FDA: Expect to Provide 5-Year Follow-Up for DES

BY ALICIA AULT
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The Food and Drug Administration has given manufacturers of coronary drug-eluting stents a look at what kind of safety and effectiveness data it will be seeking in the future—and the industry does not appear to be taken aback by what's in the 89-page document.

"This draft guidance is part of FDA's ongoing effort to provide regulated industry with recommendations on measures that can minimize the risks while preserving for patients the benefits of drug-eluting stents," said Dr. Daniel Schultz, director of the FDA's Center for Devices and Radiological Health, in a statement accompanying the document's publication.

The draft gives recommendations on assessing the toxicity of drug coatings, both on their own and as part of the stent product, according to the agency. Most of the guidance pertains to metal drug-eluting stents; there is less complete information provided on stents made from other materials, such as ceramic or polymer.

The document clearly states an expectation of postmarketing studies out to 5 years after approval. The proposed "guidance," if made final, would not carry the weight of a regulation.

The guidance is a departure for the agency, as it combines the efforts of the drug and device divisions. "This guidance demonstrates how FDA will need to work across traditional product boundaries to guide the development of innovative new products," said Dr. Janet Woodcock, director of the Center for Drug Evaluation and Research, in the statement.

Dr. Christopher White, chairman of the department of cardiovascular diseases at Ochsner Clinic Foundation, and a principal investigator for several stents, views the FDA guidance as a positive development. "The fact that FDA is willing to commit on paper the core elements of what they view as necessary for device approval is actually very helpful," said Dr. White in an interview.

He said that the draft does not seek much that companies are not already doing—with the exception of long postmarketing data—and it will take a while to be put in place.

A Boston Scientific Corp. spokesman agreed that its pipeline would likely not be affected. In any case, Boston Scientific has already been collecting 5 years of postmarketing data on its products, said the spokesman.

The FDA will accept comments on the guidance through July. ■

Physicians May Soon Be Able to See and Challenge Report Cards

BY MARY ELLEN SCHNEIDER
New York Bureau

Under an agreement among physicians, consumers, employers, and large insurers, some health plans have agreed to have their physician rating systems audited by independent experts.

The announcement comes after physicians around the country have questioned the methods used by health plans to produce the physician performance ratings for consumers.

Under the voluntary agreement, health plans would disclose their rating methods. In addition, physicians would have a chance to review their performance data and challenge it prior to publication.

"Having that transparency is a huge change," said Dr. Douglas Henley, executive vice president of the American Academy of Family Physicians, which is supporting the agreement, known as the Patient Charter for Physician Performance Measurement, Reporting, and Tiering Programs. Giving physicians a chance to ensure that the data is accurate makes the process fair, he said. It's also beneficial for consumers who will be able to better rely on the information provided by their health plan, Dr. Henley said.

The project was led by the Consumer-Purchaser Disclosure Project, a coalition of consumer, labor, and employer organizations that support publicly reported health performance information.

Other principles of the Patient Charter state that the measures should aim to assess whether care is safe, timely, effective, equitable, and patient centered. The measures used should also be based on national standards, preferably those endorsed by the National Quality Forum. The principles of the Patient Charter do not apply to pure cost-comparison or shopping tools.

This agreement provides a foundation for physicians to build on, said Dr. David C. Dale, president of the American College of Physicians, another supporter. Now when any health plan establishes a physician rating system, physicians can ask whether it is standardized and how it stacks up against the requirements of the Patient Charter, he said.

The Patient Charter also has the support of the American College of Cardiology and the American Medical Association. The ACC said in a statement that it "plans to take an active role during these phases to ensure that the ratings programs adequately take into account the needs of cardiovascular professionals."

Some heavy hitters in the insurance industry have agreed to abide by the principles of the charter, including trade group America's Health Insurance Plans (AHIP), as well as Aetna, Cigna, UnitedHealthcare, and WellPoint. ■

MedPAC Gives Final Backing to Bundled Pay

WASHINGTON — The Medicare Payment Advisory Commission has given its backing to bundling payment for hospitalization, which would essentially give hospitals and physicians an incentive to control costs and avoid readmissions.

At its April meeting, the commission (MedPAC) unanimously voted to include a bundling recommendation in its June report to Congress. As a first step, physicians and hospitals should be required to report to the Centers for Medicare and Medicaid Services (CMS) on resource use and readmissions during an "episode of care," which is proposed to include the first 30 days post hospitalization. The data would be confidential initially, but by the third year, should be made public, MedPAC commissioners recommended.

Once the resource and readmission data are in hand, CMS should start adjusting payment to hospitals, according to the recommendation. There would be the possibility for gainsharing among hospitals and physicians. The commissioners also voted to direct CMS to study the feasibility of "virtual" bundling. With virtual bundling, the payment would be adjusted based on aggregate use of services over an entire episode of care.

Finally, MedPAC voted to recommend that CMS create a voluntary pilot to test actual bundled payment in selected disease conditions. The pilot could throw some light on how the hospital or accountable care organization receiving the payment decided to share funds, and how Medicare might share in any savings, according to MedPAC staff.

The pilot represents Medicare's ultimate goal—making bundled payments, said MedPAC chairman Glenn Hackbarth, a health care consultant in Bend, Ore.

—Alicia Ault

Medicare Adds Patient Satisfaction Measures to Hospital Compare Database

BY JOYCE FRIEDEN
Senior Editor

ARLINGTON, VA. — Now that the Centers for Medicare and Medicaid has added patient satisfaction data to its Hospital Compare Web site, patients will have more to consider when deciding which hospital to use for an elective procedure.

The Web site already included hospital-specific information on clinical measures such as antibiotic prophylaxis before surgery and aspirin upon admission for a heart attack. New patient satisfaction data include items such as nurse communication and hospital room cleanliness.

"This is like Travelocity for health care," said Health and Human Services Secretary Mike Leavitt. "When people have information and they have choice, they make good choices." Mr. Leavitt spoke at the annual meeting of the Association of Health Care Journalists.

The patient satisfaction data come from the Consumer Assessment of Healthcare Providers and Systems, a survey administered by 2,500 hospitals to patients discharged between October 2006 and June 2007. The survey included 27 questions about patients' hospital experience, including communication with doctors and nurses, responsiveness of staff, cleanliness and quietness of the hospital environment, and pain management.

The database also will include the volume of certain elective procedures provided at the hospital as well as what Medicare pays for those procedures.

The Centers for Medicare and Medicaid Services (CMS) Deputy Administrator Herb Kuhn said the information will be valuable even if patients already have selected a hospital for an elective procedure. "There are three reasons people pick a hospital," he said in an interview after Mr. Leavitt spoke. "They heard it was good, it's where their physician spends a lot of his time, or it's convenient to them. We want to add another dimension here for people to understand: Okay, if that's where you're going, what do you know about this place?"

The database also will be a good motivator for hospital improvement, Mr. Leavitt said. "Every health care provider wants to provide high-quality [care]," he said. "Wherever in health care there's robust information about quality and cost, the cost goes down and the quality goes up."

Mr. Leavitt stressed that CMS was not posting the data in order to punish hospitals that aren't performing as well as others. "This is not about eliminating anyone; it's about improving everyone," he said. "The minute a provider sees that they are at lower quality than the marketplace requires, they improve. Why? Because the market will begin to discriminate against them in a forceful and powerful way if they don't."

As for whether those hospitals that don't improve might face consequences, "I hope so," Mr. Leavitt said. "This is about transparency and accountability. Without consumers and regulators and others having a means of measurement, we continue to reward mediocre—and in some cases, poor performance. While this is not about eliminating those who are not performing well, we should certainly not assume that those who are poor performers will not be eliminated, either by the marketplace or by those who oversee quality." ■