G2 INTELLIGENCE

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INSIDE *NIR*



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## Labs Breathe Sigh of Relief Over Exemption From EHR Safe Harbor Extension

Clinical and anatomic pathology laboratories are breathing a sigh of relief now that they no longer will be forced into providing referring physicians with electronic health record (EHR) software and services.

In an end-of-year announcement, the Centers for Medicare and Medicaid Services (CMS) and the Health and Human Services Office of Inspector General (OIG) said that while they were extending the EHR safe harbor scheduled to expire on Dec. 31, 2013, laboratories would be exempted.

The rule was announced Dec. 23 and published in the Dec. 27 *Federal Register*. It became effective Jan. 1.

The final rule revises the exception to the physician self-referral law that permits certain arrangements involving the donation of EHR items and services. Specifically, the rule extends the expiration date of the exception to Dec. 31, 2021, excludes laboratory companies from

*Continued on p. 2*

## Physicians Get Short-Term Reprieve From Medicare Cuts

As it has for a number of years in the past, Congress in an 11th-hour deal averted a substantial Medicare pay cut for physicians by passing a short-term "doc fix."

Lawmakers just before Christmas approved the Bipartisan Budget Act of 2013, which includes the Pathway for SGR Reform Act of 2013. President Obama signed the measure into law on Dec. 26.

The law blocks the 20.1 percent reduction in the Physician Fee Schedule update for 2014 and replaces it with a 0.5 percent increase for services provided through March 31, 2014. The reduction initially was to be 23.7 percent, but the Centers for Medicare and Medicaid Services later revised the figure downward.

This temporary payment boost is intended to provide Congress with additional time to finalize pending legislation that would permanently repeal the flawed sustainable growth rate (SGR) formula used to set Medicare payment for physicians. For details on efforts to enact long-term SGR reform, please see the Focus article beginning on page 4.

**Labs Breathe Sigh of Relief Over Exemption,** *from p. 1*
the types of entities that may donate EHR items and services, updates the provision under which EHR software is deemed interoperable, removes the electronic prescribing capability requirements, and clarifies the requirement prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services.

The exception was initially put in place in 2006 to encourage development of EHR technology. However, lab and pathology groups have long opposed the exception, saying that physician groups often used the exception as a way to essentially blackmail labs into donating EHR software and services or risk losing referrals from the physicians.

While CMS and the OIG had initially proposed extending the sunset date to Dec. 31, 2016, the final rule extended it even longer to the end of 2021. This date coincides with the end of the Medicaid incentives program. Although some commenters wanted a permanent exception, the agencies said they believe the sunset date is necessary to ensure adoption of interoperable EHR technology in the near term and to guard against "inappropriate donations" that "lock in data and referrals between a donor and physician recipient, among other risks."

## Lab Groups Applaud Exception

The College of American Pathologists (CAP) says it is "pleased that referral decisions can no longer be premised on the highest EHR donation offers and that patients will have access to laboratories referring physicians have chosen based on the quality and service rather than an EHR donation."

"While prohibited under the rules, these donations in practice were indeed quid pro quo arrangements for referrals," said George Kwass, M.D., chair of CAP's Council on Government and Professional Affairs. "Recognition by OIG and CMS of these longstanding abuses and removal of 'laboratory companies' as protected donors are true victories for the laboratory community, pathologists, and the patients they serve."

The American Society for Clinical Pathology (ASCP) also applauded the final rules, noting that it has long advocated for the removal of laboratories from the list of entities protected under the EHR safe harbor, citing the practice as a direct violation of the Stark and anti-kickback laws.

"ASCP has continually communicated to CMS that, due to the unique referral-based nature of the pathology specialty, allowing laboratories to gift EHRs has generated a slippery slope effect resulting in the essentially forced exchange of EHRs for referrals. Thus, laboratories are inadvertently forced to fund EHRs in order to sustain their referral base and compete with other laboratories looking to broaden their referral base," said ASCP in a statement.

"ASCP has also pointed out that the inclusion of laboratories under the EHR safe harbor yields unfair irony, in that pathologists are unable to participate in the EHR incentive program but are allowed to fund EHRs for physicians that are able to participate."

***Takeaway: Clinical and anatomic pathology laboratories will no longer feel pressured into providing referral sources with EHR software and services or risk losing referrals.***

  

# Pennsylvania Prohibits Several Common Lab Practices

Pennsylvania has become the most recent state to crack down on common laboratory practices, such as placing phlebotomists in physician offices and leasing space or equipment from a physician's office.

Senate Bill 1042, enacted in December, amends Pennsylvania's Clinical Laboratory Act and applies to all laboratories doing business in the state, regardless of where they are headquartered.

The law makes clear that it is unlawful for a "person or clinical laboratory" to pay or receive a commission, bonus, kickback, or rebate or to engage in a split-fee arrangement in any form with a health care provider or health care practitioner, either directly or indirectly, for patients or their specimens referred to any clinical laboratory operating in Pennsylvania or testing a specimen collected or accepted in Pennsylvania.

What's more, the law specifically prohibits the following:

- ❑ Leasing or renting space, shelves, or equipment or other services within a health care provider's or practitioner's office for any reason, including operation of a collection station;
- ❑ Providing, directly or indirectly, through employees, contractors, independent staffing companies, lease agreements, or otherwise, personnel to perform functions or duties in the provider's office for any purpose *regardless of whether fair market value is offered*, including for the collection or handling of specimens, unless the clinical laboratory and the health care provider's office are wholly owned and operated by the same entity; and
- ❑ Placing in a health care provider's or practitioner's office paid or unpaid personnel to perform services, including but not limited to specimen collection, specimen processing, packaging or handling services, or genetic counseling, *regardless of whether fair market value is offered or given*.

SB 1042 specifically authorizes the Pennsylvania Department of Public Health (DOH) to investigate facts submitted in an application for laboratory licensure and to conduct inspections as necessary. It also allows for DOH to exempt out-of-state laboratories from inspection as long as the laboratory holds a certificate under the Clinical Laboratory Improvement Act of 1967 and is licensed by its home state, if applicable.

According to Samantha Kingsbury, Esq., and Karen Lovitch, Esq., attorneys with Mintz Levin (Washington, D.C.), there has long been confusion about laboratories regarding whether Pennsylvania requires laboratories doing business there to hold a Pennsylvania license. In May 2012, the DOH clarified its position on this issue in a letter posted on its Web site.

"The legislation is likely an effort to curb potentially abusive business practices, particularly in the more competitive clinical laboratory industry sectors," write Kingsbury and Lovitch in a blog at *www.healthlawpolicymatters.com*. "Other states, such as Florida and New York, also have specific prohibitions related to placement of laboratory personnel in physician offices and renting space from physicians. In addition, relevant agencies have interpreted California's kickback prohibition as also placing limits on such practices."

***Takeaway: Pennsylvania is cracking down on what it believes are abusive business practices by some clinical laboratories.*** G2

  

focus on: *Medicare Physician Pay*

# Lawmakers Still Working on Long-Term SGR Reform

While Congress in late December passed a short-term Medicare Physician Fee Schedule patch blocking a planned 20.1 percent reduction in the fee schedule update for 2014, lawmakers still face the task of agreeing on a long-term fix to the sustainable growth rate (SGR) formula used to establish physician payment.

Bipartisan SGR reform bills have been overwhelmingly approved by the Senate Finance Committee, the House Ways and Means Committee, and the House Energy and Commerce Committee, but differences in the measures must still be resolved, and spending offsets need to be identified.

The Senate Finance Committee Dec. 19 released the text of a bill (S. 1871) that would permanently replace the current Medicare physician reimbursement rate system. Although the Finance Committee approved the measure on Dec. 12, the 322-page bill the committee released Dec. 19 is the first version available to the public written in legislative language.

The Senate Finance bill would permanently repeal Medicare's sustainable growth rate formula, which each year requires mandatory cuts in physician payments that are routinely canceled by Congress with what is commonly referred to as a doc fix.

*The nomination of Senate Finance Committee Chairman Max Baucus (D-Mont.) to be U.S. ambassador to China, which the White House officially announced Dec. 20, has the potential to affect the progress of the committee's SGR bill depending on how quickly the nomination moves through the Senate, according to health care industry lobbyists.*

Replacing the SGR would be a new "value-based performance program" that attempts to align Medicare physician payments with medical outcomes, moving away over a period of years from the current fee-for-service system, which critics say rewards volume over quality.

As the new system is being phased in, the Finance Committee bill would freeze guaranteed physician pay increases, or "updates," for 10 years.

The Finance Committee measure is similar to a bill approved Dec. 12 by the House Ways and Means Committee. However, the Ways and Means bill (H.R. 2810) would provide physicians with a 0.5 percent increase during each of the first three years of the new program.

In October, the two committees released a conceptual summary of a plan developed by staff from both committees. However, the final bills approved by each committee differ in certain respects, including whether they freeze physician payments or allow small increases during the phase-in period.

Unlike the Ways and Means bill, the Senate Finance bill also would extend a series of government health programs set to expire after Dec. 31.

The two-year budget agreement recently approved by Congress includes a three-month extension of current Medicare physician pay rates through March 31 in order to allow lawmakers to agree on a final version of an SGR replacement plan.

  

Another important part of any final SGR replacement plan is how the transition to the new system would be paid for—with cuts in other programs or new revenues. The Congressional Budget Office estimated that the Senate plan would cost $148.6 billion over 10 years. So far, lawmakers have said their focus has been on coming to agreement on the policy rather than the "pay-fors."

### New Pay Incentives

In addition to eliminating guaranteed annual increases through 2023, in subsequent years the Senate Finance Committee measure would provide physicians and other medical professionals who participate in "alternative payment models" annual increases of 2 percent. All other professionals would receive annual updates of 1 percent.

Beginning in 2017, the new Value-Based Performance Incentive Program also would take effect, streamlining and consolidating three existing programs: the Physician Quality Reporting System, which provides incentives to professionals to report on quality-of-care measures; the Value-Based Modifier, which adjusts payments based on quality and resource use; and meaningful use of electronic health records.

### Anti-Fraud Provisions

The Senate SGR reform bill includes several anti-fraud provisions, including strengthened penalties for Medicare and Medicaid fraud, improved fraud data sharing between federal and state programs, and enhanced monitoring of Recovery Audit Contractor (RAC)-identified overpayments.

The bill includes provisions from the Preventing and Reducing Improper Medicare and Medicaid Expenditures (PRIME) Act (S. 1123; H.R. 2305), which was introduced in June by Sens. Tom Carper (D-Del.) and Tom Coburn (R-Okla.). A House companion bill to the PRIME Act was introduced at the same time by Reps. Peter Roskam (R-Ill.) and John Carney (D-Del.).

The House SGR bill doesn't include the PRIME Act provisions, but both the House and Senate SGR bills include provisions for the creation of a free, publicly accessible database containing Medicare claims data.

Anti-fraud provisions in the bill include:

- Requiring the Centers for Medicare and Medicaid Services to adopt a National Prescriber Identifier to be used as the sole identifier for the Medicare Part D program;
- Requiring the Department of Health and Human Services (HHS) to create a system to monitor changes made to fix overpayment vulnerabilities identified by RACs;
- Requiring HHS to submit an annual report to Congress on the types of overpayment vulnerabilities identified by RACs, along with a description of efforts taken to fix them;

### Three Percent Retention

An additional anti-fraud amendment, sponsored by Sen. Charles E. Grassley (R-Iowa), was included in the Senate SGR bill, allowing the HHS Office of Inspector General to retain 3 percent of all recoveries related to false claims or fraud involving Medicare or Medicaid.

The OIG would be able to use the 3 percent to boost oversight and enforcement efforts. This is similar to a provision enacted in 1994 that authorizes the Department of Justice to retain up to 3 percent of all recoveries that were based on civil debt collection litigation.

  

# BCBS of Tennessee Cuts Lab Reimbursement to 52% of Medicare

In what may be indicative of a new trend by payers, BlueCross BlueShield of Tennessee (BCBS-TN) has cut payment for laboratory services to 52 percent of Medicare rates, effective Jan. 1, 2014.

In a letter sent to providers on Nov. 6, 2013, BCBS-TN said its rates for physician labs are higher than national and local market levels. As a result, the payer says all codes classified as lab services will be reimbursed at 52 percent of Medicare.

In 2013, BlueCross BlueShield of Mississippi reduced reimbursement up to 25 percent for pathology and radiology procedures, ostensibly in response to Obamacare.

According to the Pathology Blawg (*www.pathologyblawg.com*), a BCBS-TN provider told a group of clinicians that this massive reimbursement cut is simply an extension of BCBS-TN's Medicaid contract with Quest Diagnostics and will give independent labs a chance to compete with Quest for BCBS-TN's business.

The Tennessee Medical Association (TMA), in a Dec. 17 letter to BCBS-TN, requested that BCBS-TN rescind the contract amendment, saying "this unilateral decrease in agreed-upon contracted rates in mid-contract is untenable for Tennessee physicians and the patients they serve."

According to the letter, there is no "congruence of message" from BCBS-TN as to whether the cuts apply to every provider receiving the amendment, just physicians who have in-office labs, both pathologists and nonpathologists, or just nonpathologists.

"Based on feedback from dozens of our members who have contacted the TMA to protest the cuts, the resulting lab reimbursement would be less than what the TennCare MCOs and other commercial payers are paying for laboratory fees," writes Christopher Young, M.D., TMA president. "What we are hearing is contrary to BCBS-TN's stated reason for the decrease, which is that these cuts will put BCBS-TN at market rate. Our members tell us that the cuts will result in payments below the cost of service or at razor thin margins that will lead medical practices to discontinue in-office lab services."

***Takeaway: Some major payers are following Medicare's lead and cutting reimbursement for laboratory services, a trend that could have serious implications for laboratories.***

# CMS Confirms Price Cut for BRCA Testing

The Centers for Medicare and Medicaid Services (CMS) in late December confirmed that its new price for CPT code 81211, full sequence analysis testing for the BRCA1 and BRCA2 genes, was not a mistake.

In a posting Dec. 27, CMS indicated that the national limitation amount of $1,438.14 contained in the final Clinical Laboratory Fee Schedule for 2014 was based on a median of prices submitted by local Medicare administrative contractors and will be effective for tests performed on or after Jan. 1, 2014. CMS will accept comments on pricing for CPT codes 81211 and 81214 (BRCA1 full sequence) through Jan. 27, 2014.

  

The announcement is a serious blow to Myriad Genetics (Salt Lake City), which until recently was the only company that performed BRCA testing. A decision by the Supreme Court in June 2013 opened the doors for other companies to begin offering BRCA testing, and since then a number of labs have launched their own BRCA tests at a lower price point than Myriad's test.

The new price represents a 48.5 percent cut from what Myriad had been paid in 2013 ($2,795). Prior to gap-fill pricing for molecular diagnostic testing, Myriad in some cases was paid more than $3,000 for the test. Myriad's list price for the test is $4,040.

Shares of Myriad Genetics plunged 17 percent to $20.02 on Dec. 30 after CMS issued its confirmation. The stock price over the past year has ranged from $20.02 to $38.27. As of Jan. 7, 2014, the stock was trading at $21.05.

Wall Street analysts say the new pricing is a significant negative for the company. J.P. Morgan's Tycho Peterson says the primary question is how quickly this will impact private payers.

*"In our view, this does not bode well for the lab space in general, particularly to the extent the gap-fill process is used to price any new sequencing-based diagnostics code and given that CMS has now declared its intention to adjust pricing on the Medicare Clinical Laboratory Fee Schedule based on technological changes."*

*—Amanda Murphy, William Blair & Co.*

"With increased competition coming to the market at significantly lower prices than MYGN [Myriad Genetics], we expect payers will begin to influence physicians to use competitive tests, while leaving open the option for patients to use MYGN's test if they want to pay the additional cost (+$1,500) out of pocket," he says. "In our prior physician survey, all 25 physicians surveyed were willing to convert away from MYGN for a competitive product and 76 percent viewed price as a 'very important' factor in the testing decision."

Amanda Murphy, an analyst with William Blair & Co., says CMS's decision is troubling because it suggests that pricing of new codes via the gap-fill process should be determined solely based on competing labs' pricing, including those tests that have been on the market for only months if not weeks intended to garner publicity and market share.

"In our view, this does not bode well for the lab space in general, particularly to the extent the gap-fill process is used to price any new sequencing-based diagnostics code and given that CMS has now declared its intention to adjust pricing on the Medicare Clinical Laboratory Fee Schedule based on technological changes."

Murphy also notes that while tests based on Sanger sequencing and next-generation sequencing may be relatively straightforward from a technical standpoint, "every discussion we have had with genetics laboratories suggests that classification of variants from the 'normal' into something clinically actionable is not and is far from commoditized."

While BRCA is one of the most well-characterized genes in literature, "we also believe that based on our analysis of the quality of publicly available variant databases and given the lack of 'hotspot' dangerous BRCA mutations, variant classification using actual clinical data based on meaningful sample size (millions) versus in silico statistical models and small sample sizes (thousands) is more robust."

***Takeaway: The deep cut to payment for BRCA testing is a blow for Myriad Genetics, but the company can offset some of the reductions through other test offerings and assays currently in its pipeline.*** G2

  

# Health Spending Rose 3.7% in 2012

Health care spending rose by just 3.7 percent in 2012, the fourth consecutive year of slow growth, as spending continued to reflect the impact of the recent economic recession, the Centers for Medicare and Medicaid Services (CMS) said Jan. 6.

In a report published in the January issue of the journal *Health Affairs*, CMS said health spending in 2012 reached $2.8 trillion, or $8,915 per person. The share of the gross domestic product devoted to health care fell from 17.3 percent in 2011 to 17.2 percent in 2012.

Health care spending growth has remained stable since 2009, rising between 3.6 percent and 3.8 percent annually. Health care spending has risen much faster in the past, increasing 9.7 percent in 2002, for example, according to the report.

The agency in September 2013 said health care spending is expected to continue growing at historically low rates in 2013 before rising faster in the coming years as the Affordable Care Act (ACA) is implemented, the economy improves, and more baby boomers enroll in Medicare. The ACA has had a minimal impact on health care spending growth from 2010 through 2012, the new report added.

Researchers have said the recession is a major reason health spending has slowed recently, a conclusion shared by CMS in the report.

"The relative stability since 2009 primarily reflects the lagged impacts of the recent severe economic recession," the report said. "In particular, income and employment growth was modest over this period, and there was a slow recovery from private health insurance enrollment losses that occurred during 2008-10."

Enrollment in private health insurance plans reached 188 million in 2012, an increase of 800,000 from the previous year, but enrollment was still 9.4 million lower in 2012 than in 2007, before the recession began, CMS said. "This declining enrollment was a major factor in the slow growth in overall private health insurance spending over the past several years," the report said.

For 2012, faster growth in hospital, physician, and clinical services was offset by slower growth in prices for prescription drugs and nursing home services, according to CMS.

Spending on hospital care rose 4.9 percent in 2012, up 1.5 percentage points from 2011, while spending for physician services grew by 4.6 percent in 2012 because more people visited their doctors as the economy improved, CMS said.Medicare spending rose 4.8 percent in 2012, compared with 5 percent a year earlier.

***Takeaway: Health care spending continues to grow at historically low rates due in part to the recession of 2008-2010. Growth is expected to rise in coming years.***



  

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