

## POLICY &amp; PRACTICE

**HHS Buys More Avian Flu Vaccine**

The Department of Health and Human Services is spending another \$62.5 million to buy vaccine to be used in the event of an avian influenza pandemic. HHS awarded the contract to Chiron Corp. to produce vaccine against the H5N1 influenza strain. "An influenza vaccine effective against the H5N1 virus is our best hope of protecting the American people from a virus for which they have no immunity," Secretary Mike Leavitt said in a statement. Last month, the government awarded a \$100 million contract to Sanofi Pasteur to produce a similar vaccine. HHS officials plan to buy enough H5N1 vaccine for 20 million people and enough influenza antiviral medication for an additional 20 million people. Both will become part of the Strategic National Stockpile.

**Finance a Challenge**

Most physicians say that managing their finances will become more challenging over the next few years, according to a survey conducted by American Express. The survey was based on online interviews with 360 mostly primary care physicians and ob.gyns. in private practice. Additionally, 100 oncologists, 102 dermatologists, 100 urologists, 101 ophthalmologists, and 116 dentists in private practice were surveyed. For 83% of the survey respondents, managing the dual role of practicing medicine and running their business is a challenge. Nearly 75% said they need more financial training.

**Humana Settles Class Action Suit**

Humana and representatives of more than 700,000 physicians settled a nationwide class action suit that had been pending in U.S. District Court for the Southern District of Florida for more than 6 years. The original lawsuit alleged a conspiracy between Humana and other HMOs against physicians, "to manipulate software to cheat the doctor out of getting paid money due for services rendered," Archie Lamb, lead co-counsel for the physicians, said in an interview. Pursuant to the settlement, Humana has agreed to pay \$40 million to physicians, as well as modify its software system to make it more fair and efficient for physicians—changes worth more than \$75 million. "Humana should be commended for joining the growing list of health insurance companies that have settled with the nation's physicians," Mr. Lamb said. Those companies include Aetna, Cigna, Prudential, and HealthNet.

**Public Favors EHRs**

Nearly three-fourths of Americans favor establishing a nationwide electronic information exchange to allow patient health records to be shared quickly among health professionals via the Internet, according to a survey of 800 adults sponsored by the Markle Foundation. However, 79% of respondents said it was important to make sure sharing could take place only after patients

gave their permission. "Americans use digital information technology to pay bills, book flights, and customize the music they listen to, and our research shows they now want to use health information technology to get the best care possible for themselves," said Zoe Baird, the foundation's president. "People realize that if they or those they love are in an accident or disaster, having their medical records available at a moment's notice through secure, electronic information exchange could mean the difference between life and death."

**Pinpointing Side Effects**

In an attempt to more quickly pinpoint the potential side effects of drugs on the market, the Food and Drug Administration has contracted with several organizations to access their prescription drug data. Ingenix Inc., a unit of UnitedHealth Group Inc.; the Kaiser Foundation Research Institute; Vanderbilt University, Nashville, Tenn.; and the privately held Harvard Pilgrim Health Care Inc. each won contracts worth about \$1.35 million to provide the data. Under the agreements, FDA scientists will be able to search each organization's database of medical claims and prescription drug use. The databases include information from patients enrolled in private insurance plans and state Medicaid programs. "These proactive efforts should enhance the FDA's ability to identify and assess issues and potential risks related to pharmaceutical agents in a more timely fashion than ever before," said Terri Madison, Ph.D., president of i3 Drug Safety, which will lead the Ingenix program. In a statement, Alan Goldhammer, Ph.D., associate vice president for regulatory affairs at Pharmaceutical Research and Manufacturers of America, said PhRMA supported "new approaches to improving pharmacovigilance." The group called on the CERTs (Centers for Education and Research on Therapeutics) to hold a workshop on this topic.

**Voters Doubt Congress on Access**

Roughly two-thirds of voters think Congress has not made much progress on helping those without health insurance, and is not likely to make much more in the next 5-10 years, according to a survey of 800 likely voters sponsored by Ceasefire on Health Care, a group whose aim is to stimulate dialogue on health care between Republican and Democratic policy makers. Overall, poll respondents listed their top four health care priorities as making sure all U.S. children have access to basic health care, guaranteeing health care to every American citizen, providing better preventive health care to all Americans, and helping control the amount of out-of-pocket health care costs. About "88% of those surveyed want Congress to compromise on the issue of the uninsured," said former Sen. John Breaux (D-La.), who is leading the group.

—Jennifer Lubell

# Physician Panel Challenges Vendor Authority in CAP

BY JENNIFER LUBELL

Associate Editor, Practice Trends

WASHINGTON — Vendors should not be allowed to cut off distribution of drugs to patients regardless of their ability to pay under Medicare's new drug acquisition program, the Practicing Physicians Advisory Council recommended.

Scheduled to begin mid-2006, the Medicare competitive acquisition program (CAP) for Part B drugs and biologicals will select vendors through a bidding process to bill Medicare for these types of drugs and collect coinsurance or deductibles from patients.

Currently, physicians must purchase these drugs and biologicals from a distributor or manufacturer and then bill Medicare for reimbursement, which is set at a statutorily mandated payment rate of 106% of the manufacturer's average sales price (or ASP + 6%). Medicare pays 80% of this rate, and the physician collects a 20% copayment from the beneficiary.

Under the CAP, the only thing the physician has to do is purchase the drugs from the preselected vendors. The program was designed to reduce the administrative burden for physicians by taking them out of the financial loop. However, it also means that physicians won't have as much control over these drugs—and that vendors can elect not to ship a drug if the patient has not met some of the copay obligations.

This system will inevitably work against patients who need therapy but have no money and the physicians who treat them, said Barbara McAneny, M.D., a member of the PPAC and an oncologist, who proposed the recommendation.

Physicians are required by law to attempt to collect those copayments, "but we know that we're going to end up eating [the cost of the drug] because the patient doesn't have it." However, the physician is going to continue treating those patients.

The provision that an executive of a vendor corporation can make the decision to cut somebody off 15 days after they've failed to make a payment is unfair, Dr. McAneny said. The vendors "never have to face that person and say, 'I'm sorry, you get to die now.' But when I'm in my practice looking at that person, that's what it will come down to. The person they'll see will be me."

From a moral and ethical standpoint, the interim final rule leaves physicians with only one option: to opt out of the CAP to avoid abandoning patients, continue to purchase drugs on the ASP + 6% market, receive 86% of the cost of the drug, "and chew up the rest," she said.

Medicare's reimbursement under ASP can fall short of what the drugs actually cost, given fluctuations in what distributors

and manufacturers charge for the drugs.

"I assume the vendors, who tend to be large pharmaceutical manufacturing corporations, would be in a much better position to eat those costs than I would as an individual physician," Dr. McAneny said.

Amy Bassano, director of the division of ambulatory services at the Centers for Medicare and Medicaid Services (CMS) Center for Medicare Management, noted that Medicare supplier provider agreements do not require services to be provided except in cases of emergency and civil rights. "That's what we're coming up against," she said. However, there are cases where coinsurance could be waived if there is a demonstrated financial hardship and the vendor made an attempt to collect, she added.

The panel decided that CMS should reevaluate its contention that working with CAP vendors would not increase the administrative burden of physicians.

In other PPAC recommendations:

- ▶ CMS should work with Bill Thomas (R-Calif.), chairman of the House Ways and Means Committee, to clarify how Congress intended the ASP and CAP to function independently of each other.

- ▶ CAP vendor prices should not be included in the calculation of the ASP. The inclusion is duplicative and unfair to physicians not participating in the CAP, the PPAC determined.

Given that the CMS has recognized the increased cost of dispensing drugs by pharmacies and has added 2% of the average sales price to cover pharmacy overhead costs under the ASP, the PPAC recommended that the CMS "treat physicians equally" and add 2% for physicians using the ASP + 6% and a dispensing fee for physicians using the CAP.

Physicians under the interim final rule would have only 14 days to submit to Medicare carriers procedural claims, including all necessary codes, for the administration of the drugs. Taking into account the challenges associated with meeting that deadline, the PPAC recommended that the time frame be extended to 30 days.

Also, CAP participation should be determined on an individual basis, and not as a group requirement, the panel recommended. Under the interim final rule, if one physician in a group practice decides to participate in the CAP, all of the physicians in that practice are forced to do so, Ronald Castellanos, M.D., chairman of the PPAC, said in an interview.

The program's launch was originally scheduled for January 2006, but it was delayed for 6 months after the CMS announced the suspension of the vendor bidding process to allow more time for review of public comments. The agency expects to publish a final rule on the CAP in late 2005, which would reopen bidding. ■

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