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Medicare Physician Fees in 2013: How Much of a Fix Is in Store?

The College of American Pathologists (CAP) is joining "with a strong offense to fight this cut," noted Jonathan Myles, M.D., FCAP, chair of the CAP Economic Affairs Committee, during a Nov. 14 webinar. "It's important to remember that the SGR cuts are not a pathology-specific issue, we have the entire House of Medicine on our side. The American Medical Association is taking the lead on reforming the SGR, and CAP is supporting and assisting in this effort."

Unless Congress intervenes, pathologists face a 26.5 percent cut in their Medicare payments as of Jan. 1, 2013, under the sustainable growth rate (SGR) system used to update the Part B physician fee schedule.

Getting lawmakers to block that cut is a top legislative priority of pathology and clinical lab advocacy groups for the lame-duck session of Congress now under way.

The scheduled cut would slash the conversion factor (CF) to $25.0008 for calendar year 2013 versus $34.0376 this year. The CF translates the relative value units of a physician's service (work, practice expense, and malpractice expense) into a dollar amount.

Congress is expected to cancel the looming cut but not to tackle an overhaul of the Medicare physician payment system by repealing the SGR, a goal long advocated by physician groups. The obstacle has been the high cost of repeal, an estimated $300 billion over 10 years.

Instead, Congress is likely to opt for another short-term SGR fix as it has done over the past decade. But even that must be paid for by

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Congress Passes CLIA PT Referral Bill

Congress has passed and sent to the president legislation that would give the Centers for Medicare and Medicaid Services (CMS) leeway in enforcing sanctions on clinical laboratories for violating proficiency testing (PT) referral rules.

The noncontroversial bipartisan legislation cleared its last hurdle in Congress when the Senate approved it Nov. 14 by unanimous consent. The House had passed it Sept. 19. The president is expected to sign it into law.

CMS has taken a strict interpretation that the Clinical Laboratory Improvement Amendments (CLIA) give it no choice but to revoke a lab's certificate for one year and bar its owner and operator from running another lab for two years for PT referrals of a test that the lab is certified to perform, even in cases of unintentional violations. The agency has said that it punishes only intentional referrals, but it considers a referral to be intentional if the lab meant to send the specimen to another lab for testing, even if it didn't intend to cheat. Now, the agency can consider sanctions on a case-by-case basis, a change that CLIA officials have said they would welcome.

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CLIA PT Referral Bill, *from p. 1*

Impact of the Legislation

Asked for comment by *NIR*, attorney Robert E. Mazer with Ober/Kaler (Baltimore) said, "Clearly, the statutory changes are potentially helpful to labs. CMS is no longer required to revoke the CLIA certificate of labs that have violated the PT specimen referral prohibition and is no longer required to revoke the CLIA certificate of a lab that has the same owner or operator of a lab which has had its CLIA certificate revoked for PT referral violations. This doesn't provide labs that have violated PT referral rules with any additional right to the lesser sanctions, however. CMS may elect to revoke the CLIA certificate of such a laboratory and related laboratories. It will be interesting to see how CMS exercises its new discretion."

Key Features of the Bill

The Taking Essential Steps for Testing (TEST) Act (H.R. 6118 and S. 3391) amends the Public Health Service Act to revise sanctions for clinical labs that unintentionally refer PT samples to other labs. It gives CMS enforcement discretion to:

- Make the one-year CLIA certificate revocation optional rather than mandatory.
- Levy intermediate sanctions instead of the two-year prohibition against ownership or operation of a lab that would otherwise apply.

Under the revised statute, Mazer noted, "CMS may, but is not required to, revoke the CLIA certificate of a lab that is found to have intentionally referred its PT samples to another lab for testing. The lab would, however, be subject to so-called intermediate penalties, including substantial monetary penalties. Generally, a lab cannot appeal the penalties imposed by the agency specifically but can challenge the finding that it violates the statute or regulation resulting in the imposition of penalties only.

"Interestingly, if a lab's CLIA certificate is revoked for any other reason, CMS continues to be required to revoke the CLIA certificate of any other lab under common ownership or operation."

Noting that the legislation does not include a specific effective date, Mazer commented, "Presumably, it would permit CMS to elect to impose lesser sanctions on a lab that has violated the PT referral prohibition any time after the new law becomes effective, even if the PT violation preceded that date."

ACLA to FDA: Exclude Lab-Developed Tests From Unique Device ID Rule

The American Clinical Laboratory Association (ACLA) wants to make sure that laboratory-developed tests (LDTs) will not be subject to a unique device identifier (UDI) system proposed by the Food and Drug Administration (FDA).

That system would require most medical devices, such as analyzers and in vitro diagnostic test kits, to carry a UDI, a numeric or alphanumeric code containing basic information on the type of device and its manufacturer or its expiration date and batch or lot number. The UDI would strengthen its market surveillance for adverse events and help manage recalls more effectively, FDA said (*NIR 12, 20/Nov. 8, p. 6*).

What concerns ACLA is the fact that the FDA has already said it intends to regulate LDTs under its medical device enforcement authority.

In comments to FDA on the proposed UDI rule, ACLA emphasized that LDTs are a testing service using processes developed in-house and performed by the lab, not a device like a commercially available test, and should not be subject to the UDI system.

"But even if LDTs were, ACLA believes that FDA should categorically exempt [them] from [it]." Compliance with the UDI rule would not be feasible because an LDT has

neither a "label" nor a "device package" on which a UDI could be placed. Further, "various lots of different reagents might be used for a test, making it difficult to create a production identifier."

Existing standards for accrediting clinical labs achieve many of the goals of the proposed UDI rule, ACLA said. "For example, lab test records contain enough information to trace back test results to a specific patient and to specific IVD kits or reagents used in the testing services."

But "to the extent the FDA might determine to apply the UDI rule to LDTs, ACLA urges FDA to allow labs a substantial period of time for achieving compliance," given the difficulties and expenses involved.

AdvaMed Weighs In

In its comments, the Advanced Medical Technology Association (AdvaMed) urged the FDA "to consider a number of changes to make the rule more practical and useful," given the diversity of the medical technology industry.

Among the significant changes:

- ❑ Manufacturers of Class III devices should be given two years after the final UDI rule is issued to comply with the rule's labeling requirements, instead of one year.
- ❑ FDA should develop a specific list of devices exempt from UDI direct marking requirements, such as absorbable sutures or stents, because such devices cannot be directly marked.
- ❑ FDA should clarify that devices manufactured before the final UDI rule's effective date but held in inventory are not subject to the rule.

The association stressed, however, that implementation of a UDI system "is a costly proposition, one that should be carefully considered such that it is implemented correctly the first time, and that its ongoing use is practical, economical, and of value to patients, health care providers, industry and the FDA."

"AdvaMed has long-supported establishment of a UDI system," said its president and CEO Stephen J. Ubl, "and believes that if appropriately implemented, it holds the promise of more accurate and consistent post-market surveillance. However, it is important to understand that any benefit from a UDI system depends on device users consistently and effectively utilizing the system for tracking recalls, adverse event reporting, and within electronic health records."

Timetable in Dispute

FDA is proposing a risk-based, phased-in approach to implementation, focusing on the highest-risk (class III) medical devices first and exempting low-risk devices from some or all of the requirements, a decision praised by industry and provider groups alike. AdvaMed and the Medical Device Manufacturers Association are asking for a two-year effective date for class III devices, instead of one year as proposed.

FDA is required to issue a final rule six months after the comment period closed Nov. 7. The proposed rule would phase in over seven years the requirement that many device labels and packages include a UDI based on international standards. Hospital and provider groups think implementation should come sooner while device makers want more time.

New Rules Proposed for Essential Health Benefits, Consumer Protections in the Health Insurance Market

Sweeping changes aimed at ensuring that consumers have access to quality, affordable health insurance coverage and are protected against discriminatory practices were announced in two proposed rules published Nov. 20 by the U.S. Department of Health and Human Services (HHS).

One rule requires that health plans offered in the individual and small-group markets, both inside and outside of affordable insurance exchanges, must provide a core package of items and services, known as essential health benefits (EHBs). The rule also sets standards for determining the EHBs' actuarial value and gives states flexibility to shape their EHB package. It further sets forth a timeline for when insurers offer coverage in a state or federally run exchange must obtain accreditation.

The second rule governing health insurance markets and premium rate reviews "would make it illegal for insurance companies to discriminate against the approximately 129 million, or 1 in 2, nonelderly Americans with pre-existing health conditions," HHS Secretary Kathleen Sebelius said, adding that the rule "will bring even greater scrutiny and transparency to proposed health insurance rate increases."

Both rules implement requirements of the health care reform law, the Patient Protection and Affordable Care Act of 2010 (PPACA).

Essential Health Benefits

(1) Ambulatory patient services
(2) Emergency services
(3) Hospitalization
(4) Maternity and newborn care
(5) Mental health and substance use disorder services, including behavioral health treatment
(6) Prescription drugs
(7) Rehabilitative and habilitative services and devices
(8) Laboratory services
(9) Preventive and wellness services and chronic disease management
(10) Pediatric services, including oral and vision care

Lab Services, Other Core Benefits

Not surprisingly, given that they form the foundation for an estimated 70 percent of medical decisionmaking, clinical laboratory services are included as one of 10 categories of services that must be offered in the EHB package (*see box*).

The core benefits requirement applies to all "nongrandfathered" individual and small-group plans, namely, those that took effect after PPACA was signed into law March 23, 2010. Its aim is to guarantee that individuals and small-business plans have benefits equivalent to what employers typically provide, said Sebelius.

To meet this requirement in every state, the proposed rule defines EHBs based on a state-specific benchmark plan, including the largest small-group health plan in the state. States may select a benchmark plan from among several options and all plans that cover EHBs must offer benefits that are substantially equal to the benefits in the benchmark plan.

The benchmark plan options include (1) the largest plan by enrollment in any of the three largest products in the state's small-group market, (2) any of the largest three state employee health benefit plans options by enrollment, (3) any of the largest three national Federal Employees Health Benefits Program plan options by enrollment, or (4) the largest insured commercial health maintenance organization in the state.

If a state does not make a choice, HHS will select as the default benchmark the largest small-group product in the state, as described in option (1). If a benchmark plan is missing any of the 10 statutory categories of benefits, the state or HHS would supplement the plan in that category.

To ensure that benchmark plans offer a full array of EHBs and services, the proposed rule:

- ❑ Prohibits benefit designs that could discriminate against potential or current enrollees.
- ❑ Includes special standards and options for benefits not typically covered by individual and small-group policies today, including habilitative services.
- ❑ Includes standards for prescription drug coverage so that individuals have access to needed medications.

The appendix of the proposed regulation includes a list of state-selected EHB benchmark plans, as well as the default plan for a state that does not select one. States can make an EHB benchmark selection until the close of the comment period for this rule on Dec. 26.

As required by the health care reform law, the proposed rules would make it illegal for insurance companies to discriminate against people with pre-existing conditions and make it easier for consumers to compare health plans and for employers to promote and encourage employee wellness, said HHS Secretary Kathleen Sebelius.

Actuarial Value

Actuarial value, or AV, is calculated as the percentage of total average costs for covered benefits that a plan will cover. For example, if a plan has an AV of 70 percent, on average, a consumer would be responsible for 30 percent of the costs of all covered benefits.

Beginning in 2014, nongrandfathered health plans in the individual and small-group markets must meet certain AVs or "metal levels": 60 percent for a bronze plan, 70 percent for a silver plan, 80 percent for a gold plan, and 90 percent for a platinum plan. In addition, health insurance issuers may offer catastrophic-only coverage with a lower AV for eligible individuals.

Metal levels will allow consumers to compare plans with similar levels of coverage, HHS said in a release. "This, along with consideration of premiums, provider participation, and other factors, will help them make an informed choice."

To standardize the AV calculation by health insurance issuers, HHS is providing a publicly available AV calculator based on a national, standard population, as required by law. Beginning in 2015, HHS will accept state-specific data for the standard population if states choose to submit alternate data for the calculator. Consumer-driven health plans, such as high-deductible plans and health savings accounts, are compatible with the AV calculator, HHS noted.

Recognizing that health insurers need some flexibility in meeting the metal levels, HHS proposes that a plan can meet a particular level if its AV is within two percentage points of the standard. For example, a silver plan may have an AV between 68

percent and 72 percent. In addition, insurers in the small-group market may exceed annual deductible limits to achieve a particular metal level.

Insurance Market Reforms

Starting in 2014, health insurers may no longer deny coverage to people with pre-existing health conditions, ranging from life-threatening illnesses like cancer to chronic conditions like diabetes, asthma, or heart disease. They also would be limited in the factors they are permitted to use to set premium rates and determine annual rate hikes.

The key market reform provisions would:

- ❑ Require insurers of nongrandfathered individual and small-group plans to sell policies to all consumers, regardless of their health status.
- ❑ Allow insurers in the individual and small-group markets to vary premiums only when based on age, tobacco use, family size, and geography. All other factors, such as pre-existing conditions, health status, claims history, duration of coverage, gender, occupation, and small employer size and industry, may no longer be used to increase premiums for those seeking insurance. Under the law, states can enact stronger consumer protections than these minimum standards. In addition, starting in 2017, states have the option of allowing large employers to purchase coverage through the affordable insurance exchanges. For states that choose to do so, the rating rules also would apply to all large-group health insurance coverage.
- ❑ Require health insurance issuers to maintain a single statewide risk pool for each of their individual and small-employer markets, unless a state chooses to merge them into one pool. Premiums and annual rate changes would be based on the health risk of the entire pool. This prevents insurers from using separate insurance pools within markets to circumvent the market reforms and charge people with greater health problems higher premiums by raising their premiums at higher rates than other, healthier risk pools.
- ❑ Reaffirm existing protections that individuals and employers have with respect to coverage renewal. For example, health insurers may not refuse to renew coverage because an individual or employee becomes sick or otherwise loses his coverage.
- ❑ Ensure that young adults and people for whom coverage would otherwise not be affordable can enroll in a catastrophic plan in the individual market. Such plans have lower premiums, protect against high out-of-pocket costs, and cover recommended preventive services without cost sharing.

Exchanges to Be Ready

While many states have indicated they do not intend to establish their own affordable insurance exchanges, Sebelius said the proposed rules should answer many of their questions about the operations and cost of an exchange.

The full text of the proposed rules on essential health benefits and insurance market reforms is available in the Nov. 26 Federal Register *and is open for comment until Dec. 26.*

But HHS will be ready with federally facilitated exchanges authorized under PPACA in states that do not create their own, Sebelius said. "No matter what, Americans in all 50 states will have access to an exchange and the benefits of the new law," beginning in October 2013, when open enrollment begins in the exchanges for policies that take effect beginning in 2014.

Routine HIV Testing Advised for 15- to 65-Year-Olds

The U.S. Preventive Services Task Force Nov. 19 invited public comments until Dec. 17 on a draft statement recommending that everyone ages 15 to 65 be screened for the human immunodeficiency virus (HIV). Younger adolescents and older adults who are at increased risk should also be screened.

The task force also urges clinicians to screen all pregnant women for HIV, including those who present in labor whose HIV status is unknown.

Both recommendations received the highest rating on the grading scale for preventive services—Grade A "strongly recommends."

"HIV is a critical public health problem," the task force said in a release. Nearly 1.2 million people in the United States are infected with HIV, but 20 percent to 25 percent of them do not know they are HIV-positive, the task force noted.

If the screening advice is finalized, all "nongrandfathered" individual and small-group health plans (those that took effect after the health care reform law was signed on March 23, 2010) would have to provide the routine testing without any cost sharing by policyholders.

The task force is an independent group of experts supported by the HHS Agency for Healthcare Research and Quality and charged with making evidence-based recommendations on clinical preventive services.

The task force currently recommends testing only for people who are at risk for HIV and pregnant women.

"The draft recommendation reflects new evidence of the benefits of both screening for and earlier treatment of HIV," task force member Douglas Owens said in the release. "Because HIV infection usually does not cause symptoms in the early stages, people need to be screened to learn if they are infected."

Beginning anti-retroviral therapy earlier reduces the risk of developing AIDS-related complications, and treatment has been shown to decrease the chance of transmitting HIV, the task force said.

Screening Intervals

The evidence is insufficient to determine optimal time intervals for HIV screening, the task force said.

"One reasonable approach would be one-time screening of adolescent and adult patients to identify persons who are already HIV-positive, with repeat screening of persons who are known to be at risk for HIV infection, those who are actively engaged in risky behaviors, or those living in a high-prevalence setting.

"As such, a reasonable approach may be to rescreen groups at very high risk for new HIV infection at least annually, and individuals at increased risk at somewhat longer intervals (such as every 3 to 5 years).

"Routine rescreening may not be necessary for individuals who have not been at increased risk since they were found to be HIV-negative. Women screened during a previous pregnancy should be rescreened in subsequent pregnancies."

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savings offsets elsewhere in the budget under pay-as-you-go rules. Clinical lab groups are lobbying against any cuts to their Medicare fees to help pay for a 2013 fix, especially since their fees were cut 2 percent over 10 years to finance the 2012 SGR fix.

One likely fix—a freeze on the physician fee update for 2013—would cost $10.6 billion, according to the latest estimates from the Congressional Budget Office (CBO). Over a decade a 0 percent update would cost $25.2 billion. Freezing fees every year over a 10-year period would cost $243.7 billion, CBO said.

Another Cut Looming

Also on the horizon are sequestration cuts mandated by the Budget Control Act of 2011 (Pub. L. No. 112-25). For Medicare the cap on spending cuts, including to providers, is 2 percent beginning in 2013 for an estimated $126 billion in savings over 10 years.

Sequestration reductions do not apply to Medicare beneficiaries or to Social Security, Medicaid, and other low-income programs.

Upcoming G2 Events

Labcast *(1 p.m. – 2 p.m. Eastern)*

Dec. 12, 2012
Navigating the Impact of FDA Regulations on LDTs
Sponsor: ARUP Laboratories
Registration fee: Waived
www.G2Intelligence.com/LDTLabcast

Conferences

Jan. 24, 2013
Molecular Coding and Billing Workshop:
How to Get the Right Payment in 2013
The Westin Atlanta Airport
Atlanta
www.G2Intelligence.com/codingworkshop

Feb. 25-27, 2013
Volume to Value
Redefining Lab Services in a Changing Market
The Westin Beach Resort & Spa
Fort Lauderdale, Fla.
www.G2Labvalue.com

Feb. 28-March 1, 2013
Pathology Institute
Grow Your Practice in Turbulent Times:
Pathology Business Models and Strategies That Work
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