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Medicare Physician Fee Fix: How Far Will Congress Go?

Physician groups want repeal of the current Medicare fee update system, but the high price tag in the current deficit-cutting political climate could deter Congress from such radical surgery for now.

Congress is expected to block a cut of 29.5 percent in Medicare physician fees scheduled for Jan. 1, but it's not clear what comes next.

The big unknown is how lawmakers will handle the cause of the cut—the sustainable growth rate (SGR) formula used to calculate the annual update to the Part B physician fee schedule. When physician spending exceeds a target growth rate, the update is negative, as happened for most of the past decade, prompting Congress to step in repeatedly to cancel the fee reductions.

This time, Congress could adopt another short-term fix, pegged by some pundits at one year, with either a freeze or a modest payment increase. A one-year fix would cost an estimated $20 billion to $25 billion. The president's budget request earlier this year called for a two-year freeze, from Jan. 1, 2012, to Jan. 1, 2014. He also supported fundamental physician payment reform, but with no specifics.

Physician groups are pushing hard for repeal of the SGR, but the high cost has prevented lawmakers from biting the bullet.

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— Webinar: Nov. 10, Coding and billing changes for 2012
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Legislation Would Expand CLIA's Authority Over Laboratory-Developed Tests

Who should regulate laboratory-developed tests (LDTs)? The Food and Drug Administration (FDA), the CLIA (Clinical Laboratory Improvement Amendments) program at the Centers for Medicare and Medicaid Services (CMS), or both?

To Rep. Michael Burgess, M.D. (R-Texas), the answer is clear—an expanded and enhanced CLIA. He is sponsoring legislation that would establish a notification and review process giving the CLIA program new authority to evaluate the clinical validity of LDTs, in vitro diagnostics manufactured by and offered in the same CLIA-certified laboratory.

The bill is H.R. 3207, the Modernizing Laboratory Test Standards for Patients Act, introduced Oct. 14.

It has the "full and strong" backing of the American Clinical Laboratory Association (ACLA), said President Alan Mertz. "This legislation offers a modern, innovative, and flexible approach that builds on the success of CLIA. It avoids regulatory overlap and redundancy, while

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CLIA and Laboratory-Developed Tests, *from p. 1*
assuring consumers that laboratory-developed tests are reliable and accurate. This is a balance that will encourage continued innovation and protect consumers."

The bill also "enhances public transparency and strengthens reporting of adverse events—all without additional government expenditures," ACLA said in a letter to Burgess. Further, it would accelerate progress on personalized medicine by encouraging the clinical lab industry to keep innovating with new tests "that detect and diagnose disease as well as inform the treating physician whether a drug or biologic is an effective means of treating a particular patient."

Challenge to FDA Jurisdiction

In introducing the bill, Burgess said, "It is important that we relieve restrictions while providing regulatory reform that positively impacts and protects patients while promoting job growth. Adding additional and duplicative FDA regulations to industries that are not under the agency's jurisdiction will further burden an overstretched institution that cannot currently process its substantial backlog due to its own regulations being a hindrance."

Laboratory-developed tests number in the thousands, industry sources estimate, and are used for a wide range of cancers, cardiovascular and neurological disease, Alzheimer's, and many other serious health conditions. LDTs are fueling the advance of personalized medicine, lab industry sources note, providing genetic testing to guide treatment and therapy to patients based on their genetic profile for individualized care, including identifying predisposition to certain diseases and optimal response to drug therapy.

FDA, however, has long asserted that it has jurisdiction over LDTs as medical devices subject to premarket review but has exercised this jurisdiction only with regard to analyte-specific reagents, the ingredients used in LDTs, and to certain assays—in vitro diagnostic multivariate index assays (IVDMIAs)—that use a proprietary algorithm to produce patient-specific results, making it difficult for the treating physician to validate the results independently.

ACLA, the College of American Pathologists, and other FDA critics dispute such overreaching oversight because LDTs, developed and performed in-house, are not sold as commercial test kits (which do require premarket review) but are offered as a laboratory service to treating physicians and patients.

Meanwhile, the FDA is reportedly close to the end of review required for its guidance on expanded oversight of LDTs. In July 2010 the FDA alerted the lab industry that it planned to expand its regulatory reach to include LDTs based on their level of risk and solicited comments from stakeholders on the methods used to calculate different levels.

That guidance was still under review at press time, but some of its outline has been discussed by FDA officials at various public forums this year. It is likely to contain exceptions for certain types of tests, said Alberto Gutierrez, Ph.D., director of FDA's Office of In Vitro Diagnostic Device Evaluation and Safety, earlier this year at the ACLA annual meeting. These types would include tests for rare diseases, biothreats, and emerging infectious diseases, as well as for "traditional, low-risk" tests.

Tests ranked as Class III medical devices, such as those for human papilloma virus (HPV), would probably be required to go through the FDA's 510(k) approval process while those classified as Class I probably would not, he said. Tougher oversight of direct-to-consumer genetic testing is also expected to be part of the FDA guidance.

FDA, CMS to Streamline Medical Device Review

Under a new federal pilot program, a new medical device can be concurrently reviewed for market approval and a Medicare coverage determination. The aim is to shorten the time it takes a manufacturer to obtain both and to give patients quicker access to innovative medical technologies.

The launch of the parallel review pilot was announced Oct. 7 by the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA). Details were published in the Oct. 11 *Federal Register*, including guiding principles the agencies will follow during product review.

The pilot program is voluntary and will not change the existing separate review standards for FDA device approval and Medicare coverage determination. It is available only for qualifying new medical device technologies.

The program will last up to two years and could be extended, the agencies said. Assessing its available resources, CMS said it would accept no more than five submissions per year under the pilot.

Guiding Principles

- ❏ Participation in parallel review will not affect the review standard for device approval by FDA or for a coverage determination by CMS.
- ❏ The agencies will adhere to all statutory and regulatory requirements as stipulated in the memorandum of understanding between FDA and CMS.
- ❏ A sponsor or requester may withdraw from, and FDA and CMS may terminate, parallel review up until the time of CMS's public posting of a National Coverage Determination (NCD) tracking sheet.
- ❏ The agencies will not publicly disclose participation of a sponsor or requester in parallel review prior to CMS's posting of an NCD tracking sheet, unless the sponsor or requester consents or has already made this information public or disclosure is required by law. If a sponsor or requester does not wish the information that would be revealed by the posting of the NCD tracking sheet to become public, it must withdraw from parallel review prior to this point.

Less Burden, Better Outcomes

Both the FDA and CMS rely on clinical data in formulating their decisions, and "the parallel review program has the potential to increase patient access to innovative devices that improve clinical outcomes," said Patrick Conway, CMS chief medical officer. "Our goal is to reduce regulatory burden and improve patient outcomes."

Early involvement of CMS will sharpen the focus on health outcomes of importance to the Medicare population and provide early awareness of any remaining evidence gaps. If there are such gaps, CMS may address them by implementing coverage with evidence development (CED) or other policy vehicles. For example, if FDA approval or clearance is conditioned on a post-approval study, CMS could decide to cover the device within the parameters of the post-approval study.

The pilot program was first proposed by FDA and CMS in September 2010 (*Federal Register*, Sept. 17). G2

focus on: Lab Payment Policy

OIG Nixes Pathology Lab Management Proposal

A proposed arrangement under which physicians would invest in a company that would provide pathology laboratory management services to a third party got a cold reception from the Office of Inspector General (OIG) at the U.S. Department of Health and Human Services.

In an advisory opinion posted Oct. 11, the OIG said the arrangement posed "more than a minimal risk of fraud and abuse." It could potentially generate prohibited remuneration under the anti-kickback statute and the OIG could potentially impose administrative sanctions, including civil monetary penalties and exclusion from federal health care programs.

The opinion was issued in response to a request from a physician-owned limited liability company to contract with another company (not yet determined, "the path lab") that either operates a licensed, Medicare-certified clinical anatomic pathology lab or would form one for the purpose of doing business with the physician-owned company.

The Proposed Arrangement

The path lab would enter into a management services contract with the physician-owned company for at least three years. The company would furnish the path lab with "the complete array of clinical laboratory pathology services for a fixed minimum number of hours each year as well as utilities, furniture, fixtures, exclusive use of lab space and equipment, marketing and billing services, and essential nonphysician staff." The lab's income could include payments from Medicare and other federal health care programs for lab services.

In turn, the path lab would pay the physician-owned company a usage fee that would be calculated on a percentage of the lab's income, fixed in advance for 12 months, that generally would correspond to the volume of the lab's use of the company's services, personnel, and equipment.

Other physicians, such as urologists, gastroenterologists, and dermatologists, who can make referrals, would be able to join the company as investors. Their investment interests in the company are expected to exceed 40 percent, and more than 40 percent of the company's health care services would be derived from income generated by physician investors through referrals to the path lab.

The OIG's Analysis

The OIG found that the proposed arrangement did not qualify for any of the safe harbors under the anti-kickback statute, noting that "among other reasons, the aggregate usage fee paid to the company by the lab would be calculated based on a percentage of the lab's income."

With no applicable safe harbors, the OIG determined that the proposed arrangement presented more than a minimal risk of fraud and abuse because the usage fee paid

to the company by the lab would take into account the business generated by new physician investor referrals.

"This fee structure would effectively link the new physician investors' profit distributions to the laboratory business they send the path lab, posing considerable risks of overutilization of laboratory services, distorted medical decision-making, and increased costs to the federal health care program," the OIG said.

The proposed arrangement "appears to have no business purpose other than to permit the physician investors to profit from the business they generate for the path lab in the form of their laboratory specimen referrals," the OIG concluded.

The advisory opinion is posted at *oig.hhs.gov*. It applies only to the party requesting it and is based on the information the party provided. It has "no application to, and cannot be relied upon by, any other individual or entity," the OIG noted.

Perspectives on the OIG's Opinion

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The advisory opinion is a good reminder that health care arrangements are subject to several different laws and regulations, each of which must be followed. For example, an arrangement can comply with the Stark self-referral law and violate the federal anti-kickback statute (FAS), or it can comply with the FAS and violate Stark.

The arrangement reviewed by the OIG would provide referring physicians, including urologists, gastroenterologists, and dermatologists, with an economic interest in anatomic pathology services that they generated. Stark prevented these physicians from owning the pathology laboratory that would perform the services that they referred. The in-office ancillary services exception to the self-referral prohibition was not available because the physicians were not members of a single group practice that might operate the pathology lab. Therefore, the arrangement provided for the referring physicians to have an ownership interest in a legal entity that provided management services to the pathology laboratory, rather than in the laboratory itself. The physician-owned entity, however, would receive a percentage of the laboratory's profits as compensation for its services.

In determining that the arrangement potentially violated the FAS, the OIG recognized that the physicians would receive compensation that reflected their referrals to the pathology lab. Put simply, the more tests that they referred to the lab, the greater the lab's income, and the greater the lab's payments to the physician-owned entity for its management services. In fact, according to OIG, this appeared to be the arrangement's purpose. The laboratory would have been able to operate independently; it did not have to obtain management services from the physician-owned entity.

The OIG expressed no opinion on the application of the Stark law, stating that Stark and the FAS are "independent legal authorities" that must be evaluated separately. When Stark was enacted, that's what Congress envisioned. But that's not always the case anymore. The regulatory exception to Stark's self-referral prohibition for indirect compensation arrangements between a physician and health care entity developed later by the Centers for Medicare and Medicaid Services—and which would potentially be applicable to this type of arrangement—prohibits a compensation arrangement that violates the FAS. Therefore, an indirect compensation arrangement that violates the FAS can also result in Stark violations.

Medicare Physician Fee Fix, *from p. 1*

The cost of repeal is an estimated $300 billion over 10 years. Repeal advocates counter that continued delay in scrapping the SGR has significantly upped the price tag for permanent Medicare payment reform. More short-term interventions will double the cost to approximately $600 billion by 2016, the groups estimate.

The legislative vehicle for either a short- or long-term fix, according to congressional aides, could be the deficit-reduction plan that the Joint Select Committee is to produce by Nov. 23, recommending between $1.2 trillion and $1.5 trillion savings over 10 years.

If a majority approves, the package of savings goes to the House and the Senate for an up-or-down vote, with no amendments or filibusters, by Dec. 23. The president retains veto power. If a savings deal of at least $1.2 trillion is not reached, a 2 percent cut in defense and nondefense spending, including Medicare, would take effect in 2013. Medicaid spending would not be reduced.

But sources close to the committee caution that it remains unclear whether the 12-member bipartisan House-Senate panel will choose to include a fix in its recommendations. If not, a Medicare physician pay fix could be moved as a stand-alone bill.

Paying for a Fix

The Medicare Payment Advisory Commission (MedPAC) triggered widespread and strong opposition from physicians and other providers, including clinical laboratories, when it voted Oct. 6 to recommend that Congress repeal the SGR and pay for it with cuts to specialists and potentially other providers and beneficiaries.

MedPAC called for a freeze on primary care payments for 10 years and a cut of 5.9 percent for other physicians for three years followed by a seven-year freeze.

The freeze and the payment cut would generate an estimated $200 billion in savings.

Given the importance of an SGR fix, the commission attached to its recommendations a list of other options that it said Congress could consider to come up with an additional $100 million in savings, though the panel did not act on them.

This "offset" list included two tiers. The first tier includes about $50 billion in savings proposals that MedPAC has previously recommended. The second tier contains about $168 billion in recommendations from other entities, such as the Congressional Budget Office and other sources, including introduction of beneficiary cost sharing for Part B covered clinical lab services, which have been exempt from coinsurance since 1984.

MedPAC staff further noted that Congress could choose to offset the cost of SGR repeal outside the Medicare program.

The American Medical Association (AMA) and more than 40 other groups had written the commission Oct. 3 urging members not to endorse provider cuts to pay for SGR repeal. After the vote, the AMA issued a statement saying that the recommendations, along with other potential cuts from requirements dealing with electronic prescribing, health information technology, and quality reporting programs, will "leave many physicians unable to care for Medicare patients or make the investments needed to participate in new models of care that can increase coordination and reduce costs."

The AMA earlier this year laid out a road map for a permanent physician fee fix. It included cancelling the 2012 scheduled 29.5 percent cut, repealing the SGR, and providing stable fee increases over five years in the transition to an assortment of reimbursement options tailored to the medical specialty, its capabilities, and the patient population it serves. Such models might include coordinated care and shared savings through accountable care organizations, the patient-centered medical home, bundled payments, capitation blends, and private contracting, the AMA noted.

"It will never be less expensive to repeal the SGR than it is right now," said MedPAC Chairman Glenn M. Hackbarth in an Oct. 14 letter to the chairmen and ranking members of congressional committees with jurisdiction over Medicare—the House committees on Ways and Means and Energy and Commerce, and the Senate Committee on Finance. "Our concern is that repealing the SGR will become increasingly difficult unless the Congress acts soon."

The letter was in follow-up to the commission's vote to pay for SGR repeal with reimbursement cuts for specialists and a freeze for primary care physicians.

Despite action taken now, Hackbarth said, the increase in the number of Medicare beneficiaries over the next 10 years and growth in the number of services would lead to a rise in total practitioner payments from Medicare from $64 billion to $121 billion. On a per-beneficiary basis, payments would continue to rise at an average rate of 2.2 percent per year.

Another recommendation that cleared MedPAC is intended to increase the shared savings opportunity for providers who join or lead "two-sided" risk accountable care organizations (ACOs) that offer both bonuses and penalties based on performance. It would require CMS to compute spending benchmarks for these ACOs using 2011 fee schedule rates. The benchmark could be based on the higher overall fee schedule growth rate subject to the freeze rather than the cut.

Clinical Lab Services Under the OIG's Microscope in 2012

In its 2012 work plan released this month, the Office of Inspector General (OIG) at the U.S. Department of Health and Human Services says it will examine payment for glycated hemoglobin A1C tests, trends in laboratory service utilization, and how payments for lab tests compare under Medicare, Medicaid, and the Federal Employee Health Benefits (FEHB) program.

The OIG will review the procedures that Medicare contractors have for screening the frequency of clinical lab claims for A1C tests and determine the appropriateness of Medicare payments for these tests. Preliminary OIG work in two contractors showed variations in the frequency-screening procedures, the work plan reported, noting that it is not considered reasonable and necessary to perform the test more often than once every three months in a controlled diabetic patient unless documentation supports the medical necessity of tests in excess of national coverage determination guidelines.

The OIG also says it will review trends in lab service usage under Medicare and will determine how the methods for setting Medicare lab test payment rates vary from state Medicaid and the FEHB program. The work plan is posted at *www.oig.hhs.gov.*

Medicare Claims Advisory

Interest Rate Dips for Medicare Overpayments, Underpayments

On two separate dates this month, the rate of interest that Medicare will pay you for claims that were underpaid, or collect from you for claims that were overpaid, will drop from the 11.5 percent in effect since July 18, 2011. Prior rates this year were 11 percent as of April 19 and 11.25 percent since Jan. 24.

The highest rate in the past decade was in early 2001, 14.125 percent, but for most of the years since, the rate has hovered between 11 percent and 12 percent.

Medicare regulations provide for assessing interest at the higher of the current value of funds rate (1 percent for calendar year 2011) or the private consumer rate fixed by the Treasury.

The Treasury Department has notified the Centers for Medicare and Medicaid Services (CMS) of changes in the private consumer rate.

Accordingly, CMS has notified Medicare contractors to implement an interest rate of 10.78 percent, effective for Oct. 19, 2011, only for Medicare overpayments and underpayments, and an interest rate of 10.875 percent effective Oct. 20, 2011 (Transmittal 197, Oct. 17, 2011, Change Request: 7569).

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