Order Code RL31631

Report for Congress
Received through the CRS Web

Patient Protection and Managed Care

October 25, 2002

Jean P. Hearne
Hinda Ripps Chaikind
Specialists in Domestic Social Policy
Domestic Social Policy Division

Patient Protection and Managed Care

Summary

Most Americans have health insurance plans that provide services through some kind of managed care arrangement. 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. Congress is responding to this concern by proposing to regulate, at the federal level, various aspects of managed care and other types of health insurance. During the 106th Congress, the House and Senate passed comprehensive patient protection bills but were unable to reconcile the differences and send a bill to the President. The 107th Congress has revisited the patients rights debate. The Senate and the House have each passed a bill (S. 1052 and H.R. 2563, respectively) that would establish federal standards mirroring various state laws as well as recommendations in the 1997 Consumer Bill of Rights as developed by former President Clinton's Advisory Commission on Consumer Rights and Quality in Health Care. However, as a conference committee has not yet been appointed to negotiate between House and Senate-passed versions of the bill, it is unlikely that agreement will be reached before adjournment of the 107th Congress. This debate will most likely continue in the 108th Congress. This document provides background information on the issues surrounding patient protection and reviews the major differences between the Senate-passed and House-passed bills.

Both of the bills under consideration would apply federal patient protections to all insured Americans. The most significant differences between these bills are in the provisions expanding patients' legal remedies against their health plan providers when medical care is unjustly denied and the denial results in harm. Other differences include provisions applying the protections to federal health programs, prohibiting discrimination on the basis of genetic information, and encouraging health insurance coverage expansions.

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, increasing 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 could jeopardize health care quality and access and that such regulation would result in only small additional costs.

Contents

List of Tables

Patient Protection and Managed Care

Introduction

Most Americans have health insurance plans that provide services through some kind of managed care arrangement. 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. Congress is responding to this latter concern by proposing to regulate, at the federal level, various aspects of managed care and other types of health insurance. During the 106th Congress, the House and Senate passed comprehensive patient protection bills but were unable to reconcile the differences and send a bill to the President. The 107th Congress has revisited the patients rights debate. The Senate and the House have each passed a bill (S. 1052 and H.R. 2563, respectively)[1] that would establish federal standards mirroring various state laws as well as recommendations in the 1997 Consumer Bill of Rights as developed by former President Clinton's Advisory Commission on Consumer Rights and Quality in Health Care. However, as a conference committee has not been appointed to negotiate between House and Senate-passed versions of the bill, it is unlikely that agreement will be reached before adjournment of the 107th Congress. This debate will most likely continue in the 108th Congress.

Traditionally, the regulation of health insurance largely has been left to the states. They 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 56 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. For enrollees of self-insured plans, federal law applies, but few protections currently exist in the federal statutes. As a result, there is a patchwork of federal and state regulation leading many to seek federal standards that would apply broadly to all health plan enrollees, regardless of who sponsors their health plan or whether they self-insure.

Both S. 1052 and H.R. 2563 would apply federal patient protections to all insured Americans. The most significant differences between these bills are in the provisions expanding patients' legal remedies against their health plan providers when medical care is unjustly denied and the denial results in harm. Other differences include provisions applying the protections to federal health programs,

---

[1] For more detailed descriptions of the provisions included in S. 1052 and H.R. 2563, see CRS Report RL30978, *Patient Protection During the 107th Congress: Side-by-Side Comparison of House and Senate Bills* by Hinda Chaikind, Jean Hearne, Fran Larkins and Angie Wellborn.

prohibiting discrimination on the basis of genetic information, and encouraging health insurance coverage expansions.

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, increasing 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 could jeopardize health care quality and access and that such regulation would result in only small additional costs.

Managed Care Organizations

Background

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, many 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. They may also select low-cost providers of services or negotiate discounted rates from providers.[2]

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 access to a wider range of 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.

Almost 93% of insured employees were covered by some form of managed care in 2001: Over 23% of covered employees were enrolled in HMOs, twice as many workers, 48%, were enrolled in PPO plans and 23% were in point-of-service plans. Point of service plans are defined as being similar to HMOs but they allow patients to use non-network providers at a higher cost than for network providers. Since the

---

[2] For more detail, see CRS Report 97-482, *Managed Health Care: The Use of Financial Incentives*, CRS Report 97-913, *Managed Health Care: A Primer* and CRS Report 98-117, *Managed Health Care Cost and Quality Control Strategies*.

early 1990s, insured workers' enrollment in traditional fee-for-service plans dropped from about 50% to only 7%, reflecting the addition of managed care features to many of the former fee-for-service plans. The broad shift to managed care has been driven, largely, by cost concerns. Among all size employers in 2001, average fee-for-service premiums were almost 20% higher than HMO premiums and between 4% and 7% higher than PPO premiums, according to the *Employer Health Benefits 2001, 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 insurance products. 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). ERISA frees employer benefit plans from state regulation but many employers offer benefit plans that include health insurance products. In this case the employer purchases health insurance from a traditional insurer (or MCO) and the insurer bears the risk of covering the cost of the benefits. Despite ERISA's preemption on employer benefit plans, these insurance products have already met state requirements for insurance. Other employers offer "self- insured" health plans – 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. One concern during the patient protection debate is 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 those plans are not considered to be insurance.[3] This preemption provision was designed to ensure uniform national requirements for multi-state 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.

Legislation and Major Issues

The two patient protection bills under consideration are S. 1052: the *"Bipartisan Patient Protection Act"*, passed by the Senate on June 29, 2001, and H.R. 2563, the *"Bipartisan Patient Protection Act"*, passed by the House on August 2, 2001. S. 1052 was introduced in the Senate by Senators McCain, Edwards and Kennedy on June 14, 2001. H.R. 2563, was introduced on July 19, and incorporated many of the amendments included in the Senate-passed bill, with several major exceptions: (1) H.R. 2563 includes only a sense of the Congress, rather than a requirement, that these protections would apply to federal health programs; and (2) H.R. 2563 does not include provisions expanding the current law prohibitions on discrimination based on genetic information, and (3) H.R. 2563 includes tax provisions not found in S. 1052.[4] H.R. 2563 was further modified before passage to include two new major amendments. The two major amendments resulted in other differences, the most significant of which are in provisions expanding the right to sue for benefits denied, increasing health insurance coverage options (Association Health Plans and Medical Savings Accounts), and defining the ability of states to apply substantially equivalent state laws in lieu of the federal laws.

Scope of Application

One important distinction among the patient protection bills considered during the 107th Congress is in their scope of application. The question here is whether the federal protections should apply to all Americans, only to those who are covered under employer-based plans, or only to those with employer-based coverage who do not have access to similar protections from their states. The reach of the proposed protections is the subject of the first of President Bush's principles: that federal protections should apply to all health plan enrollees while giving deference to

---

[3] See CRS Report 97-938, *Managed Health Care: Federal and State Regulation* and CRS Report 98-286, *ERISA's Impact on Medical Malpractice and Negligence Claims Against Managed Care Plans*.

[4] For a discussion of the tax provisions, see CRS Issue Brief IB98037, *Tax Benefits for Health Insurance: Current Legislation*, by Bob Lyke and Christopher Sroka.

existing state protections. Both of the bills passed during the 107th Congress would apply their standards to all (insured) Americans, but both also include provisions allowing state laws to apply under certain circumstances to those plans that are subject to state laws. Both bills allow for the substitution of state law, if it meets criteria for substantial compliance with federal standards with two exceptions. The first exception is that the House-passed bill does not allow state laws defining internal and external appeals processes to apply in lieu of the federal laws. The second exception is related to state laws limiting damages in health care-related lawsuits. S. 1052 would allow a state to determine non-economic damage amounts in state court, while H.R. 2563 allows states to apply their own damage limits, but only up to the federally established maximum amounts.

The bills would apply to individually-purchased plans as well as employer-sponsored plans, and to state and local government-sponsored plans. S. 1052 was amended before passage so that its provisions, including the expanded right to sue, would apply to all federally sponsored health plans including the Federal Employees Health Benefits Program, Medicare, Medicaid, the State Child Health Insurance Program, Veterans, Department of Defense and all other federal programs providing health care or coverage. H.R. 2563 does not specifically apply its provisions to federal government-sponsored plans, but since the Federal Employee Health Benefit (FEHB) program plans are offered by insurers and HMOs which are subject to the group plan provisions, FEHB plans would be expected to comply with patient protection legislation, if passed. Other federally sponsored health plans or programs, such as Medicare and Medicaid, would not be covered by the provisions of H.R. 2563, although this bill includes a provision expressing the sense of the Congress that the President should issue an Executive Order requiring federal officials take feasible steps to apply patients rights to federal health programs.

Both bills include provisions that exempt fee-for-service plans from many of the protections in the bill, including a requirement for a consumer choice option, choice of health care professional, access to emergency care, specialists, obstetricians and gynecologists (OB/GYN), pediatric care, and continuity of care. S. 1052 does not apply its exemption to federal health plans and programs. Fee-for-service plans are defined in the bills as those that reimburse providers on a fee-for-service basis without placing them at financial risk, do not vary providers' reimbursement based on contract terms or use of health care services, allow access to any provider legally authorized to provide covered services (and are willing to accept the payment terms) and do not require prior authorization.

Access and Choice of Providers

S. 1052 and H.R. 2563 include a number of identical provisions ensuring that health plan enrollees have access to certain types of services and providers without such barriers as prior authorization and increased copayments. The provisions in common include:

- *Access to Emergency Services.* Some MCOs require prior authorization for emergency department services. Without it, consumers who go directly to the emergency room, and for whom the plan later determines that emergency care was not medically necessary, may be responsible for the entire bill. The bills

addressed this issue by establishing a "prudent layperson" standard for plans that cover emergency services. This standard would require plans that cover emergency care to cover such care for the treatment of any condition which a prudent layperson would reasonably believe puts them at serious risk of injury or death. The bills also prohibit plans or issuers from charging patients more for using a non- network provider than would have been charged if the emergency services were provided in-network. The bills include a provision requiring that emergency ambulance services be subject to the same type of standard.

- *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 bills passed in the 107th Congress include provisions: (1) requiring plans that cover obstetrical and gynecological care to allow enrollees to visit physician and non-physician specialists without first receiving a referral and prohibiting prior authorization for the OB/GYN services that they order, (2) requiring that pediatricians be considered as primary care providers for plans that require such a designation, and (3) requiring plans that cover the services of specialists to ensure enrollees have timely access to those specialists.

- *Continuity of Care.* A patient undergoing a course of treatment in the care of a health care provider whose contract with an MCO is terminated would be at risk of losing access to their established providers. The bills would require plans to cover some continued care with terminated providers for certain plan enrollees undergoing a course of treatment during a transition period of at least 90 days.

- *Point-of-Service Option*. Point-of-service options allow enrollees of closed-network plans to have access to non-participating providers, though typically at a higher cost and on a fee-for-service basis. By 1996, over 80% of HMOs reported having a POS option of some kind. The bills would require group health plans that have closed networks to provide point-of-service options. S. 1052 and H.R. 2563 do not require point-of-service coverage, however, for those individuals given a choice of non-network coverage through another plan or issuer in the group market.

- *Information Disclosure*. 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. Each of the bills requires extensive information to be provided to individuals at time of enrollment and annually thereafter.

- *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. The bills include prohibitions on such contract clauses.

- *Access to Prescription Drugs and Clinical Trials.* The current bills include provisions requiring plans that limit coverage of drugs to those on a list, sometimes referred to as a formulary, to develop those formularies with physicians and pharmacists and to allow exceptions from the formulary when a non-listed drug is medically necessary and appropriate. S. 1052 and H.R. 2563 would limit additional cost-sharing for non-formulary drugs.

The bills also include provisions requiring plans to cover routine patient costs incurred through participation in an approved clinical trial.

- *Discrimination Protection for Providers.* Both bills include a provision that would prohibit discrimination with respect to participation or indemnification against any provider who is acting in accordance with license or certification under state law.

One significant set of protections included in the Senate bill are provisions that expand upon the current law prohibition on discriminating against individuals based on genetic information. The Senate bill would prohibit plans or issuers, in both group and individual markets, from: (1) establishing rules for eligibility (including continued eligibility) for any individual based on genetic information of that individual or their dependent, (2) denying eligibility or adjusting premium or contribution rates on the basis of predictive genetic information for an individual or that person's family member, and (3) requesting or requiring that an individual or that person's family members provide predictive genetic information. It would also require plans to provide notice of confidentiality safeguards when requesting such information, to post or provide notice of confidentiality practices and to have safeguards in place with respect to predictive genetic information.

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.

The House- and Senate-passed patient protections bills under consideration in the 107th Congress include provisions requiring and defining the internal review procedures for coverage denials.

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[5]. Plans must conform with those requirements for all claims filed on or after January 1, 2002. The rules have established some uniformity of internal appeals procedures. 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 under ERISA 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.

---

[5] See 29 CFR Part 2560, 11/21/2000 for the final rule.

Table 1. Timeframes for Appeals: 107th Congress Patient Protection Proposals

	S. 1052 and H.R. 2563
Initial decision	ASAP – "As soon as possible" in accordance with the medical exigencies of the case, but no later than: *Routine*: 14 days after receiving information but no later than 28 days; *Expedited*: 72 hours; *Ongoing*: ASAP with sufficient time for appeal; *Previously provided services:* 30 days after receiving necessary information, but no later than 60 days
Internal review	ASAP – "As soon as possible" in accordance with the medical exigencies of the case, but no later than: *Routine*: 14 days after receiving information but no later than 28 days; *Expedited*: 72 hours after request; *Previously provided services:* 30 days after receiving necessary information, but no later than 60 days.
External review	ASAP – "As soon as possible" in accordance with the medical exigencies of the case, but no later than:
	Routine: 14 days after receiving necessary information, but no longer than 21 days after request; *Expedited*: 72 hours after request; *Ongoing*: 24 hours after request; *Previously provided services*: 30 days after receiving information, but no later than 60 days after request.

The 107th Congressional bills broadly allow for denied claims for benefits or coverage or disputes over cost sharing amounts to proceed to internal review. The bills would require that internal reviews be conducted by individuals with appropriate expertise so long as those individuals were not involved in the initial determination. They also would require that physicians with appropriate expertise conduct reviews for appeals of denials that require the evaluation of medical facts, that are based on a determination that the treatment is not medically necessary, or are experimental or investigational. The only difference between the two bills on internal review is that S. 1052 would allow state internal review statutes that are determined to be substantially similar to those described in the bill, to apply in lieu of the federal provisions while H.R. 2563 would not.

Table 1. summarizes the timelines for initial decision making, as well as for internal and external review of requests for payment of claims as proposed under S. 1052 and H.R. 2563. The bills set timelines for routine and expedited reviews – those that occur before the service is provided to the patient. The timelines ensure that the patient does not wait too long for approval or denial at each stage of the review process. Expedited reviews may be requested by a patient (or their authorized representative) when the timeline for a routine determination would seriously jeopardize the life or health of the patient to maintain or regain maximum function. The bills also specify timelines for claims related to ongoing care, such

as when a patient is in a hospital and is requesting approval for a longer stay, and for care that has already been provided.

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 have evolved significantly since the 106th Congress where there were major differences between the bills especially with respect to the characteristics of the external review entities, standards for review (including the consideration of plans' medical necessity definitions), whether the decisions of the reviewers are binding, and whether other types of dispute resolution are allowed. Today the bills are mostly alike in those areas, with a few remaining differences. H.R. 2563 would not allow state external review laws to apply in lieu of the federal provisions, and further specifies that the external review panel: (1) would consist of three individuals, and (2) in a case involving a physician, all three reviewers would be physicians.

The two bills are the same with respect to the types of adverse coverage decisions that may enter into external review. They would require a system for the external review for benefits denied because they are determined by the plan to not be medically necessary, are investigational or experimental, or involve medical judgement. The bills would also allow insurers to require payment of a refundable filing fee of no more than $25. They would allow plans to condition the external review on the completion of an internal review except when internal review decisions do not meet specified time lines, and to waive the internal review process allowing claims to proceed directly to external review.

The bills include selection criteria for external reviewers designed to ensure adequate expertise of panel members, independence from the plan or issuer, as well as fairness. Both bills would also require the "applicable authority" to implement procedures to assure that the process of selecting the external review entity will not create incentives to bias the decisions of the entity. In addition, they would prohibit participants, beneficiaries, enrollees or the plan or issuer from determining or influencing the selection of the external review entity.

The bills would require the reviewing entities to screen claims to determine if they meet the criteria to proceed to external review. Reviewers would be directed to take into account whether the plan or issuer's decision is in accordance with the medical needs of the patient; 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 would not 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 be considered. The bills would require a de novo determination. The decision of the external reviewer would be considered to be binding.

S. 1052 and H.R. 2563 would authorize 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 appropriate Secretary[6] determines that there is a pattern or practice of repeated refusals to authorize benefits following external review. This penalty could not exceed the lesser of 25% of the value of benefits not provided or $500,000. In addition, both bills would allow the Secretary to assess a civil penalty against any plan of up to $10,000 for the plan's failure to comply with deadlines, to be paid to the participant or beneficiary if the determination of the external reviewers is not followed.

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 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 exception 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 that MCOs or

---

[6] The Secretaries of Labor and Health and Human Services would be jointly responsible for the execution of this Act. The bills require them to issue an interagency memorandum of understanding to ensure that (1) regulations, rulings, and interpretations issued by each relating to the same matter under the provisions of this Act (and any amendments) are administered so as to have the same effect at all times; and (2) there is a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

other entities that contract with an ERISA plan can 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, the current bills propose 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 providers' 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, which 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.[7]

---

[7] For more information on this issue, see CRS Report 98-286, *ERISA's Impact on Medical Malpractice and Negligence Claims Against Managed Care Plans*.

Remedies and Access to Courts: The bills. Provisions involving judicial remedies and access to courts have proved to be the most difficult to resolve during the debates in both of the chambers. While both the House- and Senate-passed bills allow some lawsuits to proceed at the state level and expand both the causes of action and the damages available at the federal level, the approaches approved by the House and Senate are significantly different. Compromise during conference negotiations will require addressing the two different approaches.

S. 1052 would allow state law causes of action involving medically reviewable decisions and would expand federal law causes of action for denials of benefits that are not based on medical decisions. This approach is based on the traditional authority of ERISA over the administrative duties of the plan's fiduciary. S. 1052 would create a federal cause of action for personal injury or wrongful death but only when a state cause of action is pre-empted by ERISA. It would also expand the remedies available under ERISA to include economic and non-economic damages in cases of personal injury or death but would not allow for exemplary or punitive damages. For state law claims, S. 1052 would not allow for punitive or exemplary damages when plans meet the requirements for the review and appeals process, with two exceptions: (1) when state law allows *only* for punitive or exemplary damages in cases of wrongful death, or (2) when the defendant can prove the plan's willful or wanton disregard for the rights or safety of others. Finally, S. 1052 would allow a civil assessment in any action of up to $5 million payable to the claimant if he can establish the bad faith and flagrant disregard on the part of the plan for the rights of its participants or beneficiaries.

H.R. 2563 would amend ERISA to create a federal cause of action if a designated decision maker fails to exercise ordinary care in making a determination for either an initial claim or for internal review, or fails to comply with the external review decision; if that failure is the proximate cause of personal injury or death. State courts would have concurrent jurisdiction over claims under this new federal cause of action, which means that state courts could hear those claims, the federal law would apply, but the state courts' procedural rules could be used to process those claims. The designated decision maker would be liable for economic and noneconomic damages. Noneconomic damages would be limited to $1.5 million and punitive damages of up to $1.5 million could only be awarded when benefits were not provided following an independent reviewer's determination that they should be provided. States may further limit those damages for federal law claims heard in state courts. Economic damages are uncapped.

Both bills include provisions intended to protect employers, by limiting federal or state causes of action against a group health plan, employer or plan sponsor unless such person or persons directly participated in the consideration of a claim for benefits and in doing so, failed to exercise ordinary care. The bills would shield employers from liability when those employers have "designated decision makers". Designated decision makers would assume all liability of the employer or plan sponsor. Finally, S. 1052 would prohibit any federal cause of action against a group health plan that is self-insured and self-administered by an employer or a multi-employer plan, for the performance of, or the failure to perform any non-medically reviewable duty under the plan.

Both bills generally require administrative processes (internal and external review) to be completed before a cause of action may be brought against any individual in connection with a denial of a claim for benefits. The bills allow, in federal causes of action, for a participant or beneficiary to seek injunctive relief before finishing internal and/or external review if he can demonstrate that completing the processes would result in irreparable harm. In state causes of action, S. 1052 and H.R. 2563 allow an exception to the exhaustion rule in cases where the external review entity fails to make a determination within the defined timelines. Finally, both bills would limit certain class action lawsuits and S. 1052 would limit attorneys' contingency fees.

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 or a higher number of uninsured individuals. Conversely, many of those who support the modification of ERISA 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. However, it should be noted that CBO cautioned that this estimate "depends on assumptions for which the supporting data are extremely limited or nonexistent." Recent CBO cost estimates for S. 1052 conclude the liability provisions would increase premiums by .8%.

Association Health Plans and Qualified Health Benefit Purchasing Coalitions

The House bill identifies two types of employer purchasing arrangements; Association Health Plans (AHPs) and Qualified Health Benefit Purchasing Coalitions (HBPCs). The purpose of such groups is to provide a mechanism for employers to band together to purchase insurance coverage for their employees. The concept of employers grouping together to purchase insurance is not new. 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 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.

AHPs. The House-passed bill establishes 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 most state insurance laws including 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), solvency standards, and pricing rules. Those AHPs with at least one self-insured offering would be required to meet the bill's reserve requirements and provisions for solvency.

Other major requirements include the following:

- AHPs must offer at least one insured health coverage option unless the self-insured plan existed on the date of enactment of the Bipartisan Patient Protection Act, or it does not restrict membership to one or more trades but whose eligible participating employers represent a broad cross section of trades and businesses or industries, or the plan covers eligible participating employees in one or more high risk trades that are listed in the bill.
- The association sponsoring the plan must have been in existence for at least 3 years and must be operated by a board of trustees with complete fiscal control and responsibility for all operations.
- Self-insured AHPs must meet 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 establishes an "Association Health Plan Fund" from which the Secretary of Labor (or applicable authority) would make (or authorize to the Secretary of Labor) payments to ensure continued benefits on behalf of AHPs in distress. The AHPF would be funded by annual payments made by AHPs. In addition, the Secretary of Labor would be required to report to Congress no later than January 1, 2006, on the effect of AHPs on reducing the number of uninsured individuals.

Advocates of purchasing groups look to them as a mechanism to extend coverage among the working uninsured by reducing the barriers that small employers face in providing coverage for their employees. AHP proponents argue that state consumer protections, benefits mandates, and solvency standards raise the

price of health insurance and that the resulting inflated cost of insurance is a major barrier that prevents small employers from sponsoring health benefits. Under current law, large employers that self-insure their employees are exempt from such state laws while small employers are not. The advocates say that by exempting association-sponsored plans from state laws, the playing field will be made more level between small and large employers.

Opponents of the AHP provisions as they appear in the House bill, on the other hand, raise the concern that the provisions create increased opportunities for risk segmentation – that AHPs will be able to offer plans to healthy groups at better prices leaving relatively more unhealthy people in the insured market and subject to states' laws. Opponents in the insurance industry as well as those representing consumers, are concerned that the additional risk segmentation could actually increase the number of uninsured by undermining the traditional insurance industry while substituting a market without the many protections that states have put into place over the last several decades. Some health policy analysts have staked out a middle ground arguing that association health plans are not likely to have a significant impact on the number of uninsured, but raise fears that establishing association plans as entities exempt from state consumer protections will bring back the fraudulent health insurance schemes and insecure entities that have plagued association sponsored plans in the past.

HBPCs. Qualified HBPCs are defined as private not-for-profit corporations that sell three or more (where feasible) unaffiliated health plans through licensed insurers to small employers in the service area. The House bill sets composition requirements for the boards of HBPCs, requires HBPCs to accept all eligible small employers, and prohibits HBPCs from assuming financial risk for plans. The bill would pre-empt state laws that impede the establishment and operation of a HBPC and that prohibit health insurance issuers from reducing premiums to reflect administrative savings for health insurance sold through HBPCs. Finally, it would provide tax advantaged status for funds provided by private foundations to HBPCs.

Legislative Options

The following bills to establish comprehensive patient protections have been introduced during the 107th Congress.

S. 6 (Daschle)
Patients' Bill of Rights Act. Introduced January 22, 2001. Referred to Senate Committee on Health, Education, Labor, and Pensions.

S. 283 (McCain, Kennedy and Edwards)
Bipartisan Patient Protection Act of 2001. Introduced February 7, 2001. Referred to Senate Committee on Senate Health, Education, Labor, and Pensions.

H.R. 526 (Ganske)
Bipartisan Patient Protection Act of 2001. Introduced February 8, 2001. Referred to House Committees on Education and the Workforce and Energy and Commerce.

S. 872 (McCain, Kennedy and Edwards)

Bipartisan Patient Protection Act. Introduced May 14, 2001 and placed on Senate Legislative Calendar under General Orders on May 15, 2001.

S. 889 (Frist, Breaux and Jeffords)

Bipartisan Patients' Bill of Rights Act of 2001. Introduced May 15, 2001. Referred to Senate Committee on Health, Education, Labor, and Pensions.

H.R. 2563 (Ganske)

Bipartisan Patient Protection Act. Introduced July 19, 2001. Referred to House Committees on Education and the Workforce, Energy and Commerce, and Ways and Means Passed House August 2, 2001.

S. 1052 (McCain, Kennedy and Edwards)

Bipartisan Patient Protection Act. Introduced June 14, 2001. Referred to Senate Committee on Senate Health, Education, Labor, and Pensions. Passed Senate June 29, 2001.

H.R. 2315 (Fletcher)

Patients' Bill of Rights Act of 2001. Introduced on June 26, 2001.

Additional Relevant CRS Reports

CRS Report RL30978, *Patient Protection During the 107th Congress*: *Side by Side Comparison of House and Senate Bills*

CRS Report RS20868, *Employer Liability Provisions in Selected Patient Protection Bills*

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 Report 98-286, *ERISAs 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*