



# **A Guide to the Federal Patients' Bill of Rights Debate**

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## Introduction

Managed care's principal goals are to deliver quality care and at the same time curb health care costs by reducing overuse of services. Some are concerned, however, that the cost control strategies used have resulted in burdens on consumers and providers and led to some enrollees not receiving needed care. This concern has given rise to managed care consumer protection legislation — also known as "Patients' Bill of Rights" (PBOR). Among other things, these laws require clear disclosure of plan rules, promote access to the emergency room and specialists for certain conditions, limit the ability of managed care organizations to deny care in certain circumstances and set up procedures for appealing plan decisions and resolving disputes. The U.S. Congress has debated how to structure such protections since 1995. Last year, the 106<sup>th</sup> Congress deadlocked in its consideration of a patients' bill of rights.<sup>1</sup>

With the new 107<sup>th</sup> Congress, earlier bills must be reintroduced and debated anew. In June, the Senate passed the "Bipartisan Patient Protection Act" (S. 1052) sponsored by Senators McCain (R-Ariz), Kennedy (D-Mass) and Edwards (D-N.C.) (the "Senate bill"). The House of Representatives followed with passage of its own bill (H.R. 2563) in early August (the "House bill"). The House bill, sponsored by Representatives Ganske (R-Iowa), Dingell (D-Mich) and Norwood (R-Ga.) includes an amendment reflecting substantial negotiations between Mr. Norwood and the Bush Administration. Further, President Bush outlined his principles for patient protections and has indicated opposition to the Senate bill.<sup>2</sup> Representatives from the House and the Senate will now to seek to resolve the differences between their bills in a conference committee.

This guide explores key issues in this debate. The first section gives an overview of private health insurance market regulation and its relationship to the patient protection debate. The second section examines areas of consensus in the patient protection debate relating to such issues as access to care and information, scope of coverage and preemption. And, the final

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<sup>1</sup>While consensus on a large number of issues were reached in previous Congresses, a lack of consensus on critical substantive issues has frustrated the passage of a bill. In the 106<sup>th</sup> Congress, the U.S. Senate passed S. 1344 on July 14, 1999. The U.S. House of Representatives passed H.R. 2990 on October 7, 1999. Upon receipt of the House bill in its chambers, the U.S. Senate substituted the contents of H.R. 2990 with S. 1344. The version of the bill passed by the House is thus labeled H.R. 2990.EAS and the Senate's version is labeled H.R. 2990.RDS. Because Congress was unable to reconcile the differences between these bills in conference committee, no final legislation was ultimately produced in the 106<sup>th</sup> Congress. For a side-by-side comparison of these bills, see Phyllis Borzi and Sara Rosenbaum, "A Brief Overview of Major Features of Pending Patient Protection Legislation: House and Senate Versions of H.R. 2990," (Kaiser Family Foundation May 2000). The document can be found on the Foundation's web site ([www.kff.org](http://www.kff.org)).

<sup>2</sup> On February 7, 2001, the White House issued two documents: a Letter from the President to the Speaker of the House of Representatives and the Senate Majority Leader and Principles for a Bipartisan Patients' Bill of Rights. In these documents the President supports federal patient protections for all Americans but has expressed concerns about the scope of liability reform. Comments on the bills can be found in "Remarks by the President in Meeting with House Leaders on Patients' Bill of Rights" June 27, 2001 (The White House Office of the Press Secretary).

section provides a discussion of the key differences between the House and Senate bills — in particular, how they handle external review of health plan decisions and liability.

## **Overview of Private Health Insurance Market Regulation**

To appreciate many of the issues in the patients' rights debate, it is important to understand the different ways people get private health insurance and how that insurance is regulated.

Private health insurance is provided on either a group or individual basis. About 160 million people get group health insurance through an employer, while about 16 million people buy it directly from an insurance company (e.g., because they are self-employed or don't work for an employer that offers coverage). When employers sponsor coverage, they do so on either an "insured" or "self-funded" basis, with 51% of workers in self-funded arrangements.<sup>3</sup> Under an insured arrangement, the employer buys coverage by paying a premium to a private insurer, and the insurer accepts the financial risk for paying the cost of claims. Under a self-funded arrangement, the employer pays claims directly – or, as is usually the case, contracts with a company to pay the claims and administer the coverage – and essentially acts in the role of the insurer. Many employers – particularly larger ones – offer multiple coverage options to employees (e.g., a PPO option and one or more HMO options), and some of those options may be "self-funded" while others are "insured."

These distinctions between types of coverage arrangements are important because they are regulated in very different ways under current federal and state laws:

- Individual insurance purchased directly by consumers is regulated almost entirely by states. For example, states can require insurers to include certain benefits in the policies they sell. Subject to state restrictions, individuals can also sue their health plans for damages if benefits are denied inappropriately.
- Regulation of coverage sponsored by employers is subject to a complicated combination of federal and state laws. A key part of this is the federal Employee Retirement Income Security Act of 1974 (ERISA). ERISA completely exempts self-funded employer plans from state regulation, meaning that patient protections passed by states do not apply to these plans. For insured plans offered by employers, states can indirectly regulate them by regulating the insurer itself (as they do for individual insurance). Even so, ERISA still preempts (i.e., supersedes) state law in a number of areas, particularly around the rights and remedies that consumers have when a health plan denies coverage for a particular benefit (e.g., the right to sue for damages). In these circumstances, ERISA's preemption of state law applies to all types of plans offered by employers, whether they are insured or self-funded.

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<sup>3</sup> Kaiser Family Foundation and Health Research and Educational Trust, Employer Health Benefits Survey, 2000.

(For ease of discussion, the term ‘health plan’ will generally be used to refer both to ERISA health plans and to insurers, even though they are in fact separate entities.)

While most states have enacted a range of patient protection laws over the past decade that apply to health insurers, ERISA contains very few comparable provisions.<sup>4</sup> As a result, enrollees of self-funded plans lack the protections available to enrollees of insured plans. The proposals under debate in the Congress would eliminate this disparity by establishing minimum protections for all Americans, no matter what type of coverage arrangement they have.

The current mix of federal and state laws also leads to some important areas of legal ambiguity, where it has been unclear whether authority rests with the federal ERISA law or with states. For example, 39 states and the District of Columbia have established “external review” systems, where consumers can appeal certain health plan denials to independent medical experts. States clearly do not have the authority to apply these external review systems to self-funded employer plans. However, while states have generally applied the external review protections to insured employer plans, a number of legal cases pending in the courts challenge their right to do so under ERISA. In these cases, health plans argue that external review systems are not part of normal state regulations governing private insurance companies – which are permitted under ERISA – but rather that they conflict with ERISA’s rules governing consumer remedies when a health plan denies benefits. The United States Supreme Court recently agreed to review a case — *Rush Prudential HMO v. Moran* (No. 00-1021) — that held a state’s external review law was not preempted by ERISA.<sup>5</sup> Notwithstanding the Supreme Court’s actions, new federal legislation that guaranteed all consumers the right to external review – which is included in all major proposals considered by Congress – would clear up this legal confusion.

Federal action is also needed if the legal options for enrollees who have been injured because of a health plan’s decisions are to be clarified and expanded, as most of the Congressional proposals seek to do. Presently, enrollees of ERISA plans, whether insured or self-funded, have very limited legal remedies available to them. While they can technically sue a health plan over denied benefits, these enrollees can only recover the denied benefit itself (or the cost of the benefit). They cannot recover additional related medical costs or lost wages, pain

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<sup>4</sup> In 1996, Congress did pass a few laws of limited application — the Mental Health Parity Act of 1996 and the Newborns’ and Mothers’ Health Protection Act of 1996. The Mental Health Parity Act requires group health plans to provide parity in its application of lifetime and annual dollar limits between mental health benefits and medical/surgical benefits. The law sunsets for benefits received on or after September 30, 2001 absent further Congressional action. The Newborns’ and Mothers’ Health Act restricts health plans’ ability to limit coverage of benefits for hospital stays connected to childbirth to less than 48 hours after vaginal delivery or 96 hours after delivery by caesarean section.

<sup>5</sup> In *Moran v. Rush Prudential HMO*, 230 F.3d 959 (7<sup>th</sup> Cir 2000), the Seventh Circuit of the U.S. Court of Appeals held that ERISA did not preempt the state’s external review law. Therefore, the health plan should have complied with the external reviewer’s decision that surgery for the enrollee was medically necessary. In contrast, in *Corporate Health Insurance, Inc. v. Texas Dept. of Ins.*, 215 F.3d 626 (5<sup>th</sup> Cir. 2000), the Fifth Circuit of the U.S. Court of Appeals held that ERISA preempted the state’s external review law. If federal legislation is not enacted, the Supreme Court’s decision could clear up the conflict between these court decisions.

and suffering, or “punitive” damages. In contrast, enrollees covered through non-ERISA health insurance coverage can file a lawsuit in state court and recover state remedies that may include broader damages. In some states, state and local government workers covered under their public employer’s group plan also can sue their plans (since they are not covered by ERISA). Further complicating this picture, nine states have enacted liability laws that allow enrollees in insured plans to sue for personal injury and wrongful death in state court, generally in response to decisions by plans that concern the “medical necessity” of a treatment. It is currently unclear how the federal courts will respond to this state activity, though courts have generally permitted suits against health plans over poor quality medical care under “common law.”

### **Areas of Consensus in the Federal Patient Protection Debate**

Though there remains disagreement over details, many of the elements contained in the House and Senate bills are similar. There is consensus, for example, that:

- Health plans should be required to provide information to enrollees about how the plan operates;
- Enrollees should have access to out-of-network specialists — those who do not participate in the network of the enrollee’s plan — when the plan’s network does not include an appropriate specialist;
- Health plans should be required to pay for emergency care provided to enrollees who reasonably believe that they need immediate medical care because of their symptoms (called the “prudent layperson” standard);
- Enrollees who are in an ongoing course of treatment should be able to continue receiving care from a physician or other provider for a limited period of time after the provider leaves the plan’s network;
- Health plans must have in place internal processes to review denials and other decisions;
- Federal protections should apply to all health plans whether they are self-funded or insured;
- State laws are not preempted if they substantially meet or exceed federal standards (except in the areas of internal and external review).

## **Key Differences in the Federal Patient Protection Debate**

However, while a substantial degree of consensus has been reached on some of the issues that were contentious in the past, there are issues that still remain controversial, as reflected by the key differences in the House and Senate bills. This section will examine in more detail these issues — external review and expanding the rights of consumers to sue their health plans.

*External Review: How should an independent system of review for enrollees who seek to challenge their health plan's decisions be structured?*

When insured health plans make a decision unfavorable to an enrollee, such as denying coverage for treatment, state laws now allow the enrollee to appeal the decision to the plan. There is concern, however, that a conflict of interest exists when health plans assess their own decisions. As a result, most states have also established an independent external review process to handle appeals. Appropriate medical experts and other professionals conduct this independent process. In most states, it is binding on the health plan and available once the enrollee exhausts the health plan's internal process of review.

There is strong support at the federal level for external review, and both the Senate and the House bills allow enrollees to appeal to an external reviewer whose decision is binding on the health plan. In addition, the Bush Administration favors a binding independent review process.

Both bills limit the scope of external review to clinical judgment issues such as medical necessity denials or denials of coverage for recommended treatment that it considers experimental and investigational. In addition, the Senate and House bills extend eligibility for external review to health plan decisions that require the use of medical judgment or facts to decide if a benefit is covered by the health plan. Further, the proposals make external review immediately available to enrollees if a plan fails to resolve their concerns in a timely manner during the internal review process. They also make clear that the reviewer is not limited to the plan's definition of medical necessity. Instead, the reviewer must also consider the evidence independent of the plan's decision and definition of medical necessity. Additionally, both bills require regulators to set standards to guard against either the health plan or enrollee influencing the selection of the external review entity. They also require that regulators audit a sample of decisions to assess whether there has been bias in the decision-making process.

Nonetheless, there are some differences in the details between the bills. The House bill requires external review decisions to be made by a panel of 3 independent medical reviewers, while the Senate bill envisions one or more independent reviewers deciding on appeals. More notably, while the House bill only allows the review panel to uphold or reverse a decision, the Senate bill allows the external reviewer to modify a health plan's decision as well.

Possibly the most important difference between the two bills lies in how federal law interacts with rules in the 41 states (including the District of Columbia) that already have external review programs for insured health plans. The House bill preempts (i.e., overrides) state rules governing appeals both internal and external to group health plans, meaning that states cannot retain existing programs (regardless of whether or not they are stronger than the federal protections). Under the Senate bill, federal law establishes minimum standards, but permits states to go further in establishing their own rules and programs.

***Liability: Should consumers be able to sue all health plans? If so, what standards should apply and what damages should be available?***

Currently, the federal patient protection debate is focused on another form of recourse for enrollees — access to the courts. Specifically, Congress has been considering the extent to which enrollees should have access to the courts when they believe that their health plan’s failure to authorize or provide needed care contributed to personal injury or death, and what legal damages should be available to them. Policymakers have also been considering whether enrollees should have access to federal or state courts. There has been a sharp debate on this issue, and it has been one of the key reasons why passage of a federal law has stalled.

The liability issue arises because enrollees of ERISA plans offered by employers, whether self-funded or insured, currently have very limited legal remedies available to them. Consequently, should they become injured, disabled or die as a result of a plan’s denial of coverage for medical care, enrollees have traditionally had little recourse to the courts.<sup>6</sup>

Organizations representing employers and health plans are generally opposed to any federal law that would expand enrollees’ legal remedies under ERISA. They argue that external review provides sufficient independent recourse for enrollees, and that an opportunity to sue will raise health insurance costs because health plans will be required to pay legal settlements and will be more likely to approve coverage for care that is not necessary in order to avoid

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<sup>6</sup> In recent years, there has been some movement in how the courts are interpreting ERISA. The courts, for instance, have recently begun to create distinctions between types of cases. If the case involves an allegation that a plan provider has been negligent (malpractice) then the courts have ruled that ERISA generally does not preempt state law and the case can proceed in state court. If the case involves a benefit question, however, the plaintiff’s case is likely to be resolved in federal court. But whether such a case is resolved in state or federal court, federal standards apply. As a result, they are subject to ERISA’s limitations on remedies. This distinction has allowed some lawsuits to proceed, although it is often difficult to distinguish neatly between these categories.

In addition, some courts have been interpreting ERISA more broadly, allowing suits in state courts. Moreover, state legislatures have begun explicitly outlining or expanding the grounds on which enrollees can bring suit in state court. Traditionally, enrollees suing in state court have done so under state right to sue laws and common law. Several states have recently enacted legislation that would specifically allow enrollees in insured plans to sue for personal injury or wrongful death in state court. The nine states that have enacted liability laws are Arizona, California, Georgia, Maine, New Jersey, Oklahoma, Texas, Washington and West Virginia. Nevertheless, these efforts toward a broader interpretation of ERISA are neither comprehensive nor evenly applied by the courts. It is currently unclear how the federal courts will respond to this state activity.

potential lawsuits. Further, they argue that the threat of litigation will cause employers to drop health insurance coverage or weaken the health benefits that they provide.

Advocates for a broad right to sue, on the other hand, argue that it is unfair not to hold health plans responsible for injuries they cause. They question why plans and insurers should be exempt from the same kind of liability to which other commercial enterprises (and physicians) are subject, and argue that liability will make plans think twice before denying medically necessary care. Further, they note that public sector employee benefit programs, where a right to sue already exists, have not experienced the substantial cost increases that plans and insurers suggest will be the consequence of right to sue legislation.<sup>7</sup> Moreover, these advocates argue that relatively few enrollees appeal health plan decisions at the state level, and even fewer would be likely to sue plans after exhausting both internal and external review processes.

Liability reform provisions are included in both the Senate and House bills, and the President has stated that he supports a limited right to sue. However, there are significant differences between the proposals. Among the issues are:

***Under what circumstances can an enrollee sue a health plan?*** Traditionally, enrollees suing in state courts have done so under state right to sue statutes or state common law (that is, rules created through judicial decisions instead of statutes). But the ability for recourse in state courts has been significantly limited for enrollees covered by ERISA plans. Both the House and Senate bills define a cause of action against health plans in state court for lawsuits involving medically reviewable decisions (that is, decisions involving medical judgment). Generally, enrollees can sue for personal injury or death resulting from a health plan decision only after they have exhausted their internal and external appeal rights. The Senate bill permits these suits over medical judgments to proceed in state courts under state statutes or common law. However, the House bill would permit such lawsuits in state courts only under new federal rules governing burden or proof and damage limits (as described below).<sup>8</sup> This could have the result of putting new federal limits on lawsuits against health plans over poor quality medical care that are already proceeding under existing state laws.

Both the House and Senate bills also provide a cause of action for enrollees in federal court for benefit decisions (such as whether a service is a covered item under the health plan's contract) if they have suffered a personal injury or death because the health plan did not exercise ordinary care in making a determination.<sup>9</sup>

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<sup>7</sup> Coopers & Lybrand, Impact of Potential Changes to ERISA: Litigation and Appeal Experiences of CalPERS, Other Large Public Employers and a Large California Health Plan (Kaiser Family Foundation June 1998).

<sup>8</sup> Both bills shield employers who sponsor health plans against liability if they were not involved in health plan decisions that resulted in patient harm. They allow an employer's liability to be assumed by a "designated decisionmaker" (e.g. a health insurer or third party administrator) who has exclusive authority to make decisions.

<sup>9</sup> The House bill, however, also allows the enrollee to bring such a case in state court but does not prevent it from being removed to federal court.

***What burden of proof must enrollees meet to prevail in a suit?*** While the bills provide similar causes of action, the enrollee must meet a higher burden of proof under the House bill than under the Senate bill in two areas:

- If an independent review panel upholds a plan’s decision to deny a claim for benefits, the burden of proof under the House bill would be on the enrollee to demonstrate through clear and convincing evidence that the plan did not exercise “ordinary care” in making its decision. Under the Senate bill, the burden of proof would be as it more commonly is in civil lawsuits (e.g., that the enrollee needs to show that it is more likely than not that the plan’s negligence caused the harm called the preponderance of the evidence standard).<sup>10</sup>
- While the House bill requires enrollees to demonstrate in court that a health plan’s actions were *the* proximate cause of personal injury or death, the Senate bill requires only that the health plan’s actions were only *a* proximate cause, a much easier standard to meet.

***What damages should enrollees be able to recover?*** The proposals also vary significantly on the damages that enrollees may be able to recover.

The debate over damages has focused primarily on whether enrollees will be able to recover punitive damages and whether there will be limits, or caps, on the economic damages recoverable under state or federal law.

Under the Senate bill, for instance, there is no limit on economic or non-economic damages in

federal courts. However, a statutory limit of \$5,000,000 in civil penalties is established for federal suits where the health plan’s actions were in flagrant disregard of the enrollee’s rights and a proximate cause of the enrollee’s personal injury or death. This assessment is analogous to punitive damages. For cases pursued in state court, the damages available are generally determined in accordance with state law. There are, however, limitations on when

#### LEGAL DAMAGES

There are several forms of damages that an enrollee might recover: **actual economic damages**, **non-economic damages** (e.g. pain & suffering) and **punitive damages**. Under ERISA, an enrollee can only recover the cost of the benefit denied (a subset of economic damages). The House and Senate bills allow for a broader range of damages to varying degrees.

**Actual economic damages** include medical costs, lost wages and other expenses incurred as a result of the injury or death (such as childcare).

**Non-economic damages** compensate for pain and suffering and other non-financial losses.

**Punitive damages** are awarded to discourage egregious behavior and punish a plan for engaging in such behavior.

<sup>10</sup>There are a few state liability laws that place a higher burden on enrollees. For example, the House bill’s provision is similar to Georgia’s liability law, in which there is a rebuttable presumption in favor of the health plan if it wins the external review decision. And, West Virginia’s liability law only allows an enrollee to sue if the health plan does not comply with the external review decision. Patricia Butler, J.D., Dr.Ph., Key Characteristics of State Managed Care Organization Liability Laws: Current Status and Experience (Kaiser Family Foundation August 2001).

punitive damages may apply under state law (e.g., punitive damages are available if there is clear and convincing evidence that the health plan's actions were made with willful and wanton disregard when making a medically reviewable decision and those actions were a proximate cause of the enrollee's personal injury or death).

In the House bill, a far more limited approach is proposed. While this proposal places no limits on actual economic damages, it places a \$1,500,000 cap on non-economic damages. It also allows no punitive damages, except in the presumably rare instance that an external review panel reverses a health plan's decision to deny coverage and the plan does not comply with that decision. In this case, up to \$1,500,000 in punitive damages are permitted. The bill permits states to apply lower limits on non-economic and punitive damages than the federal law, but not higher ones.

## **Conclusion**

Over the past several years, significant progress has been made in developing consensus on the key elements of federal patient protection legislation, with some real movement toward agreement on controversial issues such as external review and scope of coverage. There remain, however, significant areas of debate. Most notably, policymakers continue to struggle with the practical effects of liability reform. It is in this area where the Senate bill and House bill differ substantially, over such issues as: the circumstances under which enrollees can sue, the burden of proof they must meet, and the damages available to them if they win in court. In addition, while both bills seek to provide significant deference to states that wish to enact stronger protections, a key difference between the bills remains on whether state laws governing internal and external appeals will be preempted by federal law. How these issues are resolved may have important implications for the ultimate outcome of the debate and the nature of the protections finally enacted, as well as for the relationship between federal and state regulation.

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