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CMS Proposes Medicare Physician Fee Cut, Molecular Pathology Pricing Approaches for 2013

Congress is expected to block the looming fee cut but how to pay for it is an open question. It is also unclear whether lawmakers will impose an update freeze or grant a modest increase.

Among the many payment policy changes proposed in the Medicare physician fee schedule (PFS) for calendar year 2013 are two of immediate import for pathologists and clinical laboratories.

In the proposed rule released July 6, the Centers for Medicare and Medicaid Services (CMS) estimates a cut of 27 percent in the PFS update and unveils two approaches it would consider in establishing payment rates for newly created molecular pathology codes.

First, the 27 percent cut is required under the current statutory PFS update, which includes the sustainable growth rate factor and a budget-neutrality adjustment. The conversion factor used to translate the relative value units for services on the PFS would fall to $24.8441 in 2013 compared with $34.0376 this year.

These are preliminary estimates only, CMS cautions. The final fee update and the actual values used to compute physician payments for 2013 will be based on later data and will be published by Nov. 1 as part of the PFS final rule.

Continued on p. 7

Labs Face Multiple Medicare Fee Threats

For the clinical laboratory industry a key priority is to protect their Medicare reimbursement as Congress returns to work with a few legislative months remaining and a host of big-ticket items to resolve by year's end, including deficit-reduction, expiring tax breaks, an increase in the debt ceiling, the physician fee cut, and other controversial measures.

Lab groups are particularly anxious to avoid having their fees cut further to pay for a physician fee fix, as happened this year when Congress approved a $2.7 billion reduction in Part B lab fees over 10 years to help pay for the 2012 physician fee fix. As of Jan. 1, 2013, Medicare physician fees are scheduled for a cut of 27 percent, according to the latest projection from the Centers for Medicare and Medicaid Services.

With Congress and the Obama administration in election-year campaigning mode, decisions on the above are likely to be pushed off to a lame-duck session after the voters decide in November who will

Continued on p. 2

INSIDE *NIR*

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Labs Face Multiple Medicare Fee Threats, *from p. 1*

control the House, the Senate, and the White House. This would leave only 25 working days to tackle a lengthy legislative "must-do" agenda.

Looming in 2013 is an additional 2 percent cut in lab fee schedule payments (or sequestration) under the deficit-reduction deal reached in 2011. Under this deal, Congress must achieve at least $1.2 trillion in savings over 10 years or automatic cuts would be triggered in defense and nondefense spending, including a 2 percent reduction in all Medicare provider payments over 10 years.

For labs, this would come on top of any cut required by the fee schedule update formula that was revised by the health care reform law, including a productivity adjustment (now minus 1.3 percent) and a 1.75 percent cut in place from 2011 through 2015 ($5 billion through 2019).

"When you couple the 2 percent rebasing of the Medicare lab fee schedule required to pay for this year's physician fee fix with the cuts required by the health care reform law plus the looming sequestration," the American Clinical Laboratory Association notes, "test reimbursements will drop by approximately 23 percent over the next 10 years. In January 2013 alone, payment rates for clinical laboratory services will be reduced by almost 7 percent."

Lab-Developed Tests Get a Break in User Fee Law

Laboratory-developed tests (LDTs) got a break in medical device user fee legislation (S. 3187) that passed the Senate June 26 and was signed into law by the president on July 9.

The bill allows the Food and Drug Administration (FDA) to waive user fees on LDTs over the next five years, and in negotiations with stakeholders the agency has agreed to do so. But the agency is limited in the number of LDTs that it could decide to target for premarket approval and user fees over this period.

The bill also requires the FDA to notify Congress 60 days in advance of issuing any guidance on LDT regulation and report on what this guidance will entail. The FDA currently is working on a risk-based LDT regulatory framework with exceptions for rare diseases as well as emerging biothreats and infectious diseases; however, any final guidance will likely be delayed until after the November elections, say industry sources.

While lab industry advocates would have preferred that Congress adopt the Burgess bill (H.R. 3207), which would give the Centers for Medicare and Medicaid Services lead responsibility over LDTs, they say the 60-day notification requirement at least provides transparency and early warning.

The bipartisan bill (S. 3187), which emerged from House-Senate negotiations, reauthorizes the Prescription Drug User Fee Act and the Medical Device User Fee Act, due to expire Sept. 30. It creates new user fee programs for generic drugs and biosimilar (or follow-on biologic) drugs. The user fees supplement what Congress appropriates for the FDA.

In a blog post June 26, FDA Commissioner Margaret Hamburg noted that medical device fees will nearly double from current levels, rising from 20 percent of the total of FDA's review activity to 35 percent. With the added funding, she said, the FDA will be able to hire over 200 full-time workers by fiscal year 2017.

S. 3187 also includes regulatory provisions for incentives for development of antibiotics, prevention of drug shortages, and a requirement that FDA issue guidance on use of the Internet and social media to promote FDA-regulated medical products.

Pathologists Seek Relief From 'Meaningful Use' Penalties

More than 100,000 health care providers have qualified for over $7 billion in incentive payments for "meaningful use" of electronic health records (EHRs), the Centers for Medicare and Medicaid Services (CMS) announced, but pathologists aren't among those reaping the rewards.

Pathologists cannot only not meet meaningful use rules that require face-to-face encounters with patients and don't fit pathology practice, but they also face financial penalties for not satisfying those rules.

Under current law, pathologists and all other physicians who don't demonstrate meaningful use of a certified EHR system will be subject to a 1 percent cut in Medicare payments beginning in 2015. Payment cuts increase to 2 percent in 2016 and could go higher thereafter.

Now, pathology groups are asking Congress for relief. In letters to Rep. Dave Camp (R-Mich.), chairman of the House Ways and Means Committee, the College of American Pathologists (CAP) and the American Society for Clinical Pathology (ASCP) urge support for legislation that would exclude pathologists from both incentive funding and payment penalties. That bill is H.R. 4066, the Health Information Technology Reform Act, introduced by Rep. Tom Price (R-Ga.) and Ron Kind (D-Wis.).

Both CAP and ASCP call for a permanent hold-harmless provision. "Although CMS is considering administrative relief, the law only allows for annual waivers over a five-year period," CAP noted. ASCP said, "The absence of a permanent exemption for those specialists and other providers that cannot meet programmatic requirements demonstrates the dilemma posed by one-size-fits-all approaches."

Both groups also urged Congress to give CMS the authority to create alternative requirements that would allow pathologists to participate in incentive payment programs, provided these are technically feasible and not overly burdensome.

In announcing the EHR incentive payment results, CMS said that as of the end of May 2012:

- More than 110,000 eligible professionals and over 2,400 eligible hospitals have been paid by the Medicare and Medicaid EHR Incentive Programs.
- Approximately 48 percent of all eligible hospitals and critical-access hospitals in the United States have received an incentive payment.
- One of every five Medicare- and Medicaid-eligible professionals in the United States has received an incentive payment.
- Over $5.7 billion in EHR Incentive Program payments were made.
- More than $3 billion in Medicare incentive payments were made between May 2011 (when the first payments were released) and the end of May 2012, and more than $2.6 billion in Medicaid incentive payments were made between January 2011 (when the first states launched their programs) and the end of May 2012.

Supreme Court Ruling on Health Care Reform Law: Key Impacts on Medicare, Labs, and Pathologists

The Supreme Court ruling June 28 upholding the Patient Protection and Affordable Care Act (PPACA) is a mixed bag for health care providers, including clinical laboratories and pathologists, who may benefit from an influx of newly insured patients but also face major reimbursement challenges.

The thrust of the law is to expand health insurance coverage to an estimated 33 million uninsured either through exchanges offering coverage options and premium subsidies for those without on-the-job coverage or through state Medicaid programs. The law also introduces a range of new consumer protections, most notably no denial of coverage by private health plans based on pre-existing medical conditions (now in effect for children and due to start for adults in 2014).

But the high court barred the federal government from withholding its share of Medicaid funding if states failed to expand access to coverage benefits to certain required levels, leaving this issue to be debated among the White House, Congress, and the states. Several Republican governors have already said they intend to turn down the additional Medicaid funding the law provides and not expand their programs.

One clear benefit of the expanded coverage due to begin in 2014 is to relieve hospitals and labs of the costs for uncompensated care of the uninsured while spurring demand for medical services from people who previously had to rely on the emergency room for care.

For clinical labs and pathologists, another benefit now in place is that the law requires Medicare and private health plans to fully cover the cost of preventive services, including screening tests, that are rated A or B by the U.S. Preventive Services Task Force.

But the law also poses new challenges to traditional Medicare fee-for-service (FFS) that clinical labs and pathologists historically have relied on. It propels a shift to alternative payment methods through new Medicare demonstrations of coordinated care delivery models aimed at improving the quality of care for beneficiaries while lowering costs.

The impact here is unclear, notes Dennis Weissman, an industry expert and founder of Washington G-2 Reports (now G2 Intelligence). “The most challenging issue is how reimbursement is going to migrate from a system based on volume to one based on quality and outcomes. We haven’t quite figured out how labs and pathologists are going to fit under that scenario.”

CMS already is forging ahead to experiment with FFS alternatives such as shared savings and bundled payment programs through voluntary accountable care organizations (ACOs), patient-centered medical homes, and at-home independence service teams.

The agency announced July 9 that it has entered into coordinated care agreements with 89 new ACOs serving 1.2 million people with Medicare in 40 states and Washington, D.C., as of July 1. "This new group of ACOs adds to a solid foundation," said CMS acting administrator Marilyn Tavenner. "The ACO program opened for business in January, and already more than 2.4 million beneficiaries are receiving care from providers in these important initiatives."

This brings the total number of ACOs in the Medicare shared savings program to 154. The ACOs operate in a wide range of areas of the country and many serve fewer than 10,000 beneficiaries, demonstrating, CMS said, that smaller organizations are as interested in operating as ACOs as are hospitals, health systems, and large medical group practices.

At the core of an ACO and other shared savings programs is the clinical team whose decisions on quality and cost savings determine its financial rewards or losses. For 2012, CMS has established 33 quality measures for care coordination and patient safety, appropriate use of preventive health services, improved care for at-risk populations, and patient and caregiver experience of care.

It's essential that clinical labs and pathologists be an integral part of the clinical team, not an adjunct, Weissman said, and both are well positioned to argue for that integral spot. Their expertise will be needed to ensure cost-effective test ordering and to enable physicians to best use the results to guide diagnosis and follow-up. Clinicians in turn will increasingly rely on them to keep up with advances in testing technology, especially in the fast-evolving field of personalized medicine where genomic testing requires more complex analysis and interpretation. A crucial step for pathologists and clinical labs is to negotiate reimbursement rates that reflect their contribution to the enterprise.

Another threat to lab and pathology reimbursement is created by the health care reform law in the form of the Independent Payment Advisory Board (IPAB), which is charged with helping control the rate of Medicare spending growth.

Beginning in 2014, in any year in which the Medicare per capita growth rate exceeds a target growth rate, the 15-member board, appointed by the president and subject to Senate confirmation, must recommend program spending reductions that would become law unless Congress passes an alternative. But the law also bars the board from making recommendations that would ration care, increase beneficiary cost sharing, or otherwise restrict benefits or modify eligibility criteria.

Still, its recommendations would be difficult for legislators to override. Under the law, Congress cannot consider any amendment to the IPAB cost-cutting proposal that does not meet the same cost-reduction goals unless both houses of Congress and three-fifths of the Senate vote to waive this requirement.

The GOP-controlled House has voted to repeal the IPAB, a move supported by a range of business groups and health care providers, including clinical laboratory and pathology organizations, that say the board encroaches on congressional power over spending and lacks accountability since it is not required to get public comment and its actions are not subject to judicial review. But the bill is seen as a "nonstarter" in the Democratic-controlled Senate. The White House also opposes IPAB repeal.

Much of Medicare spending is exempt from the IPAB's oversight until 2020 (hospital spending, for example), so those most affected by any cuts that must be made are physicians, clinical labs, and other providers and suppliers.

Diagnostic Testing Deal Passes OIG Muster

In its latest advisory opinion the Health and Human Services Office of Inspector General (OIG) said it would not impose administrative sanctions on a proposed arrangement whereby an independent diagnostic testing facility (IDTF) would hire a physician to read and interpret test results even though the physician is closely related to owners of the facility and is also employed by a clinic that employs other potential referral sources.

Facts Presented to the OIG

The physician would be a bona fide employee of the IDTF, hired to interpret results of home sleep test kits furnished by the facility to patients of referring doctors. He would receive a set salary that would not be linked to the number of sleep study tests he interprets. He would not be permitted to make referrals to the IDTF. Although he does not have an ownership interest in the facility, his wife and father are two of the three owners (holding 50 percent and 20 percent, respectively). The owners are not in a position to refer patients to their facility.

The advisory opinion (No. 12-08), released June 29, is found at www.oig.gov. *It applies only to the party requesting it and not to any others even if their arrangements appear similar in nature or scope. Further, it applies only to the federal anti-kickback law and not to any statute, including the federal physician self-referral law.*

The IDTF would bill a patient's insurance for the home sleep test kit as well as the physician's interpretation services and would not provide patients with any durable medical equipment (DME), such as constant positive airway pressure (CPAP) machines.

The physician, whose areas of practice include pulmonary and sleep medicine, would to be employed at a local clinic that employs other physicians in this specialty. He does not have an ownership interest in the clinic and none of the other physicians share office space with him, nor are they a group practice. The home sleep tests that he orders and interprets and those that other clinic physicians refer to him are run on clinic-owned equipment or at a nearby hospital laboratory for facility-based testing. The work does not involve an IDTF. In addition, neither he nor any of the other physician employees of the clinic supply DME, including CPAP, to patients.

The OIG's Analysis

While the proposed arrangement could potentially implicate the anti-kickback statute, the OIG concluded that two key factors lower the risk of any violations:

- The IDTF certified that the physician would not make any referrals to the IDTF or otherwise solicit business for it. In addition, the home sleep tests that he orders based on referrals from other clinic employees are performed using clinic-owned equipment. "Thus, it is unlikely that he could influence these physicians to refer to the IDTF or otherwise direct the referrals to the IDTF."

- Neither the IDTF nor the physician would supply DME, including CPAP. "If either party supplied DME that could be ordered for patients whose test results indicated a need for the device, then the physician could have an incentive to skew the interpretations to demonstrate such a need. Because the physician would not have a financial interest in the test outcome under the proposed arrangement, this risk of overutilization is not present."

The OIG's conclusion: "The physician's compensation would be protected under the employee safe harbor, and the other facts and circumstances of the proposed arrangement present a sufficiently low risk under the anti-kickback statute."

CMS Proposes Medicare Physician Fee Cut, *from p. 1*

Second, for the 101 molecular pathology codes introduced in this year's CPT update but not yet recognized by Medicare (CPT 81200-81383 and 81400-81408), CMS proposes two approaches:

- ❑ Price them all via a single fee schedule using the same methodology, either the Part B clinical lab fee schedule (CLFS), which sets prices by a crosswalk to an existing code or gap-filling based on local pricing patterns with a one-time only reconsideration and no beneficiary cost sharing, or the PFS, where fees factor in physician work and practice expense and beneficiaries are liable for a 20 percent copay.

The new molecular pathology codes are intended to replace Medicare billing for molecular pathology procedures using "stacking codes" (CPT 83890–83914) that focus on methodology rather than analyte. The new codes are posted at www.cms.gov/ClinicalLabFeeSched/. *Click on "Laboratory Public Meetings" to access the 2013 code download.*

"After meeting with stakeholders and reviewing each CPT code, we believe there is little variation in the laboratory methodologies, as all of them employ gene sequencing processes," CMS says. "Establishing different prices for comparable laboratory services across two different payment systems would create a financial incentive to choose one test over another simply because of its fee schedule placement. We are also concerned that the differences in prices would become more pronounced over time as the PFS continues to review the values for physician work and practice expense inputs relative to established CLFS prices."

- ❑ If it is determined that the new codes should be paid under the PFS, Medicare contractors would set the payment rates for 2013. "The price of these tests can vary locally," CMS notes, "and we do not believe we have sufficient information at this time to engage in accurate national pricing."

After reviewing comments on the above proposals and after hearing a related discussion on molecular pathology pricing at the CLFS annual public meeting set for July 16-17, CMS says, "We will determine the appropriate basis for establishing payment amounts for these codes and publish the final decision in the PFS final rule. At the same time, we will post final payment determinations, if any, for those codes that will be paid under the CLFS."

CMS bases its hesitation about setting payment rates for the molecular pathology codes on what it termed "many outstanding questions," including:

- ❑ If these services are furnished by a physician, what are the appropriate physician work relative value units and times relative to other similar services?

- ❑ Where and how are each of these services typically furnished—for example, what is the typical laboratory setting and batch size?

- ❑ What is the correct projected utilization for each of these services?

The proposed PFS rule for 2013 will appear in the July 30 *Federal Register* and be open for comment until Sept. 4.

FDA Approves OraQuick In-Home HIV Test

The Food and Drug Administration (FDA) has approved the OraQuick In-Home HIV Test for sale in stores and online to anyone aged 17 and older. It is the only test available that enables consumers to collect a sample for testing and obtain a preliminary result within minutes in their own home.

The manufacturer, OraSure Technologies (Bethlehem, Pa.), said the kit will be available at more than 30,000 retailers and online starting in October, with the price to be set closer to the launch date, though expected to be higher than the $17.50 now charged for professional use.

The test is targeted to people who would not otherwise get tested by a doctor or a health care facility. About 1.2 million people in the United States are living with HIV infection, and about one in five of them don't know it, increasing the chance that they will unknowingly spread it.

The test checks for antibodies to HIV, the virus that causes AIDS. The user swabs upper and lower gums for an oral fluid sample with the test device, which is then placed in a tube with a developing solution. After 20 to 40 minutes, one line will appear if the test is negative, two lines if antibodies were detected. Positive results must be confirmed by follow-up lab-based testing, the FDA cautioned. False negatives can occur if the individual is HIV-infected within three months prior to testing and even thereafter. Those who have unprotected sex with new partners or inject illegal drugs should be retested on a regular basis.

Upcoming G2 Events

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Aug. 21

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Featured Speaker:
Sherri Huber, Laboratory Quality and Informatics Coordinator, HealthPartners Central Laboratory

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NIR 7/12A

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