# Physician Panel Challenges Vendor Authority in CAP

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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. If the patient is unemployed, "there is no way to make that copay," she said.

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. This is the only requirement under Medicare where an individual determines whether a group participates, he said.

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 the bidding process. Drugs could be first delivered under the program by July 2006. ■

## POLICY & PRACTICE

### Rituximab Reviewed for RA

Rituximab marketers Biogen Idec Inc. and Genentech Inc. are seeking Food and Drug Administration approval for a new indication for the drug in patients with active rheumatoid arthritis that inadequately responds to anti-TNF therapy. The submission of the supplemental Biologics License Application to the FDA is based in large part on the results of a 24-week phase III study known as Randomized Evaluation of Long-term Efficacy of Rituximab in RA (REFLEX). Patients who received a single course of two infusions of Rituximab with a stable dose of methotrexate had a statistically significant improvement in symptoms at 24 weeks, compared with patients who received placebo and methotrexate. The results of the REFLEX trial are slated to be presented at the American College of Rheumatology meeting in San Diego next month.

### Pediatric Rheumatology Grant

Officials at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) are trying to address the national shortage of pediatric rheumatologists through grants to training programs. One 5-year grant to train fellows in pediatric rheumatology was awarded to the Children's Hospital of Pittsburgh. The program will receive funding to train four fellows a year. There are currently 207 certified pediatric rheumatologists in the United States, according to the American Board of Pediatrics. "There is a tremendous need for this because pediatric rheumatology is one of the most underrepresented pediatric specialties, with only about 20 fellows a year in training nationwide," Raphael Hirsch, M.D., division chief of pediatric rheumatology at Children's Hospital of Pittsburgh said in a statement. This is the second NIAMS grant awarded specifically for training pediatric rheumatologists. The first grant was awarded to the Children's Hospital Medical Center of Cincinnati.

### Number of Uninsured Grows

The Census Bureau reports that 45.8 million Americans were without health insurance in 2004, up from 45 million in 2003. While the increase is statistically small, it means that "an additional 860,000 Americans live without the safety net of health insurance," J. Edward Hill, M.D., president of the American Medical Association, said in a statement. "As the decrease in employment-based health insurance continues, the AMA renews its call for health insurance solutions that put patients in the driver's seat, along with their physicians," Dr. Hill said. In other statistics, the number of people with health insurance increased by 2 million, to 245.3 million, between 2003 and 2004. Those covered by government health insurance rose from 76.8 million in 2003 to 79 million—driven by increases in the percentage and number of people covered by Medicaid.

### Split on Medicare's Rx Benefit

Patients' optimism about Medicare's new prescription drug benefit has improved over the last few months, although beneficiaries remain split on their support, an August poll conducted by the Kaiser Family Foundation indicated. About one in three (32%) seniors has a favorable impression of the benefit, and an equal portion (32%) have a negative one. This figure can be compared with April, when only one in five (21%) had a favorable impression of it. Comprehension of the benefit has improved: Overall, 37% of seniors now say they understand the new benefit "very" or "somewhat" well, up from 29% in April. Six in 10 seniors (60%) say they don't understand the benefit well or at all. Slightly more than one in five seniors (22%) say they plan to enroll in the benefit, up from 9% in April. The poll represented 1,205 adults aged 18 and older, including 300 respondents aged 65 years and older, interviewed by telephone by Princeton Survey Research Associates, on behalf of Kaiser.

### Driven Into Debt

An estimated 77 million Americans aged 19 years and older—nearly two of five adults—have had difficulty paying medical bills, have accrued medical debt, or both, according to an analysis of the 2003 Commonwealth Fund Biennial Health Insurance Survey. Adults of working age incur significantly higher rates of medical-bill and debt problems than adults 65 and older, with rates highest among the uninsured. "Even working-age adults who are continually insured have problems paying their medical bills and have medical debt," the analysis stated. Two-thirds of people with a medical bill or debt issue went without needed care because of cost.

### Walter Reed to Close

Walter Reed Army Medical Center in Washington, which has cared for hundreds of thousands of soldiers and dignitaries for the past 96 years, is slated to close as part of the base realignment and closure process. The medical center was tapped by the Department of Defense to be closed, and that recommendation was recently approved by members of the Defense Base Realignment and Closure Commission. The commission sent its final report to President Bush on Sept. 8. If the president agrees with the recommendations, he will send the entire list to Congress for a vote. Congress must accept or reject the list in full, but they cannot amend it. If the closure is approved, most of the staff and services from the army hospital will be combined with services at the National Naval Medical Center in Bethesda, Md., and renamed the Walter Reed National Military Medical Center. Other services will be moved to Fort Belvoir, Va. Closures and realignments must begin within 2 years of Congressional approval and be completed within 6 years, according to the Base Realignment and Closure statute.

**—Mary Ellen Schneider**

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