

FDA Aims to Reduce Preventable Drug Injuries

BY ELIZABETH
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SILVER SPRING, MD. — Reducing preventable injuries from medication errors, misuse, and abuse is the goal of an initiative being launched by the Food and Drug Administration, agency officials announced at a briefing.

The Safe Use Initiative is intended to “reduce preventable harm by identifying specific, preventable medication risks and developing, implementing, and evaluating cross-sector interventions with partners who are committed to safe medication use,” FDA officials said. In addition to health care professionals, partners will include federal agencies, professional societies, pharmacies, hospitals, and manufacturers, as well as patients, caregivers, and consumers.

Drugs, drug classes, and ther-

apeutic situations associated with preventable harm will be identified as part of the initiative.

In addition, the initiative will use measures of success to evaluate the impact of those interventions, Dr. Margaret Hamburg, FDA Commissioner, said during the briefing. Each year, adverse events from drug use result in more than 4 million visits to emergency rooms, physicians’ offices, and outpatient facilities, and 117,000 hospitalizations, she said.

As many as half of all medication injuries—which include dosing errors, mixups during drug administration, and unintentional misuse of the medication—could be prevented with currently available information about the medication, Dr. Hamburg added.

During the briefing, Dr. Janet Woodcock, who will be spearheading the initiative, distin-

guished between the events targeted by the initiative and inherent medication risks that are not preventable, such as side effects of chemotherapy. Most preventable injuries are caused by a lack of knowledge about the medication, including by prescribers and patients at the point of care, said Dr. Woodcock, director of the FDA’s Center for Drug Evaluation and Research.

Dr. Woodcock said that the agency has discussed the initiative with physicians’ and nurses’ professional groups, and will seek input from the health care community and the public to determine what they perceive to be the biggest problems. Proposed interventions will be specific to a particular problem, she said. For example, measures could be taken to reduce the number of operating room fires (currently about 600 a year), the

risks of inadvertent overexposure to acetaminophen, and contamination from multiple-use medication vials.

Dr. Woodcock and Dr. Hamburg cited the following estimates during the briefing:

► The Institute of Medicine estimated that every year 400,000 hospitalized patients have a preventable injury.

► The cost of preventable injuries from medications exceeds \$4 billion annually, according to the IOM.

► An estimated 600,000 emergency department visits per year are caused by unsupervised ingestion of medications among children under age 12.

The agency also announced a new draft guidance document on delivery devices for over-the-counter liquid drug products for companies that manufacture, market, or distribute medications such as elixirs, suspen-

sions, and syrups, which are packaged with calibrated cups, droppers, syringes, or other dosage delivery devices.

The draft guidance addresses “ongoing safety concerns about the serious potential for accidental drug overdoses of OTC liquid drug products that can result from the use of dosage delivery devices with markings that are inconsistent or incompatible with the labeled dosage directions for OTC drug products,” according to the document published in the Federal Register on Nov. 4. ■

For information on the safety initiative, visit www.fda.gov/Drugs/DrugSafety/ucm187806.htm. For information on the draft guidance for OTC dosage delivery devices, visit www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM188992.pdf.

Survey: Physician Groups Prefer Medicare to Private Insurers

BY ERIK GOLDMAN

DENVER — Physicians may not be enamored of Medicare, but they like it a whole lot better than private insurance plans, according to a survey by the Medical Group Management Association.

MGMA’s Payer Performance Study—covering more than 1,700 group practices—showed that physicians groups ranked Medicare Part B well ahead of six of the largest private insurance companies in terms of overall satisfaction. The organization released the data at its annual meeting.

The survey asked participants, all of whom were members of MGMA, to rank seven of the largest payers—Medicare Part B, UnitedHealthcare, Aetna, Cigna, Humana, Coventry, and Anthem—on parameters including payer communications, provider credentialing, contract negotiation, payment processing, systems transparency, and overall satisfaction.

Medicare led the pack with a mean aggregate satisfaction score of 3.59 on a 6-point scale (1 = totally dissatisfied, 6 = completely satisfied). Aetna took second place with a score of 3.14.

The big loser? UnitedHealthcare, with a score of 2.45.

Medicare scored particularly well on the amount of time it takes to respond to questions from physicians or practice managers, the accuracy of its responses, and transparency in disclosing fee

schedules and reimbursement policies.

The respondents were much less satisfied with Medicare’s provider credentialing processes. On that measure, the Medicare ranked last, with Aetna and Anthem taking first and second place. “The Medicare credentialing process is completely out of synch with that of the private payers, and it is a problem,” said Dr. William Jessee, president and chief executive officer of MGMA.

Dr. Jessee said that the data show particularly strong member dissatisfaction with the private insurers on the matter of negotiating contracts. “MGMA members feel

there is disproportionate power on the side of the payers.”

Although Medicare may have scored better than the private insurers, the scores suggest there’s much room for improvement in the federal program. Dr. Jessee said that the MGMA survey deliberately did not ask about satisfaction with actual reimbursement rates, but he anticipated that Medicare’s relatively favorable ranking could drop considerably if the federal government goes forward with its proposed 21% physician fee cuts next year.

The fee-shearing is among a number of federal-level issues on which MGMA is taking action. “We have three major tasks: repeal the sustainable growth rate [SGR] formula as outlined in HR3200 and most other bills; create a reimbursement formula that accurately reimburses physicians for their actu-

al costs; and simplify administrative transactions,” he said.

Medical group operating costs have been increasing at a rate of 6.5% per year, on average, for the last decade, yet Medicare reimbursement has been flat. That, said Dr. Jessee, is making it difficult for many groups to stay in business. Any

further cuts in fees will likely discourage many doctors from continuing to participate in Medicare.

MGMA is committed to fighting the cuts and repealing the SGR formula, and the group has made some progress in Washington, but “there’s a lot more game to be played,” he said. ■

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