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Patient Protection and Managed Care: Legislation in the 106th Congress

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SUMMARY

A growing number of Americans have health insurance plans that provide services through managed care (over 160 million in 1999). While financial incentives under fee-for-service insurance can lead to wasteful and possibly harmful excess services, incentives under managed care plans could lead to underutilization of necessary services. The 106th Congress responded to this concern by proposing to regulate, at the federal level, various aspects of managed care and other types of health insurance. The proposals considered by the 106th Congress would have established federal standards mirroring various state laws as well as recommendations in the President's Advisory Commission's Consumer Bill of Rights. In 1999, several leadership bills from the 105th Congress were reintroduced with relatively minor modifications. After debate in the House and the Senate, both chambers passed patient protection bills. The House of Representatives passed H.R. 2990 on October 7th, 1999, a bill comprised largely of two earlier bills: a bipartisan patient protections bill that was introduced by Representatives Norwood and Dingell (H.R. 2723), and a bill intended to increase access to health insurance introduced by Representatives Talent and Shadegg (H.R. 2990). The Senate amendment, originally the Patients' Bill of Rights Plus Act (S. 1344) which cleared the Senate on July 15, 1999, was comprised of both patient protections and access to insurance provisions that had been a part of earlier Republican leadership bills. The two bills are described in detail in CRS Report RL30144: *Side by Side Comparison of Selected Patient Protection Bills in the 106th Congress.*

Traditionally, the regulation of health insurance largely has been left to the states, which have passed numerous managed care and patient protection laws. However, the federal Employee Retirement Income Security Act of 1974 (ERISA) preempts the application of such laws for about 54 million persons enrolled in "self-insured" group health plans through private employers. These are plans in which the employer takes some or all of the risk of paying for covered items and services. As a result, there is a patchwork of federal and state regulation which has led many to seek federal standards that would apply broadly to enrollees, regardless of who sponsors their health plan or whether they self-insure.

While there are many substantive differences between the House-passed bill and the Senate amendment, the largest differences are in the scope of their application in the private insurance market, the expansion of patients' legal remedies, and the provisions intended to increase access to health insurance coverage.

The health insurance industry and many employer groups are strongly opposed to increased federal regulation of managed health care. They argue that it is unnecessary because the market is responding to consumer concerns, and that more regulation will raise health care costs and increase the number of uninsured Americans. On the other hand, supporters of increased federal regulation, including many provider and consumer advocacy groups, believe that such regulation is needed to restrain market excesses that may jeopardize health care quality and access.

This issue brief describes the major provisions of leading patient protection bills during the 106th Congress, bills that are likely to provide a starting point for debate in the 107th if such a debate occurs.

MOST RECENT DEVELOPMENTS

It is too early in the 107th Congress to report on progress in the area of patient protection. Congressional leaders are determining the priorities and agenda for the next session of Congress. Patient protection remains an important topic to the public and to many members of Congress and so it is likely to be raised and debated again this year.

At the close of the 106th Congress, several new proposals surfaced offering patient protections but no action was taken and the 106th Congress adjourned without sending a bill to the President. In the late fall of 2000, the Clinton administration, anticipating the ultimate inaction of the 106th Congress, issued a final regulation that included some important protections for enrollees in employer-based plans. The rules established a process for the internal review and appeal of disputed medical claims. The Clinton administration proposed this rule in 1998, but did not move to finalize it at that time because of pending House and Senate action.

The House bill, the "Bipartisan Consensus Managed Care Improvement Act of 1999" (H.R. 2990) was passed on October 7, 1999. H.R. 2990 combines two bills: the "Quality Care for the Uninsured Act of 1999" (originally H.R. 2990) passed on October 6, 1999 and the "Bipartisan Consensus Managed Care Improvement Act of 1999" (originally H.R. 2723) was then added as new matter to H.R. 2990 and passed on October 7, 1999. The provisions of the original H.R. 2990 are contained in Division A of the new bill and the provisions of H.R. 2723 are Division B. Division A is intended to provide individuals greater access to health insurance by expanding tax benefits for health insurance and health care and by creating incentives for employers to use association plans and HealthMarts for coverage of their employees. Division B is intended to protect consumers in managed care plans and other insurance arrangements. The Senate passed the Patients' Bill of Rights Plus Act (S. 1344) on July 15, 1999. S. 1344, which also included provisions intended to increase access to health insurance and to protect consumers in managed care plans, became the Senate amendment to H.R. 2990 on October 14, 1999. While the House and Senate bills differ in many respects, their major points of divergence include 1) the scope of their application in the private insurance market, 2) the expansion of patients' legal remedies, and 3) the provisions intended to increase access to health insurance coverage.

In July 2000, a patient protections amendment introduced by Senator Nickles (S.Amdt. 3694) was attached to the bill making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for FY2002 (H.R. 4577). While it was later stripped from the bill, the Nickles amendment is reported to represent the Senate majority position prior to adjournment. The major difference between the amendment and the S. 1344 is that the amendment included a limited expansion of the right to sue health plans in federal court.

This Issue Brief discusses the major non-tax provisions of the leading patient protections bills of the 106th Congress: H.R. 2990, the House-passed bill and the Senate amendment. A more detailed description of the provisions are included in CRS Report RL30144: Side by Side Comparison of Selected Patient Protection Bills in the 106th Congress. Tax provisions are addressed in CRS Issue Brief IB98037.

BACKGROUND AND ANALYSIS

Managed care generally refers to a payment system or delivery arrangement in which a health plan attempts to control or coordinate the use of health services by its enrollees in order to control spending and promote health. Like fee-for-service insurers, managed care organizations (MCOs) accept financial responsibility for a set of benefits in return for a premium paid by or on behalf of each enrollee. Unlike fee-for-service insurers, MCOs directly provide or arrange for health care services, through affiliated physicians, hospitals and other providers, instead of simply paying bills.

MCOs try to control hospital admissions, 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. (For more detail, see CRS Report 97-482, CRS Report 97-913 and CRS Report 98-117.)

At one time, the only type of arrangement that offered managed care was a health maintenance organization (HMO). Today, managed care 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 access to providers than do traditional HMOs. Like 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.

Over 60% of the U.S. population and over 75% of insured employees were covered by some form of managed care in 1999. Between 70 to 80 million persons (over 25% of the U.S. population) were enrolled in over 600 HMOs in 1999. A larger number— between 80 to 90 million persons—were enrolled in more than 1,000 PPOs. Since the early 1990s, insured workers' enrollment in traditional fee-for-service plans has dropped from about 50% to under 25%. The broad shift to managed care has been driven, largely, by cost concerns. Among all size employers in 2000, average fee-for-service premiums were at least 25% higher than HMO premiums and about 13% higher than PPO premiums, according to the *Employer Health Benefits 2000, Annual Survey by the Kaiser Family Foundation and Health Research and Educational Trust*.

Regulation of Managed Health Care

Employers' benefit plans, which often include health insurance (or health benefits through managed care), are regulated by the federal government under the Employee Retirement Income Security Act (ERISA). Such "ERISA plans" are subject to standards for reporting and disclosure, fiduciary conduct, enforcement of rights, and protections against discrimination whether the employer purchases health insurance for employees or self-insures by accepting some or all of the risk for the cost of services. Consequently, managed care entities that provide benefits under an employer benefit plan must include those ERISA protections in their products. (Employer benefit plans sponsored by governmental employers and churches are not subject to ERISA.)

States, too, regulate many health plans. States have traditionally had regulatory authority over the business of insurance and most have exercised that authority in areas where ERISA standards are largely absent or viewed to be inadequate. For example, reporting and disclosure rules under ERISA may not be particularly timely, procedures for claims denial leave great room for variation among plans, and court remedies available under ERISA do not allow for money damages. As a result, many states have stepped in to establish stronger protections for health plan beneficiaries. Since many managed care products are considered insurance, managed care entities must include those protections in the products they sell.

States, on the other hand, are not permitted under ERISA to regulate employers' benefit plans (this is known as the ERISA preemption clause, discussed in greater detail below), many of which are "self insured" - where the employer bears some or all of the risk of paying for the plan's covered services. Such *self-insured* (or self-funded) plans are not generally considered insurance and therefore, are not subject to many of the states' insurance and patient protection laws.

This division of regulation between the states and the federal government is further complicated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191), as amended. Prior to HIPAA, the states regulated such aspects of health insurance and managed care as licensure, solvency, benefits, and rating. HIPAA, however, imposes *federal* requirements relating to portability of health insurance on state-regulated insurers and MCOs. It also applies such requirements to ERISA plans. (The term "portability" as used in HIPAA means, for example, the ability to change health plans without experiencing preexisting condition exclusions.)

Whether more federal regulation of health insurance is desirable or needed is hotly debated. HIPAA regulates only certain aspects of eligibility and coverage. It does not regulate broader aspects of health care delivery, such as choice of providers, grievance procedures, and quality assurance. States have been passing managed care laws, but these do not apply to the enrollees in self-insured ERISA plans. This means that roughly 30%of a state's privately insured population is not covered by these laws. State laws also are widely variable, with some providing for comprehensive protections, and others providing for narrowly targeted measures.

It is partly because of this patchwork of regulation that some are seeking federal standards for managed health care that would apply to all enrollees, regardless of whether the plan is sponsored by an employer or by an MCO. Proponents of federal action are divided, however, over the scope of federal regulation, how it should interact with ERISA, and its relationship to state laws. Should standards govern the entire range of plan-provider and plan-enrollee relationships or should they be more targeted? Should standards apply to fee-for-service insurance as well as managed care? Should there be uniform national standards or should there be flexibility for state laws similar to or more protective of consumer and provider rights?

MCOs and employer groups tend to oppose federal regulation of managed care. They argue that a market unimpeded by federal interference is the most efficient way to ensure that health plans meet consumer demands for affordable, accessible, and high quality health care. In their view, government regulation is not only unnecessary because the market is already responding to consumer concerns but also would add significantly to the cost of health

insurance. This, in turn, would lead to greater numbers of uninsured. Moreover, they assert that national standards are inflexible and would impede cost-effective innovations in the design of health insurance coverage.

The Role of ERISA. Should Congress decide in favor of federal standards for health plans, a major issue will be whether to apply such standards only to self-insured plans or to all group health plans and health insurance issuers ("health insurance issuers" is defined in HIPAA to include insurance companies, insurance services, or insurance organizations including HMOs licensed to engage in the business of insurance). As mentioned above, ERISA already imposes minimum standards for plans sponsored by private-sector employers, including fiduciary standards, reporting and disclosure requirements, nondiscrimination, and grievance procedures. It also requires such plans to comply with federal portability, maternity stay, coverage for reconstructive surgery following mastectomy (discussed below), and mental health requirements as a result of HIPAA, P.L. 104-204, and P.L. 105-277) .

The ERISA preemption clause impedes states from implementing laws that "relate to" employer benefit plans. In practice, this frees self-insured plans from state laws regulating insurance because they are not considered to be insurance. (See CRS Report 97-938 and CRS Report 98-286.) This preemption provision was designed to ensure uniform national requirements for multistate employer plans, and protects self-insured health plans from potentially costly state regulation, such as state mandated benefit laws, risk pool assessments, premium taxes, and consumer protection managed care laws. Continuation of ERISA preemption is viewed as critical by the self-insured, employer community. Other stakeholders, in contrast, such as governors, state insurance regulators, and consumer groups, see ERISA as a major impediment to state insurance reform. In their view, it is largely because of ERISA's regulatory limitations and its preemption of state insurance law that Congress needs to act.

Major Issues

One important distinction among the patient protection bills considered during the 106th Congress was their scope of application. All provisions in the House-passed bill would have applied to group health plans and health insurance issuers offering health insurance coverage in the group market as well as health insurance issuers offering coverage in the individual market. Such legislation would have covered approximately 141 million people. The Senate amendment was more restrictive in scope. The access provisions (described immediately below) and provider protections would have applied to self-insured group health plans (roughly 54 million persons). The remaining provisions of the Senate amendment described in this Issue Brief would have applied to all group plans encompassing the roughly 125 million persons enrolled in private, employer-sponsored group health plans.

Access and Choice of Providers

The House-passed bill and Senate amendment on patient protections included provisions that would ensure enrollees access to certain types of services and providers without such barriers as prior authorization or increased copayments.

Access to Emergency Services. Some MCOs require prior authorization for emergency department services. In such cases, if the consumer goes directly to the emergency room, and the plan later determines that emergency care was not medically necessary, the consumer may be responsible for the entire bill.

The House-passed bill and Senate amendment would have replaced prior authorization with a "prudent layperson" standard for allowing and approving payment for emergency medical screening examinations. (In this case, a prudent layperson is one who could reasonably expect the absence of medical attention to place his or her health in serious jeopardy.) The House-passed bill would have applied the standard to an emergency medical screening exam and any further medical treatments required to stabilize the patient for transfer. The Senate amendment would have applied, for self-insured plans only, the prudent layperson standard to payment for emergency screening exams and ambulance services, and would have required plans to provide coverage for additional emergency care provided in an emergency room to stabilize an emergency medical condition if indicated by the medical screening exam.

Access to Physicians Specializing in Ob/Gyn and Pediatric Care and other Specialty Services. Some MCOs restrict access to specialty care and specialists by requiring referrals from primary care or "gatekeeper" physicians. Although gatekeeping has enabled plans to reduce costs, its use has led to consumer complaints about difficulties in gaining access to medical services.

The House-passed bill would have required plans and issuers to allow direct access to participating *health care professionals* who specialize in ob/gyn care for women seeking routine ob/gyn care and would have treated the ordering of other ob/gyn care by the health care professional as if ordered by the primary care provider. The Senate amendment included a similar requirement for direct access to ob/gyn care but it would have applied only to self-insured plans. The provision would have required that women be provided with direct access to obstetrical care, related follow-up care, and routine gynecological care and does not specify the types of health care providers to whom direct access would be required. On the other hand, the Senate amendment would have required that the ordering of other routine care by a *physician* specializing in ob/gyn care be treated as if ordered by the primary care provider.

The House-passed bill would have required plans to allow enrollees to designate a participating physician specializing in pediatrics as the primary care provider for children. The Senate amendment would have required self-insured plans to allow direct access to a participating physician for pediatric care and would treat the ordering of routine pediatric care by a pediatric specialist as if ordered by the primary care provider.

Access to other Specialists. The House-passed bill would have required access to an available and accessible specialist with adequate expertise for persons with a condition or disease of "sufficient seriousness and complexity". The bill would have prohibited plans from charging more than the usual costs for participating specialists when conditions merit the use of a nonparticipating specialist, and required that plans allow persons with ongoing special conditions to have primary and specialty care coordinated and provided by a specialist for their condition. For enrollees with conditions that require ongoing specialty care, the bill would have required plans to allow standing referrals to such specialists. For other persons,

the House bill would have required plans to allow enrollees access to needed specialty care from any available and participating primary care provider or specialist *unless* they are clearly informed of the limits on their choices. The Senate amendment would have required self-insured plans and issuers in the group market to provide timely access to primary and specialty care providers.

Continuity of Care. If a health care provider's contract with an MCO terminates while an enrollee is undergoing a course of treatment, both bills would require some continuity of care with the terminated provider during a transition period of at least 90 days. The House-passed bill allowed for an extended transition period only for patients who are pregnant, or are under treatment for an ongoing special condition. The Senate amendment applied the 90-day transition period to all plan beneficiaries in self insured plans, and allowed for an extended transition period for patients who are in at least the second trimester of pregnancy, are terminally ill, or are institutionalized.

Other Access Issues. Each of the two bills included other provisions intended to increase access to certain providers or treatments. The House-passed bill would have prohibited plans and issuers from denying, limiting, or otherwise restricting coverage of routine patient costs incurred in certain *clinical trials*. The Senate amendment included a similar prohibition but only for self-insured plans and only for clinical trials relating to the treatment of cancer. Both bills included provisions requiring plans that use *drug formularies* to provide exceptions to the list when an alternative is medically indicated.

The Senate amendment would have forbidden plans from prohibiting *self-payment for behavioral health* services following a denial or from terminating providers that accept self payments; prohibited discrimination on the basis of *genetic information*; and required health plans to ensure that *inpatient coverage following mastectomy* or certain other treatments for breast cancer continue for as long as the doctor and patient determine to be medically necessary.

Point-of-Service Option. By 1995, nearly 75% of HMOs reported having a POS option of some kind. This option allows enrollees in closed-network plans to access non-participating providers, though typically at a higher cost and on a fee-for-service basis.

Both bills would have required plans and issuers in the group market to offer a POS option to enrollees although they differ with respect to the exceptions they allow. The House-passed bill exempts plans or issuers if their enrollees have a choice of health insurance coverage through another plan or issuer in the group market. The Senate amendment is similar to the House bill except that the POS requirement would have applied only to self-insured plans. Furthermore, the Senate amendment included additional exemptions for small employers (2-50 employees) and group plans in areas for which POS coverage is not available and accessible with reasonable promptness.

Information Disclosure

Information. Economists maintain that access to information and the ability to choose among competing options are the hallmarks of an efficiently functioning market. They reason that informed consumers and purchasers can help maximize value if cost and quality data are readily available and understandable. Although the health care system in total may diverge

in significant ways from a free market model, many observers nevertheless believe that the disclosure of useful health care information is an important goal.

Both the House-passed bill and the Senate amendment would have required the disclosure of some information by health plans and/or health insurance issuers to beneficiaries and enrollees. They differed with respect to the type of information that would have been required and the type that could have been provided only upon request, the frequency with which information was to have been provided, who information was to be provided to, and whether a charge could have been imposed to cover information costs.

Both bills would have applied such standards to all group health plans and health insurance issuers in the group market and the House-passed bill would have applied to health insurance issuers in the individual market as well. The House bill required reporting of any publicly available quality and performance indicators and the Senate amendment would have made such information available upon request.

Both bills would have required group plans to provide the required information at least annually to enrollees, and upon request to potential enrollees.

Medical Communications. The phrase "gag rules" refers to clauses in provider contracts that prohibit or limit provider-patient communications about (1) medical conditions, care, and treatment; and (2) compensation arrangements that produce financial incentives to under-provide care. Although some recent studies suggest that gag clauses are not prevalent in today's contracts, other observers point to some of the more subtle ways plans may discourage certain forms of medical communications between health care professionals and patients.

Both patient protection bills would have precluded health plans from prohibiting or restricting health care professionals from advising patients about their health status or medical care or treatment for a condition or disease. The provisions of the Senate amendment would have applied only to self-insured plans.

Grievance and Appeals Processes and Remedies

Most MCOs have internal procedures to address enrollee complaints about waiting times, unresponsive staff, and other quality of service issues. While such grievances may or may not be resolved to an enrollee's satisfaction, often they are not appealable. (Enrollees in state-regulated MCOs can complain to the state's department of insurance.)

In addition, many health plans have procedures to deal with complaints about reimbursement for, and coverage of, medical care. Under the traditional fee-for-service system where the insurer is separate from the health care provider, such complaints usually relate to a health plan issuer refusing to pay for care already received. In certain MCOs, on the other hand, where the entity managing care is also providing care, patients may be denied certain services or treatments in the first place — a practice which has led many to complain that they are not receiving sufficient medical care to retain or regain their health.

Both patient protection bills would have required a procedure for addressing grievances and reviewing adverse coverage decisions. The major differences in the grievance and appeals

provisions were in the areas of: (a) the procedural rules, (b) the types of grievances or appeals that fall under the rules, (c) the characteristics of the reviewers, (d) the standards required for reviews, and (e) the timeframes within which coverage and review decisions would be made. The timeframes for reviews are reflected in **Table 1.** Other major differences are described below.

Table 1. Comparison of Timeframes for Appeals: 106th Congress Patient Protection Proposals

	House-passed bill	**Senate Amendment**
Initial decision	ASAP, but no later than: Routine: 14 D (+ possible 14 D extension); Expedited 72H; Concurrent: ASAP with sufficient time for appeal; Retrospective: 30 D after receipt of all necessary information but no later than 60D Clock starts: after receipt of request.	ASD: Routine: 30 D + 2 BD for notice; Expedited: 72 H; Concurrent: 1 BD for notice; Retrospective: 30 BD+ 5 BD for notice Clock starts: after receipt of request., except for Retrospective: after receipt of all necessary information
Internal review	ASAP, but no later than: Routine: 14 D (+ possible 14 D extension); Expedited: 72 H. Clock starts: upon requesting review.	 Routine: 30 BD + 2 BD for notice; Expedited: ASAP, but no later than 72 H + 72 H for notice Clock starts: upon requesting review.
External review	ASAP, but no later than: Routine: 21 D; Expedited: 72 H Clock starts: upon requesting review.	ASAP, but no later than: Routine: 5BD to select review entity + 30 D for entity to select reviewer + 30 D for review; Expedited: Routine: 5BD to select review entity + 30 D for entity to select reviewer + 72H or after receipt of all necessary information Clock for review starts: the later of (1) the date on which the external reviewer is designated, or (2) after receipt of all necessary information.

Abbreviations:
ASAP = "As soon as possible" in accordance with the medical exigencies of the case;
ME = In accordance with the medical exigencies of the case;
ASD = timeframes can be extended "at Secretary's discretion";
BD = business day;
D = day;
H = hour.

Internal Appeals Process. An enrollee in an ERISA plan has a right to reasonable opportunity for a full and fair review by the plan of a decision denying a claim. The Department of Labor has established procedures for such reviews (see 29 CFR Part 2560, 11/21/2000 for the final rule). Plans must conform with those requirements for all claimes filed on or after January 1, 2002. Until the rules are in effect, there is little uniformity of internal appeals procedures. At present, if the internal review determination is in the enrollee's favor, then the plan provides the service and/or pays the claim. If it is not in the enrollee's favor, he or she may sue in court for the benefit that has been denied (see below). As an intermediate step, some employers provide for an independent external review of the benefit denial (see below).

For an enrollee who is not in an ERISA plan (such as a managed care plan bought in the individual market or one that covers state and local governmental employees), the internal appeals process is different. State laws require that HMOs have a procedure in which they reconsider initial denials of payment or coverage. Upon being notified that an HMO has denied approval of a service or benefit, an enrollee (or an enrollee's provider) has a right to appeal a decision to an individual or panel within the HMO.

In addressing internal review the House-passed and Senate amendment differed with respect to the types of adverse decisions that may go to internal review and who would be qualified to conduct the reviews. The House bill did not define the types of decisions that qualified for internal review. The Senate amendment broadly defined denials that may proceed to internal review as those relating to payment, coverage and cost-sharing.

With respect to who conducts reviews, the House bill would have required that internal review be conducted by a named fiduciary if the dispute involves a claim for benefits; an appropriate individual if the dispute involves denied coverage; and a physician if the claim involves medical judgement. Likewise, the Senate amendment allowed for reviews by a health care professional with appropriate expertise unless the denial was based on medical necessity, in which case the review would have been conducted by a physician.

External Appeals. Under current law, ERISA does not require plans and issuers to provide for external review of coverage determinations, although some private employers voluntarily provide such a process. Enrollees in these plans, whether the plans are fully-insured or not, can appeal adverse coverage decisions to an external appeals entity if one exists. On the other hand, enrollees in non-ERISA plans may have external appeal rights if they reside in states that have enacted laws requiring MCOs to provide for an external appeals process.

The debate on codifying a definition of "medical necessity" most often comes up with respect to establishing a standard of review for external appeals, although such a definition could also impact initial coverage decisions. Today, physicians and their patients sometimes

complain that their treatment decisions and referrals are determined by the plan not to be "medically necessary". As a result, insurers refuse to pay for such services or MCOs refuse to provide the services. Some states have responded to such complaints by establishing a definition of medical necessity in state law— thereby legislating a standard for medical decision making. Such a definition could provide enrollees who are appealing adverse coverage decisions with an objective standard to claim that a service is needed — a standard that is not set by the plan itself. Some advocates, including providers, argue for a standard of care for medical necessity that is the "generally accepted standard of practice". Opponents believe that a federal definition of medical necessity will be overly bureaucratic and will result in defensive and costly medical practices. Others propose that a federal definition of medical necessity is unnecessary if strong, valid, and scientific standards for external reviewers are defined and if those standards make clear that the review cannot be limited by insurers' contract clauses that define medical necessity in a restrictive way.

The external review provisions differ with respect to the conditions that trigger the review process and the characteristics of the external review entity. Other important differences are in the establishment of a definition of medical necessity and other standards for review, whether the decisions of the reviewers are binding, and whether other types of dispute resolution are allowed.

The bills considered during the 106th Congress were similar with respect to the types of adverse coverage decisions that may enter into external review. The House-passed bill would have required a system for external review for denied services that are covered benefits and are determined not to be medically necessary, are investigational or experimental, or involve medical judgement. The House bill would have allowed insurers to require payment of a refundable filing fee that can be no more than $25 and to condition the use of the external appeals process on the completion of an internal review. The Senate amendment provided for three conditions to be met before a claim could proceed to external review: (1) the denied item or service, when medically necessary, is a covered benefit, the cost of which exceeds a "significant" financial threshold and there is a significant risk of jeopardizing the enrollee's life or health, (2) the denied item or service is an experimental or investigational treatment, and (3) the internal appeals process has been exhausted. In both bills, internal review decisions that were not timely would be allowed to proceed to external review.

Both bills proposed selection criteria for external reviewers designed to ensure adequate expertise of panel members as well as their independence from the plan or issuer and their fairness. The decision of the external reviewer would have been considered binding in both bills. The House bill would have required the plan or issuer to pay the costs of the external reviews. The Senate amendment was silent on payment for reviews.

The House-passed bill would have required reviews to be consistent with standards developed by the appropriate Secretary. Those standards were to define a de novo determination that includes a judgment of whether the plan or issuer's decision is in accordance with the medical needs of the patient. Reviewers would have been required to consider the medical condition and personal medical information of the patient; the opinion of treating physicians or health care professionals; the plans' definition of medical necessity and experimental coverage, although the reviewers were not to be bound by such definitions; and the decisions of internal reviewers. Other information, such as valid scientific and clinical

evidence, treatment guidelines, and community standards of care may also have been considered.

The Senate amendment would have required the determinations of reviewers to be independent, based on valid, relevant, scientific and clinical evidence to determine the medical necessity, appropriateness, experimental or investigational nature of the proposed treatment and take into consideration evidence-based decision making or clinical practice guidelines of the plan; the patient's medical record; expert consensus; and medical studies, research and literature; and other evidence or information submitted by the plan, patient or the physician.

The House bill would have authorized civil penalties of up to $1,000 a day if the determination of the external reviewers was not followed and additional penalties for cases in which the relevant Secretary determines that there is a pattern or practice of repeated refusals to authorize benefits following external review. The penalty could not exceed the lesser of 25% of the value of benefits not provided or $500,000. The Senate amendment allowed the Secretary to assess a civil penalty against any plan of up to $10,000 for the plan's failure to comply with deadlines and an additional $10,000 to be paid to the participant or beneficiary if the determination of the external reviewers is not followed. In addition, the bill would have authorized a civil action to recover the amount of unpaid reimbursement and legal costs for beneficiaries whose plans have failed to pay for care that external reviewers have found the beneficiary entitled to.

Remedies and Access to Courts. ***ERISA plans.*** Under ERISA, enrollees in employer-sponsored plans can only sue an ERISA plan for benefits due under the plan. State law causes of action, which include consequential and punitive damages, are not available and ERISA does not provide for such damages. This is the case whether the employer-sponsored health benefits are fully-insured or self-insured. It is also an exception to the usual interpretation of ERISA preemption - that is, that ERISA overrides state laws regulating employer benefit plans but not those regulating the business of insurance. This unusual interpretation results from a 1987 Supreme Court decision (Pilot Life Insurance Co. vs. Dedeaux, 481 U.S. 41).

It is less clear whether or not enrollees in ERISA plans can sue for negligence, wrongful death, or medical malpractice. Some courts have found MCOs or other entities that contract with an ERISA plan could be held liable for the quality of the medical care, including substandard care and negligent or faulty delivery of services. In this case, an enrollee would be able to sue under state law. If, however, an enrollee sues the ERISA plan itself for malpractice, wrongful death, or negligence, the court could dismiss the suit because no such cause of action exists under ERISA and any state laws relating to the plan could be preempted.

Further complicating the question of liability is that for many self-insured employer plans, the line between the administrative functions of the plan and the medical decisions of the plan can be blurred. The courts have been clear that state laws that relate to administrative functions of ERISA plans are preempted. On the other hand, the courts have spoken equivocally on the question of where an administrative (i.e., quantitative) decision ends and a medical or qualitative decision begins. If, for example, a plan denies urgently needed medical care that a patient cannot afford to pay on his or her own, or promised coverage is delayed until it is too late to do any good, then is that a benefit decision or a medical decision?

Because the federal circuit courts are divided on this issue, some legal experts predict the Supreme Court will take it up. Against this backdrop, however, are proposals to resolve the ERISA plan liability issue through legislation.

Non-ERISA plans. If an enrollee in an individually purchased plan or other non-ERISA plan receives an adverse coverage determination at the external review stage, then he or she can attempt to sue the MCO in state court. Remedies vary by state. Typically, they include the cost of the denied service as well as consequential costs (such as lost wages) and non-economic costs (such as pain and suffering). An enrollee may also be able to sue for punitive damages.

State laws also vary as to whether they allow enrollees in non-ERISA plans to sue MCOs (as opposed to doctors or other providers) for medical malpractice. In many states, such suits never get to trial because the organization is protected by the anti-corporate practice of medicine laws. Simply stated, those laws hold that an HMO cannot make medical decisions because the HMO is not a health care professional. Since it cannot make medical decisions, it cannot be held responsible for medical malpractice. Many would like to see this shield against HMO liability removed. In their view, the organization should be legally responsible for withholding care or delivering poor quality care because it influences provider's actions through financial incentives or more direct controls over medical practice. In May 1997, Texas became the first state to explicitly override its corporate practice of medicine law with a new law that holds MCOs liable for medical decisions affecting a patient's health. This law was challenged in federal court by Aetna Health Plans, who argued that the law is preempted by ERISA because it improperly interferes with administration of employee benefit plans (see below). The court upheld the states' provisions subjecting MCOs to liability for such decisions. (For more information on this issue, see CRS Report 98-286)

The House bill would have amended ERISA (§514) to prevent its preemption provision from interfering with a state law that would allow individuals to recover damages for personal injury or wrongful death but would have prevent the award of punitive damages if an external review was conducted and the plan followed the reviewers' recommendations. In the case of an action filed before external review has taken place, punitive damages could have been avoided if the plan or issuer involved requests external review within 30 days after the benefit denial. This provision would not have applied in the case of wrongful death in states in which state law only provides for punitive damages. The bill attempted to protect employer-sponsored health plans by expressly stating that it did not authorize a cause of action against a group health plan, employer or plan sponsor nor did it permit a cause of action under state law for failing to provide a benefit or service that is not covered by the plan, and it would have prohibited persons from seeking recovery, indemnification, or contribution from group plans, employers or plans sponsors for damaged under the Act. An exception to all of those conditions, when a plan, employer or sponsor exercises "discretionary authority" to make a benefits decision that results in harm, was included.

The Senate amendment would not have changed current law which allows for a civil action to recover the cost of benefits and some legal costs if a health plan fails to provide reimbursement for a medical item or service that external reviewers have determined a beneficiary is entitled to receive.

MCOs, employers and the health insurance industry are strongly opposed to changes in the ERISA preemption enjoyed by private employer-sponsored plans. These and other critics argue that increasing access to such remedies as compensatory and punitive damages would significantly inflate health care costs. They assume that patients, attorneys and even providers would much more readily pursue state law causes of action against health plans and plan sponsors for medical negligence and malpractice. The result, critics predict, would be defensive medicine, higher liability insurance and thus premiums, and perhaps even reductions in covered benefits. Conversely, many of those who support the modification of ERISA §514 consider the likely cost effects to be far more modest. To support this view, they cite the absence of runaway medical cost inflation in those sectors — non-ERISA employer sponsored plans and the individual insurance market — that do not now enjoy preemption from state causes of action. In June 1998, CBO estimated the cost of ending the ERISA preemption as 1.2% of the premiums of all employer sponsored plans (an increase of currently liability costs of about 60 to 75%). However, it should be noted that CBO cautioned that this estimate "depends on assumptions for which the supporting data are extremely limited or nonexistent."

Association Health Plans and HealthMarts

The House bill would have created two new legal entities; Association Health Plans (AHPs) and HealthMarts (HMs). Both AHPs and HMs are intended to increase incentives for employers to band together to purchase insurance coverage for their employees. The concept of employers grouping together to purchase insurance is not a new one. A number of different styles of employer-based health insurance purchasing groups exist today. There are both public purchasing groups and private purchasing groups; some that are exempt from state regulation of insurance and others that must meet those state laws; some that self-insure and others that bargain with carriers to offer a single or multiple insured products. There are a number of possible advantages for employers that purchase insurance through a well-designed group. By pooling their insurance risks together, the employers in the group may be able to increase their bargaining power with carriers and share administrative functions resulting in lower premium costs. Employees of those firms may be able to select from a larger number of plans than if their employers were to obtain insurance independently. Multiple employer welfare arrangements (MEWAs), a broad category of employer purchasing groups, have traditionally been established by trade or business associations to provide insurance to a particular group of employers. While the primary purpose of MEWAs is to enjoy the economies of scale of banding together, a secondary purpose, for those groups with below-average risk, is to buy lower-priced coverage reflecting their lower risk.

Advocates of purchasing groups look to them as a mechanism to extend coverage among the working uninsured by reducing the barriers that small employers currently face in providing coverage for their employees. One such barrier is state laws requiring coverage of specific benefits. Under current law, large employers that self-insure their employees are exempt from such state laws while small employers are not able to do so. Opponents of the provisions as they appeared in the bill passed by the House during the 106th Congress raise the concern that without stronger incentives for uninsured small employer groups to join the health marts or association health plans, the impact on the number of uninsured would not be significant. Further, some provisions could have created opportunities for risk segmentation, thereby raising the risk of actually increasing the number of uninsured. Opponents argue that the preemption of state benefits mandates for both AHPs and HMs would undermine state

based consumer protections. Further, the broad preemption of any state "requirement that directly or indirectly impedes offering coverage through a HM" raises concerns about possible court litigation to clarify the meaning of the preemption. Finally, the AHP provisions are likely to raise concerns because association plans have a checkered history that includes a number of fraudulent health insurance schemes.

The House-passed bill would have established AHPs as certified group health plans sponsored by associations. The primary differences between AHPs and existing MEWAs is that AHPs would not be subject to state benefit mandates (except that they must comply with any federal or state laws that require coverage of specific diseases, maternal and newborn hospitalization, and mental health) and those that self-insure would be required to meet the bill's reserve requirements and provisions for solvency.

Other major requirements of AHPs as defined in the House-passed bill would have included the following:

- The AHP must offer at least one fully-insured health coverage option (unless it is not available).
- The association sponsoring the plan must have been in existence for at least 3 years for purposes other than providing health insurance coverage and must be operated by a board of trustees with complete fiscal control and responsibility for all operations.
- Certain *self-insured* AHPs may be certified as group health plans. In addition to meeting reserve requirements and provisions for solvency, they must have at least 1,000 participants and beneficiaries, and have offered coverage on the date of enactment or represent a broad cross-section of trades, or represent one or more trades with average or above average health insurance risk.
- All employers who are members must be eligible to enroll, all geographically available coverage options must be made available upon request to eligible employers, and eligible individuals cannot be excluded because of health status.
- Premiums for any particular small employer are prohibited from being based on the health status or claims experience of its plan participants or on the type of business or industry in which the employer is engaged.

The bill also would have required the Secretary of Labor to report to Congress no later than January 1, 2004, on the effect of AHPs on reducing the number of uninsured individuals.

The House bill also included provisions defining (HMs) as legal nonprofit entities. HMs would have been defined as private entities that make health benefits coverage available to all small employers and eligible employees in a specified geographic area that is no smaller than a county and would provide administrative services for purchasers. The primary differences between HMs and existing employer purchasing coalitions are that HMs would be exempt from state laws related to benefits (except for those requiring coverage of specific diseases, maternal and newborn hospitalization, and mental health). They would also be preempted from grouping requirements (which bar employers from joining together for the sole purpose of purchasing health insurance), and any other requirement that directly or indirectly impedes offering coverage through an HM.

Other characteristics of HMs would have included the following:

- HMs would operate under the direction of a board that includes representatives from small employers, employees, health care providers, and entities that underwrite or administer health benefits coverage;
- they would be required to offer at least two coverage options and must have at least 10 purchasers and 100 members by the end of the first year of operation;
- they would not be allowed to self-insure but rather would provide coverage through contracts with health insurance issuers and would be considered a group health plan for purposes of ERISA fiduciary and disclosure requirements;
- Premiums for benefits offered through HMs would be allowed to vary only as permissible under State law and may not vary among similarly situated individuals on the basis of health status. HMs would be prohibited from denying enrollment or renewal of coverage on the basis of health status-related factors.

The bill would have created an "Health Care Marketplace Division" in HHS to administer the HM provisions and would have required the Secretary to submit periodic reports to Congress on the effectiveness of HMs in promoting coverage of uninsured individuals.

LEGISLATION

The following bills to establish comprehensive patient protections were introduced during the 106th Congress.

H.R. 216 (Norwood)
Access to Quality Care Act of 1999. Introduced January 6, 1999.

H.R. 358 (Dingell/Gephardt)/S. 6 (Daschle/Kennedy)
Patients' Bill of Rights Act of 1999. H.R. 358 introduced March 31, 1998. S. 6 introduced January 19, 1999.

S. 300 (Lott)
Patients' Bill of Rights Plus Act. Introduced January 22, 1999.

S. 326 (Jeffords)
Patients Bill of Rights Act. Introduced January 22, 1999.

H.R. 448 (Bilirakis)
Patient Protection Act of 1999. Introduced February 2, 1999.

S. 374 (Chafee/Graham)
Promoting Responsible Managed Care Act of 1999. Introduced February 4, 1999.

H.R. 719 (Ganske)
Managed Care Reform Act of 1999. Introduced February 11, 1999.

H.R. 2041, H.R. 2042, H.R. 2043, H.R. 2044, H.R. 2045, H.R. 2046, H.R. 2047, H.R. 2089
(Bills introduced as package on patient protections.) These bills were individually introduced.

S. 1344 (Lott)
The Patients' Bill of Rights Plus Act. Passed Senate July 15, 1999.

H.R. 2723 (Norwood, Dingell and Ganske)
The Bipartisan Consensus Managed Care Improvement Act of 1999. Introduced August 5, 1999.

H.R. 2824 (Coburn and Shadegg)
Health Care Quality and Choice Act of 1999. Introduced September 9, 1999.

H.R. 2926 (Boehner)
Comprehensive Access and Responsibility in Health Care Act of 1999. Introduced September 23, 1999.

H.R. 2990 (Talent and Shadegg)
A bill to amend Internal Revenue Code of 1986 to allow individuals greater access to health insurance and to protect consumers in managed care plans and other health coverage; and for other purposes. Introduced September 30, 1999. Passed House October 6, 1999. Combined with H.R. 2723 and passed as H.R. 2990 in House October 7, 1999. Received, amended and passed Senate October 14, 1999.

S.Amdt. 3694 (Nickels)
An amendment to increase access to health care and to protect consumers in managed care plans and in other health coverage. Amendment to bill making appropriations for Departments of Labor, Health and Human Services, and Education, and related agencies for FY2001 (H.R. 4577).

FOR ADDITIONAL READING

CRS Report RL30144, *Side by Side Comparison of Selected Patient Protection Bills in the 106th Congress*
CRS Report RS20315, *ERISA Regulation of Health Plans*
CRS Report RS20258, *Patient Protection and Mandatory External Review: Amending ERISA's Claims Procedure*
CRS Report RL30077, *Managed Care: Recent Proposals for New Grievance and Appeals Procedures*
CRS Issue Brief IB98037, *Tax Benefits for Health Insurance*
CRS Report 97-643, *Medical Savings Accounts*
CRS Issue Brief IB98002, *Medical Records Confidentiality*
CRS Report 98-286, *ERISA's Impact on Medical Malpractice and Negligence Claims*

CRS Series on *Managed Health Care*:

CRS Report 97-913, *A Primer*
CRS Report 97-938, *Federal and State Regulation*
CRS Report 98-117, *Cost and Quality Control Strategies*
CRS Report 97-482, *The Use of Financial Incentives*