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INSIDE *NIR*

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President's Budget Would Cut Lab Services Another $7.9 Billion Over 10 Years

The hits to the clinical laboratory industry just keep coming. President Obama's proposed budget for 2015, sent to Congress March 4, includes Medicare cuts of $7.9 billion for lab services over 10 years. The proposal quickly drew fire from lab groups, which blasted what would amount to an overall 14 percent funding reduction.

Medicare payment for clinical laboratory services has been reduced substantially in recent years as a result of the Affordable Care Act, a short-term patch to the Medicare sustainable growth rate formula, and sequestration. Now, the president's budget proposes to extend the annual 1.75 percent cut to the Clinical Laboratory Fee Schedule (CLFS), which had been scheduled to end in 2015, until 2023.

According to the American Clinical Laboratory Association, the proposed budget includes reduction on top of cuts already scheduled under current law and disregards that the Centers for Medicare and Medicaid Services (CMS) is already moving forward to update all rates within the CLFS to reflect "technological changes."

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Obama Proposes to Close Stark Loophole

For the first time, President Obama has proposed excluding anatomic pathology (AP) services from the in-office ancillary services exception (IOAS) to the Stark law. The proposal is included in the president's 2015 budget sent to Congress on March 4.

While the administration previously has proposed to remove advanced imaging, physical therapy, and radiation therapy from the IOAS exception, AP services were never included. According to the Office of Management and Budget (OMB), the estimated savings to the Medicare program for removing all four services would be more than $6 billion over 10 years.

The IOAS exception was created to ensure patients could have easy access to a range of medical tests or services that inform diagnosis and treatment during the time of their physician visit, such as strep and glucose testing, urinalysis, and other clinical laboratory tests. According to the College of American Pathologists (CAP), it was never intended to include AP services that involve a complex multistep process and analysis of a tissue specimen procured as part of a

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The administration made a similar proposal last year in the proposed budget for 2014. Republicans on Capitol Hill said the proposed budget was dead on arrival, but lawmakers also are looking for ways to reduce Medicare spending, and labs continue to be a favorite target.

Altogether, the proposed budget would provide nearly $1 trillion for federal health programs administered by the Department of Health and Human Services, including some $77.1 billion in discretionary spending authority for the department, a reduction of $1.3 billion from fiscal 2014.

"Cuts to Medicare laboratory payment rates do nothing to modernize payments," says Mark Birenbaum Ph.D., administrator of the National Independent Laboratory Association (NILA). "They only succeed in eliminating market competition and the ability to ensure seniors have access to laboratory services. Community laboratories that provide test results that doctors rely on every day to make appropriate diagnoses and treatment decisions do not survive in the face of double-digit payment cuts."

In the 2014 Physician Fee Schedule final rule, CMS states that it will review laboratory test payment rates and make adjustments as soon as 2015. Though this process will begin in 2014, CMS has yet to outline how it will conduct such an analysis, how it will attribute its analysis to payment adjustments, and how deep those reductions will be.

"If Congress and the administration want to improve patient health outcomes and reduce health care expenditures, laboratories must be considered a key partner in meeting those goals, not a repeated target for cuts," says Birenbaum. "NILA has been working with Congress to truly modernize how Medicare pays for clinical laboratory services. We ask that Congress and the administration work with us, not against us, and initiate reforms that do not compromise the quality and availability of laboratory services that Medicare beneficiaries and their physicians need to support their health and well-being."

Takeaway: The Obama administration once again is trying to cut Medicare payment for laboratory testing as a way to save money even though reimbursement has already been reduced substantially over the last three years.

Congress Nearing Deadline for Medicare 'Doc Fix'

Congress has a little over two weeks to pass legislation reforming the system used to set Medicare payment for physicians or to extend the short-term fix already in place. If lawmakers do not act by March 31, physician payment under Medicare will be cut by 20.1 percent.

The House is expected to vote March 14 on legislation (H.R. 4015) that would overhaul the Medicare physician payment system, but if the measure includes a controversial delay of the Affordable Care Act's "individual mandate" as a possible way to pay for the overhaul, it is unlikely to advance in the Democratic-controlled Senate.

House Republicans March 12 unveiled a plan to pay for the overhaul by delaying the individual mandate penalty in the Affordable Care Act for five years. The delay would save about $169 billion from 2014 to 2024, according to the Congressional Budget Office (CBO).

While lawmakers agreed on the general framework of reform, they remain divided on how to pay for it. The CBO on Feb. 27 said the reform legislation would cost $138 billion from 2014 through 2024. The estimate is in the mid-range of scores the CBO gave to earlier versions of compromise legislation.

Because of the difficulty in paying for a long-term reform, it is likely that Congress will end up passing another shorter-term measure, perhaps through the end of 2014 (and after the midterm elections). Even then, lawmakers will have to find ways to pay for any fix to the physician payment formula.

House Minority Whip Steny Hoyer (D-Md.) has called paying for the bill by delaying the mandate a "poison pill," and Senate Majority Leader Harry Reid (D-Nev.) said March 11 the offset is evidence that Republicans aren't serious about enacting a doc pay fix.

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Among provisions that Congress could implement to help pay for the sustainable growth rate fix are a couple that would affect clinical laboratories and pathologists. Lawmakers could adopt the proposed clinical laboratory payment cuts included in the president's proposed budget for 2015, which would provide almost $8 billion over 10 years. They also could adopt the proposal to close the in-office ancillary services (IOAS) loophole in the Stark law, which would save more than $6 billion over 10 years.

Laboratory and pathology groups are urging Congress to spare clinical and anatomic pathology labs from further Medicare cuts, noting that closing the IOAS loophole would provide significant funding for physician payment reform.

Takeaway: The House and Senate are still split on how to pay for proposed reform of the system used to set Medicare payment for physicians. If they can't agree on pay fors, Congress is likely to pass another short-term "doc fix." G2

Pressure Building on TRICARE Over Noncoverage Of Molecular Diagnostic Testing

Lawmakers and military groups are stepping up the pressure on TRICARE to reverse its noncoverage policies for many molecular diagnostic tests.

More than 50 U.S. senators and representatives signed on to a Feb. 27 letter to Chuck Hagel, secretary of defense, expressing concerns regarding TRICARE's change in reimbursement policy. The letter notes that on Jan. 1, 2013, TRICARE placed more than 100 molecular pathology (MoPath) tests on the No Government Pay Procedure Code List (NGPPCL) and discontinued reimbursement for these tests.

"We are concerned that this policy change was not appropriately communicated to TRICARE beneficiaries or medical providers as [Department of Defense] policy requires," write the lawmakers. "The [tests] that were placed on the NGPPCL include MoPath tests frequently used to test for diseases or conditions, including those that may develop during a pregnancy (Cystic Fibrosis, Fragile X syndrome, and spinal muscular atrophy)."

According to the American Clinical Laboratory Association (ACLA), TRICARE's rationale for failing to cover these tests is that they are laboratory-developed tests (LDTs) that are not approved by the Food and Drug

The letter also notes that certain molecular pathology tests may still be covered for TRICARE beneficiaries who use a military treatment facility (MTF) but that in most cases, those same tests will no longer be covered for beneficiaries who do not have access to an MTF and who use a civilian medical provider.

"We are concerned that TRICARE's decision will jeopardize patient access to [molecular diagnostic tests] and ultimately creates two levels of care within the military health system and the TRICARE network: one that discriminates against beneficiaries with limited access or those unable to access a[n] MTF," says the letter.

According to the American Clinical Laboratory Association (ACLA), TRICARE's rationale for failing to cover these tests is that they are laboratory-developed tests (LDTs) that are not approved by the Food and Drug Administration. However, many, if not most, molecular diagnostics today are performed as LDTs.

In a statement provided to the House Armed Services Committee on Feb. 26, ACLA notes that the molecular tests that TRICARE stopped covering were not new tests in 2013. Rather, they were simply assigned new CPT codes.

"In January 2013, all payers switched to new codes identifying the individual test," says ACLA. "Most payers promptly covered the test utilizing the new codes; however, TRICARE has become an outlier with its persistent policy of noncoverage."

In their Feb. 27 letter to Hagel, lawmakers requested that he respond to several questions, among them:

- ❑ What are TRICARE's policies for providing a notification and public comment period for reimbursement policy changes impacting beneficiaries?
- ❑ What stakeholder input and feedback did TRICARE consider?
- ❑ What is TRICARE's justification for denying coverage for LDTs for patients who receive care outside of an MTF but continuing coverage and reimbursement for LDTs provided for patients who receive care within an MTF?

- ❑ Does TRICARE have an appeal process for services that a physician determines are medically necessary for a specific patient but that are not covered under current TRICARE policy?

According to Julie Khani, ACLA senior vice president, there has been no official response from TRICARE though officials have indicated they will publish guidance on a demonstration project. "We believe current regulations allow LDTs to be covered; a demonstration project is unnecessary and will result in delays in TRICARE beneficiaries from receiving access to these essential health services," she says.

Takeaway: TRICARE, which provides medical services for military families and retirees, has stopped reimbursing clinical laboratories for molecular pathology testing provided by civilian medical providers. Military groups and lawmakers are pressuring the Defense Department to reverse its noncoverage policy. G2

No More Delays for Health IT Programs, Says Tavenner

The Centers for Medicare and Medicaid Services (CMS) will not further delay the deadlines of any of its health information technology programs because agency officials see them as critical to the success of their payment-reform efforts, CMS Administrator Marilyn Tavenner said Feb. 27 at the Healthcare Information Management and System Society's (HIMSS's) conference in Orlando, Fla.

Tavenner said the use of information technology by health care providers will play a key role in CMS's efforts to tether Medicare and Medicaid reimbursement payments to clinical quality measure performance data. CMS is already working to do this through a number of Medicare programs such as the Hospital Value-Based Purchasing Program and the End-Stage Renal Disease Quality Incentive Program.

The ability to electronically record and report clinical quality measures—a requirement in Stage 2 of the meaningful use program—will be "critical to the success of these programs" and CMS's overall goal of reducing the cost of care delivery, Tavenner said.

"All of these programs use tools to link outcomes, link cost of care, link quality, and link payments together," she said.

Calls for Delay

While CMS will make it easier for providers to obtain hardship exemptions in 2014 if they aren't able to meet Stage 2 requirements of the meaningful use incentive program, Tavenner said the agency will not delay the penalty phase of the program. She also said CMS has no plans to extend the Oct. 1 ICD-10 (International Classification of Diseases, 10th Revision) implementation deadline.

Health care industry associations warned the Department of Health and Human Services this week that hospitals could lose billions in Medicare reimbursement dollars without a delay to the meaningful use program or the transition to ICD-10.

Despite those warnings, Tavenner said the ICD-10 transition has "already been delayed more than once and it's time to move on."

"We've already delayed the adoption of the standard, a standard that the rest of the world uses," she said. "There will not be a change in the deadline for ICD-10."

Takeaway: An additional delay for ICD-10 implementation and compliance with Stage 2 requirements of the meaningful use incentive program is unlikely. G2

Obama Proposes to Close Stark Loophole, *from p. 1*

procedure to diagnose cancer or other diseases and conditions. The process can almost never be completed with results available at the time of the patient's office visit.

CAP has long advocated for removal of AP services from the exception, which has led many specialists to open their own pathology labs in connection with their practices. In 2010, CAP sponsored the first research focused solely on self-referral of AP services. That study, conducted by Jean Mitchell, Ph.D., a leading health policy economist, and published in *Health Affairs*, found that self-referring urologists billed Medicare for 72 percent more prostate biopsy specimens compared to non-self-referring physicians.

In addition, a series of Government Accountability Office reports found increases in self-referrals for magnetic resonance imaging, computed tomography, radiation therapy, and AP services.

"The CAP's strategy has been to provide reliable data, share individual case studies, and provide the facts to educate policymakers about the unintended consequences of including AP services under the IOAS exception," said CAP President Gene Herbek, M.D., FCAP, in a statement. "In multiple meetings with White House domestic policy staff, the OMB, Congress, and the Centers for Medicare and Medicaid Services, the CAP made the case that closing the loophole protecting physicians who refer AP services to laboratories in which they, or an immediate family member, own or have a financial interest will generate significant Medicare savings, reduce unnecessary utilization, and benefit patient care."

CAP has long advocated for removal of AP services from the exception, which has led many specialists to open their own pathology labs in connection with their practices.

Takeaway: Pathology groups are applauding a proposal to remove anatomic pathology services from the in-office ancillary services exception to the Stark law. G2

CMS Proposes Hepatitis C Screening for Eligible Adults

The Centers for Medicare and Medicaid Services (CMS) March 4 proposed covering screenings for hepatitis C virus (HCV) in adults eligible for Medicare Part A or enrolled in Part B.

The agency said it is seeking comments by April 3 on the proposal, and it expects to complete a national coverage analysis by June 2.

In the proposed coverage decision, CMS said screening adults "is reasonable and necessary for the prevention or early detection of an illness or disability." Currently, HCV screening isn't covered by Medicare. The coverage analysis was generated internally, the agency said.

CMS said screenings would need to be conducted with the appropriate Food and Drug Administration-approved or -cleared laboratory tests "used consistent with FDA approved labeling and in compliance with the Clinical Laboratory Improvement [Amendments] (CLIA) regulations."

The agency said it would cover a screening only if a beneficiary was at "high risk" for infection. If the beneficiary wasn't considered "high risk," a single screening test would be covered for adults who were born from 1945 through 1965.

CMS defined those at "high risk" as persons with a current or past history of illicit injection drug use and persons who have a history of receiving a blood transfusion prior to 1992. Repeat screening for high-risk persons is covered annually only for those who have had continued illicit injection drug use since the prior negative screening test, the agency said.

In the United States, for the population already infected with HCV, veterans and baby boomers (those born between 1946 and 1964) are most at risk for becoming symptomatic.

According to the agency, hepatitis C is an infection that attacks the liver and leads to inflammation. It is often asymptomatic and can go undiagnosed for decades. It is difficult for the human immune system to eliminate the HCV, and it is a major cause of chronic liver disease. HCV is a bloodborne infection, and risks for transmission are primarily associated with exposure to contaminated blood or blood products via transfusions, shared needles, and reused medical supplies, the agency said.

In the United States, for the population already infected with HCV, veterans and baby boomers (those born between 1946 and 1964) are most at risk for becoming symptomatic. Veterans have an infection rate at least three times that of the general population, and baby boomers, who make up about 30 percent of the U.S. population, account for two-thirds of the people with HCV in the United States, CMS said.

FDA-Approved Tests, Treatments

Numerous laboratory tests that can detect the presence of HCV antibody, as well as HCV polymerase chain reaction tests, are FDA-approved or -cleared and available, CMS said.

In terms of hepatitis C treatment, FDA in the past several years has approved two protease inhibitors, Victrelis (boceprevir) and Incivek (telaprevir), for the treatment of genotype 1 infection, CMS said. These anti-virals are commonly referred to as direct acting anti-virals (DAAs). The use of a DAA in combination with interferon and ribavirin is commonly referred to as triple therapy, CMS said.

In November 2013, the FDA approved a third anti-viral called Olysio (simeprevir), which is a protease inhibitor indicated for HCV genotype 1 infection. Olysio is marketed by Raritan, N.J.-based Janssen Pharmaceuticals, part of Johnson & Johnson.

The FDA in December 2013 also approved Sovaldi (sofosbuvir) to treat chronic hepatitis C virus infection. Sovaldi is the first drug that has demonstrated safety and efficacy to treat certain types of HCV infection without the need for coadministration of interferon, the agency said. The drug is marketed by Foster City, Calif.-based Gilead Sciences Inc.

Takeaway: Medicare may soon begin covering screening of certain high-risk eligible adults for the hepatitis C virus. G2

Senator Questions 'Conflicting' HHS Policies On Patient Access to Lab Data

Sen. Lamar Alexander (R-Tenn.) is asking Health and Human Services Secretary Kathleen Sebelius to explain what he says are conflicting federal policies about giving patients access to their personal lab data.

Alexander said in a Feb. 20 letter to Sebelius that a warning letter to the genetic test maker 23andMe Inc. conflicted with a recent final rule from the federal agency giving patients the right to access their medical test results directly, rather than rely on their doctors to pass on the information.

The Food and Drug Administration (FDA) told 23andMe in November 2013 to immediately stop marketing its Saliva Collection Kit and Personal Genome Service to consumers until it received federal marketing approval for the product. At the time, the FDA said, "serious concerns are raised if test results are not adequately understood by patients or if incorrect test results are reported."

Since receiving the FDA letter, 23andMe has stopped offering new consumers access to health-related genetic tests while the company moves forward with the agency's regulatory review process. However, CEO Anne Wojcicki says she stands behind the data the company has generated for customers, noting that its lab partner adheres to strict quality standards under the Clinical Laboratory Improvement Amendments.

But Alexander said that patients were given the right under a final rule (79 Fed. Reg. 7,289) published Feb. 6 to directly access their laboratory test results. The FDA warning letter, he concluded, conflicted with the HHS's new policy to give patients access to their lab results without physician interpretation of the results.

"These are two conflicting actions from your Department in just a few months' time and raise questions about your agency's commitment to making personal health information available to support medical innovation," the senator wrote. "The conflicting decisions coming from agencies within your Department will slow down the access to or availability of novel diagnostics and targeted therapies. Targeted drug therapies rely on the availability of a wide array of diagnostic products, and consumers who want to take control of their health should have the right to their personal information to help in making personal health care decisions."

Alexander asked Sebelius to explain the HHS's position on "greater direct access to personal health information for patients" and to describe the criteria used to evaluate the tests described in the FDA warning letter and the final rule on patient access to test results.

Since receiving the FDA letter, 23andMe has stopped offering new consumers access to health-related genetic tests while the company moves forward with the agency's regulatory review process. However, CEO Anne Wojcicki says she stands behind the data the company has generated for customers, noting that its lab partner adheres to strict quality standards under the Clinical Laboratory Improvement Amendments.

Takeaway: HHS policies on providing consumers with access to their own test results appear to be contradictory, believes a U.S. senator who is seeking clarification from HHS Secretary Kathleen Sebelius.

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