G2 INTELLIGENCE

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President's Budget Seeks Major Cuts in Health Care Savings

Overall, the budget seeks an additional $1.8 trillion of deficit reduction over 10 years, for a total of $4.3 trillion, while raising $700 billion in new revenue through changes in the tax code that benefit wealthier Americans.

President Obama's fiscal 2014 budget request to Congress, released April 10, calls for $400 billion in health care savings and cancels the automatic sequestration cuts, including the 2 percent reduction annually in Medicare payments to providers.

While the budget makes no structural changes to Medicare, it does make payment reductions to certain health care providers and increases the income-related premiums that beneficiaries pay under Part B fee-for-service and the Part D prescription drug program, beginning in 2017, saving an estimated $50 billion over 10 years.

The biggest Medicare savings in the budget package, $123 billion over 10 years, would come by allowing the program to get the same rebates that Medicaid gets for brand-name and generic drugs.

In other major Medicare proposals, the budget would:

- ❑ Reduce payments to hospitals and skilled nursing facilities (SNFs) for bad debt from 75 percent to 25 percent over three years, saving $35.9 billion over 10 years.

Continued on p. 2

INSIDE *NIR*

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ACLA, NILA Blast Lab Cuts in Budget

The American Clinical Laboratory Association (ACLA) and the National Independent Laboratory Association (NILA) issued statements opposing a proposal in the budget to reduce reimbursement for clinical laboratory services in Medicare by an additional $9.46 billion over 10 years, a cut of at least 14 percent. This, on top of cuts scheduled under current law, would slash lab fees by 35 percent to 37 percent over the next 10 years.

"While the President's budget proposes cutting an additional 14 percent under the pretext of 'modernizing payments for clinical lab services,' in fact, the reduction is so severe when added to cuts in current law that the ability of many labs to continue serving beneficiaries would be in doubt," said ACLA President Alan Mertz. "Medicare spent $8.9 billion on clinical lab services in 2011, representing just 1.6% of total Medicare spending, yet 70 percent of physician clinical decisions are based on laboratory results."

Mark Birenbaum, Ph.D., NILA administrator, said, "The reality is that these cuts devastate the community clinical labs that provide services to seniors, including those in long-term care facilities. These small and midsized labs simply cannot sustain these cuts." G2

President's Budget, *from p. 1*

- ❑ Reduce payments by up to 3 percent to SNFs with high rates of care-intensive, preventable hospital readmissions, beginning in 2016, for a savings of $2 billion over 10 years.

- ❑ Introduce a $100 copay per home health episode, beginning in 2017, saving $350 million over 10 years.

On the issue of Medicare physician payment reform, the administration says it is committed to working with Congress "to provide predictable payments that incentivize quality and efficiency in a fiscally responsible way. Failing to address this issue creates uncertainty about beneficiaries' access to care."

The budget request supports "a period of payment stability lasting several years to allow time for the continued development of scalable accountable payment models. Such models can take different forms, but all will have several common attributes such as encouraging care coordination, rewarding practitioners who provide high-quality, efficient care, and holding practitioners at financial risk for consistently providing low quality care at excessive costs."

CMS, OIG Propose Extending Safe Harbor for EHR Donations

Despite concerns from some lab and pathology industry groups, the Centers for Medicare and Medicaid Services (CMS) has proposed a rule that would extend the safe harbor exception for donations of electronic health records (EHRs) until Dec. 31, 2016. The safe harbor is scheduled to expire at the end of 2013.

Under the EHR safe harbor, pathology providers, laboratories, and other permitted donors can subsidize the cost of compliant EHR technology for referring physicians at up to 85 percent of the cost of such technology.

The CMS proposed rule would extend the sunset date for EHR exceptions under the Stark law while the Office of Inspector General (OIG)-proposed rule would extend the sunset date for the anti-kickback safe harbor, among other provisions. The proposed rules were published in the April 10 *Federal Register*. Comments are due June 7.

The exception was originally intended to prevent donations of EHR technology to providers from running afoul of the Stark law. The 2013 date was selected because it was thought the need for EHR donations would decrease by then.

"However, while the industry has made great progress, use of such technology has not yet been universally adopted nationwide, and continued electronic health record technology adoption remains an important departmental goal," said CMS in the proposed rule.

The 2016 date was chosen because it is the last year providers can receive Medicare EHR incentive payments and the last year providers can start participating in the Medicaid EHR incentive program.

Considerable Controversy

The EHR donation exception and safe harbor have generated considerable controversy since their publication in 2006. While everyone in health care would agree

that widespread adoption of EHR technology is an important goal, there is disagreement regarding whether the exception and safe harbor are a good idea, notes Karen Lovitch, an attorney with Mintz Levin (Washington, D.C.).

"The College of American Pathologists (CAP) has previously urged OIG to reconsider its inclusion of laboratories as protected donors, and the American Clinical Laboratory Association (ACLA) has questioned whether the safe harbor and exception are needed now that physicians who engage in 'meaningful use' of EHR technology can qualify to receive incentive payments from the government," Lovitch writes in a blog, *www.healthlawpolicymatters.com*.

CAP's position on the safe harbor is that clinical laboratories are effectively coerced by the competitive market into underwriting EHR donations as an improper inducement for physician practices to refer patients. "The financial benefits conferred on the physician practice that receives such donations may effectively influence medical decisionmaking and the choice of laboratory providers," says CAP in an issue brief. "Consequently, these arrangements may result in laboratory selection that is not optimal for the patient population served and may engender business relationships that generate overutilization of laboratory services."

A number of states have issued rulings that limit or forbid clinical laboratory EHR donations. Federal safe harbors do not preempt or displace state anti-kickback laws and regulations, so labs and pathology groups need to be aware of the state rulings in this area. Among the states that have imposed such limits are Tennessee, Washington, Pennsylvania, Missouri, New Jersey, New York, and West Virginia. If the OIG decides to extend the federal protection for EHR donations, other states may follow suit, notes Lovitch.

Jane Pine Wood, an attorney with McDonald Hopkins (Dennis, Mass., office) who represents many pathology practices, says this proposal if finalized would continue to force pathologists and labs to shell out money to physicians just to keep their referral sources. She urges pathologists and laboratories to submit comments to CMS and OIG urging that the safe harbor not be extended.

Interoperability

The CMS proposed rule would also update a provision in the exception that protects donated EHR systems that are deemed interoperable from violating the Stark law. Currently, an EHR system can qualify for the Stark exception if a recognized certifying agency considers the EHR interoperable no more than 12 months before it is given to a provider. The proposed rule would clarify that the Office of the National Coordinator for Health Information Technology is responsible for recognizing certifying agencies and would remove the 12-month time frame from the exception.

"Accordingly, we propose that software would be eligible for deeming if, on the date it is provided to the recipient, it has been certified to any edition of the electronic health record certification criteria that is identified in the then-applicable definition of certified EHR technology in 45 CFR part 170," the proposed rule said.

It would also remove a requirement that donated EHRs must contain electronic prescribing capabilities to qualify for a Stark law exception. CMS said the health care industry has made substantial progress in implementing e-prescribing, obviating the need for its inclusion in the Stark law exception.

focus on: Medicare Physician Pay

2014 Forecast: Slight Dip in Medicare Physician Pay Cut; House Committees Work on New Reimbursement Scheme

Physician payments under the Part B Medicare fee schedule are due for a 24.4 percent reduction under the sustainable growth rate (SGR) formula starting Jan. 1, 2014, according to a preliminary estimate that the Centers for Medicare and Medicaid Services (CMS) sent to the Medicare Payment Advisory Commission (MedPAC).

This compares with the 26.5 percent cut that was to have taken effect at the first of this year until Congress stepped in to block it and froze physician fees through Dec. 31, 2013, under the American Taxpayer Relief Act of 2012.

"Physicians are already facing an enormous gap between what Medicare pays and the actual cost of caring for seniors," said American Medical Association President Jeremy Lazarus. "A two percent cut from sequestration makes this even worse, and a cut of 24.4 percent is simply unfathomable."

The latest projection from CMS leaves the conversion factor at $34 through this year, said Jonathan Blum, CMS's acting principal deputy administrator, in the letter to MedPAC Chairman Glenn M. Hackbarth. Next year, however, the factor is estimated to fall to $25.70. The conversion factor is used to translate the relative value units of a physician's service (work, practice expense, and malpractice expense) into a dollar amount.

Earlier this year, the Congressional Budget Office (CBO) pegged the 2014 fee cut at about 25 percent. It also lowered the cost of freezing Medicare physician payments from $245 billion over 10 years to $138 billion because of lower-than-expected growth in Medicare costs. This has encouraged hopes that Congress may find it easier to repeal the SGR since the question of how to pay for it has remained a major obstacle to an overhaul of the Medicare physician payment system. Hackbarth has said the time is ripe for reform because costs could rise again, prompting CBO to hike the amount it would take for a program overhaul.

Blum said in the letter that CMS would continue to refine its estimate of the SGR cut and will provide more information on the conversion factor in the proposed 2014 physician fee schedule due for release this summer.

SGR Background

Inception: Enacted in the 1997 Balanced Budget Act.

Purpose: To prevent annual increases in physician spending for Medicare beneficiary services from exceeding the growth in the gross domestic product.

How it works: In any year in which physician spending exceeds a target growth rate, the update to the Part B physician fee schedule is adjusted downward. If spending comes in below the target, the update is adjusted upward.

Effect thus far: Over the past decade, the SGR has triggered negative updates, prompting Congress to block them repeatedly with a series of short-term fixes.

Scrapping the SGR for a New Reimbursement System

Meanwhile on Capitol Hill, the House Energy and Commerce and Ways and Means committees, which share jurisdiction over Medicare, released on April 3 a second draft of their proposal to replace the current physician reimbursement system with a new permanent payment model and have requested feedback by April 15.

The second draft furnishes further details on their initial proposal issued Feb. 7 and incorporates comments from stakeholder groups. But the latest version focuses on policy, leaving the issue of how to pay for the change until later.

The key refinements in the transition include:

- **Phase 1:** Repeal of the SGR followed by a period of stable payments (the time span is not specified, but physician groups favor having it last for five years).
- **Phase 2:** Payments based on the quality of care delivered to beneficiaries, using physician-devised performance measures. Payments would be risk-adjusted so as not to penalize those who serve beneficiaries who are sicker or require complex care. Physicians would have three ways to determine their performance-based payment rate: their scores on quality measures compared with their peers', major improvements in quality scores from the previous year, and clinical improvement activities. Doctors could opt to be measured at the individual or group practice level.
- **Phase 3:** Financial rewards for providing efficient care, using a risk-based ranking system that also accounts for geographic differences in practice costs.

Throughout all three phases, physicians would be allowed to remain in fee-for-service Medicare or choose an alternative payment model.

"Designing a system that is inclusive of all specialties and practice types presents a great challenge, and this draft makes a concerted effort to avoid a 'one-size fits all' approach in favor of a versatile and inclusive process that provides for the maximum amount of individual choice," the committees said. "Based on respondent input, we envision a system where providers have the flexibility to participate in the payment and delivery system model that best fits their practice."

Legislators are aiming to have legislation that permanently fixes the Medicare physician payment system on the House floor this summer. It is not yet clear whether this would be a stand-alone bill or be part of a deficit-reduction deal between the White House and Congress.

Physician groups have generally responded favorably to the work of the two committees and have said that specialty-specific registries could be used to determine evidence-based quality measures. They also have called for timely feedback on these measures so doctors can improve and take full advantage of incentive payments.

They have further sought to include medical liability reform and to repeal the Independent Payment Advisory Board. That body, created by the health care reform law, would issue proposals to reduce Medicare spending if it breaches a specific target and these would take effect unless Congress comes up with an alternative that achieves the same amount of savings. The continuing resolution that funds government agencies through Sept. 30 provides no funding to make the board operational.

But the rub is likely to come when legislative language is presented that would define how the new reimbursement system would work. Some groups may take issue with what that language entails.

Clinical Labs Face Ongoing Payment Threats

Clinical laboratories, which have faced significant Medicare reimbursement cuts in recent years, are likely to face additional payment threats this year, according to speakers at the annual meeting of the American Clinical Laboratory Association (ACLA), held April 3-4 in Washington, D.C.

"We are clearly in an era of fiscal austerity, and everyone is being affected," said Norman Ornstein, resident scholar at the American Enterprise Institute. As lawmakers look for a way to reform the sustainable growth rate and Medicare, they also will be looking for offsets to help pay for these changes. Such changes could include a lab copay or additional cuts, said speakers.

To help prevent such cuts, it's critically important that lab representatives make personal connections with lawmakers, said Dave King, ACLA chairman of the board and chairman and chief executive officer of Laboratory Corporation of America. "I challenge you to get a member of Congress into your lab. It's very important to put a face on the industry."

These types of personal connections are crucial when it comes time for senators and congressmen to vote on legislation that affects labs, he noted. Labs already were hit this year with an almost 5 percent cut in Medicare payment in addition to substantial reductions in Medicare reimbursement for molecular diagnostic tests. The industry cannot absorb any more cuts, said King.

Negotiated Rulemaking Redux?

In a separate exchange with Marc Hartstein, director of the Hospital and Ambulatory Policy Group at the Centers for Medicare and Medicaid Services (CMS), King called for a more constructive relationship with CMS, noting that there has been little transparency in the process used by Medicare contractors to set new payment rates for more than 100 new molecular pathology (MoPath) codes. He suggested that industry representatives sit down with CMS officials and Medicare contractors to discuss code pricing, much as they did during the negotiated rulemaking in 2001 that established national coverage and administrative policies for clinical laboratory services under Medicare Part B.

In response, Hartstein said that there already is a process in place by which Medicare contractors are gathering information from labs that they need to set the MoPath prices. Meeting participants responded that many contractors have rebuffed attempts to provide additional information or to engage them in conversation.

According to Hartstein, contractors are supposed to determine pricing based on a number of factors: charges for the test and discounts to charges, resources required to perform the tests, payment amounts determined by other payers, and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

Contractors were to have submitted their draft prices to CMS by April 1. CMS will post these contractor-specific amounts on the agency Web site by April 30, and the industry and public will have 60 days to comment. Contractor prices may be adjusted based on comments and will be finalized by Sept. 30, with a 30-day reconsideration period. According to Hartstein, contractors are required to provide a rationale for their final pricing amounts.

Labs to Get Refunds From New York State Health Department

More than 200 independent and hospital clinical laboratories, including members of the American Association of Bioanalysts (AAB), will benefit from the recent successful conclusion of a lawsuit by AAB and other laboratories against the New York State Department of Health (NYSDOH).

The lawsuit charged that the department's clinical lab evaluation program overcharged clinical labs for inspection and reference fees to subsidize activities that had no relation to the regulation of clinical labs.

Under the recent settlement, NYSDOH will refund a total of $18 million. It covers fees paid from 2007-2008 through 2010-2011. In addition, 23 AAB labs that were part of a previous lawsuit (1998-2006) are also entitled to recover a portion of their fees for 2006-2007.

In a statement on the refunds, Mark S. Birenbaum, Ph.D., AAB's administrator, said, "AAB is glad that we were able to lay the groundwork and assist our members and other labs in New York to recover the fees that continued to be wrongfully charged to them. We have successfully fought this battle for our members since 1984 in three separate lawsuits."

This complaint followed a 1999 AAB lawsuit that resulted in a $5 million refund in 2011 to 35 AAB member laboratories. When NYSDOH accounting and billing practices remained unchanged, AAB and individual labs took new action in 2009 to recover the excess fees that continued to be collected each year. The lawsuit was extended through the 2010-2011 fiscal year, until it was just settled, shortly before the setting of a trial date.

AAB's general counsel Jeffrey J. Sherrin of O'Connell & Aronowitz (Albany, N.Y.) handled all three lawsuits against NYSDOH. "Even in difficult fiscal times, the state recognized the need to make the laboratories whole and found the monies to do so, he said. "Hopefully, this brings an end to the need for these lawsuits."

New Bill Would Spare Pathologists From Penalties Under Meaningful Use Program

Pathology groups have long felt shut out of financial incentives under the Meaningful Use (MU) program of electronic health records (EHRs) while at the same time they faced penalties for not participating.

New legislation (H.R. 1309, the Health Information Technology Reform Act) would remedy that permanently. It would exempt pathologists from participating in the program and protect them from penalties for failing to meet federal requirements for meaningful use of EHRs.

H.R. 1309 states that pathologists should not be subject to payment penalties under the EHR program for failing to meet standards that do not apply to their practices or their typical interactions with patients.

Under the program, incentive payments are awarded to Medicare and Medicaid physicians who can demonstrate meaningful use based on a set of strict specific requirements. But starting in 2015, doctors who fail to do so will face a 1 percent penalty of their Medicare payments, and it could rise to as much as 5 percent in 2017 and beyond, warns the College of American Pathologists (CAP). *Continued on p. 8*

A Research Opportunity for Independent Labs

G2 Intelligence is conducting an online survey on the lab industry lab management personnel who oversee the overall operation of the lab (test volume, revenue, test menu, etc.).

You must be affiliated with an **independent** lab to qualify. If you qualify for and complete the entire survey (**10-15 minutes** in length), you will be given a Visa gift card of **$25** as well as an executive summary of the report in exchange for your time.

If you are interested, please enter the following URL in your browser to start the survey: *www.G2Intelligence.com/LabIndustrySurvey*

Only one person per lab is allowed to complete the survey. Any questions, please e-mail Jenny Xu at *jxu@G2Intelligence.com*.

We look forward to your participation!

New Bill Would Spare Pathologists, *from p. 7*

The MU requirements are geared toward office-based physicians and hospitals, so most pathologists are unable to participate in the current program, CAP says, "because the requirements do not allow for differences among physician practices, and specialists like pathologists who practice in medical labs using laboratory information systems, rather than EHRs, cannot meet the prescribed requirements."

Under lobbying by CAP, the Centers for Medicare and Medicaid Services granted pathologists a hardship exception from penalties in 2015, but the exception is only for one year at a time, up to five years.

The bill is co-sponsored by Rep. Tom Price, M.D., (R-Ga.) and Rep. Ron Kind (D-Wis.), both members of the House Ways and Means Committee. It has been referred to that committee and the Energy and Commerce Committee.

Upcoming G2 Events

Webinar *(2 p.m.-3:30 p.m. Eastern)*

May 9

Blood Management for the Lab: Collaboration for Better Patient Outcomes and Fewer Transfusions

Featured Speakers: **Nanci Fredrich, RN, BSN, MM,** Transfusion Safety & Blood Management Officer, Blood Center of Wisconsin; **Kathleen Puca, M.D., MT(ASCP)SBB**, Medical Director, Blood Center of Wisconsin; and **Sandy Holdcraft, RN, BSN**, Haemovigilance Specialist, Children's Medical Center, Dallas

Conferences

May 16

Lab Contracting Workshop: How to Master Changing Market Realities in Dealing with Payers

Westin Atlanta Airport
www.G2Intelligence.com/ContractingWorkshop

June 12-14

MDx Next 2013 Gaining Ground in Molecular Testing andGenomic Medicine

Westin Las Vegas Hotel Casino and Spa
www.mdxconference.com

Oct. 16-18

Lab Institute 2013

Hyatt Regency Crystal City
Arlington, Va.

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