POLICY & PRACTICE

CMS Tests PQRI Measures

The Centers for Medicare and Medicaid Services said it will begin testing 11 new quality measures for future adoption into the Physician Quality Reporting Initiative. PQRI provides incentive payments to providers who satisfactorily report data on covered Medicare services. CMS said it intends to track quality of care in influenza immunization in chronic kidney disease, assessment for use of anti-inflammatory or analgesic over-the-counter medications in osteoarthritis, and care plans for pain in medical and radiation oncology. CMS also will test melanoma- and radiology-related measures, as well as measures dealing with cataracts and age-related macular degeneration. CMS said it encourages providers to submit data for these test measures on Part B claims from July 1 through Sept. 30, 2008, but providers will not receive financial incentives for reporting the measures.

AMA Launches Insurer Report Card

The American Medical Association has launched a campaign to cut waste from the insurance claims process with a new health insurer report card. "To diagnose the areas of greatest concern within the claims processing system, the AMA has developed its first online rating of health insurers," said Dr. William Dolan, an AMA board member. Analysis of a random sample pulled from more than 5 million services billed electronically to Medicare and seven health insurers showed that insurers reported to physicians the correct contracted payment rate only 62%-87% of the time. Also, payers varied widely as to how often they applied computer-generated edits to reduce payments—from a low of less than 0.5% to a high of more than 9%. Physicians spend as much as 14% of their total revenue to ensure accurate insurance payments for their services, according to the AMA.

ACP Helps Members Choose EHRs

The American College of Physicians has launched a program designed to help members purchase and install electronic health record systems that match the needs of their practices. The EHR Partners Program is a collaboration between the college and participating EHR companies that have achieved 2006 and/or 2007 certification by the Certification Commission for Healthcare Information Technology (CCHIT). The ACP said it strongly recommends that physicians entering the EHR arena for the first time, or who are seeking to upgrade older systems, consider certified EHRs.

Areas Chosen for EHR Demo

Twelve areas across the country, ranging from entire states to smaller cities, will participate in a Medicare demonstration project that provides incentive payments to physicians for using certified EHRs to improve quality of care. The 5-year project is designed to help increase use of the technology in practices where adoption has been the slowest—at the individual physician and small practice level, CMS said. The areas selected to participate include Alabama; Delaware; Jacksonville, Fla.; Georgia; Maine; Louisiana; Maryland/Washington; Oklahoma; Pittsburgh; South Dakota; Virginia; and Madison, Wis. Financial incentives and bonus payments will be provided to as many as 1,200 primary care practices that use EHRs to improve quality, as measured by performance on clinical quality measures. Total payments for all 5 years may be up to $58,000 per physician or $290,000 per practice, CMS said.

Drug Lobby Spending Up 32%

The pharmaceutical and medical device industries had another banner year for spending on lobbying in 2007, according to a report by the Washington-based Center for Public Integrity. Last year, the pharmaceutical industry alone spent at least $168 million on lobbying Congress, a 32% increase from 2006, according to the report. Forty companies and three trade organizations (the Pharmaceutical Research and Manufacturers of America, the Biotechnology Industry Organization, and the Advanced Medical Technology Association) accounted for 90% of the spending. PhRMA led the way, spending $23 million in 2007. Amgen Inc. and Pfizer Inc. were the two biggest individual spenders, at $16 million and $13 million, respectively. Most efforts went into blocking drug reimportation, protecting patents, and supporting free-trade agreements. The industry also went to bat for reauthorization of the State Children's Health Insurance Program and extensions of the Prescription Drug User Fee and Best Pharmaceuticals for Children acts, according to the center's analysis of lobbying records submitted to the Senate Office of Public Records.

Insurers Back Medical Home

The board of directors of America's Health Insurance Plans has endorsed the concept of a medical home. The board voted to approve the principles for achieving coordinated, comprehensive care at the organization's Institute 2008 meeting. "The patient-centered medical home is a promising concept that would replace episodic care with a sustained relationship between patient and physician," the board said in a statement. The board suggested that "many clinical settings can potentially constitute a patient-centered medical home," but that all should follow eight broad principles: Care should be comprehensive and individualized to suit each patient; coordination should include strategies to engage the patient; health information technology should be used; clinicians should commit to being accountable for quality and to report on outcomes and cost-effectiveness; and payments should reflect the level of management involved and help support the cost of developing a medical home infrastructure.

—Jane Anderson

FDA System to Search For Adverse Events

BY MARY ELLEN SCHNEIDER
New York Bureau

The Food and Drug Administration has developed a new national electronic surveillance system that will allow it to search and analyze claims data and other clinical databases for possible postmarket adverse events for drugs and medical devices.

The Sentinel Initiative is designed to bring safety concerns from approved drugs and other medical products to the FDA's attention faster than the traditional MedWatch adverse event reporting system alone.

We are moving from a reactive dependence on voluntary reporting to a proactive surveillance of current products.

MR. LEAVITT

"We are moving from a reactive dependence on voluntary reporting of product safety concerns to a proactive surveillance of medical products that are currently on the market," Health and Human Services Secretary Mike Leavitt said during a press conference to announce the initiative.

"The result will be much-improved safety and protections for the American people," he said.

During the first phase of the surveillance project, the FDA will rely on Medicare data. As part of a pilot collaboration with the Centers for Medicare and Medicaid Services, FDA officials will use the Sentinel system to query Medicare Part D prescription drug claims data, which will be linked to Medicare inpatient and outpatient claims data.

The Part D database currently holds information on medications used by more than 25 million beneficiaries, according to HHS.

The FDA will begin to look into the data in 30 days, following the publication of a final regulation that will allow federal agencies, states, and academic researchers to use claims data from the Medicare Part D program for safety research and quality initiatives.

Starting with the Medicare population will provide valuable data on the elderly and disabled population, said Kerry N. Weems, acting CMS administrator. Drug safety and efficacy data is usually limited in this group because the elderly and disabled often are excluded from clinical trials. This population also is at greater risk for medication side effects because of polypharmacy and many chronic diseases, according to CMS.

In the future, FDA officials hope to be able to query data from other government agencies, such as the Department of Defense and the Department of Veterans Affairs, as well as from large private health plans, said Dr. Andrew C. von Eschenbach, FDA commissioner.

He added that the Sentinel Initiative includes patient privacy protections. The system queries existing databases without actually acquiring the data. Essentially, the system asks questions and gets answers without identifying patient information, Dr. von Eschenbach said.

The Sentinel system will work in conjunction with the existing FDA surveillance systems. For example, if the FDA receives a report of an adverse event following the use of a drug, officials will be able to query data on a large number of subjects who have taken the drug. And, in the future, agency officials may even be able to compare data from patients taking the drug with a control group of similar patients who have not taken the drug. This will allow FDA officials to give physicians better information about what particular groups of patients may be at higher risk for a specific adverse event, said Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research.

"Although it won't answer all the questions, it will provide us with a tremendous new source of information," Dr. Woodcock said.

The Institute of Medicine called on the FDA in a 2006 report to create an active surveillance system as a way to improve the safety of drugs. In addition, the Food and Drug Administration Amendments Act of 2007 (FDAAA) directs the FDA to develop a proactive surveillance system.

The Sentinel Initiative has garnered the support of the Pharmaceutical Research and Manufacturers of America. The group issued a statement praising the movement from voluntary reporting alone to a system that incorporates proactive monitoring of drugs and other medical products.

"Clearly, this program should improve the efficiency of postmarket surveillance of medicines and, in the end, the beneficiaries will be the many patients using these products," said Ken Johnson, senior vice president of PhRMA. ■

Consumer Guide to Complaint Reporting

A Web site with detailed instructions on how to use the Food and Drug Administration's consumer complaint system and Medwatch is available at www.fda.gov/consumer/updates/reporting061008.html. The site details which problems should be reported and how to report them, and provides phone numbers for reporting emergencies. A printer-friendly PDF is also available at www.fda.gov/consumer/updates/reporting061008.pdf.