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INSIDE *NIR*

Burgess Opposes Short-Term Doc Pay Patch Without Progress Toward Permanent Fix

Rep. Michael C. Burgess (R-Texas), principal sponsor of a House bill (H.R. 2810) to fix the problematic Medicare physician pay system, said Nov. 19 he will oppose a short-term fix if Congress fails to enact legislation to change the system by the end of the year.

Noting the dwindling number of days left in the current congressional session, Burgess said he would support a short-term "doc fix" only if "things are moving in the right direction" in both the House and Senate by December.

If Congress fails to approve a new pay system or extend current rates with a "doc fix," Medicare physician reimbursement rates will drop by about 24 percent beginning Jan. 1.

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Lab Group, Hospitals Say CMS Needs More Discretion in CLIA Enforcement

The Centers for Medicare and Medicaid Services (CMS) needs to allow itself more discretion in implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), hospital and clinical laboratory stakeholder groups said in comment letters to the agency on a recent proposed rule regarding rural health clinics and labs.

The American Hospital Association (AHA) and the American Clinical Laboratory Association (ACLA) told the CMS that its proposal to penalize clinical laboratories that send proficiency testing (PT) samples to an outside laboratory for analysis didn't take full advantage of the discretion given to it under the Taking Essential Steps for Testing (TEST) Act of 2012.

In the proposed rule, published Sept. 23 (*78 Fed. Reg. 58,385*), CMS explained its interpretation of the CLIA penalties under the TEST Act. In the proposed rule, CMS said it would divide the sanctions for PT referral into three categories based on severity and extent of the referrals. The agency would revoke a lab's certification for the most egregious violations in the first category; the second and third would call for suspension or limitation (category 2) and general sanctions (category 3). The severity of the penalty would be determined by when the erroneous referral was discovered (*NIR, Sept. 26, 2013, p. 1*).

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Burgess Opposes Short-Term Doc Pay Patch, *from p. 1*

The House bill to replace the sustainable growth rate (SGR) formula for Medicare physician reimbursements received a unanimous vote in the Energy and Commerce Committee in July. In October, the Senate Finance Committee and House Ways and Means Committee issued a discussion draft of another plan to change the system.

Burgess, speaking at a program on SGR change at the Brookings Institution, said he had been told the Senate Finance Committee would mark up a legislative version of the discussion draft during the second week of December. A Senate Finance Committee aide declined to confirm whether a specific date had been set.

During a question-and-answer session, Burgess acknowledged that having Congress "careening toward the end of the year again" without a new Medicare payment plan in place "is an uncomfortable place to be." But he added that "if a short-term patch is necessary to get us to action on a solution to this problem, as long as we're moving in the right direction, I won't say 'no.'"

The House is scheduled to be in session 10 more days before the end of the year, while a final Senate schedule through December hasn't been announced.

Fee-for-Service Targeted

Both the Energy and Commerce measure and the Senate Finance-House Ways and Means proposal attempt to better 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.

One difference between the two proposals is that while a new payment system is being phased in, the Energy and Commerce measure would allow physicians a series of small yearly payment increases, and the Senate Finance-House Ways and Means proposal wouldn't.

As lawmakers look for ways to pay for an SGR fix, lab groups are lobbying hard to keep clinical laboratories from bearing any more of the brunt of increased physician payment.

Instead, under the Senate Finance-House Ways and Means proposal, physicians would be eligible for incentive payments if they shifted a portion of their practices into alternative care models, such as bundled payments and accountable care organizations.

Concern About Cost of Plans

Burgess acknowledged that the cost of both plans to change the SGR was a major consideration as they were being developed. In September, the Congressional Budget Office (CBO) estimated the Energy and Commerce SGR bill would cost $175 billion over 10 years, through 2023.

The CBO hasn't estimated the cost of the Senate Finance-House Ways and Means proposal because it isn't yet in legislative form. However, the plan is expected to cost less than the Energy and Commerce measure because it would freeze physician rates for 10 years, rather than allow increases of 0.5 percent over five years, as the Energy and Commerce measure would provide.

Burgess said the Energy and Commerce bill focused on the policy rather than on how the payment changes would be paid for. "When we are ready to actually move this, sure, I've got pay-fors in the back of my mind," he said. "But you don't throw your friends under the bus until the end of the parade," he added, noting that was

a lesson he learned from former House Ways and Means Chairman Bill Thomas (R-Calif.).

Challenges Cited

Following Burgess's remarks, a panel of five congressional aides who worked on the SGR proposals acknowledged the difficulty in coming up with cuts or new revenue to help pay for the new payment plans.

"The challenge is the offsets," said Amy Hall, with the Democratic staff on the Energy and Commerce Committee. "There may be a lot of unhappy customers on the outside."

Added James Paluskiewicz, Burgess's deputy chief of staff and senior health care adviser, "There's always pain associated with offsets, absolutely, but the pain now comes at the end of every year [with annual doc fixes] and if it's going to be happening anyway, why not do the reform today instead of delivering pain year after year?"

Labs a Potential Target

As lawmakers look for ways to pay for an SGR fix, lab groups are lobbying hard to keep clinical laboratories from bearing any more of the brunt of increased physician payment. They note that since 2010, laboratory payments have been reduced by more than 11 percent. Reductions implemented in recent years include a 1.75 percent reduction every year for five years (2010-2015), a permanent annual productivity adjustment, a 2 percent cut to pay for the 2012 SGR "fix," and a 2 percent reduction in fiscal 2013 as a result of sequestration.

In an action alert sent to members, the American Association for Clinical Chemistry notes that as members of Congress discuss ways to cut federal spending to fix problems with the sustainable growth rate and reform entitlement programs, "everything, including laboratory services, is on the table."

President Obama has proposed extending the 1.75 percent cut, due to expire in 2015, for another eight years. Speaking at G2 Intelligence's Lab Institute last month, Alan Mertz, president of the American Clinical Laboratory Association, said that while lab copay and competitive bidding could be brought up again, he is most worried about continued cuts to the clinical laboratory fee schedule. Extending the 1.75 percent cut to 2023 would reduce Medicare test reimbursement by an additional $9.46 billion over 10 years.

Takeaway: As lawmakers look for a way to "fix" the sustainable growth rate used to set Medicare payment for physicians, labs remain a potential target for cost savings.

Labs Groups Oppose MolDx Expansion

Groups representing more than 150,000 medical laboratory professionals are pushing back against plans by the Centers for Medicare and Medicaid Services (CMS) to extend the Molecular Diagnostic Service (MolDx) program to Medicare contractors across the nation.

Officials with Palmetto GBA, the Medicare contractor that developed and currently administers the program, have said they intend to work with other Medicare administrative contractors to deploy key elements of the MolDx program (test registration, new test evaluation, and inclusion of the test ID on the claim).

Under the MolDx program, labs that perform molecular diagnostic testing and bill in Jurisdiction E (formerly J1) or Jurisdiction M (formerly J11) must register their tests, obtain a unique identifier, and provide additional information on the test that Palmetto uses to determine coverage. According to an analysis conducted by G2 Intelligence in September, Palmetto had issued coverage decisions for 18 tests and noncoverage decisions for 49 tests.

In an Oct. 30 letter to CMS Administrator Marilyn Tavenner, the groups say that fundamentally, they believe the MolDx program and its extension to other Medicare contractors creates serious concerns about Medicare beneficiaries' access to medically necessary testing used to diagnose disease, identify potential therapies, and monitor the progress of therapy for life-threatening diseases such as breast, colon, and lung cancer. The groups include the College of American Pathologists, the Association for Molecular Pathology, the American College of Medical Genetics and Genomics, the American Society for Clinical Pathology, the American Society for Clinical Laboratory Science, and the American Society for Histocompatibility and Immunogenetics.

"Actions taken by some Medicare contractors follow neither the letter nor the spirit of the law, which require that coverage decisions be transparent and based on medical evidence," they write. "Further, we are concerned that Medicare assumes that tests performed primarily in pediatric population would never have other uses in adults that would be covered by Medicare. This assumption is resulting in inappropriately denying access to medically indicated testing for younger Medicare beneficiaries who are eligible based on disability status. Yet another consequence is that by not pricing tests that are primarily performed in the pediatric population, some state Medicaid programs are not paying for the appropriate molecular pathology procedures."

Takeaway: Plans to expand Palmetto's MolDx program to other Medicare contractors are raising concern among laboratories, who argue the program restricts beneficiary access to important tests. G2

AACC Call for Uniformity in Lab Test Results

The American Association for Clinical Chemistry (AACC) is calling for harmonization of clinical laboratory test results to help patients receive appropriate diagnosis and treatment.

In a statement released Nov. 22, AACC noted that the few laboratory tests that have been harmonized to date, such as those for cholesterol, glucose, and hemoglobin A1c, have made a marked positive impact on diagnosis and treatment of heart disease and diabetes.

"In addition to improved patient care, harmonizing these tests may also lead to reduction in health care spending," said the association. "As a striking example, the initiative to harmonize cholesterol tests only cost $1.7 million per year, while the health benefits it has yielded now save more than $338 million annually."

To ensure that progress in harmonizing all types of test results continues, AACC has spearheaded the International Consortium for Harmonization of Clinical Laboratory Results, an oversight body that will organize the worldwide effort to harmonize the most important diagnostic tests.

Takeaway: Harmonization of diagnostic test results improves patient care and can help reduce health care costs. G2

CLIA Enforcement, *from p. 1*

In comments submitted ahead of the Nov. 18 deadline, AHA said it was "concerned that several of the proposed sanctions are unduly severe. While the categories that CMS establishes are reasonable, we are concerned that some of the corresponding sanctions remain too severe."

ACLA said that CMS "has not taken full advantage of the flexibility" that Congress granted the health and human services secretary in the TEST Act. Under the law, the agency was granted the discretion to consider the circumstances under which a PT sample was sent to another laboratory and to impose lesser sanctions for referrals that may have been unintended or inadvertent.

According to ACLA, CMS "should retain maximum flexibility and apply a 'facts and circumstances' analysis when a laboratory sends out a PT sample, which would allow it to respond more appropriately to innocent PT referrals and to concentrate its corrective efforts on referrals whose purpose is to circumvent the PT program."

TEST Act

The TEST Act was passed in December 2012. Until then, the CLIA statute required the revocation of a laboratory's CLIA certificate and a subsequent two-year ban of the owner or operator of the laboratory from owning or operating any CLIA-certified laboratory when a PT referral had been confirmed.

"These automatic and severe sanctions effectively shut down laboratories for even minor or inadvertent PT referrals."
—American Hospital Association

According to AHA, "these automatic and severe sanctions effectively shut down laboratories for even minor or inadvertent PT referrals."

The hospital group said the two-year ban for the owner and operator "has been especially problematic for hospitals and health systems because they may have multiple laboratories that share a common owner or operator. Additionally, hospitals and health systems often have many laboratories operating under a single CLIA certificate. In these circumstances, if a PT referral violation occurred in a single laboratory within the hospital or health system and the CLIA certificate was revoked, all laboratories under that hospital or health system's certificate would be banned from performing laboratory testing, a situation that poses severe risk to patient safety and quality of care."

According to ACLA, the purpose of the TEST Act is to give CMS greater discretion in dealing with inadvertent referrals so that the agency doesn't always have to impose the most severe sanction of license revocation, regardless of the circumstances surrounding the particular referral.

The legislation permitted CMS to impose alternative sanctions prior to revoking a laboratory's CLIA certificate in cases where a PT sample was referred to another laboratory for confirmatory testing or because the laboratory didn't offer a specific test.

Penalties Too Severe?

According to ACLA, "the three categories of referrals are overly specific, leaving little room for consideration of whether or not a PT specimen was sent out accidentally and whether a laboratory should be subject to sanctions."

The group said CMS needs to define "intentionally referred" as "knowingly and willfully sent a PT sample to another laboratory for the purpose of using that laboratory's test results as its own or as a comparison for its own results."

JoAnne Glisson, senior vice president for ACLA, said the proposed CMS guidelines "are just as rigid as before" the TEST Act. "CMS failed to take advantage of the flex-

ibility in the law," Glisson said, adding that ACLA doesn't necessarily object to the creation of three categories for penalties, but rather to the fact that they are too specific.

Glisson said many PT referrals won't fall neatly into one of the three categories, which means they are too restrictive.

In its comment letter, ACLA said CMS "should be able to consider factors such as the adequacy of a laboratory's operating procedures, the degree of automation in the laboratory, the training and experience of the individual who made the referral, the laboratory's history of referrals, and other relevant factors as appropriate."

AHA recommended that CMS "allow itself some discretion, particularly in instances in which imposing an ownership ban across an entire health system would endanger the public's health. This could be accomplished by indicating that in category 1 violations, CMS 'may' prohibit the owner and operator from owning or operating a CLIA-certified laboratory for at least one year."

Takeaway: Hospitals and clinical laboratory groups say penalties are still too severe for labs that make certain proficiency testing referrals.

More Doctors Implicated in Biodiagnostic Lab Case

Two doctors with a practice in New York have admitted to federal charges of accepting bribes in exchange for test referrals as part of a long-running scheme operated by Biodiagnostic Laboratory Services LLC (BLS), a clinical laboratory in Parsippany, N.J.

Richard Goldberg and Gary Leeds each pleaded guilty Nov. 21 in U.S. District Court for the District of New Jersey in Newark to one count of accepting bribes, which brings to 20 the number of people who have entered guilty pleas in connection with the BLS cash-for-patients scheme.

Goldberg and Leeds admitted to accepting thousands of dollars per month in cash between September 2010 and April 2013 in return for referring patient blood specimens to BLS, the U.S. Attorney's Office said in an announcement.

The two doctors acknowledged they each accepted more than $100,000 in cash from BLS in exchange for referring a combined $1.8 million in lab business from their joint practice, Family Medical Group of Manhattan.

As part of their guilty pleas, Goldberg and Leeds each agreed to forfeit $108,000. Sentencing is scheduled for April 1, 2014.

Organizers Admit Guilt

Organizers of the scheme, including David Nicoll, BLS president and part owner; his brother Scott Nicoll, a senior BLS employee; and their cousin Craig Nordman, a BLS employee and chief executive officer of Advantech Sales LLC, have admitted it involved millions of dollars in bribes and resulted in more than $100 million in payments to BLS from Medicare and various private insurance companies.

They and four BLS sales representatives each pleaded guilty in June to one count of conspiracy to commit bribery and one count of money laundering for their participation in the scheme.

The investigation has recovered more than $6.5 million to date through forfeiture, the U.S. Attorney's Office said.

Takeaway: The kickback case involving Biodiagnostic Laboratory Services continues to expand as additional physicians admit to accepting bribes in exchange for test referrals.

Dialysis Payments Under Medicare to Remain Stable

Dialysis facilities will get the same amount of Medicare reimbursement in calendar year 2014 as they did in CY 2013 under the final end-stage renal disease prospective payment system (ESRD PPS) released Nov. 22 by the Centers for Medicare and Medicaid Services (CMS).

According to CMS, the final rule also implements a provision in the American Taxpayer Relief Act of 2012 that reduces payments to account for changes in the utilization of ESRD-related drugs and biologicals. However, the final rule provides for a multiyear phase-in of this adjustment to mitigate its impact on providers, the agency said.

The final rule (CMS-1526-F) will be published in the *Federal Register* Dec. 2 and will take effect Jan. 1. Ordinarily, CMS said it provides a 60-day delay in the effective date of final rules after the date they are issued. However, the final rule was delayed as a result of the government shutdown, and the agency said "it would be contrary to the public interest to delay the effective date" of the ESRD PPS and ESRD Quality Incentive Program portions of the final rule.

The final rule is a change from the proposed rule, in which ESRD facilities were scheduled to see their Medicare payments cut by $970 million in CY 2014.

The rule also addresses issues related to the coverage of and payment for durable medical equipment, prosthetics, orthotics, and supplies. Additionally, the rule will make changes to the ESRD Quality Incentive Program for payment year 2016.

The final rule is a change from the proposed rule, in which ESRD facilities were scheduled to see their Medicare payments cut by $970 million in CY 2014.

The CMS in the final rule estimated that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2014 will be approximately $8.8 billion. The estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 3.1 percent in CY 2014, the agency said.

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 0 percent overall increase in the final ESRD PPS payment amounts in CY 2014, the agency estimated that there will be no increase in beneficiary coinsurance.

The rule also finalized a 50 percent increase to the home dialysis training add-on payment adjustment that is made for both peritoneal dialysis and home hemodialysis training treatments.

Bundled Payments

According to the agency, the bundled payment under the ESRD PPS includes all renal dialysis services furnished for outpatient maintenance dialysis, including ESRD-related drugs and biologicals (with the exception of certain oral-only ESRD drugs until 2016) and other ESRD-related items and services that were formerly separately payable under the previous payment methodologies, the CMS said.

Under the CY 2014 final rule, the CMS finalized a marketbasket update—minus a multifactor productivity (MFP) factor—of 2.8 percent. That update reflects the CY 2014 marketbasket increase of 3.2 percent, minus the current forecast of the MFP adjustment of 0.4 percent.

Takeaway: Dialysis facilities will not see their Medicare payments cut in 2014. G2

23andMe Ordered to Stop Marketing Genome Service

In a setback for genetic testing company 23andMe, the Food and Drug Administration (FDA) has ordered the company to stop marketing its personal genome service (PGS) to consumers because it failed to respond adequately to FDA's questions about the product.

In a Nov. 22 warning letter sent to CEO Anne Wojcicki, FDA said the company must immediately discontinue marketing the PGS until it receives FDA marketing authorization for the service, which the FDA considers a class III device.

23andMe, based in Mountain View, Calif., in 2012 submitted 510(k) premarket submissions to FDA seeking approval to sell the service. But in the Nov. 22 letter, FDA says to date, the company has failed to address the issues described during previous interactions with the agency to provide additional information requested.

The 23andMe Web site says its personal genome service provides health reports on 254 diseases and conditions, including categories for health risks, carrier status, and drug response.

According to Alberto Gutierrez, director of the Office of In Vitro Diagnostics and Radiological Health, the FDA has been diligently working to help 23andMe comply with regulatory requirements regarding safety and effectiveness and obtain marketing authorization for the PGS.

Gutierrez says that in 14 face-to-face and teleconference meetings, hundreds of e-mail exchanges, and dozens of written communications, FDA has provided the company with specific feedback on study protocols and clinical and analytical validation requirements, discussed potential classifications and regulatory pathways, provided statistical advice, and discussed potential risk mitigation strategies.

"However, even after these many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically validated the PGS for its intended uses, which have expanded from the uses that the firm identified in its submissions," writes Gutierrez.

In a statement posted on the 23andMe blog, the company acknowledges that it has "not met the FDA's expectations regarding timeline and communication regarding our submission. Our relationship with the FDA is extremely important to us, and we are committed to fully engaging with them to address their concerns."

Takeaway: Genetic testing company 23andMe must halt marketing its personal genome service after failing to receive necessary FDA approval.

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