

FDA Restructuring Aims to Improve Drug Safety

BY MARY ELLEN SCHNEIDER
Senior Writer

Officials at the Food and Drug Administration are planning to reorganize its Center for Drug Evaluation and Research in an effort to improve the agency's approach to drug safety and to help improve drug development.

The FDA plans to appoint a new associate director at the Center for Drug Evaluation and Research (CDER) to focus on broad drug safety, policy, and communication issues. Agency officials also plan to consolidate some drug safety-related activities and have that staff report to the new associate director. This would include MedWatch reporting staff and Drug Safety Oversight Board staff.

The reorganization plans also call for elevating the status of the current Office of Drug Safety, which is primarily responsible for epidemiology and surveillance activities, and its staff will report to the CDER director. The name of the office will also be changed.

"Over the past year, the Center has been the focus of intense internal and external scrutiny regarding drug safe-

ty," CDER Director Steven K. Galson, M.D., said in a memo to the center staff. "The current organizational structure perpetuates the misperception that ensuring drug safety is solely the responsibility of the current Office of Drug Safety."

While the Office of Drug Safety is a small unit, about half of CDER's resources are dedicated to drug safety activities, said Deborah Henderson, R.N., director of the Office of Executive Programs at CDER.

But the proposal includes no plans to make the Office of Drug Safety independent from CDER, as some in Congress have proposed.

When reviewing drugs, FDA staff members need to balance the effectiveness of the drug against the risks, Ms. Henderson said, so pulling the safety activities out of the center wouldn't be in the best interests of public health.

FDA officials plan to implement the changes over the next 6 months.

The changes will also help to improve regulatory and drug development science through the agency's Critical Path Initiative—a top FDA priority that calls for partner-

ing with industry and academia to improve the drug development process. Through the Critical Path Initiative, FDA hopes to help industry find better biomarkers and improve clinical trial designs, Ms. Henderson said, which would ultimately lead to better, more targeted drugs.

While a number of CDER staff have been working on the Critical Path Initiative, there has not been a central office within CDER. Under the proposed reorganization, the FDA will create a new office that will report to the CDER director and provide a hub for Critical Path activities.

The FDA also plans to make other changes, including establishing an Office of Counterterrorism and Emergency Operations, which will report to the Office of the Center Director; and realigning the Division of Scientific Investigations from the Office of Medical Policy into the Office of Compliance.

"A reorganization is not designed to achieve instant solutions to the challenges CDER faces, although I believe it will address many of the criticisms and suggestions which have been offered on how to approach our work, including drug safety," Dr. Galson said in a memo to CDER staff. ■

Physicians Make Final Appeal for Action to Fix Fee Schedule

BY JENNIFER LUBELL
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WASHINGTON — Physicians will see a 4.4% cut in their Medicare fees under rules announcing next year's fee schedule, unless legislation pending in Congress supersedes those rules. Mark D. McClellan, M.D., administrator of the Centers for Medicare and Medicaid Services, announced the fee cut at a press teleconference.

At press time, it was unclear how Congress ultimately would address the issue. The Senate had passed a budget-reconciliation package containing several provisions on pay for performance, sponsored by Sen. Charles E. "Chuck" Grassley (R-Iowa), as well as a yearlong, 1% Medicare pay increase for physicians. In the meantime, legislation by the House of Representatives did not address the pay cut.

In announcing the final rule on the 2006 fee schedule, Dr. McClellan clarified that the 1% increase contained in the Senate legislation "would link to creating a pay-for-performance fund for physician services. While we have not endorsed that approach and think that in the short term, it may be better to get more quality reporting in place effectively, we definitely want to work with interested members [of Congress] on payment reform for physicians in 2006," he told reporters.

The American College of Cardiology supports the 1% update in the fee schedule, John W. Schaeffer, M.D., who serves on the college's advocacy committee, said in an interview.

Moving ahead with pay for performance at this time however, "is unfair and inap-

propriate," he said. The Senate language barely provides an incremental increase in fees to support such a process and cover current practice expense increases.

Another problem is that pay for performance has never been tested, he said. "There are no clinical trials to show that it's safe, fair, responsible, accurate, and appropriate." The 1% update is just a temporary fix to the serious long-term problem of correcting the sustainable growth rate (SGR), he said.



Physician groups will work with Congress to maintain access to services for Medicare patients, Dr. C. Anderson Hedberg said.

Mary Frank, M.D., board chair of the American Academy of Family Physicians, said the hope is that the budget-reconciliation package will incorporate the 1% increase with provisions from Rep. Nancy Johnson's (R-Conn.) pay-for-performance bill, which also would repeal the SGR and base future payments on the Medicare Economic Index.

As has been the case for years, the SGR is driving the cut in Medicare physician pay.

The SGR is a component in the Medicare payment formula that determines the conversion factor update each year. Errors made to the formula in 1998

and 1999 led to a 5.4% decrease in physician payments in 2002—decreases that will continue unless the payment formula is corrected. Indeed, only congressional intervention has stopped payment cuts in the years since 2002; instead, short-term laws have provided small increases in pay.

The SGR is determined by several factors, including the projected increase in the gross domestic product; in essence, it ties medical spending to the ups and downs of the national economy.

Several organizations, such as the AAFP and Medical Group Management Association, oppose the "value-based purchasing" pay-for-performance bill sponsored by Sen. Grassley, which would link 2% of physician Medicare payments to reporting of quality data and demonstrated progress toward quality and efficiency measures but would not fix the SGR. Although the program would be voluntary, those choosing not to participate would lose the 2%.

Value-based measures require physicians to deliver more services, Michael Maves, M.D., executive vice president of the American Medical Association, recently wrote in a letter to Sen. Grassley. "Under the SGR, more physician services will result in a series of severe cuts, compounding current problems. This would make future SGR reforms more expensive."

On the surface, pay for performance sounds good, because it would force physicians to meet certain standards, Daniel Siegel, M.D., said in an interview. Dr. Siegel of Smithtown, N.Y., represents the American Academy of Dermatology on the AMA Resource-Based Relative Value Update Committee (RUC).

The problem, he said, is that "we're not

sure those measures are all that valuable." Taking into account that 2% drop in reimbursement for not participating in Sen. Grassley's program, "the most distressing part is, it's really not pay for performance but a penalty for not meeting the new minimum standard."

The physician fee schedule was the subject of much debate at the interim meeting of the AMA's House of Delegates.

The AMA's support for any type of pay for performance or other type of quality reporting program "is dependent on stopping the Medicare pay cuts," AMA president J. Edward Hill, M.D., said at the meeting. In a resolution, the House of Delegates asked the organization to advocate for a repeal of the SGR without compromising the organization's principles on pay for performance. ■

Joyce Frieden, Associate Editor for Practice Trends, contributed to this report.

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