G2 INTELLIGENCE

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Congressional Clock Running Out on Lab, Pathology Priorities

Should the deficit-reduction super committee fail to act on lab, pathology priorities, these could be handled in stand-alone legislation or in some cases in a Medicare extenders bill. But in the deficit-cutting climate on Capitol Hill, achieving all these priorities may prove problematic, say industry sources.

With only a few weeks left on the legislative calendar before Congress adjourns for the year, clinical laboratory and pathology groups are lobbying hard for lawmakers to act on their major priorities.

For pathology, the immediate threat is the 27.5 percent cut in Medicare physician fees, scheduled for Jan. 1, under the sustainable growth rate (SGR) formula. Pathology groups are urging Congress to cancel the cut and repeal the SGR, but the estimated cost is $300 billion over 10 years.

Proponents of repeal have petitioned the Joint Select Committee on Deficit Reduction to include an SGR overhaul in its recommendations to cut up to $1.5 trillion in federal spending. The committee is to vote on a deficit-reduction plan by Nov. 23. If approved, the plan goes to the House and the Senate for an up-or-down vote, with no amendments or filibuster, by Dec. 23. The president retains veto power, however.

The American Medical Association wants the committee to replace the SGR with stable fee increases over the next five years in the transition to a system based on payment and delivery alternatives to traditional fee-for-service.

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Lab Discounts Under Scrutiny by Senate Finance Committee Leaders

The chairman and the ranking minority member of the Senate Finance Committee have asked Quest Diagnostics, LabCorp, and three major health insurance companies for information about their discount and billing practices for clinical laboratory services.

In a Nov. 8 letter, chairman Max Baucus (D-Mont.) and ranking Republican Charles Grassley (Iowa) said they are investigating a practice, known as "pull-through." It involves the alleged offering by a clinical lab testing company that contracts with an insurer for discounted or below-cost pricing, in exchange for the insurer directing its in-network physicians to refer, or arrange for the referral of, other lab testing business, including testing for Medicare beneficiaries, to that clinical lab company.

"Congress passed the anti-kickback law to protect patients and federal health programs from potential influence of financial arrangements on health care decisions," the senators noted. "The Inspector General for the Department of Health and Human Services (OIG) has issued advisory opinions about the pull-through practice, noting that discount arrangements such as those at issue here are 'particularly suspect'."

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Lab Discounts Under Scrutiny, *from p. 1*

Wide Range of Documents Requested

Grassley and Baucus asked Cigna, LabCorp, Aetna, UnitedHealth Group, and Quest Diagnostics to submit by Dec. 1 copies of lab services agreements, correspondence related to negotiation of the contracts, presentations to the board about contracts, presentations to clinical laboratory testing providers, and other documents related to pull-through practices, including those provided in response to subpoenas from attorneys general.

On the list of requested documents from Quest and LabCorp are pricing schedules for the 10 most commonly ordered lab tests, presenting the price per test charged to each of their five largest managed care clients and the price paid by Medicare.

The request from the Senate Finance leaders is significant because, until now, most challenges to lab pricing practices have come at the state, not the federal, level. It comes in the wake of recent settlements with the state of California by Quest and LabCorp over allegations that they engaged in illegal price discounting by not offering the state's Medicaid program, known as Medi-Cal, the lowest price offered to other payers.

Both Quest, which settled for $241 million, and LabCorp, which settled for $49.5 million, denied any wrongdoing. The settlements have spawned investigations in Florida, Georgia, Minnesota, Massachusetts, Nevada, and Virginia.

In the aftermath of the Medi-Cal settlements, Pat Hooper, partner at the national health care law firm Hooper, Lundy & Bookman, said at last month's G2 Lab Institute, "The real impact will be if this [gets] lifted to the Medicare level." Right now, it's a settlement not binding on others and it does not establish precedent, he said, though "it may give guidance on how the government views pricing."

Inconsistency on Lab Discounts

Hooper reviewed over 30 years of case law and policy positions that showed the government has been inconsistent with its interpretation of terms such as "substantially in excess" and "usual charge" for lab test pricing to the Medicare and Medicaid programs.

The OIG jumped into this minefield in 2003 when it proposed a rule Sept. 18 to define overcharges to these programs, but after the proposal languished for four years, the OIG threw in the towel, abandoning its effort to establish a "bright-line" standard to determine when the statutory ban on discriminatory pricing is violated and when sanctions, including exclusion from Medicare and Medicare, would be imposed. Under that rule, the OIG would have had discretion to exclude any provider that charged the programs "substantially in excess" (or more than 120 percent) of its usual charge for the same service or item (though physician services, including anatomic pathology, would have been exempt).

In withdrawing the rule in June 2007, the OIG concluded it did not have sufficient information to set a single, fixed benchmark that could apply across health care sectors. Still, the agency said it would address overcharging on a case-by-case basis. The OIG has kept its eye on comparative lab test pricing in its annual work plan over the last few years. The plan for fiscal year 2011 is no exception. It includes a review of Medicare lab test payment rates versus those of other government and private payers (*NIR 11, 19/Oct. 20, p. 9*).

CMS Formally Scraps Controversial Physician Signature Requirement

It's official—the Centers for Medicare and Medicaid Services (CMS) has formally rescinded its policy requiring the signature of a physician or a nonphysician practitioner (NPP) on paper requisitions for clinical laboratory services payable under the Medicare lab fee schedule.

The policy retraction was published in the final 2012 Medicare physician fee schedule rule, released Nov. 1 and scheduled to appear in the Nov. 28 *Federal Register*.

At the same time, the agency has reinstated its prior policy that the signature of the physician or NPP is not required on a paper requisition for a clinical diagnostic laboratory test paid under the Medicare lab fee schedule.

Under that policy, formalized in 2001 by a congressionally mandated negotiated rulemaking, while a signature is one way to document who ordered a test, it is not the only permissible way as long as the order is documented in an alternate format, such as the beneficiary's medical record.

There was unanimous support among all comments received, the agency said, on its June 30 proposed rule to expunge the maligned policy from the books and reinstate prior policy based on the congressionally mandated negotiated rulemaking for lab services.

While CMS had finalized the controversial signature requirement for lab test requisitions in the 2011 physician fee schedule, the agency never implemented it after running into a firestorm of criticism from clinical lab, pathology, a host of other medical groups, and members of Congress. In response, the agency issued a proposed rule on June 30 to expunge the maligned policy from the books.

CMS said it based its decision on "continued and new concerns noted by stakeholders regarding the practical effect of the finalized policy on beneficiaries, physicians, and NPPs." The requirement would have had "detrimental implications for expeditious patient care that were not evident to us."

Despite its change of mind, CMS noted in the 2012 final physician fee rule that it remains concerned about the potential for fraud and abuse, emphasizing that "the requirement that the treating physician or NPP must document the ordering of the test remains, as does our longstanding policy that requires orders, including those for clinical diagnostic laboratory tests, to be signed by the ordering physician or NPP."

Addressing clinical laboratories, CMS said, "We believe it is the [lab's] responsibility, as it is for the provider of any service, to have sufficient processes and safeguards in place to ensure that all services are delivered only when ordered by a physician or NPP."

This does not preclude an individual lab from requiring a physician's or NPP's signature on paper requisitions, CMS noted. The laboratory may develop its own compliance procedures to ensure that it only furnishes services in response to a physician or NPP order.

Such procedures could include internal audits; agreements with ordering physicians or NPPs to provide medical record evidence of the order in the event of an internal or external audit; confirming the existence of an order under certain circumstances (for example, testing in emergencies and follow-up on documentation); or any other measures including the acceptance of risk by the clinical lab.

focus on: Molecular Diagnostics

Quick Guide to Palmetto GBA's Coverage, Payment Program

Could a new program by Medicare contractor Palmetto GBA for coverage and reimbursement of molecular diagnostic tests provide a template for other Medicare contractors and private payers throughout the country?

That's a question on the minds of clinical laboratory providers as Palmetto prepares to launch, at the direction of the Centers for Medicare and Medicaid Services, the MolDx program in March 2012.

The program is the first to tackle the thorny issue of how to deal with payment for molecular diagnostic tests in the absence of specific federal policies. Currently, molecular diagnostic tests are paid through "code stacking." This involves using a series of current procedural terminology (CPT) codes to describe a test that does not have a designated code. Payers contend this makes it difficult to know precisely what is being tested and what they are paying for.

Palmetto signaled its intent to address the issue in October when it issued two local coverage decisions, to take effect in February 2012, that restrict payment on genomic tests not previously reviewed and specifically approved by Palmetto policy staff.

How will the MolDX program operate?

Laboratory service providers will register their molecular diagnostic tests with Palmetto and submit test information and supporting evidence for a coverage and reimbursement determination. Subject matter experts in academia and industry will provide technical assessments. They will sign confidentiality agreements and can only assess the data that Palmetto gives them.

Each test will be assigned a unique McKesson Z-Code™ that is maintained in an automated registry that can accommodate changes on the fly, McKesson says. Palmetto will use the system to identify the billed test, determine if evidence supports it as reasonable and necessary, and apply appropriate reimbursement. Palmetto will set a specific value for each test using enhanced gap-filled, value-based, and market-based methodologies. Once a Z-Code is assigned using McKesson's proprietary software, the provider will not have to submit documentation with every claim for the test.

The onus is on the lab to make the best case using any and all evidence to support clinical utility. Labs and manufacturers that get a determination of noncoverage may ask for a new technical assessment six months after the noncoverage notice was issued.

Which laboratories will be affected?

All hospital, private, and reference laboratories that perform molecular diagnostic testing and bill Medicare in A/B MAC Jurisdiction 1 (J1). This includes California, Nevada, Hawaii, and the Pacific Territories of Guam, American Samoa, and the Northern Marianas. Labs that bill J1 services performed by a lab not in J1 will have to register their molecular tests.

What are the key timelines?

Effective Nov. 14, lab providers can request Z-Codes via a downloaded template. In

January 2012, they can go online to access their existing Z-Code assignments and register new tests in an interactive data repository (McKesson Diagnostic Exchange™).

Starting March 1, 2012, claims without a Z-Code will be rejected. Claims will not be considered for adjudication unless the test has been submitted to the registry for review and a Z-Code has been assigned. Providers will use existing CPT codes in the formal claim lines and the Z-Codes in the "comment" box of the claim form.

Which types of molecular assays are subject to the MolDx program?
Gene tests, infectious disease probes, tumor markers, pharmacogenomic assays, predictive and risk assessment assays, and other molecular tests, with or without an existing CPT or Healthcare Common Procedure Coding System (HCPCS) code that does not specify one test per unique CPT or HCPCS code. Multivariant molecular testing (predictive and prognostic) is a subset of molecular diagnostic testing.

Which diagnostic tests will be affected?
Tests that are coded as follows:

- ❏ Require or use more than one CPT code to identify the service.
- ❏ Use the methodology-based stacking CPT codes (83890-83914), microarray CPT codes (88384-88386), and cytogenetic CPT codes (88230-88291).
- ❏ All pathology and laboratory codes listed as Not Otherwise Classified (NOC).

How does MolDX align with the effort by the American Medical Association (AMA) to publish roughly 101 new codes for molecular diagnostics in 2012?
MolDx and the AMA effort are not related or interdependent. As coding expert Diana Voorhees, president of DV & Associates (Salt Lake City), noted during the Nov. 10 G2 webinar on coding and payment changes for 2012, Palmetto will not recognize the AMA-developed molecular codes but instead will require that providers obtain a unique Z-Code from McKesson Inc. for each test.

What are initial major concerns about the MolDx program?
These surfaced at the meeting this month of the California Clinical Laboratory Association and were summarized in a Nov. 3 blog by Lâle White, president of Xifin, a San Diego company that offers revenue cycle management software and solutions.

The new policy makes labs "very nervous," she wrote, and "it generated almost an hour of Q&A about the role of a private vendor known to primarily contract with payers and the implication of a registry that is designed to review new tests for coverage by an already appointed anonymous panel."

"This, coupled with the two local coverage policies that target elimination of stacking codes, array codes, cytogenetic codes, serology and anatomic pathology codes, leaves the potential for the contractor to also re-price common assays as well as new tests and leaves labs with the possibility of significant reimbursement disruption. Palmetto tried to address fears that this was not the intention, but other associations, including the College of American Pathologists and the American Medical Association, have already mobilized to get further clarification."

Expect the Palmetto policy to be watched closely by other Medicare contractors and by private payers. Some could decide to tackle something similar. It could easily spread, analysts note, since Palmetto already serves as the Medicare contractor for North and South Carolina, West Virginia, and Virginia as well the states and territories in A/B MAC Jurisdiction 1. G2

Congressional Clock Running Out, *from p. 1*

Fixing the Physician Fee Update Formula

On Nov. 9 Democrats on the super committee offered a package of spending cuts and tax provisions that would pay for an SGR fix with funds from a portion of the overseas contingency operations budget. That package included $1 trillion in tax and revenue changes and $1 trillion in spending cuts. As part of the latter, $350 billion would come from Medicare: $250 billion from payments to providers and $100 billion from beneficiaries. No entitlement cuts would go into effect before tax reform parts of the plan are enacted. That, however, would not likely occur until after the 2012 elections, pundits predict. Republicans spurned the deal, saying it was just another way to raise taxes and avoid entitlement cuts.

Regardless of what the super committee decides, House Majority Leader Eric Cantor (R-Va.) said Nov. 14 that he expects the House to act on legislation to change the Medicare payment system for physicians. In his weekly meeting with reporters, he said he has met with members of the House who are physicians to discuss changing the SGR formula. "I look forward to coming up with a long-term fix," he said, but did not allude to any specific legislation.

Congress has repeatedly stepped in over the past decade to block SGR cuts to physician fees with a series of short-term fixes, and Washington sources speculate that lawmakers may take this route again, granting an SGR reprieve for one or two years with either a freeze or a modest increase.

The Medicare Payment Advisory Commission (MedPAC) has urged Congress to act quickly to change the SGR, saying, "It will never be less expensive to repeal the SGR than it is right now." MedPAC, which advises Congress on ways to reform Medicare, voted in October to recommend financing repeal with cuts to specialists, a freeze on primary care, and cuts to other Medicare providers, of which 9 percent would be squeezed from Part B lab spending, or $21 billion. This option also would cut payments for lab services on the physician fee schedule.

Lab Cost-Sharing Threat

The commission also sent to Congress a list of other savings options to consider, including two that are anathema to clinical lab interests:

- ❏ Introducing lab coinsurance as part of a uniform 20 percent coinsurance requirement for all Medicare services. Beneficiaries currently have no copay, and labs are paid at 100 percent of the applicable fee. Opponents say a coinsurance requirement would increase the out-of-pocket expenses of beneficiaries for needed and recommended testing and burden labs with the added costs of billing and collecting the coinsurance. In many cases, this would cost labs more to collect than the amount owed (*NIR 11, 16/Sept. 8, p. 1*).
- ❏ Requiring both coinsurance and a deductible for Medicare lab services. Prepared by House Democratic staff, this option reflects proposals previously advanced by various commissions and lawmakers, including the Congressional Budget Office which estimated that requiring full cost sharing would save Medicare $24 billion over 10 years. None has been required since the 1984 debut of the lab fee schedule.

While agreeing that the SGR payment system should be replaced with one that is stable and predictable, the American Clinical Laboratory Association (ACLA) took issue with MedPAC over paying for it by "sharing the cost across physicians, other

health professionals, and beneficiaries." Additional lab cuts are "unsustainable," said ACLA President Alan Mertz in a letter to MedPAC. Clinical lab services inform 70 percent of health care decisions but account for only 1.6 percent of Medicare spending. Yet, payments for these services have been cut by about 40 percent in real (inflation-adjusted) terms over the past 20 years. They are scheduled to decline an additional 19 percent over the next 10 years under changes mandated by the health care reform law.

Saving the Pathology Grandfather Protection

This legislative priority would extend the grandfather provision that allows qualified independent clinical labs to bill Medicare Part B for the technical component (TC) of physician pathology services to hospital inpatients and outpatients. The provision is set to expire Dec. 31 and the Centers for Medicare and Medicaid Services (CMS) has targeted it for elimination in the 2012 final physician fee schedule rule.

Bipartisan bills supporting the grandfather protection have been introduced in the Senate and in the House. The Senate bill (S. 1680) would extend the protection for another year, through Dec. 31, 2012. The House bill (H.R. 2461) would make it permanent.

CMS estimates that the savings from ending the protection at approximately $80 million for 2012. The agency contends that payment for the TC (the preparation of the slide involving tissue or cells that a pathologist interprets) is included in the hospital's prospective payment, and labs should seek reimbursement from the hospital, not the Part B program.

The grandfather provision applies to hospital-lab arrangements in effect as of July 22, 1999, when the Medicare program first proposed to end such billings. The protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

Removing Pathology From the Stark In-Office Service Exception

The College of American Pathologists (CAP) has been hosting a "fly-in" campaign this fall to advocate for removal of anatomic pathology from the in-office ancillary services exception under the Stark physician self-referral law.

Since October, CAP's *Statline* reported, 23 CAP members have come to Washington, D.C., to meet with staff of 10 of the 12 members of the deficit-reduction committee on this issue, arguing that "closing this loophole can contribute to health care savings [by curbing overutilization] without impeding delivery of health care services." Also, the presidents of 44 state pathology societies have written to the super committee, making the same argument. "Congress understands the issues, and members are interested in the potential savings. However, they are cautious about the political fallout from making a policy change without more detailed information," *Statline* reported.

The Alliance for Integrity in Medicare—which includes CAP, ACLA, and the American Society for Clinical Pathology—has sent the super committee draft legislative language to exclude anatomic pathology, radiation therapy and supplies, advanced diagnostic imaging, and physical therapy from Stark exceptions.

New Screening Coverage for Sexually Transmitted Infections

The Centers for Medicare and Medicaid Services announced Nov. 8 that Medicare will cover screening for chlamydia, gonorrhea, syphilis, and hepatitis B, with the appropriate laboratory tests, when ordered by a primary care physician or practitioner.

Medicare also announced Nov. 8 that it will begin coverage of behavioral counseling and screening to prevent cardiovascular disease, the nation's leading cause of death, and promote heart-healthy diet and exercise.

In general, the new coverage is aimed at pregnant women; however, it will also cover annual syphilis screening for men and women at increased risk for sexually transmitted infections (STIs) and annual chlamydia and gonorrhea screening for women at increased risk for STIs. In addition, Medicare will cover up to two individual 20-to-30 minute, face-to-face counseling sessions annually for beneficiaries, if referred for this service by a primary care provider and furnished by a Medicare-eligible primary care provider in a primary care setting.

Screening for the above sexually transmitted infections must be with laboratory tests approved or cleared by the Food and Drug Administration, consistent with FDA-approved labeling and in compliance with CLIA regulations, when ordered by the primary care physician or practitioner and performed by an eligible Medicare provider for these services.

Upcoming G2 Events

Webinar

(2 p.m. – 3:30 p.m. Eastern)

Jan. 5
Labs and Pathologists in the Crosshairs … Again: Medicare Policy and Payment Changes for 2012

Conferences

Dec. 12-14
LabCompete: Laboratory Sales & Marketing
Sheraton Wild Horse Pass Resort
Chandler, Ariz.
www.labcompete.com

Feb. 9-10
Pathology Institute 2012
Pathology Under Attack: Practice Models and Business Strategies for a New Era
Program partner: Laboratory Economics
Westin Beach Resort and Spa
Fort Lauderdale, Fla.
www.g2path.com

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