LAW & MEDICINE

ERISA's Tangled Web

Can a managed care enrollee sue his plan if he is injured because of what he claims was the result of poor care and treatment by a plan physician? If he dies, can his estate sue the plan for damages?

Before 2004, the answers to these questions were uncertain. The legal cases that had been decided were definitely a mixed bag, depending upon whether the assertions against the managed care plan were found to involve strictly patient care, just administrative decisions, or a combination of both.

BY MILES J. ZAREMSKI, J.D.

The former two were easy enough, because strict patient care would fall under state law governing medical negligence cases. If the allegations were solely administrative, then the case would come under a federal statute known as the Employee Retirement Income Security Act, or ERISA.

ERISA was originally intended by Congress to govern the rights of pension plan beneficiaries. But legal cases morphed this legislation into protection for ERISA health plans against state-filed lawsuits based on medical malpractice.

When allegations involved both patient care and administrative decisions, some cases were not preempted by ERISA while others were—it depended on how the court interpreted what the injured party asserted in a lawsuit. If the court decided that the lawsuit fell under ERISA, that party would be entitled to only a limited remedy: the cost of the denied benefit (generally just the cost of the treatment or procedure in question). If ERISA did not preempt the lawsuit (or if the health plan was not governed by ERISA), the enrollee would be entitled to all remedies allowed under state law.

The landscape for these types of decisions changed in 2004, when the U.S. Supreme Court decided two cases: Aetna Health Inc. v. Davila (Davila) and Cigna Corp. v. Calad (Calad). In both cases, the patient sued for wrongful denial of coverage.

In the *Calad* case, Ruby Calad's physician recommended an extended hospital stay after Ms. Calad had a surgical procedure. The managed care plan, through its discharge nurse, thought the extension was unnecessary, and Ms. Calad was discharged from the hospital. Once home, she experienced postsurgical complications that required follow-up care.

In the *Davila* case, Juan Davila had various ailments, including diabetes, gastric ulcer disease, and arthritis. He was insured through Aetna's managed care plan, which he obtained through his employer. His physician, who was not in Aetna's network, recommended Vioxx (rofecoxib) for the treatment of his arthritis.

However, before allowing the use of Vioxx, Aetna required that Mr. Davila try two other medications, both less expensive than Vioxx. While on those "preferred" drugs, he experienced bleeding ulcers, internal bleeding, and a near heart attack. Because of the additional gastric impairment, he was no longer able to take medication absorbed through his stomach.

Both lawsuits were filed in Texas state court and then transferred to federal court. They made their way through the court system and eventually to the Supreme Court. The Supreme Court decided that the lawsuits fell under ERISA and that both lawsuits concerned benefits (coverage) promised to each plaintiff. The suits were not interpreted as asserting inappropriate medical care and treatment. Therefore, the plaintiffs could seek only the benefits promised but not delivered and no other damages.

In a separate but concurring opinion, Justice Ruth Bader Ginsburg, citing the words of an appeals court judge in another case, said, "I also join 'the rising judicial chorus urging that Congress and [this] Court revisit what is an unjust and increasingly tangled ERISA regime.' " That is to say, ERISA has been interpreted to provide protections to managed care plans that were never intended when this legislation was first signed into law.

In a way, this Supreme Court decision is good news for physicians, because it means that if they are named in a lawsuit together with a managed care plan, and the suit is found to fall under the ERISA statute, the odds are great that the only exposure to both parties will be ERISA's remedy: the cost of the benefit denied. They will escape the prospect of having to pay damages allowed for under state law, which are usually much higher.

That doesn't mean that the physician might not be sued separately, especially if there is a claim not related to treatment provided through the managed care plan. And of course if the health plan is found not to be an ERISA plan, then state laws apply. But unless and until Congress revisits the ERISA statute, physicians might find that being part of an ERISA plan isn't such a bad position to be in. ■

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Comments Sought on Proposed Patient Safety Regulations

BY DENISE NAPOLI
Assistant Editor

Draft federal regulations more than 2 years in the making aim to give hospital networks, physician groups, and similar organizations the ability to help doctors reduce medical errors and improve the quality of care they provide to patients.

The 72-page proposed rule offers the government's first pass on how to implement the Patient Safety and Quality Improvement Act of 2005 and gives guidance on how to create confidential patient safety organizations (PSOs). Comments on the proposed rule are being accepted until April 14.

First called for by the Institute of Medicine in its 1999 report "To Err is Human," PSOs will be entities to which physicians and other health care providers can voluntarily report "patient safety events" with anonymity and without fear of tort liability. PSOs will collect, aggregate, and analyze data and provide feedback to help clinicians and health care organizations improve on those events in the future, according to the law and proposed rule.

In an interview, Dr. Bill Munier, director of the Center for Quality Improvement and Patient Safety at the Agency for Health Care Research and Quality, said that patient safety events can be anything from health care–associated infections and patient falls to adverse drug reactions and wrong-site surgery.

According to the proposed rule, "a patient safety event may include an error of omission or commission, mistake, or malfunction in a patient care process; it may also involve an input to such process (such as a drug or device) or the environment in which such process occurs."

The term is intentionally more flexible than the more commonly used "medical errors" to account for not only traditional health care settings, but also for patients participating in clinical trials, and for ambulances, school clinics, and even locations where a provider is not present, such as a patient's home, according to the rule.

Until now, there has been no clear guidance on how an organization can become a PSO. But according to the proposed rule, public and private entities, both for-profit and not-for-profit, can seek listing as a PSO. This includes individual hospitals, hospital networks, professional associations, and almost any group related to providers with a solid network through which safety information can be aggregated and analyzed, said Dr. Munier.

Insurance companies, accreditation boards, and licensure agencies cannot be PSOs because of potential conflicts of interest.

"We know that clinicians and health care organizations want to participate in efforts to improve patient care, but they often are inhibited by fears of liability and sanctions," said Dr. Carolyn M. Clancy, AHRQ director. "The proposed regulation provides a framework for [PSOs] to facilitate a shared-learning approach that supports effective interventions that reduce risk of harm to patients."

Dr. Munier said that the rule took a long time to issue partly because its authors had to be sure it didn't conflict with state reporting requirements and the Health Insurance Portability and Accountability Act (HIPAA).

Dr. Bruce Bagley, medical director for quality improvement at the American Academy of Family Physicians, said in an interview that back in 2005, the AAFP had convened a work group to determine whether the academy ought to become a PSO. The proposed rule on what it would take to be a PSO was expected within the year, he said. But as implementation of the law languished, those plans were abandoned.

Now, Dr. Bagley said, he expects that the AAFP will once again look into becoming a PSO for its members, but he thinks that big institutions such as large hospital systems or the Mayo Clinic will be the best candidates for PSOs. Nevertheless, he said, "This is something that's been long needed, to be able to have medical professionals and other clinicians be open about reporting errors that can be analyzed in a systematic way, and see if we can prevent them in the future."

In a statement, Rich Umbdenstock, president and CEO of the American Hospital Association, said that his group was in strong support of the creation of PSOs. "Hospitals have already waited 2 years for this rule and this is only a first step in the process toward establishing PSOs. We will continue to work with HHS to ensure the timely creation of PSOs," he said.

Dr. J. James Rohack, a board member of the American Medical Association, agreed. In a statement, he said, "Since the passage of patient safety legislation in 2005, the American Medical Association and other patient safety advocates have eagerly awaited guidance for implementation from the administration. The proposed rule … will allow health care professionals to report errors voluntarily without fear of legal prosecution and transform the current culture of blame and punishment into one of open communication and prevention."

Also in a statement, the American College of Surgeons said that it was in the process of reviewing the proposed rule and it planned on submitting comments. "Along with these other health care system stakeholders, the college has been waiting with eager anticipation for the guidance and protections these regulations should offer, which will enable us to … truly improve surgical patient safety in both the inpatient and outpatient settings," said a representative of the college. ■

To view the proposed rule and learn how to comment, go to www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=AHRQ-2008-0001. Comments will be accepted until April 14.