The Center for Medicare and Medicaid Innovation: Activity on Many Fronts

Timely Analysis of Immediate Health Policy Issues
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One of the few health policy issues that receives bipartisan support is the need to dramatically alter the way providers are paid, shifting from "paying for volume" to "paying for value." New payment approaches and new organizations capable of accepting value-based payments are seen by some as transformative innovations that can alter the trajectory of health care spending while improving quality of care. The Patient Protection and Affordable Care Act of 2010 (ACA) has equipped the Centers for Medicare & Medicaid Services (CMS) with a range of cost-cutting and quality-enhancing tools, the most significant of which might be the Center for Medicare and Medicaid Innovation (Innovation Center).

The Innovation Center is pursuing a groundbreaking portfolio of payment and delivery reform initiatives that will attempt to fundamentally change the way we deliver and pay for care in the future. The ACA appropriates $10 billion for Innovation Center activities initiated between and including fiscal years 2011 to 2019, and then appropriates an additional $10 billion for each of the following decades (without an end date).[1] Congress appropriates rather than authorizes the Innovation Center's funding to ensure that it does not have to return to Congress each year or even each decade for additional funding. Although $10 billion per decade represents a major spending commitment, it is still less than 0.1 percent of Medicare and Medicaid spending through the end of this decade—far less than most organizations commit to research and development.[2]

There seems to be broad agreement in the policy community on the objectives the Innovation Center was established to achieve. A 2011 Commonwealth Fund/*Modern Healthcare* survey of health care opinion leaders found that 83 percent of respondents thought the Innovation Center was an important initiative—support that is about 20 percentage points higher than for the Patient-Centered Outcomes Research Institute and the Independent Payment Advisory Board.[3]

Nevertheless, a contrary view is skeptical about the role of government, as centralized in the Innovation Center, in promoting and adopting true innovation. Advocates of market-based solutions to cost and quality problems argue that innovation springs from competitive forces—from the ground up—and cannot be determined and spread from a government agency, however worthy its intentions. And, perhaps reacting to claims by White House officials that the Innovation Center would be a source of job creation,[4] three members of the Senate Finance Committee recently publicly voiced concerns in letters to both the Government Accountability Office (GAO) and the Department of Health and Human Services' (HHS) Secretary Sebelius. Senators Orrin Hatch, Mike Enzi, and Tom Coburn asked the GAO to review the Innovation Center's activities and funding decisions, its fiscal impact on Medicare and Medicaid, and the degree of redundancy in CMS due to the Innovation Center's existence.[5]

While required to carry out initiatives specified in the ACA, the Innovation Center also has placed emphasis on promoting change from the ground up, in an attempt to be responsive to new ideas. In November 2011, it announced an Innovation Challenge to award between $1 million and $30 million in grants (totaling $1 billion) to any applicant who proposes to implement compelling new ideas to deliver better care to people enrolled in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). In various ways, the Innovation Center has also made a commitment to actively seek collaboration with other payers of health care services, including states and private insurance companies, to find common innovations in payment and care delivery. Since its inception, the Innovation Center has announced over a dozen major initiatives, ranging from a program that helps individuals build the skills needed to innovate from the ground up to a demonstration that invites public and private payer collaboration in developing a medical home approach to a set of initiatives that complement Medicare's existing

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accountable care organization (ACO) program.

Given all of this activity, some now express concern that the Innovation Center may be doing too much too soon, providing overwhelming numbers of program options without an articulated vision or clear road map of the direction it wants the health delivery system to take.[6] According to this viewpoint, the rapid succession of requests for proposals (RFPs) with tight time deadlines seems geared more to large, well-financed organizations than to the majority of providers who may need longer to generate innovative approaches. Yet, conversations with Innovation Center leadership make clear that they are proceeding with "a sense of urgency" to address the Triple Aim to (1) improve the individual experience of care, (2) improve the health of populations, and (3) reduce per capita costs of care for populations.[7]

The goal of this paper is to provide a status report on the Center for Medicare and Medicaid Innovation. The paper first defines the goals Congress envisioned for the Innovation Center and the new tools it was given, emphasizing how the enhanced authority compares with CMS' traditional demonstration programs. Next, the paper outlines the Innovation Center's organization and staffing, how it sets priorities and decides on funding, and its approach to altering traditional approaches to testing innovative ideas, while also seeking a much more collaborative interaction with providers, other payers, and the public. The paper concludes with a description of the major activities to date, along with a table listing the projects that the Innovation Center has initiated so far (see Table 1).

Most of the information in this paper was found in publicly available sources. We supplemented that review by interviewing senior leadership within the Innovation Center. We have also drawn on observations by some providers and delivery system reform experts who have interacted with the Innovation Center, to understand the perspective of those on the outside. To facilitate frank discussion, we promised that we would not attribute comments to specific individuals.

Why Was the Innovation Center Created?

Congress established the Innovation Center in the ACA primarily to test new payment and delivery models. The law specifically charges the Innovation Center with identifying, developing, assessing, supporting, and spreading new models that might reduce expenditures under Medicare, Medicaid, or CHIP while improving or maintaining care quality. The statute also suggests that the Innovation Center make multipayer initiatives one of its priorities.[8]

The ACA directs the Innovation Center to give preference to models that enhance coordination, quality, and efficiency of care provided to Medicare and Medicaid beneficiaries, as well as those dually eligible for the two programs. Congress further suggests that the Innovation Center give preference to models that address "a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." The law suggests but does not require that it explore 18 priorities, called models, for delivery reform**.** [9] It is important to note that the ACA also enables the Secretary of HHS to waive certain provisions of existing law that otherwise would prevent CMS from testing models with alternative provider payment systems and/or coverage policies.[10]

How Does the Innovation Center's Authority Compare to CMS' Traditional Demonstration Authority?

The Innovation Center is in many ways an extension of and improvement on CMS' existing authority to conduct demonstrations in Medicare, Medicaid, and CHIP. CMS' authority to conduct Medicare demonstrations is most commonly based on Section 402 of the Social Security Amendments of 1967 (as amended by Section 222(b) of the 1972 Social Security Amendments). CMS' "Section 1115 Medicaid demonstration" authority, the most common source of authority for Medicaid demonstrations, dates back to 1962, when Section 1115 of the Social Security Act was enacted. Section 1115 also is the basis for CMS' authority to conduct demonstrations under CHIP, though that program was created much later as part of the Balanced Budget Act (BBA) of 1997.[11]

Over time, Medicare and Medicaid demonstrations have taken on different roles within each program. CMS uses Medicare demonstrations as a tool to (1) test the effectiveness of delivery, payment, and benefit innovations on a small population of beneficiaries or a specific geographic area over a short time period, and (2) gain operational experience applicable to future demonstrations or programmatic changes.[12]

Medicaid demonstrations are used commonly to waive provisions of statute that limit the range of

programmatic changes available to states and provide matching federal funds for services and/or populations that otherwise would not be eligible for federal reimbursement. Many states have used Medicaid demonstrations to redesign significant portions of their programs, to the point, in the analysis of a Medicaid policy expert, that "in many states, the demonstrations have become the Medicaid programs."[13]

The Innovation Center's authority to conduct demonstrations marks an important departure from CMS' traditional demonstration authority. The ACA gives the Innovation Center a reliable stream of funding—appropriated rather than simply authorized by Congress—and the Secretary of HHS new authority over the demonstration approval process, the scope of models to be tested, and the decision to scale up successful models to the national level.

The Office of Management and Budget (OMB) actively participates in the development and final review of Innovation Center initiatives, but models tested, evaluated, or expanded under Innovation Center authority are exempt from OMB review and approval of information collections under the Paperwork Reduction Act and of CMS' budget neutrality analysis.[14]

However, to ensure spending discipline in the demonstration process, the Secretary is required to terminate or alter a demonstration unless the Secretary finds that the demonstration is (1) improving quality while maintaining or decreasing cost levels, or (2) reducing costs while maintaining or improving quality. The CMS chief actuary must also certify the Secretary's findings regarding demonstration spending levels. The law, however, is silent on the length of time needed to make this determination—giving the Secretary flexibility on ending a demonstration.[15]

ACA also gives the Secretary the authority to scale up nationally successful demonstrations without first obtaining congressional approval. To broaden a model, the Secretary must determine that such action "would not deny or limit [beneficiary] coverage or provision of benefits" to beneficiaries, in addition to passing the quality and spending requirements, mentioned above, for continuing a demonstration. The CMS chief actuary also must independently verify that model reduced trust fund expenditures before the Secretary can authorize scaling up the model.[16]

Medicare Demonstration Authority

Under CMS' traditional Medicare demonstration authority, demonstrations can be initiated through an act of Congress or action on the part of the Secretary. Medicare demonstrations initiated by CMS under this authority generally have tested delivery, payment, and/or benefit changes. These demonstrations cannot proceed if they lower the quality of care that beneficiaries receive, expand program eligibility, or waive beneficiaries' freedom to choose their providers.[17]

Congress can mandate that CMS implement a new Medicare demonstration project through legislation or the annual appropriations process, or Congress can extend existing demonstrations beyond their planned date of completion. In the past, Congress mandated few Medicare demonstrations. Over time, Congress has become more active in this area. As of April 2010, Congress had mandated 17 of the 31 active or upcoming Medicare demonstrations in CMS' active portfolio.[18] Despite the increase in congressionally mandated demonstrations, funding levels in the 2000s for research, demonstrations, and evaluations have varied considerably—ranging from $138 million in 2001 to only $31 million in 2008.[19]

Medicaid Demonstration Authority

Under Section 1115 demonstration authority, the Secretary is permitted to waive certain provisions of Medicaid statute relating to the design and operation of state programs. For example, the Secretary can waive provisions that cover Medicaid eligibility criteria, the range of offered services, and the delivery and payment system approach used in a state. The state also becomes eligible for federal matching funds to cover the new services or population.[20]

Since Section 1115 demonstrations must be budget neutral, the cost of any proposed program expansions must be offset by savings to the program in other areas. In the past, states have generated savings to offset new costs by implementing managed care capitated payments (the most common method); redirecting Medicaid payments made to hospitals that serve a disproportionate share of Medicaid and/or uninsured patients; and limiting offered benefits to or increasing cost sharing for existing Medicaid patient populations. OMB also allows states to count program expansions already permitted under federal law but not adopted by the state as savings for the purpose of calculating a demonstration's budget neutrality.[21]

In 1993, the Clinton administration signaled that it would begin to use Section 1115 authority as a tool for achieving statewide health reform—

OMB Authority to Review Budget Neutrality

To pass OMB review, a demonstration's total spending cannot exceed anticipated spending levels under existing law and must generate savings to offset the agency's operational costs.[1]

When the Health Care Financing Administration[2] (HCFA) was created in 1977, it had almost unlimited power over the demonstration process. Tension between OMB and HCFA began to mount immediately over both the agency's decisions to authorize certain demonstrations and the size of the Medicare budget devoted to research and demonstrations (as much as 20 percent of Medicare's budget from the late 1970s to the early 1980s).[3]

During the fiscal 1983 budget process, OMB assumed greater control over the demonstration process through an agreement brokered between then-OMB Director David Stockman and then-HHS Secretary Richard Schweiker, giving OMB clearance authority over demonstrations and creating the budget neutrality requirement.[4]

Over the years, some have raised concerns about the narrowness of OMB's budget neutrality review. The budget neutrality determination may not recognize savings generated after the demonstration period has ended—as is often the case with primary and secondary prevention interventions—or even savings to another government program. The budget neutrality requirement also may limit CMS' ability to test ideas with unproven potential to reduce or maintain spending levels while improving quality, or ideas that could give CMS important operational experience that could be applied subsequently in demonstrations and program administration.[5]

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[1] Medicare Payment Advisory Commission. "Report to the Congress: Aligning Incentives in Medicare," 2010.
[2] HCFA was renamed CMS in 2001.
[3] Dobson A, Moran D and Young G. "The role of federal waivers in the health policy process." *Health Affairs*, 11(4): 72-94 2010; Shirk C. "Shaping Public Programs through Medicare, Medicaid, and SCHIP Waivers: The Fundamentals." Washington, DC: National Health Policy Forum, 2003.
[4] Dobson et al, "The role of federal waivers in the health policy process"; Shirk, "Shaping Public Programs through Medicare, Medicaid, and SCHIP Waivers."
[5] Cassidy M. "The Fundamentals of Medicare Demonstrations." National Health Policy Forum, 63, 2008; Greenwald L. "Converting Successful Medicare Demonstrations into National Programs." In *Pay for Performance in Health Care: Methods and Approaches*, Cromwell J, Trisolini M, Pope G, et al. (eds). Research Triangle Park, NC: RTI Press, 2011; Medicare Payment Advisory Commission, "Report to the Congress."

significantly expanding the scope of Medicaid demonstrations. By 2003, 16 statewide health reform demonstrations were operating under Section 1115 authority.[22]

Successes in the Traditional Medicare Demonstration Program

Among the permanent programs that have been developed out of Medicare demonstrations are the hospice benefit, the Program of All-Inclusive Care for the Elderly, and competitive bidding for durable medical equipment. In addition, several broader initiatives have been developed as demonstrations, including the inpatient prospective payment system (IPPS) to replace cost-plus reimbursement to hospitals, the Medicare risk program (now known as Medicare Advantage), and other prospective payment systems.[23] The IPPS is still used today in the Medicare program, and this payment approach has been adopted by other U.S. payers and at least 12 European countries.[24]

Sometimes even a negative result can be useful. Success can be found in conducting a sound demonstration that adequately tests a proposed approach and provides evidence as to whether the approach works or not. CMS' experience with disease management demonstrations is a case in point. During the 1990s, employers and private health insurers began to use a form of disease management in which a nurse, usually based in a call center, periodically telephones patients with particular chronic conditions to provide education to support patient self-management and to monitor the patient's condition. The goal was to facilitate early intervention to head off clinical deterioration that might result in a hospitalization. The intervention did not directly involve patients' physicians, yet took advantage of the health plan's relationship with its subscribers. The approach was considered a useful tool for delivering evidence-based care to those with chronic illnesses and widely adopted by private health insurers, yet never subjected to a rigorous evaluation to demonstrate its impact on patient well-being and health spending.[25]

The CMS-sponsored demonstration, the Medicare Health Support (MHS) pilot program, was the first large study of this common form of disease management; it failed to reduce spending and was terminated. However, participants point to a number of problems with the operational implementation of the MHS program that suggest the need for so-called "rapid cycle" implementation, which has been

adopted as a core approach for the Innovation Center, as discussed later.[26] Whatever the operational lessons for conducting improved demonstrations, however, CMS ended funding of some of the pilot sites early because failure to engage complex Medicare patients in the disease management approach contributed to a reconsideration of this approach among private insurers as well as public payers, leading to a renewed effort to include patients' physicians directly in the care management endeavor.

Between 1999 and 2008, the Medicare program conducted seven disease management or care coordination demonstrations that included 300,000 beneficiaries across 35 programs in 22 states, including the MHS pilot program.[27] As of January 2009, only three of the 20 programs with final evaluations showed evidence of quality improvement while being close to budget neutrality (minus fees), and early findings of the remaining 15 programs suggested that only four would be able to pay for their fees.[28] Lessons learned from this experience show that three types of interventions can reduce hospitalizations among Medicare beneficiaries who have multiple chronic conditions—transitional care, self-management education, and coordinated care.[29] So even "failed" demonstrations provide lessons that can be used to focus on promising approaches for improving care delivery.

Addressing Problems in the Demonstration Process

Despite these complete or partial successes, operational and political challenges have routinely constrained the scope and reach of Medicare demonstrations.[30] A major challenge has been overcoming political influence and non-evidence-based policymaking. For example, the Medicare Participating Heart Bypass Center Demonstration, which operated from 1991 to 1996, tested an approach that used bundled payments for hospital and physician services for coronary artery bypass graft surgery. The subsequent evaluation showed that the approach cut costs by 10 percent, reduced inpatient mortality rates, and improved patient satisfaction with nursing care, length of stay, and the amount of paperwork.[31] CMS attempted to build on this success by implementing the Centers for Excellence Demonstration, which would have expanded the approach to other cardiac procedures and to hip and knee replacements, but political pressure from hospitals and physicians prevented CMS from following through with these efforts.[32]

In many cases the problem can be traced to the length of the demonstration process. A demonstration that lasts one year can take three times that long to complete—one year for research and design, one year for operation, and one year for evaluation.[33] Completion of longer demonstrations can take twice as long as their actual operation. An often cited example, the five-year Physician Group Practice (PGP) Demonstration, took more than 10 years to complete—from enactment of the congressional mandate to conduct of the demonstration in 2000 to CMS' announcement of the five-year results in 2011. The Medicare Coordinated Care Demonstration process took even longer; it was authorized in the BBA of 1997 and completed 14 years later.[34]

The Innovation Center's new authority is designed to shorten the demonstration process. At the front end, ACA exempts demonstrations initiated under the Innovation Center's authority from OMB's cumbersome and lengthy budget neutrality and Paperwork Reduction Act review. The Secretary grants the Innovation Center authority to conduct rapid cycle evaluation (explained below) on top of its formal demonstration evaluation—enabling the Innovation Center to produce usable findings for policymakers, providers, and other stakeholders more quickly. And finally, the Secretary's new authority to scale up successful demonstration nationally or program-wide without new statutory authority will help to speed the pace at which policymakers act on a demonstration's results.

Another set of problems with the demonstration process stems from the perceived rigidity of CMS' formal evaluation process when used to test all innovations. Some proposed innovations lend themselves more readily to traditional randomized trial methods and may fill important evidence gaps,[35] such as the MHS pilot. However, under this formal evaluation approach, CMS is unable to obtain feedback from participants about needed alterations to the intervention, generate early assessments of impact, and then make midcourse corrections while the demonstration is operating.

Participants in the failed MHS pilot observed that evaluation methods other than controlled trials better facilitate "rapid learning" and are more appropriate for models of care not well-suited to randomization.[36] Indeed, some types of complex social experiments, such as new models for providing chronic care management, are not conducted in laboratories but rather in a changing environment. This makes it difficult to maintain

control over important aspects of such trials, and attempts to do so can be counterproductive.[37]

A particular challenge is whether all possible innovations are best tested in a demonstration. For example, it is not surprising that the PGP Demonstration did not cause providers to alter the way they deliver care to achieve significant reductions in Medicare spending. After all, the current fee-for-service payment system penalizes providers for doing what was asked in this demonstration: namely, to reduce the volume of services they deliver through better care coordination and to pay greater attention to evidence of what actually benefits patients. Given the initial three-year limit on CMS' commitment to the payment approach used in this demonstration (a typical time commitment for demonstrations), it might have been foolhardy for participants to overhaul their business model, including reducing their revenues from hospital admissions, for a temporary opportunity being offered by only one payer, even one as important as Medicare.[38] Yet, many of the operational lessons learned from the PGP Demonstration now permit CMS to proceed with the Shared Savings Program and the Pioneer ACO demonstrations, as discussed below.

In short, these examples point to the fact that different kinds of innovation require different approaches to testing and evaluation. Some can undergo classic randomization in a formal trial, as CMS has long done. However, other innovations need to be tested with more flexible approaches, using rapid cycle evaluation approaches, and still others may need to be fostered without formal demonstrations at all because of the nature of the change being promoted.

The examples also point to the need for a multipayer approach to test new models in order to magnify the power of new incentives, reduce administrative burden on providers, and help address unwarranted and contradictory variation in payment methods and rates across payers.[39]

About the Innovation Center

How Is the Innovation Center Staffed and Organized?

Former CMS Administrator Donald Berwick, MD, named Richard Gilfillan, MD, acting director of the Innovation Center in September 2010. With his 20-year experience as head of the Institute for Healthcare Improvement, Berwick was actively involved with forming the Innovation Center and helping formulate its strategic direction. With his departure, Dr. Gilfillan now reports directly to CMS' acting administrator, Marilyn Tavenner, whom President Obama recently nominated to become permanent administrator.[40] A search is still in progress for a permanent director for the Innovation Center.

The Innovation Center's leadership initially arranged the organization to reflect its research priorities, focusing on three primary areas: models that improve care in individual episodes, models that cover populations across time and settings, and models that aim to improve community or population health. The Innovation Center has created corresponding research and model development groups: the Patient Care Models Group, directed by Director Valinda Rutledge; the Seamless Care Models Group, directed by Director Richard Baron, MD; and the Community Improvement Models Group, directed by Acting Director James Hester, PhD.[41]

The Innovation Center has also formed a Learning and Diffusion Group, led by Joseph McCannon, which will provide technical assistance, introduce ideas, and spread successful ones; a Stakeholder Engagement Group, led by Mandy Cohen, MD, which generates awareness about the Innovation Center and communicates its activities to the public and stakeholders; a Program and Policy Group, led by Thomas Reilly, PhD, which focuses on vetting ideas the organization receives; and a Rapid Cycle Evaluation Group, led by William Shrank, MD.[42]

The Innovation Center's leadership has also created a Portfolio Management Committee—comprised of the Innovation Center's directors, Dr. Gilfillan, and other senior staff—recognizing that the lines across the research groups do not always accommodate particular initiatives. Innovation Center staff members present potential opportunities to the Portfolio Management Committee, which in turn identifies the most promising ideas for further development. This arrangement helps to balance workloads and increases collaboration among the directors and their groups.

Since the Innovation Center's creation in 2010, an immediate task was hiring staff. To expedite the hiring process, the Office of Personnel Management granted the Innovation Center direct hiring authority until March 2011—enabling the organization to hire 80 staff members in its first five months of existence. Six months later, the Innovation Center had doubled in size to 160 staff, due in part to the organization's absorption of the Office of Research, Development, and Information's (ORDI) evaluation and demonstration groups.

What Is Rapid Cycle Evaluation?

The typical CMS evaluation generally has involved independent evaluation by contracted researchers using several basic elements:

- Careful definition of the target population and how it is to be assessed to judge success.
- One or more comparison or control groups to serve as a benchmark for what would have happened without the intervention.
- Metrics defining the outcomes of interest and how they change over time, often requiring new forms of data collection or unique data files.
- Long time frames designed to distinguish immediate effects from more stable, longer term effects.[1]

The evaluation designs seek to distinguish true effects of an innovation from those that can be explained by other factors, including secular trends, changes in patient mix, or other changes in the environment for those being evaluated.[2] As discussed earlier, this approach does not work well to evaluate many possible innovations. To address an inflexible evaluation process, the Innovation Center has emphasized an approach that will enable the organization to make "rapid cycle" changes during a demonstration's implementation phase.

The Innovation Center's Federal Register notice, which lays out the organization's basic functions and delegated authorities, specifies that the Innovation Center perform "rapid cycle evaluation of innovation and demonstration activities to determine effectiveness and feasibility for broader dissemination, scale, and sustainability."[3] Rapid cycle evaluation offers a way for the Innovation Center to capture real-time data on and incorporate early insights into demonstrations as they unfold, learning from failure and success along the way.[4]

However, although formal evaluations will still be conducted, those evaluations must deal with imperfect controls, incomplete data,[5] and even changing interventions, all leading to a probability of "messy" evaluations, in the words of a member of the Innovation Center leadership. In its commitment to rapid learning, the challenge for the Innovation Center will be to maintain the appropriate balance between scientific rigor and practical need to adapt to actual conditions being experienced by the demonstration participants.

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[1] Gold M, Helms D and Guterman S. "Identifying, Monitoring, and Assessing Promising Innovations: Using Evaluation to Support Rapid-Cycle Change." *The Commonwealth Fund*, 1512(12), 2011.
[2] ibid.
[3] *Federal Register*. "Department of Health and Human Services: Centers for Medicare and Medicaid Services: Statement of Organization, Functions, and Delegations of Authority," 2010.
[4] Gold et al, "Identifying, Monitoring, and Assessing Promising Innovations."
[5] Guterman S and Drake H. "Developing Innovative Payment Approaches: Finding the Path to High Performance." *The Commonwealth Fund*, 1401(87), 2010.

ORDI's demonstration group, renamed the Medicare Demonstrations Program Group under the Innovation Center and led by Linda Magno, focuses on demonstrations that predate the Innovation Center or that are congressionally mandated. ORDI had administered most of CMS' demonstrations for the past decade under the agency's traditional authority.

CMS' internal reorganization centralizes management of almost all Medicare and Medicaid demonstrations under one entity, the Innovation Center. With the addition of ORDI's demonstrations and evaluations components, the Innovation Center has gained career staff who have long-term experience in the demonstration and evaluation process and thus are well positioned to inform the Innovation Center's decisions going forward. About half of the Innovation Center's staff consists of individuals with government experience. The Innovation Center's leadership objective has been to pair directors who are new to government with experienced CMS deputy directors.

The Innovation Center's leadership has recognized the need to attract personnel with extensive experience in the private sector, other CMS units, other public payers, and academia; the Innovation Center's commitment to ground-up innovation is partly based on already-tested approaches in use outside of government programs and in collaboration with other public and private payers. Likewise, the Innovation Center has made a point of recruiting seasoned CMS employees for leadership positions—individuals who, like their counterparts in the private sector and academia, are foregoing opportunities for higher pay and employment outside of the government. The Innovation Center has adopted a strategy of both hiring

full-time employees and assigning temporary staff (who might later become full-time employees) through the Intergovernment Personnel Act Mobility Program. Given the difficulty CMS sometimes has had in the past in attracting staff with specialized private sector and academic expertise,[43] partly because of inability to offer competitive salaries, the Innovation Center has been notably successful at attracting experienced experts willing to work at a General Schedule (GS) 15 salary—in the $125,000 to $155,000 range[44]—in order to be part of this new endeavor.

Recently recruited staff include Nancy Nielson, MD, an internist and former president of the American Medical Association; Richard Baron, MD, an internist with experience as the chief medical officer of a not-for-profit Medicaid health maintenance organization and the chair of the American Board of Internal Medicine Board of Directors; James Hester, PhD, the former director of Vermont's Health Care Reform Commission; William Shrank, MD, a Harvard professor of medicine and pharmacoeconomics; Joseph McCannon, former senior vice president at the Institute for Healthcare Improvement, who oversaw the 100,000 Lives Campaign for the Institute; Valinda Rutledge, former CEO of Caramont Hospital in North Carolina; Thomas Reilly, PhD, a researcher with over 20 years of CMS experience; and Mandy Cohen, MD, an internist and former executive director of Doctors for America.

How Does the Innovation Center Prioritize Projects?

The Innovation Center's leadership sees its role as twofold: (1) complementing existing efforts in the private sector, among states, in Congress, and at CMS itself to innovate; and (2) delving into new ideas. Most of the Innovation Center's efforts to date have focused on the former—implementing congressionally mandated demonstrations or ideas that Congress or policy experts have already conceived (e.g., bundled payments or accountable care organizations)—and have drawn criticism for being too rigid and prescriptive. More recently, the Innovation Center has begun to seek new ideas from innovators across the country and promote bottom-up innovation through its Innovation Challenge.

Using ACA's list of suggested models of care as a guide, the Innovation Center's leadership has developed a list of priorities—called the Portfolio Criteria—that the organization is using to build its demonstration portfolio. The Innovation Center does not expect that prospective models will be able to satisfy all elements of the Portfolio Criteria, but rather seeks to develop a model portfolio that mirrors those priority areas.

In addition to the Triple Aim of better health care, better health, and reduced costs, the Portfolio Criteria include having "the greatest potential impact on Medicare, Medicaid, and CHIP beneficiaries, and the ability to improve how care is delivered nationally," balancing short-term and long-term initiatives, and examining health conditions that have the greatest potential for improving care while reducing costs. A full list of the Portfolio Criteria is available on the Innovation Center's website.[45]

The Innovation Center is focusing on testing models that fit into its priority areas and that it determines are worth exploring. In most cases, the Innovation Center does not work one-on-one to fund innovators who present interesting proposals, but rather decides whether the idea can be converted into a model that would then be put into an RFP and funded on a competitive basis.

The Innovation Center has not yet promulgated a strategic plan that lays out a vision for the kind of health care delivery system toward which it is working, the health care delivery reforms that would get us there, and a road map for proceeding, as called for by some.[46] Absent a concrete strategic plan, the Innovation Center has developed a detailed list of priorities in which selected models must fit, a process for identifying and selecting proposals to test, and a competitive process by which interested parties can apply to participate in an initiative. The Innovation Center has not yet articulated how these priorities or specific initiatives fit into a larger plan for revolutionizing the delivery system. As noted earlier, some observers find this to be a serious omission.

Once an idea has been approved by the Portfolio Management Committee and approved within the administration, the Innovation Center generates an RFP for interested providers and/or payers. All parties interested in participating in an Innovation Center initiative must go through the competitive application process. Some have criticized the Innovation Center for exchanging transparency and flexibility for speed and competitiveness in its approach—particularly since the process generally does not accept applications on a rolling basis throughout the life of an initiative. Once the Innovation Center turns down an application for one of its initiatives, the opportunity to participate may be gone forever; rejected applicants have no opportunity to re-apply.

The Health Care Innovation Challenge offers an additional mechanism for a wide array of stakeholders to propose ideas to the Innovation Center. The Healthcare Innovation Challenge will award grants to applicants who can rapidly implement the most compelling new ideas to deliver better health, improved care, and lower costs to people enrolled in Medicare, Medicaid, and CHIP, particularly those with the highest health care needs.

The Innovation Center considered establishing a Federal Advisory Committee Act (FACA) – compliant committee – an advisory body that could potentially include agency officials, issue experts, and members of the public and professional societies—to help guide Innovation Center priorities and to provide broad-based support for the direction the Innovation Center takes,[47] perhaps modeled after the two successful FACA committees implemented to make recommendations to the National Coordinator for Health Information Technology.[48] Ultimately, the Innovation Center's leadership decided that the requirements of managing a FACA committee were potentially too burdensome, while the attendant delays to get such a committee up-and-running ran counter to the urgency CMS leadership felt to get started. Instead, the Innovation Center asserts it is attempting to achieve similar objectives without a formal Advisory Committee by emphasizing transparency of its project solicitation process and through ongoing dialogue with the public, facilitated by the Stakeholder Engagement Group. For example, the Innovation Center sponsored a Care Innovations Summit on January 26, 2012, in collaboration with the Office of the National Coordinator for Health Information Technology, the West Wireless Health Institute, and *Health Affairs*.

How Can External Innovators Interact with the Innovation Center?

The Innovation Center is continually soliciting ideas related to ways to build the organization itself and new payment and delivery models for it to test. Members of the public can submit ideas on both topics through a web portal located on the Innovation Center's website or through letters to the Innovation Center. The Innovation Center is set up to accept innovative payment and delivery reform ideas, feedback, and suggestions from the public, but not detailed proposals.

The Innovation Center currently does not have the capacity to respond to submitted comments or release them (or summaries) for public consumption. Innovation Center staff use submitted comments to inform internal discussions about building the organization's capacity and identifying potential models to test. Innovators who submit model ideas that the Innovation Center ultimately decides to test will have the opportunity to respond to the Innovation Center's RFP on specific topics, but will not be afforded preferential treatment.

What Initiatives Has the Innovation Center Started So Far?

The Innovation Center is responsible for a range of demonstrations that fall under either CMS' traditional demonstration authority or the Innovation Center's new authority as laid out in ACA. The Innovation Center has inherited most of CMS' existing demonstrations, which operate under the agency's traditional authority, through its absorption of the demonstration group within ORDI. New initiatives that are congressionally mandated also operate under traditional demonstration authority and are administered by the Innovation Center. The Innovation Center administers new demonstrations unrelated to congressional mandates under its new authority.

Since its founding, the Innovation Center has announced 13 new initiatives. This ambitious schedule highlights a new predicament for the Innovation Center's prospective applicants. In most cases, to participate in a demonstration, they have to relinquish the option of participating in potentially more desirable demonstrations in the future; an entity's participation in multiple demonstrations could potentially confound its evaluation. The Innovation Center's policy is to address this problem on a case-by-case basis, and where possible it does allow overlapping participation among its initiatives. In some instances, however, the Innovation Center has not allowed cross-participation. For example, Minnesota's statewide participation in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration has precluded public and private payers in the state from applying to participate in the Comprehensive Primary Care initiative, which may offer a preferred approach for some.

So far, the Innovation Center has announced or begun to implement demonstrations that address primary care redesign (which includes medical home initiatives like the Comprehensive Primary Care initiative), bundled payments, ACOs, dual-eligible beneficiaries, and the health care system's capacity for spreading innovative ideas. In some instances, the Innovation Center is

implementing congressionally mandated demonstrations; the MAPCP Demonstration is one example. For the projects initiated under the Innovation Center's authority, it is trying to generate top-down and bottom-up innovation: taking a more prescriptive approach with initiatives like the Pioneer ACO Model initiative; creating a pathway for homegrown solutions to issues identified by the Innovation Center, as is the case with the Health Care Innovation Challenge; and allowing the CMS Medicare-Medicaid Coordination Office to take the lead on initiatives targeting dual-eligible beneficiaries.

The appendix describes many of the Innovation Center's initiatives. For a complete list, see Table 1.

Conclusion

In its first year of operation, the Innovation Center has a long list of accomplishments: attracting experienced personnel; developing processes for prioritizing and developing projects and for soliciting applicants for those projects; bolstering CMS thinking on several policy fronts, including ACOs; and committing to incorporating rapid cycle evaluation as a more flexible approach to determining success and promoting change. Concerned about the urgency to achieve delivery system change to achieve the Triple Aim, the Innovation Center is firing on all cylinders.

Yet, some policy and health delivery observers express concern that the Innovation Center's speed and approach are leaving behind potential innovators that have not been ready to respond to the quick pace of RFPs. They seek a more deliberative process that permits establishment of a consensus vision—and plan—for achieving a reformed health care delivery system. Exactly how such a consensus would be achieved remains unclear, given divergent views of how "paying for value" can best be achieved.

Table 1. The Innovation Center's Initiatives					
Initiative	**Application Deadline**	**Initiative Start Date**	**Length**	**Participants**	**Source of Authority**
Primary Care Redesign					
Comprehensive Primary Care Initiative Demonstration	1/17/2012	Unspecified	4 years	Payers and states in 5-7 markets*; 75 practices per market*	Section 3021 of ACA
Federally Qualified Health Center Advanced Primary Care Practice Demonstration	9/16/2011	11/1/2011	3 years - ends on 10/31/14	500 FQHCs (see link for details)	Section 3021 of ACA
Multi-payer Advanced Primary Care Practice Demonstration	8/17/2010	Phased-in starting 07/01/2011	3 years	NC, ME, MI, MN, NY, PA, RI, VT	Section 402 of the Social Security Amendments of 1967 (as amended)
Bundled Payments					
Bundled Payment for Care Improvement Initiative	Model 1: 11/18/2011; Models 2-4: 3/15/2012	Unspecified	3 years (with 2-year extension option)	Unspecified number of provider organizations*	Section 3021 of ACA
Accountable Care Organizations					
Accelerated Development Learning Sessions	N/A	2011	1 year (4 sessions)	Open to any organization	Section 3021 of ACA
Advanced Payment Accountable Care Organization Model Initiative	2/1/2012 for 4/1/2012 start date; 3/30/2012 for 7/1/2012 start date	4/1/2011 or 7/1/2012 (4 years)	4 years	Physician-based and rural ACOs in the Shared Savings Program*	Section 3021 of ACA
PGP Transition Demonstration	N/A	1/1/2011	2 years	The 10 practices from the original PGP Demonstration	Section 1866A(a)(1) of the Social Security Act
Pioneer Accountable Care Organization Model Initiative	8/19/2011	3rd or 4th quarter of 2011	3 years (with 2-year extension option)	32 organizations (see link for details)	Section 3021 of ACA
Dual-eligible Beneficiaries					
Demonstration to Improve Care Quality for Nursing Facility Residents	Fall 2011	Unspecified	Unspecified	Unspecified number of independent organizations (to serve up to 150 nursing facilities)*	Section 3021 of ACA
State Demonstrations to Integrate Care for Dual-Eligible Beneficiaries	2/1/2011	April/May 2011	18 months (with extension option)	CA, CO, CT, MA, MI, MN, NY, NC, OK, OR, SC, TN, VT, WA, WI	Section 3021 of ACA

Dual-eligible Beneficiaries (cont.)					
Financial Alignment Model Demonstrations	Unspecified	2012	3 years	Unspecified number of states*	Section 3021 of ACA
Capacity to Spread Innovation					
The Partnership for Patients	Ongoing	4/12/2011	Ongoing	Over 6,400 partners (no cap)	N/A
Community-based Care Transition Program (part of the Partnership for Patients)	Applications accepted on a rolling basis starting 4/12/2011	1/1/2011	5 years	Site selection phased-in starting November 2011 with 7 sites elected	Section 3026 of ACA
Innovation Advisors Program	11/15/2011	12/1/2011	Ongoing (each cycle is 6 months)	73 individuals in the first cycle (see link for details); up to 200 individuals in the second cycle*	Section 3021 of ACA
Health Care Innovation Challenge	1/27/2012	3/30/2012	3 years	Unspecified number of public and private organizations*	Section 3021 of ACA
Miscellaneous					
Medicaid Emergency Psychiatric Demonstration	10/14/2011	1/01/2012 target date	3 years	Unspecified number of states*	Section 2707 of ACA
Medicaid Incentives for Prevention of Chronic Diseases (MIPCD) Program	5/2/2011	Sites awarded 9/13/2011	5 years	WI, MN, NY, NV, NH, MT, HI, TX, CA, CT	Section 4108 of ACA
Independence at Home Demonstration	2/6/2012 (practices applying as consortiums have an additional 90 days)	2012	3 years	Up to 50 practices*	Section 3024 of ACA
**Participants not selected yet*					

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Appendix

The Innovation Center has announced or begun to implement demonstrations that address primary care redesign, bundled payments, ACOs, dual-eligible beneficiaries, and the health care system's capacity for spreading innovative ideas. Below is a description of many of the Innovation Center's initiatives. For a complete list, please see Table 1.

Primary Care Redesign

The Innovation Center is testing various models of primary care redesign. One of those models is what is called the advanced primary care practice (APC), also known as the patient-centered medical home (PCMH). The APC is defined as "a physician-based or nurse practitioner-led medical practice that provides continuous, comprehensive, coordinated, and patient-centered medical care."[49]

The Innovation Center has inherited a new medical home initiative that Secretary Sebelius announced in 2009: the Multi-payer Advanced Primary Care Practice Demonstration. This project allows the Medicare program to join Medicaid and private payer advanced primary care initiatives (also referred to as medical homes) in eight states, but the RFP specifically targeted states with partnerships with private payers, not the private payers themselves.

The Innovation Center also is implementing a medical home initiative mandated in the ACA that targets Federally Qualified Health Centers (FQHCs). The FQHC Advanced Primary Care Practice (APCP) Demonstration will test the effectiveness of the PCMH model in the FQHC setting. To be eligible to participate, FQHCs must provide primary care services and serve at least 200 Medicare beneficiaries (including some duals). Participating FQHCs will receive a small monthly management fee for each Medicare patient in their practice. The fee is intended to cover care coordination and other services typically delivered by PCMHs.

In September 2011, the Innovation Center announced a medical home demonstration initiated by the Innovation Center called the Comprehensive Primary Care initiative. This initiative is similar to MAPCP but targets private payers as applicants instead of states, provides a higher per member/per month reimbursement fee for care coordination services, and extends for an additional year. CMS would like to collaborate with state and commercial health insurance plans in five to seven markets across the United States. CMS will pay primary care practices a monthly fee for coordinating care furnished to their Medicare patients plus the usual program fees. The additional fee will help practices lend greater support to patients with serious or chronic conditions, provide patients with access to care 24 hours a day, provide preventive care, work more closely with patients and their families, and coordinate with other physicians. Primary care practices will be chosen to participate in the initiative once CMS has identified the markets in which the demonstration will operate. Participation in the Comprehensive Primary Care initiative by state and commercial plans and providers is voluntary, but states (or, in the case of larger states where participation is not statewide, markets) participating in MAPCP are precluded from applying to the Comprehensive Primary Care initiative.

Bundled Payments

The Innovation Center is testing several variations on the bundled payment model. Under a bundled payment approach, separate payments, for example, to a hospital and physicians for services provided during an inpatient hospitalization, are combined into a single payment, with the goal of providing common financial incentives for the various providers to decrease fragmented care and improve efficiency.

The Bundled Payments for Care Improvement initiative[50] will test four approaches to bundling the care delivered around a hospitalization. Three of the four models would test retrospectively setting a bundled payment amount and would allow participating[51] providers to share in the savings generated from delivering the care at a lower cost but would incorporate different combinations of providers. One model would test bundling payments for the acute hospital stay only, a second for the acute hospital stay and the associated post-acute care, and a third for post-acute care only. The latter two models

would also include physicians' services, related readmissions, and other services such as clinical laboratory services. The fourth model would test prospectively setting a bundled payment amount for services delivered by the hospital, physicians, and other medical practitioners. Applicants have some flexibility to select the conditions that will be tested through this initiative.

Accountable Care Organizations

One of the Innovation Center's highest profile priorities is testing the ACO concept. The Innovation Center defines an ACO as a group of providers of services and supplies "that have established a mechanism for shared governance and work together to coordinate care for Medicare fee-for-service beneficiaries. ACOs enter into an agreement with CMS to be accountable for the quality, cost, and overall care of traditional fee-for-service Medicare beneficiaries who may be aligned with it."[52] The Innovation Center has announced several ACO-related initiatives over the past year based on CMS' experience with the PGP Demonstration.

In January 2011, the Innovation Center extended the PGP Demonstration (renamed the PGP Transition Demonstration) for two additional years with some adjustments. All of the practices that participated in the initial five-year demonstration have agreed to participate.

For those organizations ready to take on more risk than the Medicare Shared Savings Program allows, the Innovation Center will test a more aggressive approach through the Pioneer ACO Model initiative. In the first two years of the initiative, ACOs will operate under a shared savings and shared loss approach. After two years, ACOs that have generated savings will be eligible to shift to a population-based payment arrangement, akin to partial capitation. Organizations can participate in the Medicare Shared Savings Program or the Pioneer ACO Model initiative, but not both.

The Innovation Center also has decided to provide start-up funding for qualifying organizations accepted into the Medicare Shared Savings Program. The Advanced Payment ACO Model will give eligible ACOs a portion of their share of the savings in advance of actually generating those savings, to make the infrastructure and staffing investments needed to succeed as an ACO.

Dual-eligible Beneficiaries

A growing body of research shows that dual-eligible beneficiaries have substantially higher medical spending than other populations on average yet are less likely to receive coordinated care. Duals represent 16 percent of Medicare beneficiaries yet are responsible for 25 percent of Medicare spending. Even more striking, duals comprise 18 percent of Medicaid beneficiaries and 46 percent of Medicaid spending.[53]

Since care for duals is reimbursed through two completely separate funding streams, neither program takes responsibility for coordinating the care delivered to these beneficiaries. Each program uses coverage rules to avoid costs. Medicare generally provides restorative and recuperative care, while Medicaid often pays for care that maintains or prevents further decline in health. At times, classifying services as restorative or maintaining the status quo can be ambiguous. For example, Medicaid, which covers the long-term care of nursing home residents, has a financial incentive to hospitalize those beneficiaries; Medicare covers their hospitalization and the first 100 days of nursing home care following a hospital stay.[54]

To address this unique set of challenges, ACA established the Medicare-Medicaid Coordination Office, which focuses on coordinating dual-eligible beneficiaries' care, improving access to high-quality care, and making the system more cost-effective. This office is taking the lead on the design, implementation, and evaluation of new state-based payment and delivery system reform demonstrations, but the initiatives are being implemented through the Innovation Center's authority and funding.[55] Although the initial emphasis has been on state-based demonstrations, whether states or the federal government should hold primary responsibility for the care—and consequently cost containment—for duals remains controversial.[56]

The Innovation Center launched its first initiative targeting duals in April 2011. For the State Demonstrations to Integrate Care for Dual Eligible Individuals, CMS is working with 15 states to develop person-centered approaches to care coordination for duals. Each participating state will receive up to $1 million to develop its approach and produce a specific proposal.

In July 2011, CMS announced that the Innovation Center would be conducting two additional demonstrations targeting duals. One, the Innovation Center is administering a demonstration that would reduce preventable inpatient hospitalizations among long-term nursing facility residents, although the approach may also benefit other nursing facility residents. Organizations separate from nursing facilities would implement evidence-based interventions in nursing facilities with high hospital admission rates and a large share of duals.

Two, the Innovation Center released guidance to states on a new demonstration that would test two financial approaches to aligning Medicare and Medicaid reimbursement for duals' care: a capitated approach and a managed fee-for-service model (meaning fee-for-service that maintains freedom to choose providers but adopts some managed care techniques, such as requiring beneficiaries to obtain authorization from the insurer or payer prior to filling a prescription from the treating physician). Under the capitated approach, a state, CMS, and a managed care plan would sign a three-way contract whereby Medicare and Medicaid would provide to the plan a blended prospective payment to cover the full range of needed care. States and CMS will jointly choose plans through a competitive selection process. Under the managed fee-for-service approach, a state and CMS would agree to make the state eligible for a share of the Medicare savings generated from managed fee-for-service initiatives that are designed to improve quality and lower Medicare and Medicaid costs. States would provide an up-front investment to support care coordination in return for a share of Medicare savings once a specific savings threshold is reached. The states participating in the State Demonstrations to Integrate Care for Dual Eligible Individuals also are encouraged to use these models in their plans.

Capacity for Spreading Innovation

In April 2011, Secretary Sebelius announced the creation of a national public-private partnership called the Partnership for Patients to encourage homegrown improvements in patient safety and care quality across the health care system. The goal of the partnership is to reduce hospital-acquired conditions by 40 percent and 30-day hospital readmissions by 20 percent over the next three years. To help its private sector partners facilitate improvements in patient safety and quality, the Innovation Center has promised to award up to $500 million for initiatives that support the partnership's goals.

CMS is supporting hospitals and other providers participating in the Partnership for Patients by making available an additional $500 million for a Community-based Care Transition Program established in the ACA. This program is designed to help hospitals and community-based organizations improve the care that Medicare beneficiaries at high-risk of readmission receive as they transition from the hospital to other sites of care.

More recently, the Innovation Center has established an initiative to improve the health care system's capacity for developing innovations beyond the patient safety and care transitions targeted in the Partnership for Patients initiative. Specifically, the Innovation Center has created a program designed to broadly help individuals refine, apply, and sustain managerial and technical skills necessary to drive delivery system reform for Medicare, Medicaid, and CHIP beneficiaries, called the Innovation Advisors Program. The objective is to facilitate participants becoming part of a network of experts, who can support the Innovation Center as it tests new models, provide a unique set of skills and knowledge regarding their communities or areas of expertise, collaborate with other local organizations to facilitate change in the delivery system, develop innovative ideas for testing, and develop skills in system improvement in their region.

The Innovation Center is seeking up to 200 individuals with expertise in health care economics, population health, systems analysis, and operations research to apply to the new program. Seventy-three advisors have been selected for the first of two cycles. Participants are expected to spend 10 hours per week working on Center activities during the first six months of their fellowship. Part of that time will be spent on seminars and instruction, and the rest will be spent

developing the improvement project proposed in their application to the program. Participants will remain employees of their home organization but will receive a stipend from the Innovation Center.

As previously noted, the Innovation Center has also issued a challenge to innovators across the country to develop and implement new initiatives that deliver better health, improved care, and lower costs to Medicare, Medicaid, and CHIP beneficiaries, called the Health Care Innovation Challenge. The Innovation Center is specifically targeting initiatives that will expand the health care workforce and improve worker efficiency. Applicants who are selected will receive grants ranging from $1 million to $30 million, depending on their proposals. Prospective applicants could include providers, payers, local governments, public-private partnerships, and multipayer collaboratives. The Innovation Center has set aside $1 billion to fund these grants.

Notes

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