AMA Assails New Voluntary Reporting Program

BY JENNIFER LUBELL
Associate Editor, Practice Trends

DALLAS — Predicting more administrative burdens and an eventual mandate on performance measures, delegates at the interim meeting of the American Medical Association's House of Delegates voted to oppose the federal government's plans to implement a voluntary quality reporting program for Medicare.

Delegates adopted a report from the AMA's board of trustees that strongly objected to the coming system, and offered to assist the government in correcting the program's "strong deficiencies."

The Centers for Medicare and Medicaid Services announced the "Physician Voluntary Reporting Program" in late October, and said that the new initiative would avoid unnecessary costs and improve quality of care.

Beginning next month, physicians who choose to participate will voluntarily send information to CMS about the quality of care they provide to beneficiaries. They will receive feedback on their performance from the agency as early as next summer.

In its report and in a letter to CMS administrator Mark B. McClellan, M.D., AMA trustees expressed doubts that the new system will improve the quality of health care.

"The physician community has made a good faith effort to develop, endorse, and implement physician performance measures," some in collaboration with CMS, the letter said. "However, the excessive administrative requirements that this program will impose on physicians could doom this initiative."

The program would force primary care physicians with an already busy patient load to develop a new reporting system from scratch, said Joseph Zebley, M.D., a delegate from the American Academy of Family Physicians, during committee debate on the board's report.

During the first phase of the program, CMS will collect clinical data through a set of Healthcare Common Procedure Coding System (HCPCS) codes—also called G-codes—that will be included in the claims physicians currently submit to CMS.

The data will then be used to measure the quality of services provided to Medicare patients.

In its letter to CMS, the trustees noted that a participating primary care physician treating a 70-year-old woman with common conditions like osteoporosis, diabetes, and heart disease would have to report on approximately 2-13 measures and consider 36-39 G-codes.

Not only don't physicians use G-codes, "electronic health records don't have G-codes as part of their software," Mary Frank, M.D., AAFP board chair and delegate to the AMA House noted. "We put CPT codes [into the electronic health records], which is what we all use."

Dr. Zebley added that the program "would place a tremendous burden on family physicians and other primary care physicians."

G-codes would serve as an "interim step" until the electronic submission of data through electronic health records replaced this process, CMS said when announcing the voluntary program. The agency promised it would collaborate with participating physicians to develop such electronic data submission records.

Although CMS said in its announcement that participation in the voluntary program would not affect physician reimbursement under Medicare, many delegates expressed concern that the system would eventually become mandatory.

CMS "has indicated that there could be a link between reporting data and receiving higher Medicare payments next year," depending on the success of the voluntary reporting program, William Kobler, M.D., AMA delegate from Illinois, noted during committee proceedings.

Other business addressed by the AMA House of Delegates included:

► **Medicaid reform.** Delegates passed a resolution opposing Medicaid reform legislation—now pending in the U.S. House of Representatives—that would mandate premiums and copayments for acute care services and pharmaceuticals for children who live at or below 133% of the federal poverty level.

► **Smoking bans.** Applying a hard-line approach to kicking the habit, delegates voted that the AMA should actively support national, state, and local legislation and pursue regulations banning smoking in all workplaces. In addition, the AMA should work to ensure that federal legislation banning smoking in all workplaces does not prohibit or weaken existing and stricter state or local regulations.

The AMA should also actively pursue national legislation banning smoking in all cafeterias, restaurants, cafes, supermarkets, and other venues where food or drink is consumed on the premises.

► **Prisoner interrogation.** Delegates asked that the AMA's Council on Ethical and Judicial Affairs "clearly delineate" the boundaries of ethical practice with respect to participation in the interrogation of prisoners and detainees.

► **Medicare Part D.** Delegates voted that the AMA should support legislation and urge the Department of Health and Human Services to modify or eliminate the exclusion of various prescription drugs from coverage under Part D, and to ensure that Medicare contractors administering the new drug benefit include on their formularies medications to treat psychiatric and substance use disorders, including benzodiazepines, methadone, buprenorphine, acamprosate, disulfiram, and naltrexone.

► **Disaster preparedness and response.** Delegates called on state and local public health entities to develop a public health disaster plan specific to their locations. National legislation should also be enacted to give qualified physicians automatic medical liability immunity in the event of a declared disaster or federal emergency. ■

CMS's Reporting Criteria

Thirty-six evidence-based measures are to be reported in the first phase of the voluntary reporting program, according to CMS.

The final measures run the gamut of services, from influenza, pneumococcal vaccinations, and mammography to more complex surgery-related measures, such as prolonged intubation during isolated coronary artery bypass graft procedures. Other measures include the administration of aspirin and β-blockers at the time of arrival for acute MI, and the screening of elderly patients for falls and urinary incontinence.

According to CMS, the performance measures were developed in collaboration with physicians and physician organizations, as well as other stakeholders. Work by the National Quality Forum, the Ambulatory Care Alliance, the AMA's Physician Consortium for Quality Improvement, the National Committee for Quality Assurance, and RAND Corporation "provided the basis for the selection of these measures," CMS indicated in a statement.

Yet many AMA delegates at the interim meeting said that they felt CMS had "sprung" the program on them at a time when they were facing a 4.4% reduction in Medicare payments.

Michael Barr, M.D., vice president of practice advocacy and improvement at the American College of Physicians (ACP), said that the ACP was discussing its concerns with CMS about the voluntary reporting program, including the fact that not all of the measures had been endorsed by the National Quality Forum.

"This is just the first step of the process" and it is voluntary, CMS spokesperson Peter Ashkenaz pointed out in an interview. "We want to be able to collect information and provide analysis to see how this works." Ultimately, the goal is to establish a program in which CMS pays for services rendered on high quality of care, not on volume, he said.

Two Trials Result in Two Very Different Vioxx Verdicts

BY MARY ELLEN SCHNEIDER
Senior Writer

The pharmaceutical industry may be breathing a collective sigh of relief over the latest court verdict involving Merck & Co.'s Vioxx, but it may not be time to pop the cork on the champagne.

Experts say the two different jury decisions handed down so far could still have some negative implications for the pharmaceutical industry—and for physicians.

In August, a Texas jury awarded $253 million to the widow of a man who died after taking Vioxx (rofecoxib), but in November a New Jersey jury found no fault with the company's actions in the case of a man who claimed that Vioxx contributed to his heart attack.

This latest verdict is "definitely a huge victory for Merck," with its implication that at least some of the 6,000 pending cases against the company will be dropped, said Daphne Monie, Ph.D., an analyst in the immune and inflammatory disorders group at Decision Resources Inc., a market research firm that conducts analysis of trends in the drug industry.

However, it could spell trouble for the pharmaceutical industry.

The first case shows that a jury is willing to hold the company responsible for the adverse effects of the drug, even as a different jury concluded that the company provided adequate warning to physicians and the public about risks. When taken together, it sends the message that drug companies could be held liable for adverse effects even when the risks are properly disclosed, she said.

And it's possible that physicians could also become the target of lawsuits. If the precedent is set that Merck can be held liable for adverse events even when providing adequate warning about the risks, physicians may be held responsible for prescribing the drugs. At press time, Dr. Monie knew of no such cases against physicians involving Vioxx.

But Eric Matteson, M.D., a rheumatologist and professor of medicine at the Mayo Clinic in Rochester, Minn., said that cases against physicians are unlikely because Vioxx was an FDA-approved drug and there were limited warnings about its use. "I think physicians prescribed in good faith," he said.

The two verdicts in these cases reflect the complexity of trying to attribute cardiovascular events to exposure to a particular drug especially when other drugs and comorbidities are involved, he added.

The risk information about cyclooxygenase-2 (COX-2) inhibitors in general has made everyone a lot more cautious. It definitely seems to be slowing down the release of new COX-2s onto the market, he said, and it may affect the willingness of physicians to prescribe COX-2s when they do become available.

Regardless of the verdicts, the courtroom is not the best place to be debating the safety of Vioxx, said W. Hayes Wilson, M.D., a national medical adviser for the Arthritis Foundation and chief of rheumatology at Piedmont Hospital in Atlanta.

"There is no correlation between jury verdicts and scientific literature," Dr. Wilson said. "Scientific literature is not best evaluated in a court of law." ■