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Managed Health Care: Federal and State Regulation

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Summary

Numerous bills have been introduced in the 105th Congress to regulate managed health care. Some target specific aspects of the delivery of care, such as hospital length-of-stay for mastectomies. Others address a broad range of consumer and provider concerns that have emerged as managed care has become more commonplace. State legislatures have been even more active on this issue with over 1,000 managed care bills introduced in 1996 alone. Key to understanding these federal and state proposals is the current regulatory environment in which managed care organizations (MCOs) function.

The regulation of managed care depends on who sponsors the plan and who bears the risk for paying for the insured services. Generally, the federal government regulates managed care and other health plans sponsored by private-sector employers. On the other hand, the states regulate the business of insurance, which includes the MCO (such as a health maintenance organization (HMO)) that offers a managed care policy to an individual, employer, or other purchaser. If a private sector employer sponsors a plan that is not purchased from an MCO (i.e., the plan is self-insured), then the plan is regulated solely by the federal government. If that employer contracts with an MCO to provide managed care services to his or her employees, then the regulation of that plan depends on who bears the risk. If it is the MCO, the plan is regulated by the state; if the risk is borne to any degree by the employer, then the plan is subject to federal law only.

The traditional division of regulatory responsibilities between the federal government and the states resulted from provisions of several federal laws and subsequent decisions of federal courts. Most importantly, the Employee Retirement Income Security Act of 1974 (ERISA) preempted the states from regulating health plans of private sector employers but left to the states the regulation of the business of insurance. While the HMO Act of 1973 established certain federal standards for HMOs that elected to operate under federal law, almost all other regulatory authority over the business of health insurance remained with the states. This deferral to state regulation of insurers has been somewhat altered with the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) to the extent that it applies certain federal *minimum* requirements to state-regulated insurers as well as to employer-sponsored plans, including managed care plans.

The regulation of managed care varies significantly across the 50 states. Many have HMO laws and regulations that are based on the National Association of Insurance Commissioner's (NAIC) HMO Model Act. Some have used the NAIC model as a floor and have adopted more stringent requirements on MCOs. Responding to the emergence of varying types of risk-bearing entities that provide both insurance and medical services, the NAIC has issued model laws on quality assessment and improvement, provider credentialing, network adequacy, grievance procedures, standards for utilization review, and will be issuing one on capital standards to ensure solvency. State laws may begin to incorporate these models as they respond to these and other issues arising from the growth of managed care.

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Managed Health Care: Federal and State Regulation

Overview

Who regulates managed care plans and what requirements and standards must they meet in order to operate? This report explains the role of federal and state laws in regulating managed care, summarizes the relevant federal statutes, and highlights major regulatory issues that are arising with respect to this growing sector of the health insurance marketplace. The report also reviews the model laws developed by the National Association of Insurance Commissioners (NAIC) that often form the basis for state statutes. Last of all, it details some of the ways in which states have gone beyond NAIC model laws in regulating aspects of managed care, and provides a summary listing of selected managed care laws that have been enacted by the states.

The regulation of managed care is becoming an increasingly salient issue at all levels of government. In 1996 alone, state lawmakers introduced over 1,000 bills affecting managed care.¹ At the federal level, the 104th Congress responded to increasing consumer and provider concerns about access to and quality of managed care by passing a law to allow new mothers to remain in the hospital for at least 48 hours after a normal delivery.² Another bill, which would have prohibited the restriction of communications between providers and their patients, came close to enactment. In the first session of the 105th Congress, bills have been introduced regulating a wide range of managed care activities, including: the amount and scope of coverage for specific procedures, such as mastectomies; access to emergency care and specialist services; quality assurance; plan disclosure; due process standards for providers; and appeals and grievance procedures for enrollees.³ The White House

¹ Bodenheimer, Thomas. The HMO Backlash-Righteous or Reactionary? *New England Journal of Medicine*, v. 335, no. 21, November 21, 1996. p. 1601-1604.

² For more information, see: U.S. Library of Congress. Congressional Research Service. *Hospital Length-of-Stay for Obstetrical Care*. CRS Report 95-1114, by Sharon Kearney, updated November 1, 1996. Washington, 1996. (Hereafter cited as Kearney, *Hospital Length-of-Stay for Obstetrical Care*, 1996)

³ The Balanced Budget Act of 1997 (P.L. 105-33) includes requirements on managed care plans that contract with Medicare and Medicaid. These requirements are summarized in: U.S. Library of Congress. Congressional Research Service. *Medicare Provisions in the Balanced Budget Act of 1997 (BBA-P.L. 105-33)*. CRS Report 97-802, by Jennifer O'Sullivan, et al., August 18, 1997. Washington, 1997. (Hereafter cited O'Sullivan, et al., *Medicare Provisions in the Balanced Budget Act of 1997 (BBA 97, P.L. 105-33)*, 1997); *Medicaid: FY 1998 Budget*. CRS Issue Brief 97037, by Melvina Ford, et al., updated (continued...)

too has been active on this issue. The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry is expected to report in November, 1997 on its recommendations for a consumer bill of rights that will, in part, be a response to concerns about managed care.

A key to understanding all of these managed care proposals is an understanding of the current regulatory environment in which managed care organizations (MCOs) function. Aiding such an understanding is the purpose of this report.

Concepts and Terminology

Managed care is a term that generally means a system of payment or delivery arrangement where the health plan attempts to control or coordinate use of health services by its enrolled members in order to control spending and promote improved health. Like fee-for-service insurance, managed care arrangements accept financial responsibility for a defined set of health care benefits in return for a premium paid by or on behalf of each enrolled member. Unlike fee-for-service insurers, managed care arrangements directly provide or arrange for health care services, through affiliated physicians, hospitals and other providers, instead of simply paying bills. The enrollees covered by the managed care plan agree to obtain all covered services, except emergency and out-of-area care⁴, from or with the authorization of the managed care plan or its affiliated providers. The MCO may reduce unnecessary hospitalizations, diagnostic tests, or specialty referrals, either through programs to review the use of services or by giving participating physicians a financial stake in the cost of the services they order. It may also select low-cost providers of services or negotiate discounted rates from providers.

At one time, the only type of arrangement that offered managed care was a health maintenance organization (HMO). Today, managed care coverage is provided by an array of entities, such as preferred provider organizations (PPOs) and provider sponsored organizations (PSOs), many of which offer more open-ended coverage than do traditional HMOs. As in traditional HMOs, these arrangements provide covered services through provider networks. Enrollees are given financial incentives to use services within the plan's provider network, but still receive some coverage even if they decide to obtain care from outside providers.⁵

³(...continued)

August 13, 1997. Washington, 1997. (Hereafter cited as Ford, *Medicaid: FY 1998 Budget*, 1997)

⁴ Many managed care plans require that enrollees obtain prior authorization from the plan for emergency care services that are not life-threatening and for any such services that are obtained from providers that are not part of the MCO's network, including those who are out of the MCO's service area.

⁵ For additional background on managed care organizations, see: U.S. Library of Congress. Congressional Research Service. *Managed Health Care: A Primer*. CRS Report 97-913, by Jason Lee. Washington, 1997.

Managed care health insurance coverage, like fee-for-service coverage, is offered by several types of entities. An insurer, such as a commercial health insurance company or a Blue Cross/Blue Shield plan may offer managed care coverage to employers. It may also offer such coverage to individuals who purchase insurance directly (i.e., not as a member of a group such as an employer group). Similarly, an HMO, PPO, or other type of managed care arrangement may also offer managed care coverage to an employer. An employer may itself sponsor a health benefits program which includes one or more managed care options. It may therefore be considered the *sponsor or issuer* of the plan. Finally, a public program such as Medicare or Medicaid, may contract with MCOs to offer managed care to program beneficiaries.

To complicate matters, various forms of entities may serve as intermediaries between purchasers and insurers. Such entities help to facilitate the offering and marketing of managed care policies to employers (and sometimes individuals). Purchasing cooperatives, for example, help to give purchasers (such as small employers) more buying clout in obtaining health benefits for their employees. Others, such as third party administrators (TPAs), may offer certain types of services to employers ranging from claims administration to *stop-loss insurance* for high cost claims or for overall claims in excess of some preestablished amount of money. **Figure 1** illustrates the many different types of entities that may issue managed care health insurance.

Insurance is a way to spread risk. The *risk* for paying for services covered under a managed care plan (and a fee-for-service plan too) can be handled in different ways. An employer, for example, can fully *self-insure* the services covered under its managed care plan. In so doing, it is assuming 100% of the risk of paying for the plan's covered services. No risk is transferred to an insurer. Alternatively, the employer can purchase a *fully-insured* plan from an insurer or managed care company, thereby transferring all of the risk of paying for covered services. In return for assuming the risk, the insurer gets a premium from the employer priced to cover the expected costs of services used by the employer plan's enrollees. Sometimes, however, risk is shared between an employer and another entity, such as an insurer, managed care company, or TPA. In this case, the plan is said to be *not-fully-insured* or *partially self-insured*.

Insured Versus Self-Insured Plans

Self-insured Employer Plan — A plan in which the employer takes on some or all of the risk of paying for the plan's covered items and services. (Also known as self-funded or not-fully-insured plans.) Many self-insured plans assume risk for some amount of claims and then buy stop-loss coverage from a third party (such as a third party administrator) to cover losses over a preset amount or percentage of claims.

Insured Employer Plan — A plan purchased from an insuring entity, such as a commercial insurer, Blue Cross/Blue Shield, or a managed care organization. The employer pays the insurer a premium in exchange for the insurer assuming the risk of the plan's covered items and services.

Figure 1. Who Provides Managed Care Health Insurance?

Insurers/MCOs

(These entities offer/sell coverage to individuals, groups, or both)

- Commercial insurers
- Blue Cross/Blue Shield plans
- Managed Care Companies -- HMOs, PPOs, PSOs,

Employers

(Employers can sponsor health plans that cover their employees and employees' dependents. These plans may be insured or self-insured.)

- Private-sector employers
- Governmental employers (nonfederal which include state and local governments and federal which includes the Federal Employees Health Benefits Program)
- Church sponsored plans
- Multiple Employer/Association Sponsors
- Multiemployer Plans

Public Insurance Sponsors

- Medicare
- Medicaid
- Department of Veterans Affairs
- Department of Defense

The Division of Federal and State Responsibilities

The regulation of a managed care plan depends on who is its issuer. In general, the federal government regulates private sector employer health plans, including managed care plans that are sponsored by a private employer. The states regulate the business of insurance, which includes an HMO or other type of MCO that sells a health insurance policy to an individual, employer, or other purchaser. States also oversee plans sponsored by state and local governments. If a private sector employer sponsors a plan that is not purchased from a MCO (i.e., the plan is self-insured), then the plan is regulated solely by the federal government.⁶ If a private sector employer

⁶ This discussion refers to single-employer plans only. The regulation of multiple employer entities, known under ERISA as multiple employer welfare arrangements (MEWAs), works differently. See: U.S. Library of Congress. Congressional Research Service. *Health Insurance: Reforming the Private Market*. CRS Report 95-877, by Beth C. Fuchs, updated January 23, 1997. Washington, 1997. (Hereafter cited as Fuchs, *Health Insurance: Reforming the Private Market*, 1997)

contracts with a MCO to provide managed care services to the employer's employees, then the regulation of that plan will depend on who bears the risk.

Further complicating an understanding of this regulatory environment is the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191), as amended by P.L. 104-204.⁷ Prior to its enactment, almost all regulatory authority over the business of health insurance had rested with the states. Once HIPAA's provisions are implemented, certain federal *minimum* requirements will apply to state-regulated insurers as well as employer-sponsored managed care plans. This marks the first time that the federal government will have extended its jurisdiction to health insurers.⁸ While HIPAA generally allows states to impose on insurers requirements that provide for greater protections to consumers in lieu of federal minimum standards, certain federal standards relating to preexisting condition exclusions override state laws. Moreover, if a state fails to enforce at least the federal minimum standards, then the federal government is charged with enforcing the law in that state.

The traditional division of regulatory responsibilities between the federal government and the states resulted from provisions of several federal laws and subsequent decisions of federal courts. The following provides a basic overview of these laws, including the precedent-breaking HIPAA. The report then describes how states regulate MCOs, particularly HMOs. While this discussion is meant to be descriptive of the current regulatory environment, it also provides a foundation for a discussion of the major policy issues related to managed care facing the 105th Congress.

Major Federal Laws Affecting the Regulation of Managed Care

Numerous federal laws affect health benefits and health insurance. This section describes the key statutes, including the McCarran-Ferguson Act, ERISA, the HMO Act, and HIPAA. Other statutes, such as the health insurance continuation coverage requirement of the Consolidated Omnibus Budget Reconciliation Act (COBRA), impose requirements on certain health plans. These, however, are less directly relevant to issues of managed care and are thus not included.

McCarran-Ferguson Act of 1945 (P.L. 79-15). This Act exempts the business of insurance from federal antitrust regulation to the extent that insurance is regulated by the states, and indicates that no federal law should be interpreted as overriding state insurance regulation unless it does so explicitly. The Act did not prevent the federal government from regulating insurance in the future; it merely affirmed that the government had so far abstained from doing so. HIPAA broke with the precedent

⁷ P.L. 104-204 also includes new federal requirements relating to minimum hospital maternity stays and to mental health benefits.

⁸ Arguably, the HMO Act of 1973 was the first major federal law affecting the business of insurance. However, the HMO Act only imposed requirements on HMOs that *elected* to become "federally qualified." Similarly, the federal government regulates the policies of private insurers who sell policies that supplement Medicare and of MCOs that contract with Medicare and Medicaid.

established by the McCarran-Ferguson Act and established certain federal minimum requirements on the business of health insurance.

Employee Retirement Income Security Act of 1974 (ERISA, P.L. 93-406). ERISA establishes federal uniform requirements for employee welfare benefit plans, including health plans. It was crafted in 1974 to leave the content and design of employer health plans to employers in negotiation with their workforce. ERISA does, however, establish certain regulations for health benefit plans. These relate to reporting and disclosure, fiduciary standards, claims review, and enforcement. It also provides participants in employee plans limited protection against discrimination. (See **Figure 2.**) Governmental plans and church plans are generally exempt from ERISA. Some plans are sponsored by entities, such as fraternal organizations, in which there is no employer-employee relationship involved. These too are not considered ERISA plans.⁹

One of the most important provisions of ERISA (Section 514) preempts state laws affecting employee welfare benefit plans. While Section 514 confirms the states' continued authority to regulate insurance companies, the so-called "deemer" clause holds that no employee benefit plan or any trust established under a plan "shall be deemed to be an insurance company" The courts have generally interpreted this language to mean that states cannot regulate employer-sponsored health plans. They may, however, regulate insurance that is sold to employers. As a result, if an employer fully or partially self-insures its own health plan, it is regulated solely by ERISA, and not state insurance law. Federal regulation of employer plans includes those requirements discussed above.

As a consequence of ERISA's Section 514, employers that self-insure are exempt from state regulatory requirements such as taxes on insurance premiums, requirements that health plans include specific benefits or pay specific providers (known as state mandated benefit laws); solvency and funding standards; requirements to participate in the financing of state risk pools; and, of increasing prevalence, laws regulating various characteristics and actions of managed care plans. ERISA's preemption of state regulation has helped to increase the attractiveness of self-insurance to many employers, so that today, roughly 40% of all employees are covered by self-insured plans. (Data on rates of self-insurance widely vary depending on the survey.)¹⁰

⁹ This discussion of ERISA relates to plans sponsored by individual employers (i.e., "single-employer" plans). Different rules apply to plans that are sponsored by two or more employers, such as multiple employer welfare arrangements. The regulation of these plans is not covered in this report. For more information, see: Fuchs, *Health Insurance: Reforming the Private Market*, 1997; Butler, Patricia and Karl Polzer. *Private-Sector Health Coverage: Variation in Consumer Protections under ERISA and State Law*. National Health Policy Forum, Washington, D.C., Special Report/June 1996. (Hereafter cited as Butler, et al., *Private-Sector Health Coverage*)

¹⁰ The General Accounting Office has estimated that about 44 million Americans are in self-insured health plans that states cannot regulate. See: U.S. General Accounting Office. *Employer-Based Health Plans: Issues, Trends, and Challenges Posed by ERISA*. (GAO/HEHS-95-167), July 25, 1995. Washington, 1995. This number may actually be (continued...)

Figure 2. Major ERISA Requirements on Employer Group Health Plans

- *Fiduciary standards* — plan fiduciaries must act in the sole interest of plan participants in the management and disposition of employee benefit funds.
 - *Reporting and disclosure requirements* — plans must disclose information about the plan to participants and beneficiaries.¹¹
 - *Nondiscrimination* — a person cannot "discharge, fine, suspend, expel, discipline, or discriminate against a [plan] participant or beneficiary for exercising any right to which he is entitled under the provisions of an employee benefit plan" ¹²
 - *Claims review* — a plan must provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the reasons for the denial, and afford a reasonable opportunity for a full and fair review by the appropriate named fiduciary of the decision denying the claim.
 - *Continuation of coverage (COBRA)* — a plan with 20 more employees must offer participants and beneficiaries the option to continue group health coverage in the case of certain events (such as terminating from the job or experiencing a change in family status) for 18 to 36 months, depending on the event.
 - *Coverage of adopted children* — an employer group health plan that provides coverage for dependent children must treat children placed for adoption the same as natural children, even if the adoption does not become final until some time later.
 - *Health Insurance Portability and Accountability Act (HIPAA)* — a plan must comply with the portability, access, and renewability requirements of the Act (as described below).
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¹⁰(...continued)

declining, partially as a result of employers' switching from fee-for-service plans to fully insured managed care plans. A 1996 study, using a different research methodology than GAO's, found that the number of Americans covered under self-insured plans that the states could not regulate was 35 million in 1995, a decrease from 38 million in 1993. Liston, Derek and Martha Priddy Patterson. *Analysis of the Number of Workers Covered by Self-Insured Health Plans under ERISA of 1974-1993 and 1995*. Henry J. Kaiser Family Foundation, Menlo Park, CA, August 1996.

¹¹ Plans used to be required to file summary plan descriptions and summaries of material modifications with the Department of Labor. However, under the Taxpayer Relief Act of 1997 (P.L. 105-34), sponsors of employee benefit plans are no longer required to file such information. Such documents have to be filed, however, at the request of the Department of Labor within 30 days of the request.

¹² Section 510 of ERISA.

ERISA's exemption of employee health plans from state regulation means that a wide range of state health reforms face legal challenges by self-insured employers and unions if and when those laws are implemented.¹³ The plaintiffs are likely to argue that they do not have to comply because they are exempt from state law under Section 514 of ERISA. Organizations representing state interests have argued that the threat of such court challenges discourages new state reform efforts and limits the effectiveness of existing state laws because such laws cannot be enforced on a sizable portion of the insurance market, i.e., self-insured health plans. Opposing this view are groups representing larger employers, many of whom operate in two or more states, who argue that if they lose their preemption and become subject to state law, they will be financially and administratively burdened. Complying with 50 different state regulations would drive up their costs of operating a health plan and reduce their ability to implement innovative plan changes. Also in opposition are organizations representing self-insured firms and sellers of administrative services and stop-loss insurance to self-insured firms, arguing that ERISA preemption is necessary to ensure the continuation of their health plan arrangements.

The effect of ERISA's preemption clause on the regulation of MCOs is significant and complex. With the growth of managed care arrangements, the distinction between plans that are fully insured from those that are self-insured (i.e., to some extent risk bearing) has become less clear. An obvious case of a *fully insured* plan exists when an employer purchases for a premium a fee-for-service plan from an insurance company. Less obvious is the situation where an employer plan has contracted with an MCO to use its network of providers in order to offer plan participants an HMO option. Then the question becomes: who is bearing the risk? Is the employer paying the MCO a per enrollee premium which will not vary regardless of how much health care each participant uses? In this case, the MCO is at risk and the employer is buying a fully insured product which is clearly subject to state regulation. Alternatively, is the employer's plan operating as the risk-bearing entity and the MCO is simply contracting for a negotiated fee the use of its doctors, hospitals, and other providers?¹⁴ In this instance, the MCO may or may not be subject to state regulation. State insurance regulators may wish to regulate the MCO if it were considered to be assuming *any* insurance risk. However, the state might be blocked from applying such regulation as a result of ERISA's preemption of state regulation of employer-sponsored plans.

In the same vein, an issue arises with respect to the question of whether a state law applies to the plan offered by a MCO. Does the law relate to an employee benefit plan? More specifically, does the law regulate the structure, content, method of administration, or plan requirements? Does it directly affect the participants of the plan? The federal courts have used the concept of relatedness as a major litmus test in determining, for example, whether a state health care provider tax could be

¹³ For more information, see U.S. Library of Congress. Congressional Research Service. *Health Benefit Plans: ERISA and the States*. CRS Report 93-747, by Joan Sokolovsky, August 11, 1993. Washington, 1993.

¹⁴ About 65% of HMOs and PPOs were estimated to be offering employer self-insured products in 1996, including "network rental" options and third party administrative services, up from 53% in 1995. American Association of Health Plans. *1995 AAHP HMO/PPO Trends Report*. Washington, 1995.

assessed on participants of an employee health plan.¹⁵ This “relatedness” test may be central to judicial challenges to state laws regulating managed care arrangements. For example, an employee health plan might argue that ERISA preempts a state provider network licensing law directed only at self-insured plans because the law is seeking to regulate activities related to the employee plan.¹⁶ “Who shall regulate?” may become even more complicated with the emergence of increasingly complex risk-sharing arrangements, both between employers and MCOs, and MCOs and provider sponsored entities, such as physician-hospital organizations.

This rather intricate and confusing regulatory environment has led some to suggest that insurance regulation be federalized. In that way, one uniform set of laws would apply to health plans, regardless of whether such plans were insured or self-insured. Of course, a debate might then arise about the content of such a law. What requirements should the federal government impose on privately-sponsored health plans? The reverse view is also found. Some advocate that the states be given greater latitude to regulate the health plans sponsored by employers so that insuring entities are competing on the same “level playing field.” There appears to be growing interest in the current Congress in legislation that applies federal minimum requirements to all health plans, regardless of whether they are purchased or self-insured, but that also give states flexibility to apply their own laws if such laws are consistent with (or, in some bills, more restrictive than) the federal standard. (This approach is reflected in the HIPAA of 1996, discussed below.) Whether this approach results in more or less uniformity of insurance regulation remains to be seen.

McCarran-Ferguson and ERISA established the respective jurisdictional reach of the federal government and the states over health insuring entities. Other laws, such as the HMO Act of 1973, and the HIPAA of 1996, both affect “who regulates what” as well as the content of that regulation.

The HMO Act of 1973. The HMO Act of 1973 (P.L. 93-222) added a new title XIII to the Public Health Service (PHS) Act.¹⁷ This title, as amended, is known as “the HMO Act.” The HMO Act was enacted largely to encourage the growth of HMOs, thought by many to be a more cost-effective way to deliver health care than traditional, fee-for-service insurance. The Act originally provided federal funds to develop new HMOs and to help them through the start-up period. These funds are no longer available. The Act also created certain financial and organizational standards. Certification of federal qualification was once the responsibility of the PHS. Currently, it is done by the Health Care Financing Administration, the agency of the Department of Health and Human Services (HHS) in charge of the Medicare and Medicaid programs.

¹⁵ *New York State Conference of Blue Cross and Blue Shield Plans, et al vs. Travelers Insurance Co.*, U.S. 93-1405, April 26, 1995.

¹⁶ Butler, et al., *Private-Sector Health Coverage*, p. 57.

¹⁷ This section is from: U.S. Library of Congress. Congressional Research Service. *Health Maintenance Organizations and Employer Group Health Plans*. CRS Report 91-261, by Mark Merlis, March 19, 1991. Washington, 1991.

It once was the case that the main reason for an HMO to obtain federal qualification was to take advantage of the HMO Act's "dual choice" requirement. Any employer with 25 or more employees that was subject to the Fair Labor Standards Act and that provided group health insurance benefits was required to offer an HMO option as an alternative to its existing health plan, if a federally qualified HMO was available in its areas and asked to be included. The employer had the right to choose among qualified HMOs if there were more than one in an area. This "dual choice" requirement was eliminated by the HMO amendments of 1988, effective 7 years after enactment, or October 24, 1995.¹⁸

As of the end of 1995, about 45% of all HMOs were federally qualified, although qualified HMOs accounted for 68% of total enrollment.¹⁹ The process of seeking federal qualification is a voluntary one, and many HMOs operate only under state licensure because they choose not to meet some of the benefit and operating requirements of the HMO Act.

The HMO Act specifies that a federally qualified HMO is a public or private entity organized under the laws of any state which provides basic and supplemental health services to its members and meets certain financial and organizational requirements. These requirements include:²⁰

- Each member has to be provided basic health services which are paid for on a periodic basis without regard to when the services are provided. The payment must be fixed without regard to the frequency, extent, or kind of health service (within the basic health services) actually furnished. These basic services may be supplemented by additional nominal copayments but such copayments cannot act as a barrier to care.²¹

¹⁸ The HMO Act of 1973 also required the employer to include the HMO option in the offering on terms no less favorable with respect to the employer's monetary contribution than the terms on which other alternatives (such as a fee-for-service plan) were included. The employer's contribution had to be equal, in dollar amount, to the largest contribution made by that employer, on behalf of a particular employee, to a non-HMO alternative included in the plan offering. This is known as the nondiscrimination requirement. While the dual choice provision was repealed by the HMO amendments of 1988, the nondiscrimination requirement was retained with modifications to enable employers greater flexibility in setting their contributions to HMOs that they offer voluntarily. HCFA issued a final rule implementing these changes on May 31, 1996. See *Federal Register*, May 31, 1996. p. 27282.

¹⁹ Interstudy. *The Interstudy Competitive Edge. Part II: Industry Report*. St. Paul, 1996. Tables 3 and 5.

²⁰ Section 1301-1302 of Title XIII of the HMO Act. See also the regulations for federally qualified HMOs in *42 Code of Federal Regulations., Ch. IV*, Sections 417.1-417.169.

²¹ This provision was amended by Section 193 of HIPAA (P.L. 104-191) to allow federally qualified HMOs to offer high deductible plans that could be sold in conjunction with tax-favored medical savings accounts (MSAs).

- Basic health services include: physician services; inpatient and outpatient hospital services; medically necessary emergency services; short-term, outpatient mental health services; medical treatment and referral services for the abuse of or addiction to alcohol and drugs; diagnostic laboratory and diagnostic and therapeutic radiologic services; home health services; and preventive health services.
- Basic health services have to be available and accessible with reasonable promptness and in a manner which assures continuity, and when medically necessary, be available and accessible 24 hours a day, 7 days a week. (Exceptions are provided for rural HMOs.)
- Each HMO must have a fiscally sound operation and adequate protection against the risk of insolvency which is satisfactory to the Secretary. It must also have administrative and managerial arrangements satisfactory to the Secretary. The HMO must assume full financial risk on a prospective basis for basic health services except that it may obtain insurance or make other arrangements to cover losses in excess of a specified level.
- The HMO must enroll persons who are broadly representative of the various age, social, and income groups within its service area. (Special provisions apply in the case of HMOs in medically underserved areas.) It cannot expel or refuse to re-enroll any member because of the individual's health status or need for health services.²² It has to have meaningful procedures for hearing and resolving grievances between the HMO and the members of the organization. In addition, the HMO must have an ongoing quality assurance program, and provide for the reporting of certain information.
- The HMO must generally use "community rating," that is, premium rates may not vary according to enrollees' need for health services.

Federally qualified HMOs are also subject to state insurance laws with exceptions. The HMO Act explicitly preempts "restrictive" state laws and practices, including those that: (1) require as a condition of doing business that a medical society approve of the furnishing of services by the entity; (2) require that physicians constitute all or a specified percentage of its governing body; (3) require that all physicians or a specific percentage of physicians in a locale participate or be permitted to participate in the provision of services for the HMO; (4) require that the HMO meet state requirements for health insurers respecting initial capitalization and establishment of financial reserves against insolvency that would prevent it from doing business in the state; and (5) impose requirements which would prohibit the HMO from complying with requirements of the HMO Act.

²² Under the Act, the HMO is prohibited from denying enrollment to a member of an employer group on the basis of health status. However, it can refuse an entire group or an individual applicant. This provision is superseded by HIPAA (P.L. 104-191), which generally prohibits an HMO from denying enrollment to a small employer group (2 to 50 employees), or any member of the group, on the basis of health status and related factors. It can reject new enrollees in the event of capacity limits.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191). The HIPAA establishes federal minimal health insurance standards that apply to MCOs as well as indemnity insurers, plans sponsored by employers, and plans sponsored by unions, associations, and other entities. Most provisions take effect for plan years beginning after June 30, 1997. HIPAA also establishes some minimal standards that apply to MCOs (and other insuring entities) operating in the individual insurance market.²³ These too are generally effective beginning July 1, 1997.²⁴ The standards are established under ERISA, the PHS Act, and the Internal Revenue Code (IRC). The following summarizes the basic requirements of the Act.

- *Limits on the use of preexisting condition restrictions.* Group health plans, and health insurance issuers²⁵ offering group health insurance coverage, are prohibited from imposing a preexisting condition exclusion that exceeds 12 months (18 months for late enrollment) for conditions diagnosed or treated within the previous 6 months prior to becoming insured. Preexisting conditions cannot include pregnancy and cannot apply to newborns and newly adopted children (including those newly placed for adoption). Such plans are required to credit periods of qualified previous coverage toward the fulfillment of a preexisting condition exclusion period when an individual moves from an individual or group source of health coverage to a source of group coverage. Plans and issuers have to provide a certification of the period of creditable coverage.
- *Guaranteed availability.* Group health plans, and health insurance issuers offering group coverage, cannot exclude from coverage or fail to renew coverage based on an individual's health status or on the health status of a dependent. (Health status is defined to include, with respect to an individual, medical condition, claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), or disability.) A group health plan must provide for special enrollment periods for employees who experience a change in family composition, employment status, or employment status of a family member. The Act does not restrict the amount that an employer or issuer can charge for coverage or prevent the plan or issuer from establishing premium discounts or rebates or modifying applicable copayments or deductibles in return for adherence to programs of health promotion or prevention.

²³ More information on the HIPAA is provided in: U.S. Library of Congress. Congressional Research Service. *The Health Insurance Portability and Accountability Act of 1996: Guidance on Frequently Asked Questions*. CRS Report 96-805, by Beth C. Fuchs, Bob Lyke, Richard Price, and Madeleine Smith, updated April 10, 1997. Washington, 1997.

²⁴ The provisions applying to the individual market may become effective later than July 1, 1997 in the case of states that, for example, that do not have a legislature that meets in 1997 or indicate that they intend to implement an alternative mechanism. Alternative mechanisms generally take effect January 1, 1998.

²⁵ The term "issuer" used below is defined under HIPAA as an insurance company, Blue Cross/Blue Shield company, or insurance organization (including an HMO which is licensed to engage in the business of insurance in a state and which is subject to state law which regulates insurance).

- *Requirements on issuers of group insurance (including HMOs and similar entities).* Each small group insurer or HMO is required to accept every small employer in the state that applies for such coverage. It must also accept for enrollment under such coverage every individual who applies for enrollment during the initial enrollment period in which the individual first becomes eligible for coverage under the group health plan. No exclusions can be placed on the coverage of an eligible individual based on health status or the health status of the dependent. Exceptions apply in the case of network plans that have limited capacity. (Many managed care plans are network plans.) The small group market is generally defined as employer groups with more than 2 and less than 51 employees. *All* health insurance sold in the group market must be guaranteed renewable, regardless of firm size, except for cause (e.g., fraud and nonpayment of premiums).
- *Enforcement.* Each state may require that health insurance issuers that issue, sell, renew, or offer health insurance in the state in the small or large group markets meet the above requirements. In the case of a determination by the Secretary of HHS that a state has failed to substantially enforce these requirements, the Secretary would generally enforce them. The group health insurance rules on private sector plans would be enforced through ERISA. Plans that fail to comply could be sued for relief and for recovery of any benefits due under the plan. They could also be subject to civil money penalties. Private group health plans would be subject to an excise tax of \$100 per day violation under the IRC. Noncomplying issuers (such as an HMO) would be subject to civil money penalties under the PHS Act. Individuals would also have a private right of action against such issuers under ERISA.

P.L. 104-204. Not long after HIPAA was enacted, it was amended to provide for federal standards related to maternity stays and coverage for mental health services.²⁶ Under the Act, group health plans and issuers of insurance plans in the group and individual markets will be prohibited from restricting benefits for any hospital length-of-stay for mothers and their newborns following a vaginal delivery to less than 48 hours and following a caesarean to less than 96 hours or from requiring that a provider obtain authority from the plan or the issuer for prescribing longer length-of-stays. Such prohibitions will be inapplicable in the case in which the decision to discharge the mother or her newborn prior to the 48/96 hour minimum requirements is made by an attending provider in consultation with the mother.²⁷ The provision applies for plan years beginning on or after January 1, 1998.

P.L. 104-204 also provides limited parity for mental health coverage under group health plans. It requires annual and aggregate lifetime limits for mental health coverage to be the same as for physical health coverage. Group health plans (or health insurance coverage offered in connection with group health plans) that cover

²⁶ These provisions were part of the fiscal year 1997 appropriations act for the Departments of Veterans Affairs and Housing and Urban Development.

²⁷ For more information, see: Kearney, *Hospital Length-of-Stay for Obstetrical Care*, 1996.

mental health and medical/surgical conditions and have annual or aggregate dollar limits for medical/surgical conditions must establish either an inclusive limit for all benefits (e.g., \$1 million lifetime limit for all benefits) or separate limits for mental health services that are no more restrictive than those for medical/surgical services (e.g., separate lifetime limits of \$1 million for each type of benefit). The provisions do not apply to benefits for substance abuse or chemical dependency. Plans of employers with fewer than 50 employees are exempt from the requirement. The requirement also does not apply to any group health plan whose costs increase 1% or more due to the application of the requirement.²⁸ This provision too applies for plan years beginning on or after January 1, 1998.

Other Federal Laws Affecting Managed Care Plans. MCOs that contract with Medicare, state Medicaid programs, and military health care programs must comply with requirements specific to those programs. For example, as of August of 1997, Medicare had 292 contracts across the United States with MCOs that have agreed to provide on a risk basis coverage for Medicare beneficiaries and comply with a set of Medicare rules. In return, the MCO receives a preestablished per capita payment called the adjusted average per capita payment or AAPCC. (As of September, 1997, the capitation amount is calculated using a new methodology specified by the Balanced Budget Act of 1997 — BBA 97 — and is technically no longer the AAPCC.) Under Medicaid, many states contract with MCOs to provide services to their Medicaid beneficiaries in return for capitation payments. The regulation of managed care plans that contract with public programs is not addressed further in this document.²⁹

State Regulation of Managed Care Plans

All 50 states regulate HMOs under self-contained state HMO enabling laws which address the insurance and delivery aspects of HMOs.³⁰ It is common for the state's department of insurance to oversee the insurer functions of the HMO and for its department of health to oversee the provider and quality assurance functions.³¹

²⁸ U.S. Library of Congress. Congressional Research Service. *Mental Health Parity Under P.L. 104-20*. CRS Report 96-827, by Jennifer A. Neisner, updated October 15, 1996. Washington, 1996. Note that P.L. 104-204 amended only the ERISA and PHS sections of HIPAA. The IRC provisions were amended to include the 48-hour stay and mental health parity provisions as part of the Taxpayer Relief Act of 1997 (P.L. 105-34).

²⁹ For Medicare managed care, see: U.S. Library of Congress. Congressional Research Service. *Medicare: The Restructuring Debate in the 104th Congress*. CRS Report 97-102, by Beth C. Fuchs, Bob Lyke, Jennifer O'Sullivan, and Richard Price, January 9, 1997. Washington, 1997; *Medicare Contracts With Managed Care Organizations*. General Distribution Memorandum, by Mark Merlis, March 27, 1995, RA 413 B. Washington, 1995; O'Sullivan, et al., *Medicare Provisions in the Balanced Budget Act of 1997 (BBA 97, P.L. 105-33)*, 1997; Ford, *Medicaid: FY 1998 Budget*, 1997.

³⁰ NAIC, table attached to NAIC HMO Model Act.

³¹ Furrow, Barry R., et al. *Health Law*. St Paul, MN, 1995. p. 525-532.

In some states, the agency administering Medicaid also is involved in MCO regulation.³²

Other types of managed care arrangements may be regulated under separate state statutes. For example, as of 1996, about half of the states had statutes or regulations authorizing and overseeing PPOs. Unlike HMOs, PPOs are provider networks developed to serve people insured through indemnity plans. They typically do not bear insurance risk; those that do are then regulated as HMOs.³³ A few states have developed laws to apply to physician-hospital organizations and PSOs. These are provider-owned and provider-operated entities that combine the financial intermediary role of an insurer with the health care delivery role of a provider organization. They differ mainly from HMOs to the extent that they are provider controlled.³⁴ Many HMOs are, in fact, owned and controlled by providers, thus making them, at least by some definitions, PSOs.

The Role of the NAIC. The NAIC is an association made up of the chief regulatory officials from the 50 states, the District of Columbia, Puerto Rico and the territories. It develops model insurance laws and regulations which the states may elect to adopt, wholly or in part. The NAIC's Model HMO Act was designed to provide a flexible legal framework, enabling a wide variety of HMOs to operate; to provide a regulatory monitoring system to prevent or remedy abuse; and also to assist in the future development of this type of health care delivery system.³⁵ Twenty nine states have HMO laws which are based in part on the NAIC's Model HMO Act.³⁶

The NAIC has an initiative called "the Consolidated Licensure for Entities Accepting Risk or CLEAR," which is aimed at consolidating the NAIC model statutes for licensure of various health coverage products into one new model which would replace the existing model statutes for HMOs and PPOs. This initiative is

³² Aspen Systems Corporation. *A Report to the Governor on State Regulation of Health Maintenance Organizations*, prepared for the U.S. Department of Health and Human Services. Rockville, MD, 6th edition, 1996. (Hereafter cited as Aspen Systems Corporation, *State Regulation of Health Maintenance Organizations*); Horvath, Jane and Kimberly Irvin Snow. *Emerging Challenges in State Regulation of Managed Care. Report on a Survey of Agency Regulation of Prepaid Managed Care Entities*. National Academy for State Health Policy, Portland, ME, August 1996. This report points out that in some states, there are overlapping responsibilities for MCO oversight of two or more state agencies. In some states, regulatory gaps exist in which no agency has responsibility. These are more likely with respect to quality assurance and monitoring than financial standards.

³³ Butler, et al., *Private-Sector Health Coverage*, p. 56.

³⁴ U.S. Library of Congress. Congressional Research Service. *Medicare Restructuring and Provider Sponsored Organizations (PSOs)*. CRS Report 96-921, by Beth C. Fuchs, November 12, 1996. Washington, 1996.

³⁵ NAIC, Health Maintenance Organization Act, 1990.

³⁶ U.S. Congress. House. Ways and Means Committee. Subcommittee on Health. David Randall, Testimony of the National Association of Insurance Commissioners (Ex) Special Committee on Health Insurance. *Medicare HMO Regulation and Quality*, March 6, 1997. 105th Cong., 1st Sess. Washington, GPO, 1997. (Hereafter cited as House Ways and Means Committee, Testimony of David Randall, 1997)

partly in response to the emergence of varying types of risk-bearing entities that provide both insurance and medical services. Indeed, new types of arrangements crop up regularly, adding to the alphabet soup of existing types of MCOs. Five health plan and accountability standards have been completed: (1) quality assessment and improvement; (2) provider credentialing; (3) network adequacy; (4) grievance procedures, and (5) standards for utilization review.³⁷ As of February 1997, no state had adopted these model acts but the NAIC was expecting some to do so in the 1997 and 1998 state legislative sessions. The NAIC is in the process of finalizing risk-based capital standards for insuring entities that would base financial reserve requirements on the amount of risk assumed.³⁸ All of these model standards, those completed and those to come, are designed to be applicable to all plans “performing managed care functions, regardless of their structure or acronym.”³⁹

State Actions. States also establish their own laws regulating MCOs that differ from those of the NAIC. In recent years, a large number of laws have been passed regulating various aspects of MCOs, ranging from their organizational structure to prohibiting certain types of financial incentives to providing standards for utilization review. Most recently, these laws have been enacted in response to consumer and provider concerns about access to and quality of MCO services (sometimes referred to as the managed care “backlash”).

The following discussion summarizes state requirements on MCOs, drawing first from such requirements as spelled out in the NAIC’s *HMO Model Act*, the model acts that emerged out of the CLEAR initiative, and from state laws that may illustrate or go beyond these model acts.⁴⁰ The section ends with a table providing information on selected types of managed care laws and the states that have adopted them (see **Table 1**).

Licensure/Certification/Organization.

NAIC. The NAIC *HMO Model Act* establishes criteria for licensing an organization as an HMO. An HMO is defined as an entity that undertakes to provide or arrange for the delivery of basic health care services to enrollees on a prepaid basis, except for enrollee responsibility for copayments and/or deductibles. The Act specifies that as a prerequisite to issuance of a certificate to operate, that the state entity responsible for health (such as a public health department) determine whether the HMO applying for a license has satisfied quality assurance requirements.

³⁷ House Ways and Means Committee, Testimony of David Randall, 1997.

³⁸ National Association of Insurance Commissioners. The Risk-Bearing Entities Working Group of the State and Federal Health Insurance Legislative Policy (B) Task Force. *The Regulation of Risk-Bearing Entities*, September 1996 (Draft).

³⁹ House Ways and Means Committee, Testimony of David Randall, 1997.

⁴⁰ For additional information on the managed care laws and regulations of the 50 states, see Health Policy Tracking Service. *Major Health Care Policies: 50 State Profiles, 1996*, 5th ed. Washington, January, 1997.

The NAIC *HMO Model Act* does not regulate premium rates per se but does require that rates (or methodology for calculated the rates) be filed for approval by the state regulator, that rates be established in accordance with actuarial principles for various categories of enrollees, and that the premium applicable to an enrollee not be individually determined based on the person's health status. Rates should not be "excessive, inadequate, or unfairly discriminatory." It also provides that HMOs should be examined no less than once every 3 years for their overall operation and quality assurance program. Finally, it sets forth an enforcement process in which noncomplying HMOs could have their licenses suspended or revoked. Monetary penalties could be used in addition to or instead of suspension or revocation

State Laws. Some states require a consumer representative on the HMO board and for there to be a policymaking role for subscribers. Most states require that premium rates be approved. At least one state limits HMO licenses to non-profit organizations. Some states require that HMOs provide for annual open enrollment periods.⁴¹

Access to Services and Providers.

NAIC. The NAIC *HMO Model Act* states under its provisions related to quality assurance that the plan maintain procedures to assure availability, accessibility, and continuity of care. The new NAIC *Network Adequacy Model Act*⁴² establishes explicit standards for the creation and maintenance of provider networks which, in turn, are designed to ensure that services are available and accessible, and that enrollees benefit from continuity of care. For example, the carrier must maintain a network of providers that is sufficient in numbers and types of providers to assure that all services to covered persons are accessible without unreasonable delay. Emergency care must be accessible 24 hours per day, 7 days per week. Providers have to be within a "reasonable proximity" to covered persons. Carriers are required to file access plans with the state regulator. The *Network Adequacy Model Act* also specifies requirements to ensure that participating providers play by certain rules that protect covered persons from breaks in service in the event that the plan experiences financial shortfalls (see "Solvency" below).

The *Network Adequacy Model Act* also includes standards related to the selection of providers and the relationship between the carrier and the provider. Selection criteria for providers cannot be established in a manner that would allow a carrier to avoid high-risk populations (e.g., the MCO cannot exclude providers in a geographic area that contains populations of above-average risk or exclude providers who specialize in treating high-risk patients (e.g., oncologists or physicians who specialize in treating patients infected with the human immunodeficiency virus (HIV)). Carriers could, however, exclude from its network providers who "fail to meet the other legitimate selection criteria of the carrier developed in compliance

⁴¹ Aspen Systems Corporation, *State Regulation of Health Maintenance Organizations*, 1996, Chart 1.

⁴² National Association of Insurance Commissioners. Model Regulation Service. *Managed Care Plan Network Adequacy Model Act*. October 1996.

with this Act.” Certain procedures designed to ensure due process would have to be followed before terminating a provider without cause.

The *Network Adequacy Model Act* also addresses several issues that have been much discussed in Congress and in state legislatures. One is the nature of communications between a managed care provider and his or her patient. A restriction on communications imposed by an MCO on providers is often referred to as a “gag rule” or (if part of a contract) “gag clause.” The *Network Adequacy Model Act* includes an “anti-gag rule.” It provides that a health carrier shall not prohibit a participating provider from discussing treatment options with a covered person or from advocating on behalf of covered persons.

State Laws. As shown in **Table 1**, 28 states (as of mid-1997) had enacted laws or issued regulations requiring plans to provide access to obstetricians/gynecologists, without referral from the enrollee’s primary care physician. Twenty-eight states had enacted laws or regulations prohibiting the use of “gag rules.”⁴³ Nine states had passed laws protecting physicians from termination from MCOs “without just cause.”⁴⁴

Quality Assurance.

NAIC. The NAIC *HMO Model Act* requires an HMO to “establish procedures to assure that the health care services provided to enrollees are rendered under reasonable standards of quality of care consistent with prevailing professionally recognized standards of medical practice. Such procedures shall include mechanisms to assure availability, accessibility, and continuity of care.”⁴⁵ The organization must have an ongoing internal quality assurance program which meets specific requirements, such as having a written statement of goals and objectives emphasizing improved health status; having a written quality assurance plan; ensuring the use of an adequate patient record system; and making enrollee records available to the state public health entity to determine compliance. The *HMO Model Act* requires organizations to disclose specific information about the plan in its contracts for individual and group insurance policies, including eligibility requirements, benefits, emergency care benefits and services, cost-sharing requirements, limitations and exclusions, and enrollee grievance procedures. The organization is also required to file financial and other information at least annually and to provide enrollees notice of changes to the plan, and on how to obtain services.

The NAIC’s new *Quality Assessment and Improvement Model Act* builds on these requirements. It establishes criteria for the quality assessment activities of all health carriers that offer managed care plans; for closed network plans it establishes additional criteria for quality improvement activities. It requires a carrier to include

⁴³ *Health Policy Tracking Service*. Washington, September 1997. Unpublished tables.

⁴⁴ Families USA Foundation. *The Text of Key State HMO Consumer Protection Provisions: The Best from the States. Part I. Families USA Web*, March 1997. (Hereafter cited as Families USA Foundation, 1997)

⁴⁵ NAIC, *Model HMO Act*, Section 7, Quality Assurance Program.

a summary of its quality assessment and improvement programs in its marketing materials and in the certificates of coverage issued to enrollees. Certain findings from the carrier's quality assessment and improvement programs would have to be made available to providers and enrollees, and enrollees would have to be given an opportunity to comment on the carrier's quality improvement process. The Act advises states that they may wish to consider accreditation by a nationally recognized accrediting entity as evidence of meeting some or all of the Act's requirements.⁴⁶ Another issue relates to the use of MCOs of financial incentive arrangements to encourage providers to hold down utilization of services. The *Network Adequacy Model Act* (described above) provides that a carrier cannot offer an inducement under the plan to a provider to provide less than medically necessary services to a covered person.

State Laws. Forty-two states require HMOs to develop and implement a quality assurance plan; about one-half of these states stipulate what HMOs must include in their plans. Consumer advocates have identified Minnesota, Maine, and New Jersey as having the "most carefully crafted quality assurance requirements."⁴⁷ As of August 1997, six states prohibit the use of physician financial incentive arrangements (California, Connecticut (relating only to utilization review companies), Maryland, Louisiana, Nevada, and Texas).⁴⁸ For example, the Maryland statute prohibits the use of withhold arrangements in which a health plan holds back from participating physicians a certain amount which is then only paid if referral services do not exceed some preestablished threshold.⁴⁹ Ten states require that the use of physician incentive arrangements be disclosed (Arkansas, Colorado, Georgia, Louisiana, Minnesota, Rhode Island, Tennessee, Vermont, Virginia, and Washington.) In some cases (e.g., Colorado), the state law requires that the information be disclosed on request. In others (Louisiana), the disclosure of such arrangements must be made annually to every subscriber, enrollee, and participating provider.)

Protection Against Insolvency.

NAIC. The NAIC *HMO Model Act* requires that before issuing any certificate of authority, that the state regulator require that the HMO have an initial net worth of \$1.5 million and will thereafter maintain a net worth equal to the greater of:

- (a) \$1 million;
- (b) 2% of annual premium revenues on the first \$150 million of premiums and 1% of annual premium on the premium in excess of \$150 million;
- (c) an amount equal to 3 months uncovered health care expenditures;

⁴⁶ NAIC, Model Regulation Service. *Quality Assessment and Improvement Model Act*, July 1996.

⁴⁷ Families USA Foundation, 1997.

⁴⁸ Personal communication with American Association of Health Plans, September 1997.

⁴⁹ Families USA Foundation, 1997; also U.S. Library of Congress. Congressional Research Service. *Managed Health Care: The Use of Financial Incentives*. CRS Report 97-482, by Jason Lee and Beth C. Fuchs, April 21, 1997. Washington, 1997.

or

(d) an amount equal to the sum of 8% of annual health expenditures except those paid on a capitated basis or managed hospital payment basis and 4% of annual hospital expenditures paid on a managed hospital payment basis.

Under the HMO Model Act, each HMO has to deposit a specified amount (generally \$300,000) with a trustee or other entity acceptable to the state regulator. This amount is intended to protect the HMO's enrollees and to assure continuation of services in the event that the organization runs into financial difficulties.

The *HMO Model Act* also requires that every contract between an HMO and a participating provider be in writing. The HMO must ensure that in the event that it fails to pay for services, the subscriber or enrollee is not liable to the provider for any amounts owed by the HMO. This is known as a *hold harmless* provision. The Act further requires that each HMO have a plan for handling insolvency which allows for an enrollee's continuation of benefits for the duration of the contract period. If an HMO's uncovered expenditures⁵⁰ exceed 10% of total health expenditures, it is required under the model Act to deposit into a trust or approved account an amount equal to 120% of the HMO's outstanding liability for uncovered expenditures for enrollees in the state.

In addition, the *HMO Model Act* provides that in the event of an HMO insolvency, that other insurance carriers that participated in the enrollment process with the insolvent HMO be required by the state regulator to offer to the group's enrollees a 30-day enrollment period commencing on the date of insolvency. The carriers would have to offer the same coverage and premium rates that it had offered to enrollees of the group at its last regular enrollment period. If no such carrier existed, then the regulator would equitably allocate the insolvent HMO's enrollees to HMOs within the same service area. These HMOs would have to offer as similar coverage as possible but at rates consistent with the successor HMO's existing rating methodology. Successor HMOs could not deny benefits to an enrollee based on a preexisting medical condition.

Finally, the *HMO Model Act* provides that some states may want to adopt a mechanism to assess each HMO doing business in the state up to 2% of its premium to cover the claims for uncovered expenditures for enrollees of insolvent HMOs. This assessment could also be used to provide for the continuation of coverage for those enrollees not otherwise helped by the continuation measures described above.

It should be noted that under the Federal HMO Act of 1973, a federally qualified HMO (and an HMO that has received federal financial assistance under Title XIII of the PHS Act) is exempt from state solvency and capitalization standards that would prevent it from operating in accordance with the HMO Act. In other words, if such a state law were inconsistent with federal law, the state law would be overridden or

⁵⁰ The NAIC Model HMO Act defines "uncovered expenditures" as the costs to the HMO for health care services that are the obligation of the HMO, for which an enrollee may also be liable in the event of an HMO's insolvency and for which no alternative arrangements have been made that are acceptable to the state regulator.

preempted. It appears that most state laws are, in fact, consistent with the solvency provisions of the HMO Act. In only a few states are the laws such that a question might arise. Such a state might, for example, apply to HMOs the reserve and capital requirements of indemnity insurers instead of applying separate HMO requirements.⁵¹

As noted earlier, the NAIC is close to finishing work on a model act for regulating the capital needs of an insuring entity, officially called the *Health Organizations' Risk-Based Capital Formula*. This model standard, which is due to be voted on by the NAIC either late 1997 or early 1998, is designed to provide a uniform model act for capital requirements for all health care entities that take on risk, including HMOs, provider sponsored organizations (PSOs), and traditional indemnity insurers.

A major reason for developing the risk-based capital standard is that traditional capital/solvency requirements have not recognized some of the assets that may be held by the newer forms of MCOs. For example, a PSO that includes a hospital, may have substantial assets in real property (so-called "bricks and mortar"). It may also have a substantial asset in its group of affiliated physicians and its other health care providers.

The formula being developed will set capital requirements specific to the risk borne by the insuring entity and will address five major risk elements:

- affiliated investment risk — the risk of ownership of affiliated entities to the managed care entity (if applicable);
- asset risk — the risk that existing assets will decline in value;
- underwriting (insurance) risk — the risk of errors in assumptions used in determining premium or capitation rates or deviations between assumptions and experience in payment of medical expense;
- credit risk — risk that parties with which the managed care organization (MCO) enters contractual arrangements will not fulfill their obligations, a risk common to all types of businesses; and
- general business risk — such as risk of overruns in administrative expenses, also common to all businesses.

These factors would then be assessed based upon the arrangements under which the health care is delivered and paid for. For example, if the financial risk for delivering

⁵¹ Whether such a law is “potentially inconsistent with Section 1311(a)(1)(d) [of the HMO Act] has not been established.” See: Aspen Systems Corporation, *State Regulation of Health Maintenance Organizations*, 1996.

the service is passed on to providers through contractual arrangements, then the entity would be permitted to have less capital.⁵²

State Laws. About 14 states have adopted the NAIC reserve and capital requirements by law or regulation, although these states vary in the application of the requirement. Other states generally require HMOs to comply with specific reserve standards -- higher or lower-- that differ from those of the NAIC.⁵³

Grievances.

NAIC. The NAIC *HMO Model Act* requires that the HMO establish and maintain a grievance process that has been approved by the state insurance regulator. The HMO is required to maintain records regarding grievances which would be subject to examination by state regulators.

The *NAIC Health Carrier Grievance Procedures Model Act* contains more developed standards for internal grievance procedures to be used by carriers.⁵⁴ Carriers are required to file annually with the state regulator a certificate of compliance stating that the carrier had grievance procedures that fully comply with these standards. Grievance procedures have to be disclosed in materials provided to covered persons. Every carrier has to provide for an initial level of grievance review in which covered persons could seek to reverse the plan's decision, such as a decision not to cover or pay for a specific procedure. The covered person can appeal an adverse decision by initiating a second level of review. A majority of the individuals reviewing the grievance in this instance has to be health care professionals with appropriate expertise. In cases involving a denial of service, the reviewing health care professional generally cannot be a provider in the person's plan and cannot have a financial interest in the outcome of the review. (See "Utilization Review" below.) The time that can elapse at different stages of the grievance process is limited, especially in the case of expedited reviews involving decisions that could seriously jeopardize the life or health of a covered person or would jeopardize the covered person's ability to regain maximum function.

State Laws. All states require that HMOs have internal grievance procedures in which a plan member can appeal a benefit denial. At least 13 states provide specific direction on the nature of grievance procedures that should be used by HMOs. The remaining states require procedures for resolving grievances but "provide little direction" on what the grievance system should include.⁵⁵ Many states also regulate utilization review firms and require processes by which providers (e.g.,

⁵² Bureau of National Affairs. Plan Regulation NAIC Approves Health Organization Risk-Based Capital Formula for Testing. *Managed Care Reporter*, v. 3, no. 25, June 18, 1997.

⁵³ Aspen Systems Corporation, *State Regulation of Health Maintenance Organizations*, 1996.

⁵⁴ National Association of Insurance Commissioners. Model Regulation Service. *Health Care Grievance Procedure Model Act*. October 1996.

⁵⁵ Families USA Foundation, 1997.

hospitals and physicians) and plan members can appeal adverse decisions.⁵⁶ (See "Utilization Review" below.) Members of HMOs who are *not* participants of ERISA plans may also be able to sue for damages under state law. Damages can include the cost of the service as well as consequential costs (such as lost wages) and non-economic costs (such as pain and suffering). They may also include punitive damages.⁵⁷

Participants in health plans that are ERISA plans (private-sector, employee benefit plans) are *not* able to resolve grievances about claim denials through state remedies. This is the case regardless of whether the ERISA plan is insured or self-insured and is an exception to the more general interpretation of ERISA preemption that ERISA overrides state laws regulating employer plans but not the plan that the employer buys from an insurer. Denial of access to state courts and remedies for ERISA participants was determined in *Pilot Life Insurance Co. vs. Dedeaux*, in which the U.S. Supreme Court held that ERISA preempted those state laws which permit insurance policyholders to sue insurance carriers for damages due to the bad faith denial of their claims.⁵⁸ It held that ERISA provides that participants and beneficiaries in ERISA plans may sue only in federal court. If successful, he or she is due recovery for the cost of the test, procedure, or other benefit denied.

Whereas indemnity health insurance plan disputes are usually over whether a claim should have been paid (the care having already been received), disputes emerging in managed care arrangements are more likely to be over services that may not have been provided or about a referral to a specialist that was not allowed. Such denials may be made on the basis that the service or referral in question was not medically necessary, or because the treatment was considered experimental. The federal courts seem to be moving in the direction of distinguishing between whether the dispute is over quantity or quality of services. In several cases decided over the past 2 years, the courts have said that ERISA gives employers substantial discretion to determine what benefits they should include under their health plan. However, issues of quality, such as failing to check on a doctor's background, or negligently delaying needed care, are not covered by ERISA.⁵⁹ Therefore, state remedies may be available.

Medical societies, trial lawyers, and consumer groups have been pressing for state legislation to hold MCOs responsible for negligence and poor quality of care that will survive ERISA preemption challenges. For example, such proposals would hold a health care organization liable for the harm (personal injury or death) it causes when it delays, denies, or fails to provide health care it is contractually or legally obligated to provide. In May, 1997, Texas became the first state to enact a law that holds MCOs liable for medical decisions affecting a patient's health. A MCO whose doctor or other provider causes harm to a patient by failing to exercise "ordinary

⁵⁶ Butler, et al., *Private-Sector Health Coverage*, p. 48.

⁵⁷ *Ibid.*

⁵⁸ *Pilot Life Insurance Co. vs. DeDeaux*, 481 U.S. 41 (1987).

⁵⁹ Bills in Five States Would Make HMOs Liable in Patient Lawsuits over Quality of Care. *State Health Watch*, March 1997. p. 1, 8.

care" in making treatment decisions can be sued for malpractice. Plaintiffs have to exhaust the MCO's internal appeals and grievance procedures before filing suit. In June 1997, Aetna Health Plans of Texas sued in federal court in Houston to block the provision, arguing that it was preempted by ERISA because it improperly interferes with the administration of employee benefit plans.⁶⁰ Employers and MCOs, more generally, are concerned that the ERISA protections against liability will be eroded, thus exposing them to significant and costly litigation. However, the larger public policy question may be to what extent is an MCO merely administering a plan for an employer group health plan or is it influencing the medical treatment provided to the plan's members?

Utilization Review.

NAIC. The NAIC *HMO Model Act* does not include any specific requirements relating to utilization review. Its new *Utilization Review Model Act*⁶¹ requires health carriers that provide or perform utilization review to file certain information about utilization review with the state insurance regulator and satisfy other disclosure requirements. It would need to implement a written utilization review program that describes all review activities, including procedures to evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health services and data sources and clinical review criteria used in decision-making. The carrier would be prohibited from using incentives, direct or indirect, to encourage utilization reviewers to make inappropriate review decisions. Compensation is not allowed to be based on the quality or type of adverse determinations that reviewers render. In addition, the carrier would have to follow specific procedures in responding to requests from providers and patients for reconsiderations and appeals.

Perhaps one of the most important areas covered by the *Utilization Review Model Act* relates to emergency care services. Consumers have sometimes found that their managed care plan refuses to pay for services sought from a hospital emergency room because in the view of the plan reviewers, there was no actual medical emergency. The *Utilization Review Model Act* requires a carrier to cover emergency services necessary to screen and stabilize a covered person, without prior authorization from the plan if a "prudent layperson" acting reasonably would have believed that an emergency medical condition existed. Also, a covered person could obtain from a non-contracting provider within the carrier's service area those emergency services needed to screen and stabilize the person, without prior authorization, if a prudent layperson believed that using a contract provider would cause a delay worsening the emergency or if a provision of federal, state, or local law required the use of a specific provider.⁶²

⁶⁰ *Corporate Health Insurance Inc. vs. Texas Department of Insurance*, DC (Texas, No. H-97-2072), filed June 16, 1997. For additional information on this issue, see Coleman, David L. Crushing Your Health Plan's Legal Protection. *Business and Health*, August 1997. p. 40-46.

⁶¹ National Association of Insurance Commissioners. Model Regulation Service. *Utilization Review Model Act*. October 1996.

⁶² *Ibid.*

State Laws. Some states authorize judicial review of utilization review decisions.⁶³ Numerous states have acted to expand access to and provision of emergency services consistent with the NAIC *Utilization Review Model Act*. For example, some states prohibit plans from requiring authorization prior to the delivery of emergency services; some have adopted the prudent layperson standard; and some require payment for initial screening and stabilizing treatment in an emergency room. A few states go further. At least two states have provisions to ensure specialty and post-stabilization care in the emergency room.⁶⁴

Additional State Laws. Numerous additional aspects of managed care are regulated under state law. These range from narrowly targeted laws, such as laws requiring that health plans pay for a minimum of 48 hours of inpatient hospital care following a mastectomy to those that incorporate a wider range of consumer protections and requirements relating to provider participation in a plan's network.

Table 1 provides in summary form information on which states have enacted certain managed care laws. The data for the table were provided by the *Health Policy Tracking Service* of the National Conference of State Legislators.⁶⁵ A short description of the laws included in the table follows:

Hospital length of stay for mothers and newborns: This provision was a reaction to the perception that new mothers and their infants were being discharged prematurely from hospitals after childbirth because insurers would pay for no more than a 24-hour stay. Most of the state laws allow an "attending provider" (varying in definition), in consultation with the mother, to determine what length of stay is most beneficial. However, if a longer stay is determined to be needed, the law requires insurers to pay for coverage for at least 48 hours of inpatient hospital care following a normal vaginal delivery and 96 hours following a Caesarean section. A federal law was enacted as part of P.L. 104-204 in 1996 which is similar.⁶⁶

Hospital length of stay for mastectomies: This is a relatively new requirement on MCOs and other insurers similar to the provisions passed at the state and national level to mandate a minimum length of inpatient hospital stay for new mothers and their children. A typical state statute requires that insurers provide coverage for a defined minimum number of hours (ranging from 24 to 100) of hospital care following a mastectomy. It may also require that there be a minimum hospital stay after a lymph node dissection. Exceptions are provided in cases where a physician in consultation with a patient determines that a shorter length of stay is appropriate. Some statutes require coverage of home care if a shorter length of stay is provided.

⁶³ Furrow, Barry R., et al. *Health Law*. St. Paul, MN, West Publishing Co., 1995. p. 527.

⁶⁴ Families USA Foundation, Families USA Web (www.epn.org/families/hmostate).

⁶⁵ *Health Policy Tracking Service*. National Conference of State Legislatures. Washington, D.C. Unpublished memoranda, 1997.

⁶⁶ Kearney, *Hospital Length-of-Stay for Obstetrical Care*, 1996.

Any willing provider (AWP): A typical state requires an MCO to contract with any providers who are willing to meet the terms and conditions of the MCO's contract. Many state AWP laws apply only to pharmacies; a few apply only to other types of non-physician providers such as chiropractors and allied health professionals.

Freedom-of-choice: This provision states that an MCO or health insurer cannot limit an enrollee's choice of provider. The provision is often combined with an any willing provider clause. Together, the provisions may specify that the MCO or health insurer cannot prohibit or limit an enrollee who is eligible for reimbursement for specific services from selecting a provider of his or her choice if the provider has agreed to the plan's terms and conditions. Some state laws apply to specific providers, such as pharmacists, chiropractors, or allied health professionals. One state, New Mexico, provides any person the right to exercise full freedom of choice in the selection of any licensed doctor of oriental medicine for treatment within his/her scope of practice.

Direct access to obstetricians and gynecologists: The provision gives women enrolled in managed care plans direct access to these specialists by either not requiring the woman to first get a referral from a primary care physician or by allowing a woman to designate an obstetrician or gynecologist as her primary care physician. These requirements target managed care plans that use primary care physicians as "gatekeepers" for access to the services of specialists.

Ban on gag clauses: The provision prohibits the use of gag clauses by MCOs in contracts with providers to restrict them from discussing treatment options with their patients. The states listed in **Table 1** have enacted laws that broadly prohibit a plan from refusing to contract, terminating a contract, or financially penalizing a provider for such communication. Some state laws are very specific about the content of the communication; others just refer to communication about treatment alternatives.

Comprehensive Consumer Protection Acts: Some states have enacted laws that are based on model laws developed by the American Medical Association or by consumer organizations. These concern a range of managed care issues, such as access, choice, benefits, quality, utilization review, procedural protections for physicians and the disclosure of plan information. The laws reflected in **Table 1** significantly vary in scope, from those that address only a few issues (e.g., disclosure of certain information, freedom of choice of providers, and a ban on gag clauses) to those that address the organization, delivery, and quality of the care provided by the MCO.

Table 1. Selected State Managed Care Legislative Strategies

State	Hospital length-of-stay after childbirth	Hospital length-of-stay for mastectomies	Any willing provider	Freedom-of-choice	Direct access to Ob/Gyn services	Ban on gag clauses	Comprehensive consumer rights/protection acts
Total number of states	36 states (35 laws + 1 regulation)	13 states	24 states (23 laws + 1 regulation)	24 states	28 states (28 laws + 2 regulations)	39 states (37 laws + 2 regulations)	30 states (28 laws + 2 regulations)
Alabama	√		Rx	Rx	√		
Alaska	√						
Arizona	√					√	√
Arkansas	√	√		Rx, eye	√	√	√
California					√	√	√
Colorado					√	√	√
Connecticut	√	√	Rx	Rx	√	√	√
Delaware	voluntary		Rx	Rx	√	√	
Florida	√	√	Rx/accountable health plans		√	√	√
Georgia	√			Rx	√	√	√
Hawaii							
Idaho	√		broad/Rx	Rx	√	√	√
Illinois	√	√	non-institutional providers	preferred provider option	√		
Indiana	√		broad/preferred provider organization		√	√	
Iowa	√						voluntary initiative
Kansas	√		Rx			√	√

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State	Hospital length-of-stay after childbirth	Hospital length-of-stay for mastectomies	Any willing provider	Freedom-of-choice	Direct access to Ob/Gyn services	Ban on gag clauses	Comprehensive consumer rights/ protection acts
Kentucky	√		broad, chiropractors, psychologists, eye	chiropractor			
Louisiana			Rx	Rx	√	√	√
Maine	√	√			√	√	√
Maryland	√				√	√	√
Massachusetts	√		Rx			√	
Michigan						√	
Minnesota	√		allied		√	√	√
Mississippi			Rx	Rx	√		√
Missouri	√				√	√	√
Montana	√	√			√	√	
Nebraska					√	√	√
Nevada				allied		√	√
New Hampshire	√		Rx			√	√
New Jersey	√	√	Rx	Rx	regulation	√	√
New Mexico	√ regulation	√		oriental medicine	regulation	regulation	regulation
New York	√	√			√	√	√
North Carolina	√	√	Rx	Rx	√	regulation	regulation
North Dakota	√		Rx	Rx		√	
Ohio	√						√
Oklahoma	√	√	Rx	osteopathy, podiatry, eye, dental, surgery		√	√
Oregon	√				√	√	√
Pennsylvania	√					√	

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State	Hospital length-of-stay after childbirth	Hospital length-of-stay for mastectomies	Any willing provider	Freedom-of-choice	Direct access to Ob/Gyn services	Ban on gag clauses	Comprehensive consumer rights/ protection acts
Rhode Island	✓	✓		Rx	✓	✓	✓
South Carolina	✓		Rx, allied	Rx			
South Dakota	✓		Rx	Rx			
Tennessee	✓					✓	
Texas	✓	✓	Regulation	Rx	✓	✓	✓
Utah				broad	✓	✓	
Vermont						✓	✓
Virginia	✓		broad	Rx	✓	✓	✓
Washington	✓			opt-out	✓	✓	✓
West Virginia					✓		
Wisconsin			Rx, and other than HMOs and PPOs	Rx		✓	
Wyoming			broad			✓	

Source: Health Policy Tracking Service. National Conferences of State Legislatures. Washington, D.C. Unpublished memoranda/tables, 1997.

Notes: Allied = allied health professionals (e.g., providers such as optometrists, podiatrists, and chiropractors)
 Broad = broad array of health care providers (e.g., physicians, hospitals, pharmacies, chiropractors, etc.)
 Eye = eye care
 MD = physicians
 Rx = pharmacies
 OB = obstetricians/gynecologists

Conclusion

This report has sought to introduce the reader to the issues related to the current regulation of managed health care. Whether additional federal or state regulation is desirable or needed is likely to be an agenda item for the 105th Congress. As of October of 1997, a few congressional committees have announced plans to hold hearings and review pending managed care proposals.

In the event that Congress decides to tackle this issue, a first order question will be whether additional regulation is needed. Some may conclude that the market is better suited to weeding out MCOs that do not meet consumer demands for affordable, accessible, and high quality health care than is government regulation. Or, some may decide that the managed care industry's efforts to police itself will provide consumers and providers with sufficient protection.⁶⁷ For those who decide that regulation is necessary, opinions may be divided over whether the federal government or the states is the more appropriate locus for such regulation.

Should Congress decide to consider new federal regulations on managed care, it will be able to draw on the substantial experience of the states in regulating HMOs and to a lesser extent, other types of managed care arrangements. One of the major challenges, however, will be the regulatory treatment of managed care plans sponsored by employers. Many in Congress are reluctant to impose new requirements on employer plans, mindful of the concerns of business about the financial and administrative burdens that such requirements can entail. And perhaps most difficult will be resolving what to do when new federal law conflicts with existing state law. Should, for example, state laws be preempted thereby providing for uniform, national regulation? Or should state laws that are similar to or more protective of consumer and provider rights be allowed to apply? These and similar issues are likely to be hotly debated.

⁶⁷ In 1996, the American Association of Health Plans (AAHP), which is the national trade organization representing over 1,000 managed health care plans, initiated *Putting Patients First* "to improve communication with patients and physicians: to make clear that the AAHP and its member plans are listening to the concerns of patients and physicians and acting to meet their needs; and to demonstrate AAHP member plans' commitment to higher standards of accountability." In 1997, the membership of the AAHP voted to require health plans joining or renewing membership in the association to uphold the *Putting Patients First* initiative.

