0646 in the "Keyword" box, and then clicking "search." They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, contact or email BM1 Adam Kraft, U.S. Coast Guard Sector Lake Michigan, at 414-747-7154 or Adam.D.Kraft@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision

authorizes an agency to issue a rule without prior notice and opportunity to comment when an agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under U.S.C. 553 (b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to the fact that the application for this event was not submitted to our office in time to allow for publishing an NPRM. Based on the hazards associated with the filming of this major motion picture, delaying the publication of this rule to provide for a comment would be contrary to public interest as immediate action is necessary to protect the public.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** because delaying the effective date would be contrary to the public interest since immediate action is needed to protect the public and the event would be over by the time the 30 day period is completed.

Basis and Purpose

This temporary safety zone is necessary to protect vessels from the hazards associated with the filming of the major motion picture, Transformers 3. The combination of congested waterways and the filming of dangerous stunts taking place on or near the water pose serious risks of injury to persons and property. As such, the Captain of the Port, Sector Lake Michigan, has determined that the filming of this motion picture does pose significant risks to public safety and property and that a temporary safety zone is necessary.

Discussion of Rule

The safety zone will encompass all U.S. navigable waters of the Chicago River between the Michigan Avenue Bridge, 41°53'20" N. 087°37'27" W. and the North Columbus Drive Bascule Bridge, 41°53'19" N. 087°37'13" W. [DATUM: NAD 83].

All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port, Sector Lake Michigan, or his or her on-scene representative. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative. The Captain of the Port, Sector Lake Michigan, or his or her on-scene representative may be contacted via VHF Channel 16.

Appendix III

Implementation Timeline for Health Care Reform Preventive Services

The Affordable Care Act: U.S. Vaccine Policy and Practice

Fall, 2010

IMPLEMENTATION TIMELINE FOR HEALTH CARE REFORM PREVENTIVE SERVICES	
DATE	PREVENTION-RELATED IMPLEMENTATION ACTIVITIES
January 1, 2010	MEDICARE: The Secretary may modify coverage of any currently covered Medicare preventive services when the change is consistent with USPSTF recommendations, and the services are not used for diagnosis or treatment. <i>(Title IV, subtitle B, sec. 4104)</i>
March 23, 2010	317: States are permitted to purchase adult vaccines at the CDC-negotiated rate. <i>(Title IV, subtitle C, sec. 4204)</i> 317 AND VFC: The Secretary and the Director of the CDC may award grants to states to improve the provision of recommended immunizations for children, adolescents and adults through the use of evidence-based and population-based interventions. <i>(Title IV, subtitle C, sec. 4204)</i>
April 1, 2010	MEDICAID: If the Medicaid program amends its State Plan for Medical Assistance (State Plan), eligibility may be expanded to the following populations: 1) all non-elderly individuals whose income is below 133-percent of FPL and 2) all non-elderly, non-pregnant individuals who are not entitled to Medicare. <i>(Title II, subtitle A, sec. 2001)</i> (A State Plan for Medical Assistance (State Plan) constitutes the operating document for Medicaid programs and also serves as the agreement between a state and the federal government. The Centers for Medicare and Medicaid Services reviews and approves all State Plans and Amendments before they become operational.)
Plan years beginning on or after September 23, 2010	GRANDFATHERED PLANS (INDIVIDUAL), GRANDFATHERED PLANS (GROUP) and NON-GRANDFATHERED PLANS: Must provide coverage for adult children (up to age 26) who do not have employer-based coverage. <i>(Title I, subtitle C, sec. 1251; Health Care and Education Reconciliation Act, Title II, subtitle B, sec. 2301)</i> NON-GRANDFATHERED PLANS: Must cover preventive services and immunizations recommended by the USPSTF, ACIP, and HRSA without cost-sharing. <i>(Title I, subtitle A, sec. 1001 (amending PHSA by adding sec. 2713))</i>
January 1, 2011	MEDICARE: All beneficiaries will be entitled to an annual wellness visit and receive a comprehensive health risk assessment that includes the development of a personalized prevention plan (PPP). <i>(Title IV, subtitle B, sec. 4103)</i> Cost-sharing will be eliminated for personalized prevention plan services. <i>(Title IV, subtitle B, sec. 4103)</i> Any preventive service (pneumococcal, influenza and Hepatitis B vaccines, initial preventive physical examinations, and personalized prevention plan services) furnished by an outpatient department of a hospital, shall be reimbursed at 100-percent rather than under the prospective payment system. <i>(Title IV, subtitle B, sec. 4104)</i>
March 23, 2011	PREVENTION INITIATIVE: Depts. of HHS, Agriculture, Education, Labor, and Transportation will form an interagency council intended to establish a national prevention and health promotion strategy. The Council will report annually to Congress on health promotion activities and progress toward meeting the goals of the national strategy, and must publish a report by this date. <i>(Title III, subtitle D, sec. 4001)</i>
January 1, 2013	MEDICAID: States that elect to cover adult immunizations that are recommended by ACIP, the costs of their administration and prohibit cost-sharing, will receive a 1-percent increased FMAP for immunization services. <i>(Title IV, subtitle B, sec. 4106)</i> (2013 and 2014 ONLY) Primary care physicians who furnish primary care services FOR Medicaid enrollees will receive reimbursement of at least 100-percent of Medicare Part B payment rates in 2013 and 2014. Federal funding will be available to pay 100-percent of the additional costs to states to meet this requirement. <i>(The Health Care and Education Reconciliation Act, Title I, subtitle C, sec. 1202)</i>

IMPLEMENTATION TIMELINE FOR HEALTH CARE REFORM PREVENTIVE SERVICES

DATE	PREVENTION-RELATED IMPLEMENTATION ACTIVITIES
January 1, 2014	<p>GRANDFATHERED PLANS (INDIVIDUAL), GRANDFATHERED PLANS (GROUP), NON-GRANDFATHERED PLANS: Must provide coverage to adult children under 26 “without regard to whether [he/she] is eligible to enroll in any other coverage.” <i>(Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act; Interim Final Rule and Proposed Rule, 75 Fed. Reg. 34,538 at 34,559 (June 17, 2010) (to be codified at 26 CFR Parts 54 and 602; 29 CFR Part 2590; and 45 CFR Part 147)</i></p> <p>MEDICAID: Must provide coverage for:</p> <ul style="list-style-type: none"> • Individuals with income at or below 133-percent of the Federal Poverty Level (FPL); <i>(Title II, subtitle A, sec. 2001)</i> (In 2009, the Federal Poverty Level was \$14,404 for an individual and \$29,327 for a family of four.) • Children ages six to 19 who live in families with income at or below 133-percent of FPL. <i>(Title II, subtitle A, sec. 2001)</i> <p>States have the option to cover individuals whose income exceeds 133 percent FPL. <i>(Title II, subtitle A, sec. 2001)</i></p> <p>States will be required to provide benchmark or benchmark equivalent coverage including essential health benefits package (EHBP) for newly eligibles. <i>(Title II, subtitle A, sec. 2001)</i></p> <p>Medicaid will provide federally-funded matching payments for the cost of services for newly eligible beneficiaries (in states that have not expanded Medicaid to childless adults). This matching payment will be as follows: 100 percent 2014-2016; 95 percent in 2017; 94 percent in 2018; 93 percent in 2019 and 90 percent thereafter. <i>(“Timeline for Health Care Reform Implementation: Health Insurance Provisions,” The Commonwealth Foundation. P. 13)</i></p>
2015	<p>STATE REGULATED PLANS SOLD IN EXCHANGES: Exchanges are required to be self-sustaining by this time. <i>(“Timeline for Health Care Reform Implementation: Health Insurance Provisions,” The Commonwealth Foundation. P. 9)</i></p> <p>CHIP: From October 1, 2015 to September 30, 2019 states are provided with a 23 percentage point increase in FMAP rates, subject to a 100 percent cap. <i>(“Timeline for Health Care Reform Implementation: Health Insurance Provisions,” The Commonwealth Foundation. P. 14)</i></p>
January 1, 2019	<p>MEDICAID: Adult children through age 25 who have aged out of the foster care system will be eligible. <i>(Title II, subtitle A, sec. 2001)</i></p>
One plan year from date of recommendation	<p>STATE REGULATED PLANS SOLD IN EXCHANGES: Must comply with preventive services recommendations, based on the plan year to which they shall apply. <i>(Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41,726 at 41,728 (July 19, 2010) (to be codified at 26 CFR Part 54; 29 CFR Part 2590; and 45 CFR Part 147)</i></p>

Source: The Affordable Care Act: U.S. Vaccine Policy and Practice, GWU/SPHHS/DHP (Fall, 2010)

Appendix IV

Interaction between Health Reform and NVAC Vaccine Financing Recommendations

The Affordable Care Act: U.S. Vaccine Policy and Practice

Fall, 2010

Interaction between Health Reform and NVAC Vaccine Financing Recommendations

(March 2009)

NOT ADDRESSED

Recommendation #1. The Vaccines for Children program (VFC) should be extended to include access to VFC eligible underinsured children and adolescents receiving immunizations in public health department clinics and thus not be limited to access only at Federally Qualified Health Centers and Rural Health Clinics.

Recommendation #2. VFC should be expanded to cover vaccine administration reimbursement for all VFC-eligible children and adolescents. (Currently the vaccine administration fee is not covered by VFC.) This should include children on Medicaid as this would provide for a single system and uniform vaccine administration fee. The vaccine administration reimbursement should be sufficient to cover the costs of vaccine administration (as referenced elsewhere in these recommendations).

Recommendation #3. The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) should annually update, publish, and disseminate actual Medicaid vaccine administration reimbursement rates by state.

Recommendation #17. NVAC should convene one or more expert panels representing all impacted stakeholders to consider whether tax credits could be a tool to reduce or eliminate underinsurance. The panel would determine if policy options that would be acceptable to stakeholders could be developed to address the burden of financing for private sector child and adolescent vaccinations by using tax credits as incentives for insurers.

Recommendation #22. States and localities should develop mechanisms for billing insured children and adolescents served in the public sector. CDC should provide support to states and localities by disseminating best practices and providing technical assistance to develop these billing mechanisms. (This may require additional resources not currently in CDC's immunization program budget.) Further, NVAC urges states and localities to reinvest reimbursements from public and private payers back into immunization programs.

ADDRESSED IN PRIVATE HEALTH INSURANCE PLANS

Recommendation #11. Health insurers and all private healthcare purchasers should adopt contract benefit language that is flexible enough to permit coverage and reimbursement for new or recently altered ACIP recommendations as well as vaccine price changes that occur in the middle of a contract period.

Recommendation #12. All public and private health insurance plans should voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents.

Recommendation #18: CDC should substantially decrease the time from creation to official publication of ACIP recommendations in order to expedite coverage decisions by payers to cover new vaccines and new indications for vaccines currently available.

ADDRESSED IN EXCHANGE PLANS

Recommendation #12. All public and private health insurance plans should voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents.

Recommendation #18: CDC should substantially decrease the time from creation to official publication of ACIP recommendations in order to expedite coverage decisions by payers to cover new vaccines and new indications for vaccines currently available.

Interaction between Health Reform and NVAC Vaccine Financing Recommendations

(March 2009)

ADDRESSED IN MEDICAID COVERAGE

Recommendation #5. Increase the Federal match (i.e. a larger Federal proportion) for vaccine administration reimbursement in Medicaid to levels for other services of public health importance (e.g. family planning services).

Recommendation #12. All public and private health insurance plans should voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents.

ADDRESSED IN FEDERAL FUNDING FOR VACCINE PROGRAMS

Recommendation #9. Medical providers, particularly in smaller practices, should participate in pools of vaccine purchasers to obtain volume ordering discounts. This may be done by individual providers joining or forming purchasing collaboratives, or through a regional vaccine purchasing contract held by professional medical organizations on behalf of providers.

Recommendation #14. Congress should request an annual report on the CDC's professional judgment of the size and scope of the Section 317 program appropriation needed for vaccine purchase, vaccination infrastructure, and vaccine administration. Congress should ensure that Section 317 funding is provided at levels specified in CDC's annual report to Congress.

Recommendation #19: Congress should expand Section 317 funding to support the additional national, state and local public health infrastructure (e.g., widespread and effective education and promotion for healthcare providers, adolescents, and their parents; coordination of complementary and alternative venues for adolescent vaccinations; record keeping and immunization information systems; vaccine safety surveillance; disease surveillance) needed for adolescent vaccination programs as well as childhood vaccination programs for new recommendations such as universal influenza vaccination.

ADDRESSED IN POPULATION HEALTH AND PREVENTION INITIATIVES

Recommendation #8. Professional medical organizations should provide their members with technical assistance on efficient business practices associated with providing immunizations, such as how to contract and bill appropriately. Medical organizations should identify best business practices to assure efficient and appropriate use of ACIP recommended vaccines and appropriate use of CPT codes, including Evaluation and Management (E&M) codes, when submitting claims for vaccines and vaccine administration. These organizations may receive Federal assistance from CMS or other relevant agencies.

Recommendation #10. CDC, professional medical organizations, and other relevant stakeholders should develop and support additional employer health education efforts. These efforts should communicate the value of good preventive care including recommended vaccinations.

Recommendation #21. State, local and Federal governments along with professional organizations should conduct outreach to physicians and non-physician providers who currently serve VFC-eligible children and adolescents to encourage these providers to participate in VFC if they currently do not. Outreach directed at providers serving adolescents who may not have provided vaccinations in the past (e.g. obstetrician-gynecologists) is a particular priority.

ADDRESSED IN RESEARCH

Recommendation #4. CMS should update the maximum allowable Medicaid administration reimbursement amounts for each state and include all appropriate non-vaccine related costs as determined by current studies. These efforts should be coordinated with the American Medical Association's (AMA) review of Relative Value Unit (RVU) coding.

Recommendation #6. AMA's RVS Update Committee (RUC) should review its RVU coding to ensure that it accurately reflects the non-vaccine costs of vaccination including the potential costs and savings from the use of combination vaccines.

Interaction between Health Reform and NVAC Vaccine Financing Recommendations (March 2009)

Recommendation #7. Vaccine manufacturers and third-party vaccine distributors should work with providers on an individual basis to reduce the financial burden for initial and ongoing vaccine inventories, particularly for new vaccines. This may include extending payment periods (e.g. from 60 days to 90 or over 120 days), or until vaccine has been administered and reimbursed. It may also include options not related to payment terms for vaccine inventory.

Recommendation #13. Insurers and healthcare purchasers should develop reimbursement policies for vaccinations that are based on methodologically sound cost studies of efficient practices. These cost studies should factor in all costs associated with vaccine administration (including, for example, purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping).

Recommendation #15. CDC and CMS should continue to collect and publish data on the costs and reimbursements associated with public and private vaccine administration according to NVAC standards for vaccinating children and adolescents. These costs include costs associated with the delivery of vaccines, such as purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping. These published data should be updated every five years and also include information about reimbursement by provider type, geographic region, and insurance status. State governments should use this information in determining vaccine administration reimbursements rates in Medicaid.

Recommendation #16. NVPO should calculate the marginal increase in insurance premiums if insurance plans were to provide coverage for all routinely ACIP-recommended vaccines.

Recommendation #20: Continue Federal funding for cost-benefit studies of vaccinations targeted for children and adolescents.

SCHOOL-BASED HEALTH CENTERS

Recommendation #23: Ensure adequate funding to cover all costs (including those incurred by schools) arising from assuring compliance with child and adolescent immunization requirements for school attendance

Recommendation #24: Promote shared public and private sector approaches to help fund school-based and other complementary-venue child and adolescent immunization efforts

Source: The Affordable Care Act: U.S. Vaccine Policy and Practice, GWU/SPHHS/DHP (Fall, 2010)