

## POLICY &amp; PRACTICE

**FDA's \$2 Billion Budget**

The Bush administration is requesting \$2.1 billion for the Food and Drug Administration in fiscal 2008, a 5% increase from the previous year's request. The agency still has not received its final appropriation for fiscal 2007, so the exact amount it will receive for that year is not known yet. The budget includes \$444 million in user fees from industry, including a new program to charge generic drug makers fees to review their products. The agency estimates that generic companies will contribute \$16 million in fiscal 2008. In a statement, Generic Pharmaceutical Association CEO Kathleen Jaeger said the decision to seek user fees "will not bring generic medicines to consumers faster as long as brand companies are still permitted to use tactics that delay market entry." The budget also includes \$11 million for improving drug safety (this does not include user fee funds that will also go to that effort) and \$7 million to boost medical device safety and to speed up device review. The agency also is requesting \$13 million to move about 1,300 employees of the Center for Devices and Radiological Health to offices at the FDA's new White Oak, Md., campus. The FDA has been gradually moving its operations to the new facilities. The Coalition for a Stronger FDA, a Washington-based consumer-, patient-, and industry-supported group, said the budget did not go far enough. It is seeking at least \$175 million more, including greater increases for food, drug, and medical device safety.

**Medicare Generic Drug Use Rises**

Generic drugs accounted for 60% of the prescriptions dispensed to people who receive benefits through either Part D or Medicare Advantage plans for the first three quarters of 2006, the Centers for Medicare and Medicaid Services announced. Generic drug use in Part D enrollees is 13% higher than for Americans who receive benefits through private payers, CMS said. In comparison, generics accounted for 53% of prescriptions dispensed to privately insured Americans last year. Greater use of generics will translate into lower costs for the Part D program and possibly expanded coverage for beneficiaries, said CMS. "We will continue to promote generics where they are available as an important strategy to keep the new drug benefit affordable over the long term," acting administrator Leslie Norwalk said in a statement.

**Edwards Proposes Health Plan**

Former North Carolina Senator and 2008 presidential candidate John Edwards is calling for universal health care but modeling his proposal after a plan that is in effect in Massachusetts. The plan would essentially require all Americans to have insurance by 2012. To make coverage affordable, Sen. Edwards' plan would require employers to cover employees or to help them finance their coverage, and would create regional purchasing pools. The plan also would

create tax credits, expand Medicaid and the State Children's Health Insurance Plan, and reform insurance laws. He also said his plan would provide incentives to improve the quality of care, by promoting evidence-based medicine and more quickly getting information on advances into physicians' hands.

**Disclosing Financial Conflicts**

Experts from Johns Hopkins University, Duke University, and Wake Forest University have designed model language aimed at helping researchers disclose their financial conflicts to medical research participants in a meaningful way. The model language was published in the January/February issue of IRB: Ethics and Human Research. Included is a standard disclosure for situations in which there is a financial interest that does not represent a measurable risk to patients. The model also includes language that researchers can use to describe salary support, money received outside of a study, per capita payments, and unrestricted finders' fees, among other common conflicts. "This is language that can help these institutions craft better written materials. It can also serve as a model for how to accurately phrase disclosure in discussions with potential research subjects," Dr. Jeremy Sugarman, the lead author and professor at Johns Hopkins University, Baltimore, said in a statement. "It could also be expanded and presented in other formats, such as stand-alone pamphlets or videos about clinical research."

**Health IT Privacy Milestones**

Federal health officials need to develop an overall strategy for protecting patient privacy as health information technologies take off, according to a report from the Government Accountability Office. Although the Health and Human Services department has designated consumer privacy a top priority and has made some initial progress in that area, a more comprehensive approach is needed, the GAO report concluded. Specifically, HHS officials need to set milestones for integrating privacy-related initiatives and select an entity responsible for implementing these initiatives. But in comments on the report, HHS officials said setting specific milestones would hamper their ability to incorporate stakeholder ideas as they move forward. Since 2005, HHS has awarded several contracts aimed at addressing the privacy of personal health information exchanged within an electronic national health information network. In 2006, an HHS contractor selected sites to perform assessments of privacy and security policies. Also in 2006, the National Committee on Vital and Health Statistics and the American Health Information Community worked on privacy and security issues related to a nationwide health information network. The report was requested by Sen. Daniel Akaka (D-Hawaii) and Sen. Edward Kennedy (D-Mass.).

—Mary Ellen Schneider

# Bush Budget Proposal Targets Medicare, Medicaid for Cuts

BY MARY ELLEN SCHNEIDER  
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The Bush administration's budget proposal for fiscal 2008 could be bad news for physicians and hospitals.

The proposal, sent to Congress in early February, seeks about \$600 billion in net outlays to finance the Centers for Medicare and Medicaid Services including Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP), a \$29.2 billion increase over projected 2007 levels. But the budget also includes legislative proposals that would trim about \$4.3 billion from the Medicare program this year and \$252 billion over 10 years.

It also calls for Medicaid reforms that would save about \$28 billion over 10 years.

The president's plan outlines several provider payment changes, including reducing the update factor for hospitals, hospices, and ambulance services 0.65% each year starting in fiscal year 2008, and freezing the update for skilled nursing facilities and inpatient rehabilitation facilities in 2008.

The proposed budget does not address payments to physicians under Medicare, calling into question whether physicians will get relief from a projected 5%-10% cut in Medicare reimbursement slated for January 2008. However, Leslie Norwalk, acting administrator for the Centers for Medicare and Medicaid Services, said she has "no doubt" that proposals to address the sustainable growth rate formula—which is used to determine physician payments under Medicare—will be on the table for discussion with Congress.

The reductions in traditional entitlement programs such as Medicare, Medicaid, and Social Security are necessary to avoid tax increases, deficits, or cuts in benefits, President Bush wrote in an accompanying statement to Congress.

But the fate of the Bush proposal already is in doubt in the Democrat-con-

trolled Congress. "I doubt that Democrats will support this budget, and frankly, I will be surprised if Republicans rally around it either," Rep. John Spratt (D-S.C.), chairman of the House Budget Committee, said in a statement.

Physicians organizations also took aim at the proposed budget. Dr. James T. Dove, president-elect of the American College of Cardiology, said the budget fell short in several areas, particularly in the lack of proposals to fix the physician payment formula. "Unless we can work together to put in place a more sustainable payment system for physicians, patients will suffer," Dr. Dove said in a statement.

Officials at the American Medical Association echoed those comments in their reaction to the president's budget request. "Over the next 8 years, Medicare payments to physicians will be slashed by nearly 40%, while practice costs increase about 20%. Without adequate funding, physicians cannot make needed investments in health information technology and quality improvement, and seniors' access to health care is placed at risk," Dr. Cecil B. Wilson, AMA board chair, said in a statement.

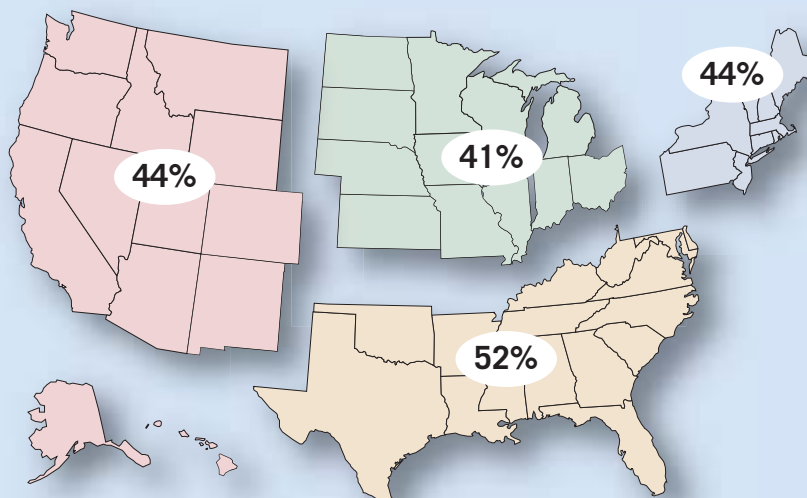
The president's proposal also came under fire from the American Hospital Association, which called it "devastating news" for children, seniors, and the disabled.

The president's plan would reauthorize SCHIP for 5 years and spend nearly \$5 billion on the program over that period. However, it would refocus the program to children at or below 200% of poverty, a smaller group than many states currently target. That level of funding would actually reduce SCHIP spending in fiscal year 2008, according to the American College of Physicians. Officials at the ACP called on Congress to provide additional funds so that SCHIP could be expanded.

President Bush also seeks the standard deduction for health insurance he outlined in his State of the Union address. ■

## DATA WATCH

## Eligibility for Medicare Drug Benefit for Low-Income Subsidy Applicants Is Higher in the South



Note: Percentage of applicants determined eligible based on Social Security Administration data as of Nov. 17, 2006.

Source: The Kaiser Family Foundation