Policy & Practice

NEJM Editors Support Plaintiff

Ten current and former New England Journal of Medicine editors have sided with the plaintiff in a U.S. Supreme Court case that could determine how much the Food and Drug Administration's approval of drugs can shield drug manufacturers from subsequent lawsuits. The high court is scheduled to hear the case, *Wyeth v. Levine*, on Nov. 3. The plaintiff, Vermont musician Diana Levine, had her right arm amputated after an infection she said was brought on by an injection of promethazine (Phenergan). She won a judgment of $6.8 million in a Vermont court. Wyeth contends that FDA approval should shield drug makers from state-based lawsuits—a legal doctrine known as preemption. "Because the preemption of state failure-to-warn claims involving prescription drugs would threaten this nation's public health by eliminating a necessary counterpart to the FDA, *Amici* urge this court to affirm the decision" of the Vermont court, the journal editors wrote in the brief they filed with the Supreme Court.

P4P Working, CMS Says

Medical practices that participated in a Medicare pay-for-performance demonstration program earned $16.7 million in incentive payments during the program's second year by improving the quality of care for patients with several chronic conditions, including heart failure, coronary artery disease, and diabetes, according to the Centers for Medicare and Medicaid Services. All 10 of the participating physician groups achieved benchmark or target performance on at least 25 out of 27 quality markers for patients with diabetes, coronary artery disease, and heart failure. Five of the groups achieved benchmark quality performance on all 27 quality measures. The groups improved their performance by changing some office processes and investing in health information technology. "These results show that by working in collaboration with the physician groups on new and innovative ways to reimburse for high-quality care, we are on the right track to find a better way to pay physicians," said Kerry Weems, CMS acting administrator. The demonstration project was originally scheduled to last 3 years but has been extended to a fourth year.

Part D Premiums for 2009

On average, Medicare beneficiaries can expect to pay about $28 per month for standard Part D prescription drug coverage next year. The estimates from the CMS are based on bids submitted for both prescription drug plans and Medicare Advantage drug plans. The estimated monthly premiums are about $3 higher than the average monthly premium costs this year, but are 37% lower than projections that were made when the Medicare prescription drug benefit was created in 2003. The $3 increase is based in part on rising drug costs in general and higher costs for catastrophic drug coverage. In some cases, price increases could be significant, Mr. Weems said during a teleconference. However, he noted that most beneficiaries will have the option to switch to a prescription drug plan with the same or lower premiums as they paid this year. Open enrollment for the fourth year of the Medicare Part D program is set to begin in November.

Genomics Collaboration

Pharmacy benefit manager Medco Health Solutions and the FDA have partnered to study genetic testing, according to Medco. The agreement extends to Aug. 31, 2010. Over the next 2 years, Medco will deliver a series of reports to the FDA that will address the safety of prescription drugs, physician participation in pharmacogenomics testing, the usefulness of the tests in prescribing, and quantifying prescription information that contains genetic information. Medco said its reports will be derived from clinical settings, including one that will examine whether physicians are willing to change the dose of a prescription based on a genetic test result. "Studying this field can advance pharmacy care to remove some of the trial and error in how medications are prescribed," Dr. Robert Epstein, Medco chief medical officer, said in a statement.

Uninsured Spend $30B on Care

Americans who lack health insurance for any part of 2008 will spend $30 billion out of pocket for health services and receive $56 billion in uncompensated care while uninsured, according to a study in Health Affairs. Government programs will pay for about $43 billion for the uncompensated care, the researchers reported. Compared with people who have full-year private health care coverage, people who are uninsured for a full year receive less than half as much care but pay a larger share out of pocket, the authors reported. Someone who is uninsured all year would pay 35%, or $583 on average, out of pocket toward average annual medical costs of $1,686. In contrast, annual medical costs of the privately insured average $3,915, with 17%, or $681 on average, paid out of pocket.

—Jane Anderson