

January 2000



ERISA Health Plan Liability: Issues and Options for Reform

***Preface**—As the year 2000 begins, congressional conferees face the task of resolving differences between “patient protection” bills passed by the House of Representatives and the Senate. In order to discuss the principal issues facing policymakers and options for reform, this paper begins by describing problems raised by the federal law governing private-sector employee health plans from a consumer perspective. It discusses approaches proposed by the federal regulators and the House and Senate to give consumers greater ability to challenge health plan decisions, focusing in particular on issues that arise should Congress decide to give health plan participants increased ability to sue for damages under state laws. Employee health plan liability then is explored from the perspectives of physicians, employers, and insurers with regard to activities such as negotiating the terms of contracts, improving the general quality of medical care, assigning liability for medical errors, and determining who has the power to decide which procedures and technologies are medically necessary. Finally, possible approaches to health plan liability—ranging from contract law to tort law notions of liability—are presented in the context of the bills passed by House and Senate in 1999.*

Perhaps no issue facing Congress today has been more divisive and difficult to resolve than reforming the legal remedies available to people in employment-based health plans who have been injured as a result of medical and administrative decisions made by plan sponsors, administrators, insurers, and medical providers. Created in the era of unfettered fee-for-service medicine, the current legal structure largely insulates group health plan sponsors as well as plan administrators and insurers under contract with them from legal liability for coverage decisions even as many have exerted greater influence over medical professionals in order to contain costs and promote efficient practices. Medical professionals complain that, while they have less control over how they practice medicine, they face exposure to malpractice suits at the same time that managed care organizations (MCOs) that sometimes influence them to stint on care are often legally insulated from liability. Plan sponsors and managed care firms argue that exposing them to increased liability will end up raising premiums, both directly by lining the pockets of trial lawyers and indirectly by hamstringing their ability to root out inefficient medical practices, thereby causing more employers stop offering health coverage and increasing

the number of uninsured Americans. Consumer advocates argue that people in employer health plans who are arbitrarily denied coverage or medical treatments promised in their health plan documents have inadequate legal remedies to enforce those promises. Furthermore, they point out, managed care companies and group medical practices competing for business (and often facing the expectations of shareholders as more convert to for-profit status) have strong incentives to contain costs. Finally, many courts have declared that current law offers inadequate legal protection from the consequences of decisions made by health plans, even in cases where those decisions were erroneous, negligent, or malicious; yet, the courts say, there is little they can do because Congress has bound their hands.

ERISA AND ITS EFFECTS

At the heart of the federal debate over restructuring the legal liability for health care provided through private-sector employee plans is the law governing such plans: the Employee Retirement Income Security Act of 1974 (ERISA).¹ Enacted in response to highly publicized incidents of fraud and mismanagement in pension and employee benefit plans, ERISA created a detailed regulatory scheme to ensure that employees receive pension benefits promised to them by private-sector employers and unions. In order to facilitate the administration of pension and benefit plans and remove barriers that otherwise might deter sponsors from offering them, Congress preempted states from enforcing laws that relate to these plans. In contrast to its treatment of pensions, ERISA set down very few regulatory requirements regarding employee benefits such as health plans (although more have been added in recent years). Furthermore, in many instances where ERISA subjects health plans to substantive requirements, such as its civil enforcement provisions, they are arguably geared toward resolving disputes over pension benefits and do not always fit the needs of health plan participants. With its roots in trust law (as well as labor law), ERISA’s claims appeal procedures and civil enforcement mechanisms are aimed at making sure that plan fiduciaries handle funds prudently over long time periods and deliver them to participants. Most of its remedies are targeted at safeguarding “plan” assets for the benefit of participants collectively as opposed to protecting the interests of individuals seeking to access services, such as medical care, covered by the plan. The framers of these rules did not anticipate that ERISA would end up becoming a major feature of health care law and would influence the shape of the health care delivery system.

The protections available to group health plan participants involved in disputes with health plans can be viewed as a continuum: first involving internal review, then external review, and finally judicial review. ERISA currently has no requirement for external, independent review of a plan denial of a benefit, including medical treatment denied under a utilization review program. A plan participant appealing a denial must go through an internal grievance process before being able to access the courts. The law states that every ERISA plan shall “afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.”² Under regulations further defining ERISA’s claim procedure, the plan official must make a decision on a claim within a reasonable period of time (but in no event later than 90 days) after receiving the claim for benefits.³ An extension of up to 90 more days is available for “special circumstances.” The plan may establish a reasonable time period of no less than 60 days in which a claimant may request an appeal. According to the regulations, an appeal decision is supposed to be made promptly—not later than 60 days after the plan’s receipt of the request for review or, if an extension is required due to special circumstances, not later than 120 days after receipt of a request for review. Despite the maximum length of time allowed for a claim decision under the regulations, most employer plans process claims far more expeditiously, according to employer representatives. A denial must be in writing and must detail the reason the claim was denied, including references to the provision of the plan supporting the denial.

Once an ERISA plan’s internal grievance and appeals process is exhausted, legal remedies available to consumers in court are narrow, compared to state law remedies. The law permits participants to seek recovery of benefits in a federal court but does not allow them to redress unreasonable delay, fraud, malice, emotional distress, or other harms.⁴ Although they can recover the denied benefit, participants cannot recover actual out-of-pocket costs, such as additional medical expenses or lost wages incurred as a consequence of denied coverage. Perhaps most significant, given the proliferation of preauthorization and concurrent review of medical care as common features of health plans along with financial and other incentives for physicians to practice more efficiently, ERISA provides no remedy for injuries caused by denials of treatment or payment, other than eventual provision of the benefit promised in the plan documents.

The Department of Labor (DOL), which administers ERISA, recently has argued that Section 502⁵ of the act permits a plan participant or his or her estate to seek restitution of savings garnered by a health insurer as a consequence of wrongfully withholding medical treatments in breach of its fiduciary duties. The Ninth Circuit Court of Appeals, however, recently held that such restitution was not an appropriate equitable remedy under ERISA.⁶ (ERISA plan participants and other parties also may sue plan administrators or other fiduciaries for breaches of fiduciary duty under Section 404; the ability to pursue such actions serves important functions, including setting future policy for a plan’s administration, but assets recovered under such suits typically are remitted to the plan, not to individuals themselves. As with Section 502 actions, individuals pressing suits for fiduciary breach under ERISA cannot collect awards for damages.)

Federal courts of appeals are divided on the issue of whether ERISA preempts state lawsuits against MCOs challenging the quality of the medical care provided by their contracting physicians.⁷ A growing number of federal courts hold that ERISA does not prohibit patients from suing an MCO for vicarious liability of physicians who are its agents. Thus, under the current state of the law, if a court concludes that a person was injured by a substandard medical decision, the plaintiff can sue the clinician who made the decision as well as the MCO, if it employs the clinician or exercises substantial control over the clinician’s practice. But if the case is characterized as a coverage decision, ERISA confines plaintiffs to recovering benefits *per se*.

In *Corcoran v. United Healthcare*,⁸ for example, the court characterized a plan’s decision to deny hospital care to a woman with a problem pregnancy (and instead to supply several hours of daily home nursing care) to be a determination about covered plan benefits. When the fetus died, allegedly as a result of the mother’s not being in a hospital setting, she could not recover damages for this loss. As a practical matter in today’s market, it is often difficult to determine where coverage decisions end and medical acts and omissions begin or to what degree they might overlap. In any event, an argument can be made that in many instances a denial of coverage means that a person will not receive the medical services at issue, as many procedures are too expensive for an individual to pay out of pocket.

Many argue that the regulations governing ERISA’s claims process, which were promulgated in 1977, are antiquated as far as health plans are concerned. When the regulation was developed, disputes over benefits

almost always involved payment by the plan after services had been rendered. Managed care practices, such as preauthorization of medical services and capitation of physician services, were not widely used.⁹ Today, many disputes involve denial of medical care itself. The length of the grievance process alone may create a barrier for participants needing immediate medical attention who are involved in disputes with plans over benefit denials. Many of the suits that go to court are brought by members of a deceased patient's family. A hypothetical "worst-case scenario" illustrates the problem from the participant's point of view: A patient needs an expensive surgery. An insurer undergoing solvency problems denies the request on the grounds of medical necessity in order to delay incurring a major expense. The patient dies by the time the case goes to court. The court rules that the patient was entitled to the surgery under the contract, but the patient is no longer alive. The family has no way to collect damages both to compensate for wrongful death and to deter company officials from engaging in similar behavior in the future.

After the limitations of ERISA's claims procedures and remedies gained attention in the context of growing consumer discontent with managed care, the Clinton administration established the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. The commission concluded that all consumers should have a "right" to a fair and efficient process to resolve disputes with health plans, providers, and institutions serving them, including a rigorous system of internal review and an independent system of external review.¹⁰ The commission also recommended that both the internal and external appeals systems should resolve disputes in a timely manner, with expedited consideration for decisions involving emergency or urgent care consistent with time frames that the Medicare program requires of its risk contractors, and that external reviews be conducted by appropriately credentialed professionals who were not involved in the initial decision and have no conflict of interest. The commission declined to make recommendations on whether to expand ERISA plan participants' legal remedies but noted that the issue needed to be addressed.

Since the quality commission issued its recommendations two years ago, the administration and congressional Democrats, led by Sen. Edward M. Kennedy (D-Mass.) and Rep. John D. Dingell (D-Mich.), have vigorously advocated giving ERISA plan participants greater legal remedies as well as the rigorous type of

internal and external review requirements recommended. President Clinton recently endorsed the compromise bill introduced by Dingell and Rep. Charlie Norwood (D-Ga.) that includes expanded remedies for participants and beneficiaries covered by ERISA plans. While amenable to increased internal and external review requirements, Republican leaders in both houses of Congress have opposed added court remedies. House Republicans, who hold a slim majority, were split on the liability issue, however. Norwood, a dentist, and Rep. Greg Ganske (D-Iowa), a surgeon, are among the strongest supporters of patients' rights legislation in the House, and they brought along enough of their Republican colleagues to ensure the expanded court remedies were included in the House bill over the objection of the leadership. The House Republican leadership, in turn, has excluded Norwood and Ganske from the conference committee that will attempt to reconcile differences with the Senate on the patient protection legislation.

CONSUMER ISSUES

From a consumer perspective the appeals procedures and court remedies available under ERISA present a series of intertwined problems, including the following:

- *Timeliness*—The time frames afforded by ERISA's internal review requirements and legal remedies can have damaging consequences, even if a consumer or his estate ultimately prevails in court in claiming a denied benefit.
- *Lack of independent administrative structure to assist consumers in resolving coverage disputes*—As noted above, ERISA contains no requirement for independent administrative review of health coverage disputes relating to any issue (for example, interpretation of contract language or disputes over medical necessity, access to specialists or medical facilities, or simply determination of whether promised benefits were arbitrarily or wrongfully denied).

If an independent review process were established, a key issue that arises is what qualifies as an appealable benefit denial. For example, if the process limited denials that could be appealed to an independent reviewer to matters pertaining to medical necessity, many denials that might result in harm could be unappealable, even in cases that actually involved medical necessity but were characterized as something else.¹¹ (The Senate bill would confine external review to medical necessity and experimental decisions, while under the House bill any decision that

involved a medical judgment could go to external review.) Therefore, the issue of who decides which benefit denials might qualify for appeal to an independent reviewer is critical. Some state regulators administering external review programs and the administrator of the review organization used by the Medicare risk program have pointed out that, for such a system to work, there needs to be a broad definition of appealable items. They and others also say that consumers need assistance in sorting out and framing legal and medical issues.

- *Lack of legal remedy to enforce plan promises and contracts made to uphold those promises*—As described above, under the current system, if the ERISA appeals process and ensuing court case eventually succeed in overturning the plan denial, but the patient’s need for the disputed benefit no longer exists due to his or her death or medical deterioration, the participant has no legal remedy.
- *Procedural impediments*—In order to sue for equitable relief, an ERISA plan participant first must exhaust the internal appeal process. Plan participants, who may be ill during the appeals process, carry a heavy burden of proving that plan administrators have ruled improperly in making a benefit denial. When a participant sues for equitable relief in federal court, the court generally will not accept new medical evidence, but rather will rule whether the plan fiduciary’s decision to deny a benefit was “arbitrary and capricious,” given the information available at the time of the decision. Under this standard, a person seeking to overcome a denial of a treatment on the basis that it was not medically necessary could not introduce the testimony of the world’s leading authorities in the relevant medical specialty if such evidence had not been introduced in the plan appeal procedure.

Because a court may or may not award attorneys’ fees to prevailing plaintiffs in such cases and because damage awards are not available, lawyers are often reluctant to take them on, making it difficult for people to find representation. In addition, courts may not award attorneys’ fees for time spent representing a participant in the claims process leading up to the legal proceeding.¹²

- *Lack of standards governing what is promised in ERISA health plans, including definition of what is medically necessary*—Most consumers are ignorant of the exclusionary language in health plan documents and the details in contracts with insurers and

providers controlling their access to benefits promised. Plans usually reserve the right to deny coverage of treatments that are not medically necessary or are experimental. Health plans currently define medical necessity in a wide variety of ways.

Some analysts have advanced the case that federal standards are needed to ensure that plan denials on the grounds of medical necessity must be justified on the basis of expert medical opinion and scientific findings, where such evidence is available.¹³ Furthermore, they argue that standards of medical necessity in ERISA health plan documents should never be decided arbitrarily—that is, at the sole discretion of plan fiduciaries, as would be possible under some legislative proposals.¹⁴

PROPOSED CLAIMS REGULATIONS

The Labor Department is in the process of revamping its claims procedure requirements but has yet to issue a final rule. On September 9, 1998, DOL issued proposed regulations that substantially revise the minimum procedural standards for handling the internal appeals process for benefit claims under ERISA-governed employee benefit plans. The proposed regulations create new maximum time frames for decision making; new disclosure requirements; new notice requirements; new standards of review on appeal; consequences for failing to establish and follow reasonable claims procedures; and other changes.¹⁵ For urgent claims, plan administrators would have to make initial coverage decisions within 72 hours. Employers and insurers have expressed many concerns about the proposed regulations, including concerns about added costs, increased complexity, and difficulty of administration.

The proposed regulation uses the term “adverse benefit determination” instead of “denial of a claim.” The broader concept is important for participants in group health plans because it encompasses not only refusals to pay for services but also terminations of or refusals or denials of treatment by a utilization review organization and refusals to precertify coverage under a plan. In addition, the proposed regulation treats as adverse benefit determinations plan decisions that a benefit is not medically necessary or appropriate, experimental, or investigational.

In a request for information before DOL issued the proposed changes, the department noted that the current regulation was drafted in response to concern about plan practices that existed prior to the passage of ERISA,

particularly with respect to participants' lack of information about claims procedures generally. The current regulation makes no distinction between pension and health plans. The department also noted that many changes since have occurred in the health care marketplace, in health policy, and in business communications. In broaching its concern about "timely resolution of requests for medical treatment from group health plans," the Labor Department also pointed to Medicare's expedited review process as a possible model.¹⁶ While considering changes to ERISA plans' internal grievance process requirements, DOL officials have publicly stated that they have no jurisdiction to require external review of plan decisions. Such a requirement would require an act of Congress.

Discussing the proposed claim procedure DOL was about to publish before the Senate Committee on Labor and Human Resources, Olena Berg, then assistant secretary of DOL's Pension and Welfare Benefits Administration (PWBA), testified in May 1998 that the department considered it within its regulatory authority to

- Make clear that a benefit denial includes adverse determinations under a utilization review program; denials of access to (or reimbursement for) medical services; denials of access to (or reimbursement for) specialists; and any decision that a service, treatment, drug, or other benefit is not medically necessary.
- Require that benefit claims and appeals involving urgent care be processed with a time frame appropriate to the medical emergency, but no more than 72 hours.
- Require, with respect to non-urgent claims, that the plan either decide the claim or notify the claimant that the claim is incomplete within 15 days of receiving the claim (claimants then would have at least 45 days to provide any information to complete the claim and, once complete, the claim would have to be decided within 15 days).
- Require that, if a non-urgent claim is denied, the claimant be afforded at least 180 days to appeal and that a decision on the appealed claim be made within 30 days of receipt of the appeal by the plan.
- Require consultation with qualified medical professionals in deciding appeals involving medical judgments.
- Require that appealed claims be reviewed *de novo* (that is, review may not be limited to information and documents considered in the initial claims

denial) and be decided by a party other than the party who made the original claim determination.

However, according to Berg and other administration officials, bolstering ERISA's internal claims procedure is not enough to adequately protect consumers. DOL Associate Solicitor for Plan Benefits Security Marc I. Machiz has testified that, while the department can promulgate a more protective claim processing regulation, it cannot assure compliance with that regulation if no cost is imposed on plans for failing to comply. According to Machiz:

Under current law, a plan fiduciary who fails to assure compliance with the time limits or notice provisions of our current regulation, or any future regulation, is not accountable for that failure. At best, an aggrieved participant may treat the claim as denied and proceed to court, still without the benefit of a clear explanation of his denial or access to pertinent documents that might help him evaluate or prove his claim. Perhaps after wasting critically important weeks attempting to avail himself of the plan's claims procedures, he may find himself in court with his health already injured and his need for treatment mooted by the progress of his illness, or even death. If the plan's delay in providing a decision, or recalcitrance in providing critical information causes injury, the participant has no recourse, and the responsible fiduciary suffers no consequences.¹⁷

Because of financial incentives to delay providing costly medical treatment and the limited ability of revamping the internal grievance process to strengthen consumer protection, the Labor Department has advocated that Congress increase the legal remedies available to ERISA plan participants injured by denials of medical care. In addition, the department has urged Congress to enact legislation providing independent, external review of plan decisions.

Limits of DOL Consumer Assistance under Current Law

Under its authority to protect private-sector employee welfare plans, DOL can investigate complaints regarding employer or union health plan conduct and file suit to impose fines or an injunction. ERISA, however, does not explicitly empower DOL to pursue court cases or administrative remedies on behalf of individuals disputing health plan benefit denials.¹⁸ In the past, DOL's PWBA (which administers compliance with ERISA) kept coverage disputes between health plan participants and plan fiduciaries at an arm's length for two stated reasons. According to PWBA officials, ERISA does not authorize the department to sue on behalf of an individual in such cases involving coverage disputes unless a benefit denial affects the plan's entire membership.

Furthermore, PWBA officials said that they lacked the manpower to investigate individual complaints. During the past four years, PWBA has added considerable staff to respond to benefit inquiries of all kinds. PWBA benefit advisors now regularly review individual disputes over health coverage and try to resolve them.¹⁹ If talking with the plan sponsors does not resolve a coverage dispute or other issue, DOL may advise participants of their legal options or refer them to legal aid organizations or other sources of legal assistance, where available. As before, the department will not to go to court on behalf of an individual in a benefit dispute that does not involve some overarching legal issue or impact the larger plan membership.

As interpreted by the courts, two of ERISA's provisions serve to define and limit the legal options of plan participants to sue health plans for denials of medical coverage and treatments. These are Section 502, which sets out ERISA's civil enforcement scheme, and Section 514, which preempts states from enforcing laws relating to ERISA plans (but allows states to continue regulating the business of insurance). In the *Pilot Life*²⁰ case, the U.S. Supreme Court held that ERISA preempted state common law damages claims against the insurer of an ERISA disability plan for two reasons. First, the Court ruled that the common law claims were not saved from preemption under ERISA's Section 514 as part of a state's effort to regulate insurance. Second, and perhaps more important, the Court said that state law remedies were preempted on grounds that Congress intended ERISA's civil enforcement scheme to be ERISA plan participants' exclusive means of remedying benefit denials.²¹ As described earlier, Section 502 offers individuals in private-sector health plans what is basically a "right to sue" to compel plan administrators to render denied benefits promised in plan documents, but ERISA contains no provision to authorize courts to award damage to compensate individuals for lost wages, additional health care costs, or pain and suffering, nor does it contain provisions allowing punitive damages to be awarded.

As noted above, ERISA health plan participants that go to court face a variety of procedural and legal obstacles in suing to gain denied benefits. Under ERISA's fiduciary standards, for example, plan fiduciaries are responsible for the collective interests of plan participants. Plan fiduciaries must act prudently and according to plan documents. Although failure to pay a valid claim or authorize promised medical treatment may constitute a breach of fiduciary duty, courts ordinarily uphold the fiduciary's decision unless

participants can prove the decision was "arbitrary and capricious."²² Where a plan administrator has discretionary authority to determine eligibility for benefits or interpret plan terms, courts will overturn the administrator's decision only if is arbitrary, capricious, or an abuse of discretion.²³ In such cases, when the issue involves whether a denied medical treatment is medically necessary, courts will generally not consider new evidence about the medical efficacy of the treatment, but rather will rule on whether a fiduciary made a prudent decision, given the information before it at the time it made that decision. Therefore, in order to pursue such cases in the courts effectively, participants must be sure that medical evidence in support of approving the requested medical treatment be presented during the internal appeal process. However, failing to realize that they may have to establish their case sufficiently during the internal appeals process to prevail later in court, people may not be represented by an attorney at this stage of the dispute. Most people, of course, do not understand the minutiae of ERISA's appeals process and case law. Arbitrary and capricious behavior on the part of ERISA fiduciaries may include (a) using undisclosed medical criteria that are more restrictive than those used by other insurers, (b) basing a denial on an ambiguous provision in a benefit document, or (c) failing to comply with ERISA's internal appeals requirements if that failure prevents a participant from requesting a reconsideration of an adverse benefit determination.²⁴

HOUSE AND SENATE BILLS

Both the House and Senate passed patient protection bills during 1999; a conference committee of members of both chambers has yet to reconcile the differences between them. In many ways, the bills take differing approaches toward regulating managed care practices, providing opportunities for appealing plan decisions, and limiting or expanding plan participants' court remedies in terms of both substance and the extent to which state law may be applied. Both the House and Senate bills would introduce a series of new federal patient protections, including bans on "gag clauses"; requirements for access to emergency services and to obstetric, gynecological, pediatric, and specialist care; and rules regarding continuity of coverage, point-of-service options, prescription drug formularies, and clinical trials. The House bill would apply these provisions to all ERISA health plans (both insured and self-insured plans)²⁵ as well as state and local government plans. The Senate bill would apply these types of provisions only to ERISA plans that were not fully

insured and leave it up to the states to set these types of standards for fully insured ERISA health plans.²⁶ Both bills would apply new disclosure rules to both self-insured and fully insured ERISA plans. The Senate bill would require both self-insured and insured plans (including state and local government plans) to provide inpatient coverage for certain breast cancer treatments (if they provide medical/surgical benefits) and not to discriminate based on genetic information.²⁷

Both the House and Senate bills would apply new claims and external review procedures to both insured and self-insured ERISA health plans (the House bill would also apply to non-ERISA plans). Both bills would apply civil penalties for failures to follow the external review procedures; decisions rendered under these procedures would be binding on plans. While the Senate bill would not expand liability, the House bill would amend ERISA's preemption clause to allow plan participants, beneficiaries, or their estates to sue under state law to recover damages "resulting from personal injury or for wrongful death" against any person in connection with the provision of insurance, administrative services, or medical services by or for the group health plan. In order to bring a state lawsuit, the plaintiff would have to suffer personal injury and have to complete the internal and external appeals unless the injury (or death) had already occurred. Under the House bill, punitive damages would not be available in instances where the plan complied with the external review procedures and rulings, except in wrongful death cases where punitive damages were all that were available under state law. Group health plans, employers, or other plan sponsors would be liable under a state cause of action only to the extent that they exercised discretionary authority on a claim for benefits covered under the plan (and that action resulted in personal injury or wrongful death). Lawsuits could not be undertaken for injuries resulting from decisions to include or exclude a particular benefit from the plan or to provide extracontractual benefits. (The latter exception might present a problem of equal treatment under a plan if it provided an incentive for plan sponsors to draft plan documents to exclude certain benefits or treatments and then informally approve them for some employees but not others.)

By imposing external review processes, both the House and Senate bills attempt to reduce the risk of medical injury that people in group health plans might face due to administrative or medical decisions by plan administrators and insurers currently shielded from legal liability. The House bill, however, provides plan

administrators and insurers with an added incentive to adhere to review procedures by amplifying their legal liability if they fail to do so. Depending on what court remedies are available in a particular state, the House bill also may provide consumers with a mechanism for winning compensatory damages (such as lost wages or payment of additional medical bills) in cases where they can prove that they were injured by actions or decisions taken by plan administrators, insurers, and medical professionals. Viewed one way, creating a mechanism for compensating patients for damages may be necessary if plan sponsors or their agents attempt to change the practice of medicine and join physicians in making medical decisions. However, viewed another way, imposing too much liability on plan sponsors may simply drive many out of the business of purchasing health coverage with an eye toward improving the quality of care. Indeed, many employers have said they will terminate their health plans if they face increased liability, and some are exploring the possibility of scaling back their involvement to giving employees a "contribution" toward health insurance that would be purchased by each individual.²⁸

By stripping back ERISA's preemption provision to allow certain state causes of action, eventual passage of the House version would represent a departure from existing policy by Congress in giving state courts and legislatures a new role in indirectly enforcing access to benefits in ERISA plans, both insured and self-insured. As noted above, the courts have ruled that ERISA's civil enforcement scheme totally preempts state law with regard to resolving disputes over benefits. In its original design, ERISA preempts states from enforcing laws that relate to private-sector employee benefit plans while allowing states to regulate insurers contracting with the plans.²⁹ Responding in part to the dual regulatory field that ERISA's original preemption structure created, Congress changed its approach to preemption somewhat in enacting the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under the regulatory structure created in HIPAA, Congress sets federal minimum standards through ERISA, the tax code, and the Public Health Service Act upon which states may build if their laws are consistent with the federal statute. Leaving a major facet of enforcement of plan behavior up to state discretion is a new development and runs against ERISA's principle of establishing a federal standard or at least a minimum federal standard for participants in federally defined (and tax-advantaged) employee benefit plans. In a practical sense, this means that different employees in the same ERISA plan operating in more than one state may have different

court remedies, given the same actions taken by plan fiduciaries such as administrators or insurers. It also means that more of such cases will end up in state courts as opposed to federal courts. An alternative approach (assuming one accepts the threshold argument that increased court remedies are needed) would be to create a federal cause of action for damages that would be available to members of group health plans, either allowing certain state causes of action as supplements or continuing to preempt them.

How much latitude the states might have to regulate claims processing or impose external review requirements for insurers and MCOs contracting with ERISA plans is also a key issue for congressional conferees. Virtually all state insurance departments have well-established mechanisms for overseeing the handling of health insurance claims. Thirty states and the District of Columbia have established external review requirements.³⁰ Most of these laws were enacted during the past few years in response to consumer concerns over managed care practices. There is great variation among state external review requirements, including differences in who must perform the reviews, whether decisions are binding, what is eligible for review, and who has access to information (as well as whether reviewable issues must exceed a cost threshold and whether filing fees are required). As noted below, whether ERISA preempts such laws has been challenged in the courts.

Both the House and the Senate bills would authorize new civil penalties. Under the Senate bill, DOL could assess a civil penalty of up to \$10,000 for failure or refusal to comply with external review time lines or the external review determination.³¹ Under the House version, a person who caused the plan or insurance issuer to refuse to comply with an external review decision may be liable to the participant for civil penalties of up to \$1,000 a day until the benefit is provided. The appropriate federal agency could also assess civil penalties for repeated refusals to authorize benefits required by the external review entity or to comply with external review requirements (in the amount of the lesser of 25 percent of the value of the benefits not provided or \$500,000) and remove the responsible person from his or her position. Under the House bill, participants and beneficiaries could not bring lawsuits under ERISA to enforce some new regulatory requirements, such as choice of coverage options and other rules relating to the relationship between physicians and patients, but DOL could still take enforcement actions. Participants could bring suits under ERISA to enforce other new rights, such as access to

specialty and emergency care, although relief would be limited to the value of benefits denied plus attorneys fees.

It is perhaps worth noting that the House bill does not open up state court remedies to non-ERISA employee health plan participants that do not already have them; such people include federal employees, dependents, and annuitants (among them, members of Congress and federal regulators enforcing ERISA) covered in the Federal Employees Health Benefits (FEHB) program. The court remedies available under current law to people covered under FEHB are quite similar to those under ERISA. Although FEHB has many characteristics that arguably lessen the degree of risk faced by plan participants from injuries caused by plan administrators (for example, more choice of plans, a solid financing base in the tax system, a great deal of public visibility, and politically powerful plan members), an argument also can be made that establishing similar remedies for FEHB as for private-sector plans could provide federal policymakers with valuable experience and information about the cost and efficacy of new external review requirements and legal remedies. (Doing this could also give federal policymakers increased sensitivity to issues that might arise and need later adjustment as all parties involved began adapting to the new system.)

OTHER OBSTACLES TO SUING HEALTH PLANS

If ERISA preemption were stripped back to allow certain types of lawsuits to proceed against plan administrators, insurers, and MCOs, several obstacles still might prevent patients from pursuing such court actions. Among these barriers (this is by no means an exhaustive list) are the common law of independent contractors, corporate practice of medicine laws, and state reforms to malpractice laws.

Independent Contractor Law

As noted earlier, in some federal courts plaintiffs have been able to pursue claims of vicarious liability against MCOs under contract with ERISA plans, in essence suing the MCO on the grounds that it is indirectly responsible for the medical malpractice of its physicians. But breaching the ERISA preemption barrier is just step one for such lawsuits to succeed. Virtually all courts have held that MCOs (and hospitals) are not responsible for the actions of independent contractors.³² Most MCOs contract with physicians instead of employing them (and physicians usually contract with many MCOs simultaneously). The most likely targets among

MCOs for vicarious medical malpractice lawsuits would be staff-model HMOs, but these are rare. When an HMO contracts with physician associations, the HMO may be held liable for negligent medical care if the patient perceives that the HMO is providing the medical care under the “ostensible agency” theory of law.³³ It is easier for such an argument to prevail if a court determines that an HMO represented the contracting physician to be its employee, if the patient looked to the HMO rather than the physician to act as its health care provider, and if the patient had no choice in selecting a treating physician.

Corporate Practice of Medicine Laws

While general common law theories provide state court remedies for MCO actions that injure consumers, in many states the “corporate practice of medicine” defense may bar such lawsuits.³⁴ Physicians have long resisted control of medical decision making by persons and organizations outside their profession for reasons including the protection of their economic interests and professional autonomy as well as concern for the quality of care for patients. From 1912 to 1979 (when federal antitrust regulators forced a change in policy), the American Medical Association’s (AMA’s) ethical standards declared that it was unprofessional for physicians to work for a corporation. In response to such concerns many states passed laws prohibiting corporate control of the practice of medicine in a variety of ways. Corporate practice of medicine is banned in about half of the states, based on statutes, court opinions, and state attorney general interpretations of physician licensure laws (and physicians, insurers, and other parties go through complex legal maneuvering to circumvent those proscriptions). Although it is not clear whether the corporate practice of medicine doctrine would bar medical malpractice suits against MCOs in all states where the doctrine remains viable, it had been held to bar negligence cases in some states, including Missouri and Texas, which are among the handful whose legislatures have recently enacted laws specifically allowing such lawsuits to proceed.

Drawing a distinction made by many other federal courts between decisions over coverage (which involve interpreting an ERISA plan’s terms) and medical care, a federal district court upheld part of the Texas MCO liability statute, which created a right to sue for both health plan “health care treatment decisions” and coverage denials or delays. The Texas court held that ERISA would not preempt cases under the state law

alleging a health plan’s direct involvement in medical treatment, but noted that ERISA would still preempt cases brought under the law regarding coverage decisions. The Texas court also held that an external review program that is an integral part of the Texas liability law was preempted by ERISA. The case is on appeal to the Fifth Circuit Court of Appeals. (Republican presidential candidate George W. Bush has said that he could support a federal law allowing patients to sue MCOs if it resembled the liability law that was enacted during his term as governor of Texas.³⁵)

Notwithstanding the above-mentioned state-level barriers, in the absence of ERISA preemption, health insurers and MCOs would probably be sued far more often for both improper coverage decisions and medical malpractice. For example, a California jury awarded \$89 million in damages (\$77 million of which was for punitive damages) to the estate of Nelene Fox based on claims of breach of contract, breach of the covenant of good faith and fair dealing, and intentional infliction of emotional distress. The case was later settled for \$5 million before appellate review. This lawsuit (*Fox v. HealthNet*³⁶) succeeded in part because it involved a government-sponsored health plan not subject to ERISA³⁷ (or other federal laws governing federally sponsored health programs that limit state-based remedies). If Fox had been covered by a private-sector plan subject to ERISA, it is extremely unlikely that there would have been any recovery. In this case, Fox underwent two radical mastectomies and conventional chemotherapy after being diagnosed with breast cancer. After the cancer metastacized to her bone marrow, she sought treatment involving a bone marrow transplant for which HealthNet denied coverage, based on its determination that the procedure was “investigational” and therefore not covered.

PHYSICIAN DISCONTENT WITH MANAGED CARE

Market Transformation

In recent years, health coverage arrangements and the medical delivery system have become increasingly complex, increasing possibilities for confusion and distrust on the part of consumers and physicians. Corporate health plan sponsors and insurers have struggled to slow the growth of health care costs, experimenting with new benefit packages and ways of contracting with physicians and other health care providers. Many physicians, in turn, have developed, joined, or affiliated

with new types of organizations. Increasingly fewer work in solo practice but many still do. By 1995, 94,000 physicians worked in groups with between three and 15 physicians and 117,000 practiced in larger organizations, while two-thirds of the nation's 613,000 physicians worked on their own or in two-physician partnerships.³⁸

In a new book describing the growth of physician group practices and other forms of medical delivery systems along with contractual and administrative innovations (which he generally refers to as “virtual integration”), economist James C. Robinson evaluates the benefits of this ongoing organizational transformation and notes that it has created a great deal of confusion not only for insurers and providers but also for consumers, purchasers, regulators, and legislators. According to Robinson:

Virtual integration in health care encompasses this ever-changing multiplicity of relationships between insurers and providers, including fee-for-service contracts with individual providers, capitated contracts with provider organizations, and every possible contractual hybrid. There exists no one best relationship between insurers and physicians, no ideal payment methodology, no final allocation of responsibility for utilization and quality. Purchasers and consumers differ in the networks and products they want to buy while physicians and physician organizations differ in the risks and responsibilities they want to assume.³⁹

The complexity and dynamism of the new relationships and ways of doing business in the health care marketplace increase the difficulty that policymakers face in sorting out who should be legally responsible for doing what, what should be regulated by government, and what government should leave alone.

Physicians: Key Players

In the course of media coverage of the “managed care backlash” and policy debates over giving patients greater access to external review procedures and the courts, the focal point is often the consumer or the patient. But in terms of the political muscle actually applied to state and federal legislators and regulators, consumers and patients are typically far less strongly represented than the lobbies representing parties such as insurers, employers, trial lawyers, and medical providers, all of whom have more concentrated economic interests in health care transactions. In many ways, the fight over liability is a subset of a much larger battle over how to contain medical cost inflation and, toward that end and others, how to reconfigure the structure of the health financing and delivery system.

As employers, MCOs, and other organizations have attempted to exert more control over the practice of medicine (in part to gain control of utilization of resources) and driven tougher bargains over the price of services, physicians have expressed increasing discontent and have played a pivotal role in shaping the patient protection packages in Congress and state legislatures. As noted above, among those leading the drive for expanded liability for MCOs in the House were congressmen who also are health care providers.

Several analysts have commented on physician discontent with managed care. An interesting perspective on physician anxiety relating to contracts with MCOs and malpractice liability has been advanced by Bryan A. Liang, M.D., J.D., who notes:

Physicians, lodged in the middle between MCOs and patients, have severely conflicting incentives. On the one hand, they have a professional and ethical responsibility to provide the appropriate amount of care consonant with patient needs; further, they have a legal imperative to do so since they shoulder virtually all the potential liability for patient injury. (n282) On the other hand, financial pressures and the threat of deselection directly contravene their ability to provide or even suggest the level of care they deem appropriate. Referrals, experimental treatments, and treatments not covered by the MCO may be extremely difficult to procure under these circumstances. (n283) Simply put, being an advocate for and attempting to fulfill ethical obligations to patients can get a physician fired. (n284)⁴⁰

A board member of the Health Administration Responsibility Project, which supports expanded court remedies for ERISA health plan participants, Liang maintains that physician liability for medical malpractice combined with independent contractor status creates misaligned incentives. Pointing out that the independent contractor relationship insulates MCOs from liability in most instances, Liang argues that MCOs can exert a great deal of influence over contracting physicians' treatment practices because the doctors, who depend on MCOs to obtain patients, fear “deselection” under contracts containing termination-without-cause clauses. Physician lobby groups have made a similar case against MCOs' contracting practices, arguing that physicians are not in an economic position to influence the content of contracts and are subject to being terminated without cause. Liang makes the following argument:

Organizationally, if MCOs were responsible for costs associated with patient injury, they would have an incentive to use their large patient and physician base to investigate what causes error in medicine and what structural and systematic changes could reduce the risk of error, as other complex industries have done.

He goes on to propose not only removing the ERISA preemption barriers to court remedies but also changing federal law to declare contracting physicians to be what he terms “independent employees” of MCOs for the purposes of civil actions (thereby overcoming the law of independent contractors barrier) as well as banning MCOs from terminating physician contracts without cause; he would apply these reforms to coverage received under all medical plans, not just those subject to ERISA.

In a somewhat related development, frustration with MCOs has driven some physicians to consider unionizing in order to improve their bargaining position. Antitrust law now prevents those operating as independent contractors from colluding to set prices. Rep. Tom Campbell (R-Calif.) is sponsoring a bill that would grant physicians and other health care professionals negotiating contracts with health plans the same treatment under antitrust laws as bargaining units recognized under the National Labor Relations Act and would deem such contractors to be “employee(s) engaged in concerted activities.” Endorsed by the AMA and strongly opposed by insurers and employers, Campbell’s bill (H.R. 1304) has yet to be formally considered by the House Judiciary Committee but is reported to have gained considerable support among House members.

EMPLOYER, INSURER LIABILITY CONCERNS

Faced with proposals to strip back the liability shield offered by ERISA, employers sponsoring health plans, health insurers, and MCOs argue that doing so will increase costs and drive many employers to terminate their health plans and that both effects of these will increase the number of uninsured Americans. They also argue that increased liability coupled with more federal managed care regulations will hamstring efforts by group purchasers to improve the quality of medical care. In making their case at congressional hearings, employers and insurers have emphasized the high level of medical error and suboptimal care now being offered throughout the medical system and have cited as evidence the high degree of regional variability in medical practice. In making these points, some large employers and insurers seem to be saying that they would like to exert more influence over medical practice. Exposing them to lawsuits might undercut their willingness to do so. On the other hand, an argument might be posed that, with the exception of a few large employers and employer coalitions, most employers so far have focused primarily on price and

have paid little attention to quality issues when negotiating contracts with MCOs.

Substandard Care and Medical Errors

Mounting evidence of substandard care and resulting medical injury clearly presents a problem for large employers facing the possibility of greater liability for administrative and medical decisions. A highly publicized report just released by the Institute of Medicine, for example, estimates that as many as 98,000 Americans die unnecessarily every year as a result of medical mistakes made by physicians, pharmacists, and other health care professionals.⁴¹ When coupled with nonfatal consequences of other medical errors, these episodes cost the nation as much as \$29 billion a year.

While health plan denials of care have received much publicity, MCOs have also identified many instances in which physicians undertreat patients. For example, a senior official in the UnitedHealth Group (United Healthcare is its health plan business) testified before Congress that the company used its databases to compare the practice patterns of its contracted physicians with established standards of medical care and found significant underuse of several treatments for which compliance rates should approach 100 percent.⁴² These findings included the following:

- Only 62 percent of eligible patients received ACE (angiotensin converting enzyme) inhibitors for their congestive health failure (using this drug for a weak heart that cannot pump blood adequately has improved outcomes, according to studies reviewed by the American College of Cardiology and the Agency for Health Care Policy and Research).
- Only 71 percent of heart attack patients received a beta blocker medication (which reduces the chance of a second heart attack by 20 to 40 percent).
- Only 71 percent of diabetics had their control of blood sugar levels measured with two glycated hemoglobins per year (this test is the most accurate method to ensure that diabetics are keeping their sugar levels low enough to prevent long term complications).

Citing studies of the frequency of hysterectomies and the prescribing of antibiotics, the UnitedHealth Group executive testified that overuse of inappropriate procedures is just as common as underuse of appropriate ones.

A literature review conducted by researchers from RAND found large gaps between the care people should receive and the care they actually receive (the authors looked at studies of three generic types of care: preventive,

acute, and chronic).⁴³ The researchers found that on average the preventive care studies that they reviewed showed that only about 50 percent of people received recommended care. An average of 70 percent of patients received recommended acute care while 30 percent received contraindicated acute care (care that should not have been delivered). For chronic conditions, 60 percent of patients received recommended care and 20 percent received contraindicated care. (The authors noted that these “values do not indicate exact levels of quality in the United States, but they do provide a quantitative sense of how much could be done in all areas to identify and eliminate overuse and underuse of care.”)

While identifying several types of procedures for which people should have been treated but did not receive treatment, the RAND study also found instances where surgery was performed on people who did not need it:

A study of seven managed care organizations revealed that about 16 percent of hysterectomies performed during a one-year period from 1989 to 1990 were carried out for inappropriate reasons. An additional 25 percent were done for reasons of uncertain clinical benefit.⁴⁴ There are also examples of patients who need surgery but do not receive it. In a study of four hospitals, 43 percent of patients with a positive exercise stress test demonstrating the need for coronary angiography had received it within 3 months; 56 percent had received it within 12 months.^{45, 46}

One study documented that 1 percent of hospitalizations in New York state resulted in an “adverse event” due to negligence. (Adverse events were defined as injuries caused by medical management of a disease rather than the disease itself). Another found an adjusted rate of preventable adverse drug reactions in two Boston hospitals of 1.8 per 100 admissions, with 20 percent of these classified as life-threatening. Concluding that their most striking finding is how little systematic knowledge is available about the quality of American health care delivery, the RAND researchers provided evidence that a great deal of the medical care people receive falls below conventional standards of appropriateness. To what degree this unevenness leads to excessive costs and patient injury is not known, they said.

Utilization Review and Denials

Although MCOs may be exerting more influence over physicians than in the past, explicit denials of care occur for only a small fraction of medical transactions. Although little national data are available on the frequency of MCO coverage denials, one widely cited study found that physicians surveyed in 1995 reported that the propor-

tion of patients initially denied coverage for recommended services was always less than 6 percent for all forms of care surveyed, while the final denial rate (after plan officials often reversed decisions) was at most 3 percent.⁴⁷ Mental health, substance abuse, and referral to a specialist were the types of coverage most frequently denied. Denial rates for other types of medical care surveyed were much lower. For example, coverage for endoscopies, cardiac catheterizations, and hospitalizations was ultimately denied in fewer than 1 percent of cases. Coverage for MRIs and surgical procedures was ultimately denied in 1 percent to 2 percent of cases. The study found that nationally the two most widely used managed care techniques reported by physicians were utilization review, which was applied to an average of 59 percent of patients, and discounted fees, which was applied to an average of 38 percent of patients. The authors concluded that, while the denial rate was low, it did not necessarily follow that utilization review had no impact because it might have a “deterrent or sentinel effect” and discourage physicians from suggesting certain treatments. In addition, the researchers found that, while coverage denial rates were very low for most physicians, a few experienced substantial denial rates. (The study could not determine what percentage of the denials involved inappropriate treatments.)

UnitedHealth Group recently announced that it will no longer require doctors to seek preauthorization before ordering tests, treatments, referrals, or hospitalizations, and the chairman of the nation’s largest health insurer, Aetna Inc., has said his company might move in the same direction.⁴⁸ While it is too early to conclude how much impact such moves might have on the patient protection debate, many analysts have noted that to be competitive large insurers will still attempt to exert control over physician behavior in a number of other ways.

MEDICAL NECESSITY: WHO DECIDES? WHO IS LIABLE?

A key issue in the debate over how liability should be split among the various parties involved in making medical decisions and allocating medical resources has to do with who has the power to decide which services and technologies are “medically necessary” under a group health plan. Instead of enumerating every possible medical intervention that might be covered, most health plan contracts refuse to cover services that are not medically necessary or are experimental or investigational. Many (but not all) coverage disputes hinge on arguments of medical necessity. Because medical

knowledge and medical technology are expanding rapidly (and economic and social conditions are constantly changing), notions of what is “medically necessary” will evolve in tandem.

While employers and insurers argue that they are seeking to improve the quality of medical practice and need flexibility in determining what they will pay for, physician and consumer groups have argued that many health care contracts give plan administrators and fiduciaries the power to arbitrarily and unilaterally define “medical necessity.” For example, in 1997 senior officials of the AMA and Florida Medical Association wrote a letter to Aetna/U.S. Healthcare taking issue with contracts that the managed care firm issued to physicians in Florida and five other states. The letter enumerated a series of complaints, including the following:

The definitions of “covered services” and “medically necessary” give Aetna the final authority to determine whether a service is “medically necessary” and consequently, on whether it is “covered,” regardless of whether the service would be considered “medically necessary” under accepted standards of medical care. By inextricably intertwining “coverage” decisions and “medical necessity” decisions, Aetna is giving itself the ultimate power to supersede a physician’s determination regarding the necessity of medical service and to deny even clearly needed medical care. This is medical decision-making for which plan administrators should be held liable.⁴⁹

The contracts at issue stipulated that the insurer had final say over what was covered and the authority to adjust or deny payments for services; they also declared that “all patient care and related decisions are the sole responsibility of Provider and Company’s medical management procedures, protocols and policies do not dictate or control Provider’s clinical decisions with respect to the medical care or treatment of Members.”

Employers and insurers argue that if government-imposed external review procedures override their ability to decide what is medically necessary in contracts with physicians and in plan documents, their ability to contain costs and standardize and improve the practice of medicine will be impeded.

APPROACHES TO LIABILITY

Contract Law versus Tort Law

The law has evolved two general types of approaches to liability most relevant to the debate over ERISA health plan and MCO/insurer liability: contract liability and tort liability. Under principles of contract

law, courts typically will enforce agreements between parties but generally limit remedies for breach of contract to “the benefit of the bargain”—that is, to what the plaintiff expected to receive from the agreement in the first place. Plaintiffs generally cannot recover consequential economic damages that were not within the reasonable contemplation of the parties at the time the contract was made (for example, unanticipated damages caused by the loss of the originally bargained-for benefit) or damages for emotional distress resulting from a breach of contract or punitive damages. The civil enforcement measures currently available to ERISA plan participants under Section 502 basically follow the contract liability model.⁵⁰ In limiting liability, contract law presumes that parties entering into private agreements are in the best position to manage their own risks. However, individuals in employee health plans, it might be noted, are third-party beneficiaries of plans whose terms they do not negotiate themselves and which they are not in a position to readily understand.

Tort law, in contrast to contract law, reflects public policies about how people and organizations should behave toward one another. Designed to deter improper or risky conduct, to compensate injured parties, and to minimize the overall social cost of accidents, tort law holds people to a standard of care that is determined by legislative bodies or the courts. (Under the contract law model, the terms of the contract can be set by the contracting parties themselves.) Under tort law remedies, plaintiffs may be compensated for all injuries resulting from the defendant’s wrongful conduct, including lost wages, medical expenses, and pain and suffering. To deter wrongful behavior in the future, courts may send a message by awarding punitive damages in tort cases.

As noted above, the patient protection bill passed by the House would strip back ERISA preemption to allow lawsuits based on state law and in some circumstances would expose ERISA plan administrators, insurers, and medical providers to tort remedies not currently available to plan participants. Though it would be difficult for anyone to predict every possible new way that health plans might be sued should the House version become law, it seems reasonable to predict that liability would increase with respect to medical care, insurance, and administrative services functions performed under group health plan contracts.

Insurance Industry Liability

With regard to the insurance industry, courts have recognized a special cause of action for “bad faith”

breaches of contracts and have permitted recovery of consequential economic and punitive damages on top of recovery of benefits promised in the contract. According to J. Clark Kelso of the University of the Pacific McGeorge School of Law:

The insurance bad faith cases are interesting because they clearly impose tort liability for bad faith in the handling of a claim under an insurance policy. The law of insurance bad faith recognizes that the insurance contract may create incentives for an insurance company to deny claims even when there is no good faith basis for denial and that the tort system may serve to balance that incentive.⁵¹

Medical Malpractice Liability

Medical malpractice is another form of tort law traditionally overseen at the state level. As noted above, MCOs contracting with ERISA health plans in some federal court jurisdictions already face increased risk of suits based on the theory that they were indirectly responsible for injuries caused by physicians under their control. The House bill would seem to greatly expand the likelihood of such lawsuits.

To what degree the current medical malpractice liability system deters the frequency of medical injuries, appropriately compensates injured patients, and unnecessarily adds costs are difficult issues that have been debated by experts for many years. In order to win medical malpractice damages, a person must prove in court that he or she was injured as a result of a medical service provider's failure to adhere to a standard of care. Malpractice claims can involve errors of commission (doing something negligently) or omission (such as failing to diagnose a disease that a reasonably competent physician should have diagnosed). Policymakers desiring more detail on the many issues that medical malpractice law raises may want to read a report written by Randall Bovbjerg of the Urban Institute in 1995.⁵² Among the many findings in the report are the following:

- About three-quarters of malpractice claims involve care in hospitals and most of the rest care provided in physicians' offices.
- Liability insurance premiums averaged roughly 4 percent of physicians' gross practice income.
- Courts compensated only a tiny fraction of patients injured by the medical system, while the best studies available showed evidence of a significant amount of patient injury (occurring, for example, in about 5 percent of hospital medical records studied).

- Liability recoveries covered only a small portion of the actual cost of malpractice injuries, most of which was passed on in the form of more health care treatments to employers, government programs, and individuals themselves.
- The medical liability system has performed poorly as a system of compensation and as a system of medical oversight but may be more defensible if viewed as a means of dispute resolution.

In response to pressure brought on by rapidly rising malpractice insurance premiums, states in the 1970s and 1980s enacted a variety of reforms that, generally speaking, either try to reduce the number of cases brought, make it harder for plaintiffs to prevail, or reduce damage awards. More than half the states have placed limits on attorneys' fees and capped damage awards but no state has fundamentally altered the underlying structure of the medical malpractice system.

CAUTIONS

Although many health policy analysts and researchers acknowledge that ERISA's remedies are not adequate to protect consumers in today's medical and insurance marketplace, many are also cautious about expanding the use of the tort system in response. In a recent article addressing injuries from medical error (as differentiated from disputes over benefits administration and coverage determinations) Bovbjerg and Robert H. Miller warned that changes in liability law should promote and not inhibit the management of health risks:

With regard to liability, the ideal is to have injury risk imposed on those best able to control the costs of injury plus the costs of injury avoidance;⁵³ negligence measured by the cost-effectiveness of alternative precautions proven by evidence-based medicine rather than expert testimony of medical custom;⁵⁴ and damages structured to send good deterrent signals without imposing unpredictable, open-ended liability.⁵⁵ There are substantial problems with the existing law of malpractice in these regards, and backlash-generated reform proposals do not even reach such issues.⁵⁶

Another group of researchers who recently interviewed several of the types of people involved in health care delivery and administration in order to assess the potential impact of expanded liability under ERISA have also sounded a cautionary note.⁵⁷ While finding that the direct costs of expanded liability were "uncertain,"⁵⁸ they concluded that the possible effects of such a reform could have significant and unintended impacts on coverage decision making, information exchange, risk

contracting, and employers' willingness to sponsor coverage. Interestingly, the research team noted that expanded liability for coverage decisions could spill over onto physician groups and networks that have accepted capitation and often make utilization review decisions (thereby functioning in some instances as both medical providers and ERISA fiduciaries).

Under the current legal structure, physician group practices and MCOs may perform several functions for an ERISA health plan simultaneously,⁵⁹ and each of these functions may be subject to different bodies of law projecting different expectations of professional behavior and disparate levels of consumer protection. For example, a physician group practice assuming insurance risk in an arrangement with a group health plan may have an incentive to characterize avoidance of expensive or high-risk treatments as "coverage decisions" made in its role as a plan fiduciary (taking advantage of the liability shield that ERISA affords) as opposed to "medical decisions" for which the medical group may be held to a far higher standard of behavior should patient injury later be proven in court.

POLICY OPTIONS

A general concern of many policymakers is that reforms to ERISA remedies should not undercut the ability of health care purchasers and MCOs to negotiate with insurers and health care providers to contain the growth of costs, improve medical quality, and reduce medical error. Ideally, any such reform would legitimize managed care in the eyes of consumers and at the same time distribute liability for medical care and plan administration decisions among those who actually take responsibility for making those decisions, with their liability being proportionate to the influence they exert. Unfortunately, the ideal policy may not be possible. Coming up with an alternative system has been extremely difficult, especially because the issue has become highly politicized. So far at least, legislators and interest groups have tended to take highly polarized positions rather than reaching out to compromise and explore practical options for reform.

In resolving the differences between the House and Senate bills on remedies available to ERISA health plan participants, congressional conferees face two major sets of issues: (a) what type or blend of types of liability to place on ERISA plan administrators and other fiduciaries and (b) whether such remedies will be based in federal or state law. In terms of substance, both the House and Senate bills would add internal and external review requirements to ERISA's current "contract-law"-like

remedy of allowing participants to sue for the value of denied benefits or the benefits themselves. The House bill takes the extra step of opening up state-based tort remedies, in part designed to encourage health plans to adhere to the new external review requirements. Exposing the administrators of multi-state employee health plans to up to 50 variants of several types of tort actions, each with up to 50 possible variants of standards of behavior for which to be liable, certainly would seem to increase their level of confusion and need to seek legal advice. Should the conference committee decide that expanded liability is desirable, a federal standard may be clearer and simpler but also has drawbacks, such as less suitability to the different market and social conditions in the states. Issues of ease of access to the courts, court capacity to handle new cases, and the competence of various types of courts to handle health benefits cases would also seem to be require some thought if the liability system is to be significantly altered.

While contract and tort-type remedies represent distinct approaches under the law, considering other approaches may be instructive. In a recent paper, Kelso suggested that policymakers look at how legislatures and courts have fashioned the rules of liability for several industries: professional services industries, including medical malpractice; employers' liability for workplace injuries; liability in the manufacturing industry; liability in the insurance industry; and liability for wrongful termination. In each instance, policymakers had to decide between contract and tort models of liability and in some they created blends of the two with special rules.

To assist policymakers in understanding the range of options (without advocating any particular one), Kelso presented five options for approaches to health plan liability.⁶⁰ These included

- Retaining the contract liability model but modifying the contract through government regulations that, among other things, might impose independent review requirements; require disclosure of financial incentives that might influence physician decisions; or mandate the offering of types of benefits, procedures, or access to providers or medical facilities.
- Creating a medical compensation fund along the lines of the workers compensation system.
- Creating a medical malpractice model that is a hybrid of tort and contract law.
- Exposing health plans to tort liability similar to that faced by insurance companies for unreasonable and bad faith claims practices.

- Holding managed care companies liable for injuries caused by all erroneous medical or coverage decisions that contributed to the end result in a system of enterprise liability (drawing on principles that have evolved for product liability in manufacturing industries).

The literature delving into many of these models is extensive and beyond the scope of this paper. These models are mentioned here primarily as illustrations of policy options, some of which fall outside the boundaries of the current congressional debate over health plan liability.

CONCLUSION

The civil enforcement scheme that Congress developed in ERISA 25 years ago is geared primarily toward resolving disputes over pensions and is arguably no longer adequate to protect plan participants making claims for promised health benefits. Consumers injured by a plan coverage decision have virtually no legal remedy available to them. And no regulatory structure is in place to compel an ERISA plan to provide a promised medical benefit that was denied by a plan fiduciary or to adequately assist consumers in doing so.

Driven in large part by a socially recognized need to contain the growth of health care costs, the health care industry has undergone fundamental changes. Plan sponsors, insurers, and MCOs have attempted to provide incentives for physicians to practice more efficiently and, through utilization review programs and other means, have attempted to influence what constitutes appropriate medical practice. Shielding ERISA plan sponsors and fiduciaries from legal liability, the law leaves physicians exposed to malpractice liability. To a still limited degree, it allows MCOs to be sued for medical malpractice as well. Under the current legal structure, ERISA plan fiduciaries—a list that may include plan sponsors, insurers, MCOs, medical groups, and others—have an incentive to characterize decisions as “coverage decisions” as opposed to “medical decisions” in order to protect themselves from liability under state law, and in many instances the courts have found the distinction difficult to draw. While consumer demand for new medical technologies coupled with the perception that insured health services are a “cost-free” good promise to intensify cost pressures, plan sponsors carry the burden of holding back the growth in costs. In the long run, efforts to contain cost growth probably will mean more intervention by purchasers in the practice of medicine, either directly or through payment

incentives. Even though it may be beneficial to society as a whole, this may lead to more patient injuries based on medical care that was not provided (as contrasted to injuries stemming from medical care that was provided but should not have been, which continues to be a major problem).

Congress is grappling with how to update ERISA’s civil enforcement provisions to give consumers added protections while accommodating the new ways of administering and purchasing health coverage and delivering medical care. Both the House and Senate have passed bills that would significantly increase regulatory requirements facing ERISA health plans, for example by adding the requirements for internal and external reviews of disputed coverage decisions. Congressional conferees face the question of whether these new administrative requirements overlaid on ERISA’s “contract-like” remedies (the approach taken by the Senate) will give plan participants sufficient means to challenge coverage decisions. The House has taken the additional step of stripping back ERISA’s preemption of state law to allow plan participants increased access to state law remedies if they are injured as a consequence of plan decisions.

Until recently, many health policy analysts and senior health policy staff on Capitol Hill gave the conferees little chance of coming to agreement, especially on a bill that might increase the liability faced by ERISA plans, insurers, and MCOs. Recent statements by the two leading Republican presidential candidates that they could support some form of increased liability may throw a different light on the prospect. As noted above, Bush has said that he could support a federal statute like the Texas liability law. Speaking before a local business group in South Carolina, Sen. John McCain (R-AZ) recently said he would support independent review requirements coupled with a limited court remedies (barring punitive damages, capping pain and suffering awards, but posing no limits on economic damages, including lost wages and future earnings). He also emphasized tort reform.⁶¹

Of paramount interest to consumers is having timely access to needed medical care. If they do suffer injury, consumers arguably also could benefit from a system to compensate them for losses. The medical malpractice system compensates very few patients who suffer medical injury but no compensation system has been developed to replace it. In the House bill, the main value of exposing plan administrators and other fiduciaries to punitive damages seems to be to deter them from irresponsible behavior and to provide an incentive to conform with new

administrative requirements for external reviews. Exposing plan sponsors to unpredictable levels of legal risk, however, runs the risk of undermining their willingness to sponsor health plans and attempt to contain costs and improve medical quality.

The author would like to thank the many people who reviewed this paper and offered helpful comments, including Patricia Butler, Phyllis Borzi, Michael Gordon, Randy Bovbjerg, Clark Kelso, Lisa Sprague, Paul Harrington, Jason Lee, and numerous staff at the U.S. Department of Labor. (The aforementioned, of course, are not responsible for the content of the paper or any errors it may contain.)

ENDNOTES

1. An estimated 127 million Americans receive coverage through private-sector employee health plans governed under ERISA. Employee health plans sponsored by governments and churches are not subject to ERISA.
2. ERISA, Sec. 503 (2).
3. 29 C.F.R. 2560.503-1.
4. Patricia Butler and Karl Polzer, "Private-Sector Health Coverage: Variation in Consumer Protections under ERISA and State Law," National Health Policy Forum, Washington, D.C., June 1996, 49.
5. Sec. 502 (a) of ERISA states: "A civil action may be brought...by a participant or beneficiary...to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan."
6. *Bast v. Prudential Ins. Co.*, 150 F.3d 1003 (9th Cir. 1998), *cert. denied*, 120 S. Ct. 170 (mem. Oct. 4, 1999). See Brief of Alexis M. Herman, Secretary of the U.S. Department of Labor, as *amicus curiae*.
7. Patricia Butler, "Managed Care Plan Liability: An Analysis of Texas and Missouri Legislation," prepared for the Henry J. Kaiser Family Foundation, Menlo Park, California, November 1997, 20.
8. 965 F. 2d 1321 (5th Cir. 1992).
9. Although managed care practices such as preauthorization of benefits intensify the problems posed for consumers by ERISA's remedies, it is unlikely that, even in the fee-for-service medical system, a doctor or hospital would perform an expensive procedure without first making sure that either a health plan or an individual could and would pay for it.
10. President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, "Quality First: Better Health Care for All Americans: Final Report to the President of the United States," Washington, D.C., 1998, A-61.
11. In *Udoni v. The Department Store Division of Dayton Hudson Corporation (N.D. Ill., 1996)*, physicians wanted to reconstruct a woman's facial bones, which had deteriorated due to osteoporosis, in order to help her eat. Her plan covered medical conditions but excluded treatments to correct conditions of the teeth, mouth, jaws, and jaw joints. The plan administrator classified the proposed operation as "dental" and denied coverage. A district court judge found that the denial of benefits was arbitrary and capricious noting that it "not only was not grounded in either recognized medical expertise or firsthand clinical observation, but it apparently ignored substantial evidence supplied by Ms. Udoni's personal physicians of the surgery's medical necessity."
12. See *Cann v. Carpenters' Pension Trust for Northern California*, 989 F. 2d 313 (9th Cir. 1992).
13. Sara Rosenbaum, David M. Frankford, Brad Moore, and Phyllis Borzi, "Who Should Determine When Health Care Is Medically Necessary?" *New England Journal of Medicine*, 340, no. 3 (January 21, 1999).
14. In one recent case, the United States Court of Appeals, Tenth Circuit, upheld a benefit denial for substance abuse treatment on grounds that it was not medically necessary. The court noted that the plan administrator had sent relevant medical information about the case to an independent reviewer who concluded that the patient did not meet the plan's criteria for admission to a particular facility but also said that "the (plan) criteria are too rigid and do not allow for individualization of case management." The court found that because the plan criteria constituted part of the plan, they lay outside the scope of judicial review, noting that under the relevant standard of review, a court may not overturn a plan administrator's decision if it was reasonable, given the terms of the plan, and made in good faith. See *Russell Jones and Susan Jones v. The Kodak Medical Assistance Plan*, 1999 WL 111147 (10th Cir. [Utah]).
15. Phyllis C. Borzi, Summary of Proposed Department of Labor Regulations Concerning Benefit Claims Procedures under Section 503 of ERISA, 1998. (Phyllis Borzi is a senior research staff scientist at the Center for Health Policy Research, George Washington University, Washington, D.C.)
16. *Federal Register*, 62, no. 173 (September 8, 1997), 47262.

17. Testimony of Marc I. Machiz, associate solicitor for plan benefits security, U.S. Department of Labor, before the Subcommittee on Roles and Responsibilities of Public/Private Purchasers and Quality Oversight Organizations, Commission on Consumer Protection and Quality in the Health Care Industry, February 25, 1998, 8.
18. Butler and Polzer, "Private-Sector Health Coverage," 47.
19. See Karl Polzer, "HIPAA as a Regulatory Model: Early Experiences and Future Prospects," National Health Policy Forum Issue Brief No. 735, April 5, 1999, 6.
20. *Pilot Life Insurance Company v. Dedeaux*, 481 U.S. 41 (1987).
21. U.S. General Accounting Office (GAO), "Employer-based Managed Care Plans: ERISA's Effect on Remedies for Benefit Denials and Medical Malpractice," GAO/HEHS-98-154, July 1998, 12-15.
22. GAO, "Employer-based Managed Care Plans."
23. See *Firestone Tire & Rubber Company v. Bruch*, 489 U.S. 101 (1989).
24. GAO, "Employer-based Managed Care Plans."
25. In many areas of regulation (for example in the case of solvency standards and most benefit mandates) the consumer protections available to participants in ERISA health plans differ depending on whether the plans are insured or self-insured. While ERISA forbids states from enforcing laws that relate to an ERISA plan, it allows states to regulate insurers. Therefore, in a sense, states can indirectly regulate ERISA health plans contracting with insurers by regulating the insurers, while self-insured ERISA plans are generally beyond states' reach. About 40 percent of people covered by ERISA health plans are in self-insured plans. Some large firms offer both self-insured and insured plans. No government agency has yet defined exactly what a self-insured plan is.
26. See Polzer, "HIPAA as a Regulatory Model."
27. Mark Hamelburg and Harry Conaway, "Side-by-side of House and Senate Health Care Bills," Washington Resource Group of William M. Mercer, Inc., Washington, D.C., October 27, 1999.
28. At two recent conferences, Patricia Nazemetz, vice president of human resources at Xerox Corp., has said that the company is exploring the possibility of giving its employees the option of receiving a financial contribution that they could use to buy "individual" health coverage.
29. For a comprehensive discussion of how ERISA preempts state law and affects policy options at the state level, see: Patricia Butler, "ERISA Preemption Manual for State Health Policy Makers," Alpha Center and National Academy for State Health Policy, forthcoming.
30. Molly Stauffer, program principal, Health Policy Tracking Service, National Conference of State Legislatures, telephone interview with author, December 20, 1999.
31. Hamelburg and Conaway, "House and Senate Health Care Bills."
32. Bryan A. Liang, "Patient Injury Incentives in Law," *Yale Law & Policy Review*, 1998.
33. GAO, "Employer-based Managed Care Plans," 19.
34. Butler, "Managed Care Plan Liability," 5.
35. "Candidate Bush Would Support Liability along Lines of Texas Managed Care Law," *BNA Pension & Benefits Reporter*, 26, no. 47 (November 29, 1999): 2765.
36. 1993 Westlaw 794305 (Riverside County Super. Ct/Central Cal. Dec. 23, 1993).
37. J. Clark Kelso, "Alternative Approaches to Liability: Models for Health Plan Liability," Henry J. Kaiser Family Foundation, Menlo Park, California, September 1999.
38. P. L. Havlicek, *Medical Groups in the U.S.: A Survey of Practice Characteristics* (Chicago: American Medical Association, Department of Data Survey and Planning, 1996).
39. James C. Robinson, *The Corporate Practice of Medicine* (Berkeley and Los Angeles, Calif.: Milbank Memorial Fund and University of California Press, 1999), 88.
40. Bryan A. Liang, "Patient Injury Incentives in Law," *Yale Law & Policy Review*, 1998.
41. Rick Weiss, "Medical Errors Blamed for Many Deaths," *Washington Post*, November 30, 1999, 1.
42. Statement by Lee N. Newcomer, M.D., senior vice president, Health Policy and Strategy, UnitedHealth Group, at a hearing of the Senate Committee on Health, Education, Labor, and Pensions on how to define medical necessity and its impact on quality of care, March 2, 1999.
43. Mark A. Schuster, Elizabeth A. McGlynn, and Robert H. Brook, "How Good Is the Quality of Health Care in the United States?," *Milbank Quarterly*, 76 (1998), no. 4: 517-563.
44. S. J. Bernstein et al., "The Appropriateness of Hysterectomy: A Comparison of Care in Seven Health Plans," *Journal of the American Medical Association*, 269 (1993): 2398-402.
45. M. Laouri et al., "Underuse of Coronary Angiography: Application of a Clinical Method," *International Journal for Quality in Health Care*, 9 (1997), no. 1: 5-22.
46. Schuster, McGlynn, and Brook, "Quality of Health Care," 535.
47. Dahlia K. Remler et al., "What Do Managed Care Plans Do to Affect Care? Results from a Survey of Physicians," *Inquiry*, 34 (Fall 1997): 196-204.
48. Carol Gentry, "Aetna May Adopt UnitedHealth's Model to Give Doctors More Say on Treatment," *Wall Street Journal*, November 22, 1999, B25.

49. Letter from P. John Seward, M.D., AMA executive vice president, and Cecil B. Wilson, M.D., president of the Florida Medical Association, to David F. Simon, chief legal officer, Aetna/U.S. Healthcare, October 31, 1997.
50. Kelso, "Alternative Approaches to Liability."
51. Kelso, "Alternative Approaches to Liability," 16.
52. Randall R. Bovbjerg, "Medical Malpractice: Problems and Reforms: A Policy-maker's Guide to Issues and Information," Urban Institute and Intergovernmental Health Policy Project, George Washington University, Washington, D.C., September 1995.
53. G. Calabresi. *The Cost of Accidents* (New Haven, Conn.: Yale University Press, 1970).
54. Randall Bovbjerg, "The Medical Malpractice Standard of Care: HMOs and Customary Practice," *Duke Law Journal*, 1975: 1375-1414; E. H. Morreim, "Medicine Meets Resource Limits: Restructuring the Legal Standard of Care," *University of Pittsburgh Law Review*, 59: 1-95.
55. Randall Bovbjerg, F. A. Sloan, and J. F. Blumstein, "Valuing Life and Limb in Tort: Scheduling 'Pain and Suffering,'" *Northwestern University Law Review*, 83 (Summer 1989): 908-976.
56. Randall R. Bovbjerg and Robert H. Miller, "Managed Care and Medical Injury: Let's Not Throw Out the Baby with the Backlash," *Journal of Health Politics, Policy and Law*, 24, no. 5 (October 1999).
57. David M. Studdert, William M. Sage, Carole Roan Gresenz, and Deborah R. Hensler, "Expanded Managed Care Liability: What Impact on Employer Coverage?" *Health Affairs*, 18, no. 6 (November/December 1999).
58. The study by Studdert, Sage, Gresenz, and Hensler summarizes efforts to estimate how much premiums might rise as a result of stripping back ERISA preemption of state tort actions. Based on a survey of expert opinion, the Congressional Budget Office estimated that health plans' liability costs would rise from 60 to 75 percent, resulting in a 1.2 percent premium increase. In a study funded by the managed care industry, the Barents Group forecast that premiums would increase 2.7 to 8.6 percent through the five-year period ending with 2003. Coopers and Lybrand looked at litigation rates in three plans where state-law remedies are available to plan participants (two large state government employee plans and one local government employee plan); extrapolating the litigation rates for these plans to ERISA plans would add only a tiny amount to premiums, the Coopers study found.
59. The Supreme Court is currently reviewing a controversial decision by the Seventh Circuit Court of Appeals, which ruled that a fiduciary duty under ERISA may be undertaken where an HMO and its physician owners receive financial incentives to control costs. In this case (*Pegram v. Herdrich*, U.S., No. 98-1949), a woman sued after her appendix ruptured following treatment by a physician at a clinic that owned the HMO. Cynthia Herdrich said she had to wait eight days to receive a basic test and that, when her appendix burst while waiting for the test, she had to travel several miles to a particular clinic for surgery. In a friend of the court brief, DOL pointed out that HMOs themselves are not ERISA plans, although, depending on the case, they may function as medical service providers to an ERISA plan or as an administrator of an ERISA plan. Insofar as it provides medical services, an HMO is no more subject to ERISA fiduciary standards than any other service provider to an ERISA plan, but if the HMO exercises discretionary authority or responsibility in administering the plan, it takes on fiduciary duties, DOL argued. The department acknowledges that, because HMOs often combine both fiduciary and nonfiduciary functions, the distinction may be difficult to draw. (See *Pegram v. Herdrich*, U.S., No. 98-1949, Brief for the United States as Amicus Curiae Supporting Petitioners. See also Barbara Yull, "American Medical Association, DOL, File Briefs in Managed Care Case," *Pension & Benefits Reporter*, 26, no. 47: 2769-70.)
60. For more detail, see Kelso, "Alternative Approaches to Liability."
61. Edward Walsh, "Sen. McCain Outlines Health Care Proposal," *Washington Post*, December 15, 1999, A4; "McCain: Joins Health Care Fray with New Reform Plan," *American Health Line*, (online news service), December 15, 1999.