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Congress Takes a Short Breather From Budget Battles

With Medicare sequestration left intact, clinical laboratories, whose Part B fee schedule payments were cut by 2.95 percent as of Jan. 1, will experience a further cut of 2 percent, for a total of 4.95 percent, from April 1 and through Sept. 30.

Before Congress left town for a two-week spring break, which ends April 8, lawmakers approved several budget matters. They passed a continuing resolution to avert a government shutdown at the end of this month, and the House and the Senate passed widely divergent spending blueprints for 2014.

The continuing resolution, which the president is expected to sign, funds day-to-day operating budgets of every Cabinet agency through Sept. 30, the end of the current fiscal year. It leaves in place the automatic spending cuts to domestic and defense programs, including the 2 percent reduction in Medicare payments to health care providers, mandated by the sequestration law.

The measure does allow certain agencies to shuffle the sequestration cuts, in particular to continue funding meat inspections and tuition assistance for military personnel. And in a last-minute reprieve from sequestration, community health centers got a $300 million increase, enabling them not to curtail services for the rest of this fiscal year.

The budget blueprints for fiscal year 2014, which begins this Oct. 1, were passed by the House on March 21 and by the Senate on March 23. Both are not binding but establish a framework for future negotiations.

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INSIDE *NIR*

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Providers Not Pleased With Initial Gap-Fill Pricing for MDx Codes

As a result of displeasure with preliminary gap-fill pricing for MDx codes, many providers and their associations are pressuring local Medicare Administrative Contractors (MACs) to revise the payment rates upward, submitting additional cost data to justify such a move.

Currently, the contractor-specific rates are set in the range of 20 percent to 30 percent below the median reimbursements provided under the previously used code-stacking method.

At issue are some 92 Tier 1 molecular pathology codes recognized by Medicare this year. The Centers for Medicare and Medicaid Services (CMS) assigned these codes to the Part B clinical lab fee schedule but punted the job of pricing them to its local contractors via the gap-fill method that relies on local pricing patterns. CMS said it lacked sufficient information to establish national payment rates for these codes

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Providers Not Pleased With Initial Gap-Fill Pricing for MDx Codes, *from p. 1*

in 2013, despite objections from industry stakeholders who contended they had furnished the agency with enough data on which it could act.

In comments to *NIR* on the gap-fill trends, Lale White, executive chairman and CEO of San Diego-based XIFIN, a revenue cycle management company for diagnostic service providers, noted, "The prices released to date clearly exemplify the lack of understanding of not just the economics of performing complex MDx services, but also of their value in reducing overall health care spending while improving outcomes.

"While all MACs were instructed to perform a thoughtful gap-fill pricing exercise, many are simply replicating the flawed results of others with some minor tweaks. Private payers appear to be following suit without thoughtful review and consideration of the reasonableness of established rates.

An analysis by equity research firm Piper Jaffray speculates that given grassroots and political pressures on the MACs, the overall rates for 2014 will be below the company's baseline Quest Diagnostics code stacks, closer to 10 percent rather than the 20 percent to 25 percent median cuts that it has tracked thus far.

"The paradigm shift in health care and promise of personalized medicine could be cut off at the knees by short-term thinking ascribing greater importance to saving a few pennies on the front end than recovering millions on the back. All lab tests eventually become commoditized, but not prior to market acceptance followed by automation breakthroughs. It appears that economic and political expediency may be trumping a more common sense approach. Some of the highest volume molecular diagnostic tests have seen a fee reduction of 70 percent to 90 percent compared with their reimbursement under stacked coding.

"This leaves labs and manufacturers in the uncomfortable position of having to either remove a high-value service from their menu or risk going out of business. While the industry is in high gear fighting for its life, we are hopeful that MACs and decision makers at the federal level will provide some relief before it is too late for many fine research labs."

MDX TEST PRICE COMPARISON AMONG CONTRACTORS

CPT CODE	TEST	CODE STACKED PRICE	CAHABA	PALMETTO	NORIDIAN	CGS
81200	Canavan Disease Mutation	$213	$123	$93.90	NA	$0.00
81210	BRAF Mutation	$259	$123	$57.51	$51.47	$57.51
81225	CYP2C19 Genotype	$290	$305	$135.26	$121.06	$135.26
81226	CYP2D6 Genotype	$159	$50	$147.50	$132.01	$147.50
81227	CYP2C9 Genotype	$219	$50	$96.78	$86.62	$96.78
81235	EGFR mutation analysis	$302	$123	$116.25	$104.04	$116.25
81241	Factor V Mutation Analysis	$136	$50	$78.39	$61.43	$68.64
81243	Fragile X DNA Test	$130	$123	$60.51	NA	$0.00
81255	Tay-Sachs DNA Analysis	$379	$123	$93.90	$84.04	$0.00
81270	JAK2 Mutation Analysis	$88	$90	$82.88	$65.16	$72.81
81275	KRAS Mutation Analysis	$911	$235	$225.88	$202.16	$225.88
81291	MTHFR DNA Analysis	$130	$50	$92.92	$83.16	$93.94
81350	UGT1A1 Genotyping	$83	$123	$67.25	NA	$0.00

Sources: XIFIN, contractor-specific amounts, March 22, 2013. Piper Jaffray, baseline code stack price (Quest Diagnostics), March 15, 2013. CPT codes © American Medical Association

In response to industry reaction about the gap-fill fees, Palmetto, the MAC for California, Nevada, Hawaii, and U.S. Pacific territories, has agreed to review information and evidence supporting a change. It has requested that labs get together to aggregate their data and provide it all in one set, and the California Clinical Laboratory Association (CCLA) has requested that XIFIN serve as the point of collection and consolidator of the information. CCLA encourages nonmembers to participate in order to provide a more robust data set, XIFIN said in a statement, and "we are aggregating data for both CCLA members and non-CCLA labs."

For more on pricing of molecular pathology codes, see G2 Intelligence's newest report: Medicare's New Payment System for Molecular Tests: Coding Methodology, Reimbursement Strategies, Rate Updates, *available in early April. Details available at* www.G2Intelligence.com/MDxPaymentGuide.

Timetable for Gap-Fill Rates and Public Comment

CMS has given its MACs until April 1 to complete gap-fill pricing for the molecular pathology codes new to the Part B lab fee schedule. The agency will post the interim contractor-specific rates on its Web site by April 30 for a 60-day period of public comment (not reconsideration requests).

When CMS finalizes the rates in August or September, it will accept reconsideration requests on the gap-fill amounts for 30 days. Once the reconsideration process is completed, CMS will publish the final national fee caps for these codes in the 2014 lab fee schedule (typically released in November or December) and they will not be subject to further reconsideration.

Survey Shows Fragmented Environment for FDA Regulation of LDTs

A new survey by the Personalized Medicine Coalition (PMC) finds the current environment for having the Food and Drug Administration (FDA) regulate laboratory-developed tests (LDTx) is divided at best. The survey, "Pathways For Oversight," noted that the FDA does intervene on occasion and regulate specific LDTs but that it is far from developing a systematic review process.

According to the 32-page survey, the FDA's Center for Devices and Radiological Health only reliably intervenes in the development of LDTs if they are considered a companion diagnostic or biologic that requires the agency's premarket review. However, it tends to be conservative in exercising such authority: In 2007, it declined to intervene in LabCorp's development with Exact Sciences Corp. an assay for colorectal screening because it appeared Exact Sciences had provided LabCorp with instructions on how to perform the assay, along with specifications for test equipment.

Although the PMC is not advocating for either side of the issue, Amy Miller, the organization's vice president of public policy, suggested the continued development of molecular-based tests that drive how medicines are prescribed may move the agency toward taking concrete action. "Personalized medicine is making drastic changes in how medicine is practiced, and there have been a lot of voices that molecular diagnostics are being used in unforeseen ways," she said. "There are strong voices that a drug that required FDA-approval that a physician who helps select or avoid due to a test means the tests should be under more scrutiny."

Miller also noted that if health insurers start requiring molecular tests be FDA-approved before authorizing their use for enrollees, it will prod more labs to seek agency approval for their LDTs. At the same time, the industry is expressing many of the same concerns expressed by biotech firms: FDA regulation is overly burdensome and stifles innovation.

That is among the reasons laboratory and medical device advocates and lobbies are split on the issue but leaning against FDA oversight. The Association for Molecular Pathology, American Clinical Laboratory Association, and College of American Pathologists all are calling primarily for enhanced regulation of LDTs from within the Clinical Laboratory Improvement Amendments.

Should the FDA need to provide oversight, it should be targeted and based on the risk posed to a patient by a malfunctioning test, according to CAP's position. The Advanced Medical Technology Association wants FDA oversight of LDTs when appropriate, but the organization also believes it should be based on risk.

Meanwhile, Miller observed that several companies are either systematically seeking FDA approval for their tests or working in conjunction with medical device manufacturers as part of their approval process.

She noted that Qiagen, the German assay developer with operations in both Germany and Florida, seeks FDA approval for all of its testing kits, even though they mostly are considered LDTs. Several other firms are also seeking FDA approvals for their tests, she added. "They believe it gives them a market advantage."

And not all LDTs slog through the FDA approval process. Miller noted that Pfizer's development of the lung cancer drug Xalkori and a companion test by Abbott Molecular received approval in a relatively swift 18 months. "They worked together and got it done pretty quickly," she said.

Standardized Naming Could Improve Accuracy in Test Ordering

"Excessively complex" nomenclature makes it difficult for clinicians to properly order even common laboratory tests, according to a study published in the March issue of the *Journal of General Internal Medicine*. The combination of standardized naming conventions for laboratory tests and the development of smart interfaces in computerized physician order entry systems will improve the ability of clinicians to accurately order appropriate lab tests, the authors say.

The paper, developed by the Centers for Disease Control and Prevention's Clinical Laboratory Integration into Healthcare Collaborative workgroup, identifies two root causes complicating the proper identification of tests. First, across laboratories there can be multiple names and abbreviations for a test—FBS, FGLU, FGLUC, GLUF, and FG all may refer to a fasting glucose test. There is not a uniform naming convention used by the laboratory industry with test names referring to the disease being looked for, the reagent used in the performance of the test, or even the name of the test developer or person who first identified the disease.

Additionally, test names for very different analytes may look similar. The authors point to 2009 Medicare Part B clinical laboratory claims to demonstrate the magnitude of the problem. There were 26.1 million basic metabolic profiles and 1.1 million brain naturetic peptide; 2.4 million C-reactive protein and 13,000 Protein C; and 17,000 lactic acid and 19.9 million lactate dehydrogenase.

Assigning similar names to different tests can have perilous consequences with incorrect test ordering contributing both to diagnostic errors and unnecessary health care costs.

"The efficient and efficacious patient care demanded by the quality care initiative requires progress beyond traditional solutions, such as convening naming conven-

tions, to the development of innovative software with intelligent, real-time, clinically driven search functions that will allow these programs to help rather than hinder physicians," write the authors, led by Elissa Passiment, from the American Society for Clinical Laboratory Science.

ACMG Recommends Labs Return Select Incidental Genetic Findings

The American College of Medical Genetics and Genomics (ACMG) now recommends that when laboratories performing exome and genome sequencing identify incidental genetic findings for certain, well-characterized conditions, they should return the findings to the ordering physician. ACMG has defined an initial "minimum list" of conditions, genes, and variants but expects the list to evolve.

The report, released at the 2013 Annual Clinical Genetics Meeting (Phoenix; March 19-23) and in an upcoming issue of *Genetics in Medicine*, says returning incidental findings is consistent with the long history of "opportunistic screening" in clinical medicine. The initial list of conditions, genes, and variants that trigger reporting were selected because they are recognized to be pathogenic and actionable. Additionally, the working group tried to include conditions for which confirmatory medical diagnosis would be available. Priority went to disorders for which preventive measures and/or treatments were available and disorders in which individuals might be asymptomatic for long periods of time.

"We recommend that laboratories performing clinical sequencing seek and report mutations of the specified classes or types in the genes listed here," writes the ACMG working group. "This evaluation and reporting should be performed for all clinical germline (constitutional) exome and genome sequencing, including the 'normal' of tumor-normal subtractive analyses in all subjects, irrespective of age, but excluding fetal samples."

Given the actionable nature of the identified variants, the group decided that clinicians and laboratory personnel have a fiduciary duty to prevent harm that outweighs patient autonomy and right to know. ACMG says laboratories should return the incidental findings to the ordering physician who will manage the information with the patient in light of current clinical presentation and family history. The ACMG suggests incorporation of the findings into an incidental or secondary results report that includes a clear summary of the analysis performed, the depth of coverage, and other quality metrics.

CMS Announces New Medicare Trip Fees for 2013

In a March 15 transmittal to local Medicare contractors, the Centers for Medicare and Medicaid Services has set the following new allowances that clinical laboratories use for reimbursement of travel to collect specimens from nursing home and homebound beneficiaries.

Travel code P9603, paid on a per mile basis where the average trip exceeds 20 miles round trip, is 56.5 cents per mile, plus an additional 45 cents per mile to cover the technician's time and travel costs, for a total of $1.015 per mile. This total is then rounded up to $1.02 due to processing systems capabilities. Higher rates may be established if local conditions warrant it.

Travel code P9604, paid on a flat rate per trip basis, is $10.15.

While the new rates are effective as of Jan. 1, 2013, the implementation date is June

17, according to the CMS Change Request 8203. Claims for these services will not be automatically adjusted. Providers must bring any previously paid claims to their contractors' attention.

Travel Allowance Policy

Payment of the Part B travel allowance is made only if a specimen collection fee is also payable when it is medically necessary for a laboratory technician to draw a specimen from either a nursing home patient or a homebound patient.

Medicare contractors have discretion in choosing to pay either on a mileage basis or a flat rate and how to set each type of allowance. Because of audit evidence that some laboratories abused the per mileage fee basis by claiming travel mileage in excess of the minimum distance necessary for a laboratory technician to travel for specimen collection, many Medicare contractors established local policy to pay on a flat-rate basis only.

Under either method, when one trip is made for multiple specimen collections (for example, at a nursing home), the travel payment component is prorated based on the number of specimens collected on that trip, for both Medicare and non-Medicare patients, either at the time the claim is submitted by the laboratory or when the flat rate is set by the contractor.

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The House plan, authored by Budget Committee Chairman Paul Ryan (R-Wis.) and approved mostly along party lines (221-207), is the more radical of the two. It would turn Medicare into a premium support program, transform Medicaid into a state block grant program, cut food stamps, and repeal large parts of the Affordable Care Act (though retaining some of the taxes associated with the act as well as the $716 billion in Medicare cuts it contains). Overall, it would cut federal spending by $4.6 trillion over 10 years and balance the federal budget.

The Medicare overhaul, beginning in 2024, would impact individuals born in 1959 and later. When they become eligible for the program at age 65, they would be offered a voucher that could be applied either toward the purchase of private health insurance or Medicare coverage.

The Senate blueprint, crafted by Budget Committee Chairman Patty Murray (D-Wash.) and passed 51-49 with all Republicans and four Democrats voting no, would not make structural changes to Medicare or Medicaid, would leave the Affordable Care Act intact (but reduce Medicare spending by $275 billion over 10 years by relying on reforms initiated under the act), and while calling for close to $2 trillion in spending cuts, would not produce a balanced budget. It also would ax further sequestration requirements in fiscal 2014 and beyond.

On one point a bipartisan majority of senators did agree. They called for repeal of the 2.3 percent medical device excise tax levied under the Affordable Care Act. This amendment, sponsored by Finance Committee ranking member Orrin G. Hatch (R-Utah) and Sen. Amy Klobuchar (D-Minn.) and co-sponsored by 21 other GOP and Democratic senators, passed by a 79-20 vote. Hatch and Klobuchar have introduced legislation to repeal the tax, the Medical Device Access and Innovation Protection Act (S. 232).

The tax was intended to generate about $30 billion to help pay for health care reforms, but the medical device industry has argued that it will lead to job losses and impede innovation. The tax has raised nearly $200 million since its inception in January, according to industry representatives. The Senate amendment includes a deficit-neutral reserve fund to allow for a payment offset if the tax is eliminated.

April Update of CLIA-Waived Tests, Billing Codes

The April 1, 2013, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes 24 more devices, the latest approved by the Food and Drug Administration for this category (*see table*). New waived tests are approved on a flow basis and are valid as soon as approved.

When billing for the tests below, you must use the QW modifier. This enables your local Medicare contractor to recognize the code as waived. Prior to payment approval, claims are checked for waived testing certification.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
82274QW	April 19, 2012	Medline iFOB One-Step Immunological Fecal Occult Blood Test
G0434QW	May 9, 2012	Wondfo Multi-Drug Urine Test Cup {Cup format}
G0434QW	May 9, 2012	Wondfo Multi-Drug Urine Test Panel {Dip card format}
83037QW	May 30, 2012	Bayer A1C Now SelfCheck
G0434QW	July 3, 2012	CLIAwaived Inc. Single Drug Dipstick Test
G0434QW	July 3, 2012	CLIAwaived Inc. Rapid Dip Drug Test
G0434QW	July 27, 2012	Wondfo Cannabinoids Urine Test {Cup Format}
G0434QW	July 27, 2012	Wondfo Cannabinoids Urine Test {Dip card Format}
G0434QW	Aug. 2, 2012	Wondfo Amphetamine Urine Test {Cup Format}
G0434QW	Aug. 2, 2012	Wondfo Amphetamine Urine Test {Dip card Format}
G0434QW	Aug. 2, 2012	Wondfo Oxazepam Urine Test {Cup Format}
G0434QW	Aug. 2, 2012	Wondfo Oxazepam Urine Test {Dip card Format}
G0434QW	Aug. 2, 2012	Wondfo Secobarbital Urine Test {Cup Format}
G0434QW	Aug. 2, 2012	Wondfo Secobarbital Urine Test {Dip card Format}
82055QW	Aug. 16, 2012	CLIAwaived Inc. Rapid Saliva Alcohol Test
G0434QW	Aug. 24, 2012	Brannan Medical Corporation Fastect II Drug Screen Dipstick Test
G0434QW	Aug. 24, 2012	Brannan Medical Corporation QuickTox Drug Screen Dipcard
G0434QW	Aug. 27, 2012	CLIAwaived Inc. Instant Nicotine Detection Test
87807QW	Sept. 13, 2012	Alere BinaxNOW RSV Card
87804QW	Sept. 13, 2012	Alere BinaxNow Influenza A & B Card {Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens}
82055QW	Sept. 13, 2012	Chematics Inc. Alco-Screen 02 Saliva Alcohol Test
85610QW	Sept. 18, 2012	Roche Diagnostics CoaguChek XS Plus System
81003QW	Sept. 26, 2012	Acon Laboratories Inc. Insight U120 Urine Analyzer
G0434QW	Oct. 5, 2012	Medimpex United Inc. MedimpexQ Test Multi X Drug Cup Test

Your carrier or Medicare Administrative Contractor is not required to search its files to either retract payment or retroactively pay claims; however, it should adjust claims you bring to its attention.

The April update, plus a complete list of CLIA-waived devices, can be found in Change Request 8146, at *www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2619CP.pdf.*

MAC Contract for Jurisdiction E Goes to Noridian

In a March 22 transmittal, the Centers for Medicare and Medicaid Services (CMS) said it will implement, as of July 1, a Part A and Part B claims processing and payment contract for Jurisdiction E to Noridian Administrative Services (Fargo, N.D.)

The jurisdiction covered by the new Medicare Administrative Contractor (MAC) includes California, Nevada, and Hawaii, as well as the U.S. territories of American Samoa, Guam, and the Northern Mariana Islands. It includes more than 3.5 million fee-for-service beneficiaries and serves some 500 hospitals and 86,500 physicians. The workload comprises approximately 8.9 percent of the national Medicare A and B fee-for-service claims volume.

Protests filed by Palmetto GBA, which previously held the contract, and CGS Administrators LLC were denied by the Government Accountability Office, which concluded that Noridian's noncost factors were superior and consistent with CMS's evaluation scheme. Both subsequently lost their appeal to the U.S. Court of Federal Claims. Palmetto will continue to process benefit claims for Jurisdiction E while CMS handles the transition of the contract to Noridian.

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