Feds Focus on Fraud in FY 2011 Budget Proposal

BY MARY ELLEN SCHNEIDER

The Obama administration wants to combat waste, fraud, and abuse in the Medicare and Medicaid programs and plans to spend more than $500 million to do it.

As part of the administration's budget proposal for fiscal year 2011, the Health and Human Services department is proposing to invest $561 million in discretionary funding to fight health care fraud, a $250 million increase over FY 2010. Specifically, the department plans to expand the Health Care Fraud Prevention and Enforcement Action Team (HEAT), which brings together high-level officials at HHS and the U.S. Department of Justice to spot trends and develop new fraud prevention tools.

HHS said the new funding also will be used to minimize inappropriate payments, pinpoint potential weaknesses in program oversight, and target emerging fraud schemes. Department officials estimate that the efforts to fight fraud and abuse will save $9.9 billion over the next decade.

HHS also expects to squeeze more savings out of the Medicare and Medicaid programs by giving more scrutiny to the provider enrollment process, increasing oversight of claims, improving the data analysis within Medicare, and reducing the overutilization of prescription drugs in Medicaid.

"This budget sends a clear message to those who commit fraud: Stop stealing from seniors and tax payers or we'll put you behind bars," Kathleen Sebelius, HHS Secretary, said during a press conference to release the HHS budget proposal.

The FY 2011 budget proposal focuses on fraud prevention, wellness, and building the public health infrastructure. While the budget documents note that the HHS proposal lays the "groundwork" for health reform, it is a stark contrast to last year's proposal, which included a $635 billion "reserve fund" dedicated to health reform over the next decade.

Ms. Sebelius said that while the current budget proposal tries to increase coverage and curb costs, it would do little to affect the overall trajectory of health care costs if it is not accompanied by health reform legislation. The FY 2011 budget aims to invest in wellness, health information technology, and comparative effectiveness research, but it won't significantly alter the rise in health care costs, fill the coverage gap, or provide security to those with coverage that they can remain insured, she said.

Overall, the Obama administration is seeking $911 billion in funding for HHS in FY 2011, an increase of $51 billion over the current fiscal year. Since the bulk of HHS's funding is tied up in mandatory obligations including Medicare and Medicaid, the budget includes $81 billion in discretionary program spending, an increase of $2.3 billion over last year.

The Obama administration's budget request assumes that Congress will step in to correct the Medicare physician payment formula, known as the Sustainable Growth Rate. At press time, physicians were scheduled to face a 21% across-the-board cut to their Medicare payments on March 1, unless Congress acted to avert the cut.

The budget request also calls for a $290 million investment in community health centers, bringing their funding to $2.5 billion. The increase should allow the health centers to continue to serve the new patients they began caring for when the centers got an infusion of funding under the American Recovery and Reinvestment Act (stimulus bill) last year. HHS estimates that community health centers will be able to serve more than 20 million patients in FY 2011.

The budget request also calls for nearly $1 billion, an increase of about $33 million, to help shore up the health care workforce. The money will help to expand loan repayment programs for physicians, nurses, and dentists who agree to practice medically underserved areas.

The Obama administration also proposes to spend $4 billion to fund the Food and Drug Administration, with $1.4 billion going toward medical product safety, including drugs, devices, vaccines, and the blood supply. The funding represents an increase of $101 million in FY 2011. The new money would go toward import safety, high-risk products, and partnerships for patient safety. About $40 million of that new funding is slated to go toward the generic drugs program, including new investments in postmarket drug safety and the establishment of a medical device registry. ■

Walgreens Enters Diabetes Care

BY ALICIA AULT

Walgreens, the nation's largest drug store chain, is dipping a toe into diabetes care by offering education and counseling in four metropolitan areas.

The company's Optimal Wellness program is based on the North Carolina Center for Pharmaceutical Care's diabetes project and also draws on a Walgreens pilot that was developed by the drug store chain and Harvard's Joslin Diabetes Center.

The program initially will be offered in Indianapolis, Phoenix, Albuquerque, and Oklahoma City, areas chosen in part because of the large number of diabetic residents, said Dr. Jay Rosan, senior VP of health innovation at Take Care Health Systems, a Walgreens company.

Dr. Mack Harrell, chair of the socioeconomics and member advocacy committee for the American Association of Clinical Endocrinologists, said the Walgreens program could be helpful but that AACE believes that any assistance, education, or counseling should be supervised by physicians.

"I'm in favor of people getting all the education they need," Dr. Harrell said in an interview. But, he added, "what we've learned from a number of recent studies is that the degree of glycemic control has to be individualized. You have to know the patient, know whether they have comorbidities that put them at higher risk, and decide what degree of control is acceptable." These nuances are beyond the capacity of a nurse practitioner and reinforce the need for a supervisory physician, he said.

Dr. Rosan emphasized that the nurse practitioners in the Optimal Wellness program will not offer treatments, and that physicians will be relied upon as primary care coordinators and supervisors.

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The program is being rolled out in concert with major insurers. The insurers, who pay a fee to Walgreens, will identify diabetic patients for the chain. When patients go to Walgreens for supplies or a prescription, pharmacists will tell them about the program's availability and then attempt to enroll them. If the store has a retail clinic, a nurse practitioner will offer counseling; otherwise, the pharmacist will conduct the sessions, Dr. Rosan explained. The pharmacists and nurses have been trained through a Joslin program certified by the Accreditation Council for Pharmacy Education.

The aim is to give patients four 30- to 60-minute sessions over a year-long period, with the potential of up to 12 interventions. Patients will pay nothing or a small copay for the sessions, Dr. Rosan said.

After each session, the counselor will fax, e-mail, or call the patient's primary care physician with information. If the primary caretaker is an endocrinologist, the counselor will reach out to that physician. For those who do not yet have a designated primary care physician, the pharmacies will make referrals, he said.

Dr. Harrell also expressed reservations about Walgreens' potential conflict of interest. "The pharmacy has a certain secondary gain from having the patient in there," he noted. For instance, the pharmacy could promote supplies or treatments that favor the pharmacy's bottom line but are not necessarily the best fit for the patient.

Dr. Rosan acknowledges that there is an opportunity to fill more prescriptions. It also expands Walgreens' growing role as a multiservice provider and gives it a chance to burnish its brand. But the program may also help improve the nation's health if more diabetics learn to manage their own care, he added.

Optimal Wellness won't be available to the uninsured, for now. Walgreens is courting pharmaceutical companies to subsidize that effort, he said. ■

NIH, FDA Team Up to Speed New Therapies

BY MARY ELLEN SCHNEIDER

Top scientists at the National Institutes of Health and the Food and Drug Administration will be working together more closely in an effort to improve regulatory science and bring new treatments to market sooner.

With more new treatments based on emerging technologies, NIH and FDA scientists must communicate earlier and more often, explained Kathleen Sebelius, secretary of the Department of Health and Human Services. From the beginning of a therapy's development, basic scientists at the NIH should share information with the FDA so that FDA regulators can develop appropriate safety and effectiveness standards early on.

At the same time, FDA scientists can help researchers identify possible safety or quality issues earlier in the process, she said during a news conference to announce the partnership.

"By communicating throughout the process, it will help researchers navigate the regulatory process and give regulators the scientific tools they need to quickly assess a treatment's risks and benefits," Ms. Sebelius said.

The initiative calls for the creation of a joint FDA–NIH Leadership Council that will include FDA Commissioner Dr. Margaret A. Hamburg and NIH Director Dr. Francis S. Collins, as well as six senior scientists from each of the two agencies. The NIH and the FDA have also pooled their resources to offer $6.75 million in grants over the next 3 years for research on regulatory science.

Government officials will be seeking public comment on how the two agencies can improve their collaboration. The NIH and the FDA will hold a public meeting jointly this spring to gather input from industry, patient advocates, and the public.

To bring safe, effective therapies into the market sooner, the science used to develop new therapeutic compounds must be closely connected to the science the FDA uses to review those compounds, said Dr. Collins of the NIH. ■