G2 INTELLIGENCE

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Lab Coalition Fights to Fend Off Medicare Lab Test Copay

At issue is a proposal to impose a uniform 20 percent copay for all Medicare services, including lab tests which have been exempt from beneficiary cost-sharing since the switch in 1984 to the Part B lab fee schedule.

A broad array of clinical laboratory and health care organizations has urged members of Congress and White House officials to "object to the inclusion of Medicare Part B coinsurance on clinical lab services as part of debt ceiling negotiations."

At press time, budget talks between Democratic and Republican leaders were deadlocked over spending cuts, including Medicare reductions, and tax increases. If a serious deal is reached and submitted to Congress, the lab copay is on the front burner, industry sources tell *NIR*, but if no such deal is achieved, the heat would be off the copay, at least for now.

In a July 7 letter, 13 lab professional groups, scientific societies, and national and regional companies said imposing a 20 percent lab copay would "simply shift health care costs to seniors, many of whom live on fixed or limited incomes or reside in long-term care facilities with no ability to pay." A copay also would have a big impact on "the viability of hundreds of community and regional labs that provide services to the majority of the Medicare population," the organizations said.

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Mixed Bag for Pathology in Proposed 2012 Medicare Physician Fee Schedule Rule

The Medicare physician fee schedule proposal for 2012 contains a steep cut in pathology and other physician Part B reimbursement, would scrap the pathology "grandfather" protection, would add three new pathology measures for quality reporting, and would include a series of pathology codes in the review of potentially misvalued codes.

Pathology and other physician fees are scheduled for a cut of 29.5 percent as of Jan. 1 under the sustainable growth rate (SGR) formula as required by law. This would result in the conversion factor, used to set payment rates, based on relative value units (RVUs), falling to $23.9635 for 2012 vs. $33.9764 this year. For the physician component of the most frequently ordered pathology code—CPT 88305, Gross and microscopic tissue exam Level 4—the fee would fall from the current $36.35 to $25.16 next year, a drop of 31 percent.

The pathology grandfather protection is yet again targeted by the Centers for Medicare and Medicaid Services (CMS) in its proposed rule. The agency is proposing to bar an independent clinical laboratory from billing Part B directly for the technical component (TC) of pathology services to hospital inpatients and outpatients.

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Medicare Lab Test Copay, *from p. 1*
"If coinsurance is put in place, labs will receive a reduction in their Medicare reimbursement and will then be required to collect from beneficiaries," often costing more than the amount due.

Signatories to the Coalition Letter

American Association for Clinical Chemistry
American Association of Bioanalysts
American Clinical Laboratory Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
America's Blood Centers
Clinical Laboratory Management Association
Coalition for 21st Century Medicine
Laboratory Corporation of America Holdings
National Independent Laboratory Association
Quest Diagnostics Inc.
Sonic Healthcare USA

Further, the copay would be a major administrative and financial burden for labs, the letter noted, "requiring them to generate at least 200 million bills annually to beneficiaries." The median cost of a lab claim under Medicare is about $30. With a 20 percent copay, the majority of bills to beneficiaries would be $6 or less. "We know from our experience with private insurance that significant amounts of coinsurance are not collectable today and that collection costs can range from $12 to $18 per claim when considering the cost to produce the bill and duplicates, provide postage, track the bills, and utilize a collection agency for uncollected payments."

Finally, a lab copay would be at odds with congressionally approved policy to remove cost barriers so that beneficiaries have access to testing for prevention and early detection of chronic diseases such as diabetes, heart disease, kidney disease, and cancer—areas where lab testing is the front-line defense. The health care reform law dropped cost-sharing for recommended preventive benefits in Medicare and in new private health plans. "Implementing lab coinsurance goes in exactly the opposite direction," the letter said.

The lab industry has beaten back proposals in Congress in 2003 and 2009 to institute a 20 percent copay targeted to clinical labs. But industry sources say it might be more difficult to counter this time since the threat is part of a larger ideological stance that "everything in Medicare should have a copay."

Supreme Court Puts Crime Labs on Notice

In a 5-4 decision released June 23, the Supreme Court ruled that a man convicted of drunken driving was denied his right to confront witnesses against him when a lower court allowed, and higher state courts upheld, testimony on a blood test by a surrogate for the lab analyst who performed the test.

The question in *Bullcoming v. New Mexico* was whether the Sixth Amendment permits the prosecution to introduce a forensic lab report containing a testimonial certification—made for the purpose of proving a particular fact—through the in-court testimony of a scientist who did not sign the certification or perform or observe the test.

Writing for the majority, Justice Ruth Bader Ginsburg said, "Surrogate testimony of that order does not meet the constitutional requirement. The accused's right is to be confronted with the analyst who made the certification, unless that witness is unavailable at trial but the accused had an opportunity, pretrial, to cross-examine that particular scientist."

Background of the Case

Donald Bullcoming was arrested on charges of driving while intoxicated (DWI). He refused to take a breath test, so the police obtained a warrant to draw blood for

alcohol analysis. The main evidence against him was a crime lab report certifying that his blood-alcohol concentration (BAC) was well above the threshold for aggravated DWI, a more serious crime.

On the day of trial, the prosecution said Curtis Caylor, the analyst who performed the test, "had very recently been put on unpaid leave" (but did not claim that he was unavailable to testify). Over the objection of the defense, the trial judge admitted the BAC report as a "business record" and the prosecution called Gerasimus Ratazos, another analyst who was familiar with the lab's testing procedures but had neither participated in nor observed the test on Bullcoming's blood sample.

The jury convicted Bullcoming and both the New Mexico Court of Appeals and the state's Supreme Court affirmed the conviction, finding that while the report qualified as testimonial evidence, its admission did not violate his right to confront witnesses against him because Caylor was a "mere scrivener," certifying machine-run results, and Ratazos qualified as an expert witness with regard to the testing machine and procedures.

Overruling the Lower Courts

In rejecting the reasoning of the New Mexico Supreme Court, Ginsburg said that "Caylor's certification reported more than a machine-generated number," including certifying the chain of custody, the integrity of the specimen, and the validity of the analysis. Operation of gas chromatography machines to determine BAC levels requires specialized knowledge and training, several steps are involved in the process, and human error can occur at each step. "Representations, relating to past events and human actions not revealed in raw, machine-generated data, are meet for cross-examination."

"The Sixth Amendment does not tolerate dispensing with confrontation simply because a court believes that questioning one witness about another's testimonial statements provides a fair enough opportunity for cross-examination."

— Justice Ruth Bader Ginsburg

Joining in full with the majority opinion in *Bullcoming v. New Mexico* was Justice Antonin Scalia, while Justices Sonia Sotomayor, Elena Kagan, and Clarence Thomas joined in part.

The ruling in *Bullcoming v. New Mexico* is in line with the high court's decision two years ago in *Melendez-Diaz v. Massachusetts*, Ginsburg noted. In that case, where the justices split 5-4 along similar lines, the court held that a forensic lab report stating that a suspect substance was cocaine ranked as a testimonial and could not be introduced by the prosecution without offering a live witness competent to testify to the truth of the statements in the report (*NIR 09, 14/July 27, p. 7*).

Dissenting Opinion

In his dissent, Justice Anthony Kennedy said the certifying analyst's role was no greater than that of anyone else in the chain of custody. "The information in the report was the result of a scientific process comprising multiple participants' acts, each with its own evidentiary significance. The procedures followed here, but now invalidated by the court, make live testimony rather than the 'solemnity' of the document the primary reason to credit the lab's scientific result."

Joining Kennedy in dissent were Chief Justice John Roberts and Justices Stephen Breyer and Samuel Alito who also said the majority ruling was a serious misstep and would wreak havoc on already backlogged caseloads in crime labs.

In light of the Supreme Court decision, the case goes back to state courts to determine whether Bullcoming's conviction will stand.

CMS Prepares for Start of New Lab Test Demo

Clinical laboratories, both hospital-based and independent, are invited to take part in a new Medicare demonstration project on separate payment for certain complex lab tests, the Centers for Medicare and Medicaid Services (CMS) announced July 5.

The project, authorized by the health care reform law, will begin making such payments as of Jan. 1, 2012. The demo will run for two years or until a total payment limit of $100 million is reached.

The demo applies to a diagnostic lab test ordered by the beneficiary's physician less than 14 days following the date of the patient's discharge from the hospital. Under standard Medicare "date of service" rules, such testing is considered bundled into payment to the hospital, and the lab must seek reimbursement from the hospital, not directly from Part B.

Participants will be paid directly in the demo under a separate fee schedule that CMS will establish for covered tests. On this fee schedule there will be no variation in local rates. Payment amounts will be national amounts.

Tests Defined

For purposes of the demonstration, the health care reform law defines a complex diagnostic laboratory test as a diagnostic laboratory test that is:

(1) an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity as say;

(2) determined by the Health and Human Services secre tary to be a laboratory test for which there is not an alternative test having equivalent performance char acteristics;

(3) billed using a code from the Healthcare Common Procedure Coding System (HCPCS) other than a not otherwise classified (NOC) code under HCPCS;

(4) approved or cleared by the Food and Drug Administration or is covered under Medicare; and

(5) described in Section 1861(s)(3) of the act, which defines "medical and other health services," including diagnostic laboratory tests.

CMS will hold a conference call July 21 to answer questions about the demonstration from interested parties. Dial: 1-800-837-1935 and Conference ID: 82798383. For TTY services, dial 7-1-1 or 1-800-855-2880. A relay communications assistant will help.

Participants may submit questions prior to the forum to ACA3113labdemo@cms.hhs.gov *by July 20.*

CMS has initially identified 36 tests that have assigned HCPCS codes that would meet these criteria, including molecular diagnostics and genetic testing codes: 23 in the chemistry series, 10 in immunology, one in microbiology, and two in anatomic pathology (*see table*).

Billing for Covered Tests

For tests on the demo list, labs directly billing Medicare must submit claims with a project identifier 56.

CMS notes there are tests that would meet the criteria for the project except they are billed under Medicare using NOC codes, but current payment methods (gap-fill or crosswalk) are not applicable to them. To participate in the project, test developers must obtain a temporary G code from CMS for these codes. Information about such tests must be submitted to CMS for review on or before Aug. 1, 2011. Laboratories would then be able to use the temporary G codes to bill directly for these tests under the demo.

Demonstration Test List (as of June 2011)

CPT/HCPCS CODE	SHORT DESCRIPTOR	CPT/HCPCS CODE	SHORT DESCRIPTOR
83890	Molecule isolate	83912	Genetic examination
83891	Molecule isolate nucleic	83913	Molecular, rna stabilization
83892	Molecular diagnostics	83914	Mutation ident ola/sbce/aspe
83893	Molecule dot/slot/blot	83950	Oncoprotein, her-2/neu
83894	Molecule gel electrophor	83951	Oncoprotein, dcp
83896	Molecular diagnostics	86215	Deoxyribonuclease, antibody
83897	Molecule nucleic transfer	86225	DNA antibody
83898	Molecule nucleic ampli, each	86226	DNA antibody, single strand
83900	Molecule nucleic ampli 2 seq	86235	Nuclear antigen antibody
83901	Molecule nucleic ampli addon	86294	Immunoassay, tumor, qual
83902	Molecular diagnostics	86300	Immunoassay, tumor, ca 15-3
83903	Molecule mutation scan	86301	Immunoassay, tumor, ca 19-9
83904	Molecule mutation identify	86304	Immunoassay, tumor, ca 125
83905	Molecule mutation identify	86305	Human epididymis protein 4
83906	Molecule mutation identify	86316	Immunoassay, tumor other
83907	Lyse cells for nucleic ext	87149	DNA/RNA direct probe
83908	Nucleic acid, signal ampli	88371	Protein, western blot tissue
83909	Nucleic acid, high resolute	88372	Protein analysis of tissue by western blot, w interpretation

Source: CMS. CPT codes © American Medical Association

Details on the project implementation are posted on the CMS Web site at *http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1240611.*

Applauding the Demo

The American Clinical Laboratory Association (ACLA) hailed the news of the demo. "For several years, ACLA has urged Medicare to change its rules to permit independent labs to perform and be compensated for these critically important services," said President Alan Mertz.

"We hope the assessment of the impact of this project on access to care, quality of care, and health outcomes will demonstrate to CMS the importance of changing its date-of-service rules," he added.

ACLA says beneficiaries can be harmed if testing that needs to be performed on fresh or archived specimens obtained during a hospital stay is delayed because of billing disputes or reluctance to pay.

It is assumed incorrectly that hospitals are willing to pay for some advanced diagnostic tests, according to ACLA. Many of these tests are new and unfamiliar to hospitals. They may analyze blood, tumor tissue, or other specimens to determine the source of a cancer or whether an expensive new drug is effective for a particular patient.

Hospitals "don't know how to bill for the test and their Medicare contractors may not know whether to cover the service and how to pay for it," ACLA said. "Since this type of testing is often performed to determine the course of treatment following the hospital stay, the hospital does not believe it should be responsible," ACLA noted.

Mixed Bag for Pathology, *from p. 1*

CMS has sought to eliminate such billings since 1999, but Congress has repeatedly thwarted this change by approving a series of extensions. The current extension ends Dec. 31, 2011, and pathology and lab groups are lobbying to have the grandfather protection made permanent or at least be further extended.

CMS estimates that the savings from ending the protection are approximately $80 million for 2012. CMS 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.

More Measures for Quality Reporting

Currently, pathologists participating in the Physician Quality Reporting System (PQRS) and eligible for incentive payments have two measures on which they can report. Next year, CMS proposes to add three more, all developed by the College of American Pathologists (CAP):

- ❏ *Barrett's Esophagus:* Esophageal biopsies with a diagnosis of Barrett's esophagus that also includes a statement on dysplasia.
- ❏ *Radical Prostatectomy Pathology Reporting:* Reports include the pT category, the pN category, the Gleason score, and a statement about margin status.
- ❏ *Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients:* Quantitative HER2 evaluation by IHC using the system recommended by the American Society of Clinical Oncology/CAP guidelines.

The additions were part of a larger set of five approved by the American Medical Association's Physician Consortium for Performance Improvement earlier this year and forwarded to CMS for review (*NIR 11, 3/Feb. 10, p. 3*).

The current two quality reporting measures for pathology, also developed by CAP, are:

- ❏ Breast cancer resection pathology reporting: pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade.
- ❏ Colorectal cancer resection pathology reporting: pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade.

In addition, there are three measures developed by the American Society of Breast Surgeons that could impact pathologists, according to early analysis of the proposed rule by CAP's *Statline*. These involve preoperative diagnosis of breast cancer, sentinel lymph node biopsy for invasive breast cancer, and biopsy follow-up.

In 2012, pathologists and other eligible Part B providers will be entitled to an incentive payment of 0.5 percent of total allowed charges, down from 1 percent this

year, for successfully reporting on quality measures. The health care reform law authorized the incentive payment program through 2014 and established a penalty for eligible providers who do not report quality measures beginning in 2015.

Potentially Misvalued Coding Initiative

CMS is expanding its effort to identify potentially misvalued codes for physician fee schedule services by looking at all specialties and proposes to merge five-year reviews of work and practice expense RVUs into this process. The proposed rule presents two lists of such codes, one for all evaluation and management (E/M) codes and the other for the highest non-E/M expenditure codes for each specialty, including three CPT pathology codes: 88342, Immunohistochemistry; 88112, Cytopath, cell enhance tech, and 88312, Special stains group.

CMS said it will send these to the American Medical Association's Relative Value Committee for review and possible revisions in the 2013 fee schedule. In response to stakeholder requests, CMS is also asking for a review of the values for CPT 88305 and in situ hybridization codes 88365, 88376, and 88368.

CMS Announces New Waived Tests, Billing Codes

The July 1, 2011, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes three more devices, the latest approved by the Food and Drug Administration (FDA) for this category. New waived tests are approved on a flow basis and are valid as soon as approved.

In announcing the update, the Centers for Medicare and Medicaid Services (CMS) cautioned that when billing for the tests below, you must use the QW modifier so your local Medicare contractor can recognize the code as waived under CLIA (Change Request 7349). Prior to approval for payment, your claims are checked to see whether you are certified for waived testing.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
82274QW, G0328QW	Jan. 1, 2011	Polymedco Poly Stat OC-light FOB Test
87804QW	Jan. 10, 2011	BTNX, Inc. Rapid Response Influenza A Test Cassette
87804QW	Jan. 10, 2011	BTNX, Inc. Rapid Response Influenza B Test Cassette

Code Revisions

Code Removed: On Feb. 8, 2011, the FDA informed CMS that the Teco Diagnostics Uritek TC-101 Urine Analyzer was no longer categorized as a waived test under CLIA. It is now a moderate-complexity test. Under CPT 81003QW, this test system was removed from the waived test list.

Code Reassigned: On Feb. 9, 2011, CMS determined that the code to assign to the OraSure Technologies OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is G0433, effective Jan. 1, 2011. In addition, the code assigned to the Clearview Complete HIV 1/2 test should be G0433. Therefore, the code assigned to these test systems was changed from 86703QW to G0433QW on the waived test list.

The official instruction, including a complete list of waived tests, is found on the CMS Web site at www.cms.gov/Transmittals/downloads/R2196CP.pdf.

Contractors are not required to search their files to either retract payment or retroactively pay claims; however, they should adjust claims if brought to their attention, CMS said.

CMS Proposes to Scrap Physician Signature Policy on Lab Test Requisitions

The proposal was published in the June 30 Federal Register. *The deadline for public comment is Aug. 29.*

The Centers for Medicare and Medicaid Services (CMS) has formally proposed to retract its controversial new policy requiring the signature of a physician or qualified nonphysician practitioner (NPP) on paper requisitions for clinical laboratory tests payable under the Part B lab fee schedule. Earlier this year, facing strong opposition from medical and lab organizations and members of Congress, CMS said it would halt enforcement of the policy and withdraw it altogether.

In a proposed rule, CMS said it would "reinstate prior policy that such a signature is not required on these requisitions." Under that policy, formalized in 2001 and agreed to 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.

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

G2 Intelligence Conference Calendar

Upcoming Conferences

Sept. 23
Molecular Diagnostics–Fall 2011
W San Francisco
San Francisco

Oct. 19
Lab Leaders Summit 2011
Come for the Summit and stay for Lab Institute
Ritz-Carlton Pentagon City
Arlington, Va.

Oct. 19-21
Lab Institute 2011
Crystal Gateway Marriott
Arlington, Va.

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

For details and registration information, go to our Web site, *www.G2Intelligence.com*.

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