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INSIDE *NIR*

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Reaction Split on New Changes to Clinical Laboratory Fee Schedule

Industry reaction to a new law that makes changes to the Clinical Laboratory Fee Schedule (CLFS) appears to be split, with some laboratory groups applauding the changes and others concerned that it places hospital labs and regional and community labs at a disadvantage.

The Protecting Access to Medicare Act of 2014, signed into law in early April, extends current Medicare payment for physicians for one year and implements a new system tying Medicare payment for lab tests paid under the CLFS to market rates.

While the American Clinical Laboratory Association (ACLA) maintains that the changes to the CLFS under the new law are preferable to potential alternatives under consideration by Congress, the National Independent Laboratory Association (NILA) says there is no way of knowing which alternative is better.

"We're not willing to say that this is better than what could have been because we don't know what could have been," says NILA Administrator Mark Birenbaum. "Cuts [under the new system] could be

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CMS Updates, Clarifies Changes To Lab Test Payment

The Centers for Medicare and Medicaid Services (CMS) has revised the 2014 Clinical Laboratory Fee Schedule (CLFS) to add several codes that were inadvertently left off the previous fee schedule files and to correct a technical oversight that led to misstatement of several prices on the fee schedule.

Transmittal R2916 (Change Request 8695), issued March 28, notes that existing codes have been recalculated so that their national limitation amount (NLA) and/or price for each Medicare administrative contractor (MAC) is correct. The MAC will not automatically adjust claims processed prior to implementation of the transmittal (implementation date is June 30, 2014). If a laboratory has claims that need adjustment, it should bring those claims to the MAC's attention.

Among the changes: Current Procedural Terminology (CPT) code 86152 is priced at the 2013 contractor gap-filled rate, and CPT code 86294QW is priced at 100 percent of the midpoint in the NLA pricing. Codes that have been recalculated are as follows:

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draconian for labs that do a lot of routine testing because they do tests with the lowest median." NILA represents small and community labs.

However, ACLA President Alan Mertz counters that under the new law, any cuts will be delayed until 2017 and will be capped. "We have two years and eight months before any cuts go into effect, and there are no across-the-board cuts, which we were facing," he notes. "We have more than a year to work with [the Centers for Medicare and Medicaid Services] on rulemaking and many more opportunities to have input."

Beginning Jan. 1, 2016, and every three years thereafter, "applicable laboratories" will be required to report payment rates paid by each private payer during the specified period, as well as volume.

Determining Payment for Lab Tests

Section 216 of the new law adds a new section to the Social Security Act that will use rates paid to laboratories by private payers to determine Medicare rates for lab tests. Private payers includes health insurers, Medicare Advantage plans under Part C, and Medicaid managed care organizations.

Beginning Jan. 1, 2016, and every three years thereafter, "applicable laboratories" will be required to report payment rates paid by each private payer during the specified period, as well as volume. An applicable laboratory required to report is one that receives the majority of its revenue under the CLFS or Physician Fee Schedule (PFS), subject to any low-volume or low-expenditure threshold established by the Department of Health and Human Services (HHS). The information reported will not include payments made on a capitated basis, but the reported rates will reflect discounts, rebates, coupons, and other price concessions.

Payment for clinical diagnostic laboratory tests furnished on or after Jan. 1, 2017, including those furnished by hospital labs that are not bundled, will be equal to the weighted median for the test for the most recent data collection period. For years 2017 through 2019, a payment amount cannot be reduced more than 10 percent of the payment amount for the previous year; for 2020 through 2022, the limit is 15 percent. There are no limits beyond 2022. Thus, CMS would develop a weighted median of private payer rates and, if the median is lower than the Medicare rate in effect at that time, limit the amount of any annual reduction in Medicare payment. The weighted median would stay in effect until the year after the next information collection period.

The law also establishes a new category for new advanced diagnostic laboratory tests, with initial payment (for the first nine months) based on the actual list charge, which the law defines as "the publicly available rate on the first day at which the test is available for purchase by a private payer." Labs offering these tests will have to report private payer rates no later than the last day of the "second quarter of the initial period." After the initial period, the data will be used to establish the payment amount using the same method described for other tests. If the secretary determines the amount paid for an advanced diagnostic lab test during the initial period is greater than 130 percent of the private payer-based payment amount, the secretary will recoup the difference between the two amounts.

A new test that is not an advanced diagnostic laboratory test would be paid using crosswalking or gap-filling. The secretary of HHS could also consider input and rec-

Penalties for Failing to Report

If HHS determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting information with respect to a clinical diagnostic laboratory test, a civil money penalty in the amount of $10,000 per day for each failure may be imposed.

Definition of Advanced Diagnostic Laboratory Test

The law defines an *advanced diagnostic laboratory test* as a test offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory and that meets one of the following criteria:

- The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a patient-specific result.
- The test is cleared or approved by the Food and Drug Administration.
- The test meets other similar criteria established by the secretary of HHS.

ommendations from a new clinical laboratory payment advisory committee, which would be composed of a variety of individuals such as molecular pathologists, researchers, laboratory economists, and those with expertise in the development, validation, performance, and application of clinical laboratory tests.

The Government Accountability Office and the HHS Office of Inspector General (OIG) would perform, publish, and submit to the House and Senate committees of jurisdiction a study that analyzes the payment rates, transition process, impact on beneficiaries and on labs that specialize in a small number of tests, the number of new Healthcare Common Procedure Coding System (HCPCS) codes, the spending trend for lab tests, and other issues. The OIG annually would publish an "analysis of the top 25 laboratory tests and expenditures" under Medicare and would conduct other analyses of implementation of the new payment system.

Must Hospital Labs Report?

A concern raised by Birenbaum is that he believes under the law, many hospital laboratories will not be required to report their private payer rates, and since those rates tend to be higher, that could actually result in lower medians overall.

However, the law does not state that hospital laboratories are excluded from reporting. Any lab that derives a majority of its revenue from the CLFS or PFS is required to report, whether it is independent or hospital-based. Mertz from ACLA tells *National Intelligence Report* that he expects that hospital outreach labs will be required to report their private payer rates.

"The burden is the same for everyone," says Mertz. "If hospitals don't report, it will hurt them. It certainly is in their best interest to report."

Small Labs v. Big Labs

Birenbaum believes that smaller community or regional labs are likely to be hurt by the law because they do more routine testing and not much advanced or esoteric testing. Larger labs that perform advanced testing will be able to develop new tests and be paid the list price, thus offsetting any potential reduction to routine testing, he argues. "Our labs would love to be on a schedule where we get paid list price for our lab tests," he says.

However, Mertz notes that even the bigger labs derive the majority of their volume from routine tests, not advanced or esoteric tests. "We are concerned about small, community labs," he says, adding that ACLA fought for an increase in the sample collection fee for labs that service skilled nursing facilities and home health agencies, which typically are smaller labs. That sample collection fee is increased $2 under the law.

Pathology Concerns

The College of American Pathologists (CAP) and the Association for Molecular Pathology (AMP) also have expressed concerns about the new law. In a March 27 letter to Sen. Harry Reid (D-Nev.) prior to the Senate vote on the legislation, AMP President Elaine Lyon, Ph.D., said she felt the measure could have significant unin-

tended consequences for hospital-based labs, which she says lack the infrastructure to collect the data outlined in the bill.

Section 216 also disregards the Current Procedural Terminology (CPT) code process by establishing a new system for use of permanent HCPCS codes for new lab tests and disregards the use of CPT codes by establishing a unique identifier system for certain tests for the purposes of tracking and monitoring, believes Lyon.

"The current CPT coding system is more than sufficient for tracking, monitoring, coverage, and payment," she wrote. "It is a waste of Medicare resources to build a redundant system. There is no need for further identifiers, which will increase costs and create administrative burdens to both CMS and laboratories."

CAP also opposes the new law, saying it fails to repeal the sustainable growth rate permanently and neglects critical Medicare reforms such as closing the self-referral loophole. "HR 4302's patch legislation does not provide stability for physician payments, does not address pathologists' specific concerns with participation in the current pay-for-performance program, and would drastically alter the payment system for clinical laboratories," said CAP President Gene Herbek, M.D., FCAP, in a statement.

Takeaway: Lab and pathology groups are split on whether the new law changing how lab tests are priced under the Clinical Lab Fee Schedule is good for the industry or not. Much uncertainty remains about how the new law will be implemented.

Coverage Policies

After Jan. 1, 2015, a Medicare administrative contractor (MAC) could issue a coverage policy for a clinical laboratory test only in accordance with the process for making a local coverage determination, including both appeals and review process. This would not apply to national coverage determinations.

In addition, the secretary may designate one or more (not to exceed four) MACs to either establish coverage policies or process claims for clinical diagnostic laboratory tests.

CMS Updates, Clarifies Changes to Clinical Lab Fee Schedule, *from p. 1*

CPT Code	NLA	CPT Code	NLA
80160	$23.48	82379	$23.01
82017	$23.01	83013	$91.89
82136	$23.01	83080	$23.01
82139	$23.01	85576	$29.31
82261	$23.01	85576QW	$29.31
82270	$4.44	86355	$51.46
82271	$4.44	86357	$51.46
82271QW	$4.44	86359	$51.46
82272	$4.44	86367	$51.46
82272QW	$4.44	G0123	$27.64
82274	$21.70	G0328	$21.70
82274QW	$21.70	G0328QW	$21.70

Source: CMS 2014 Clinical Laboratory Fee Schedule

The revised calendar year 2014 CLFS data file is available at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html.*

Takeaway: A handful of tests on the Clinical Laboratory Fee Schedule are having their payment amounts adjusted as a result of technical corrections made by the Centers for Medicare and Medicaid Services.

Myriad Rebounds After CMS Reversal on BRAC*Analysis* Pricing

Shares of Myriad Genetics (Salt Lake City) have continued to rise following last week's announcement by the Centers for Medicare and Medicaid Services (CMS) that it had reversed its previous cut in payment for the company's BRACAnalysis test (CPT 81211), increasing the reimbursement rate to $2,184.

The new rate is an increase of 52 percent over the $1,483 price announced last November. For an integrated BRAC*Analysis* test, the price is increased by 37 percent to $2,767. The new reimbursement amounts will take effect for tests ordered after April 1, 2014.

As of April 7, Myriad's stock was trading at $40.87, almost double the stock price on Dec. 30, 2013.

In an explanation posted on CMS's gap-fill inquiries Web page, the agency says the original payment amount announced in November 2013 was based on Medicare contractor Noridian's price for CPT code 81211 of $1,449.09.

"The prices in the November 2013 files were based on information current at that time," says CMS in its explanation. "We have numerous data from our contractors that test prices at that time ranged from $995 to $2,800. . . . During the two subsequent comment periods in 2014, three Medicare contractors provided additional information that they had received data indicating that the prices for CPT code 81211 ranged from $2,000 to $2,500. Based on the available information . . . we are revising the median price for CPT code 81211."

While the median price is revised to $2,200, applying the negative 0.75 percent update factor results in the new national limitation amount of $2,184. The $1,438 price

announced in November was a cut from the previously proposed rate of $2,795. The list price for the test ranges from $3,000 to $4,000.

Following the April 1 announcement, several investment banks raised the price target for the stock and upgraded the stock to "Buy" from "Neutral." Amanda Murphy, an analyst with William Blair (Chicago), says that the CMS decision is a "somewhat surprising move" but notes that single gene test pricing will be under pressure over time given that the industry is moving more toward the use of gene panels, particularly since there is building evidence that there are four or five additional genes that are relevant in hereditary breast cancer.

"We believe single-gene pricing pressure will occur over time (not across the whole book all at once) and will become more and more difficult to tease out as Myriad diversifies its revenue base (given addition of Crescendo, impact of new Colaris guidelines, ramp[ing up] of MyRisk, potential private payer contracts for hereditary cancer panels/incremental genes tests, and potential coverage for Prolaris."

Myriad's stock has been under pressure since last summer, when the Supreme Court ruled that the company could not hold patents on unaltered genes. Following that ruling, a number of labs have launched competing tests, including panels that include assays for the BRCA1 and BRCA2 genes. Among that labs that have launched competing BRCA tests are GeneDx, Ambry Genetics, and Gene by Gene. Myriad Genetics has sued a number of companies over the competing assays, arguing that the testing would infringe patent claims that have not been struck down by the high court decision.

Takeaway: Myriad's stock has rebounded in recent weeks, but the company still faces market pressure from competitors offering BRCA tests. G2

OIG: Doctors Billed Medicare $139M in 2011 For Questionable Nerve Damage Tests

Physicians billed $139 million in 2011 for questionable Medicare electrodiagnostic tests, a service area that is vulnerable to fraud, waste, and abuse, according to a report from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) released April 7.

The report, "Questionable Billing for Medicare Electrodiagnostic Tests" (OEI-04-12-00420), found that 4,901 physicians of the 21,663 physicians who billed for electrodiagnostic tests in 2011 met or exceeded the threshold for one or more questionable billing measures for electrodiagnostic tests.

In 2011, Medicare paid approximately $486 million to 21,700 physicians who billed for electrodiagnostic tests for 877,000 beneficiaries.

Of the physicians with questionable billing, the OIG found that 49 percent were neurologists and physiatrists who "have special training in electrodiagnostic medicine, and therefore may see more patients who require electrodiagnostic testing, and may bill for more of these tests."

Electrodiagnostic tests are intended to evaluate a patient's nerves for potential damage. The tests measure electrical activity in muscles and nerves and can detect

peripheral nerve damage caused by conditions such as diabetes and carpal tunnel syndrome.

The OIG report discovered that 4,257 physicians exceeded the threshold for one of the questionable billing measures, 572 exceeded the threshold for two, and 72 exceeded the threshold for three.

OIG Recommendations

The OIG said physicians may have legitimate reasons for the electrodiagnostic test billings identified in the report but further attention is warranted. As a result, the OIG recommended that the Centers for Medicare and Medicaid Services (CMS) strengthen the monitoring of electrodiagnostic test billings.

The OIG also recommended that the CMS should educate physicians on proper billing procedures for electrodiagnostic tests, as well as take any appropriate actions against the identified physicians with questionable billing practices.

The CMS partially agreed with the first and second recommendations and said it "will need to evaluate if implementing new thresholds that trigger additional manual medical review by CMS MACs is cost-effective given the high cost of medical review."

The CMS fully agreed with the third recommendation, to take appropriate action against physicians identified in the report, and asked the OIG to provide additional information on the questionable billing claims identified in the report.

Takeaway: CMS is likely to strengthen its monitoring of electrodiagnostic test billings after the HHS OIG identified $139 million in questionable billings. G2

April Update of CLIA-Waived Tests, Billing Codes

The April 4, 2014, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes eight new tests approved by the Food and Drug Administration.

When billing for these tests, you must use the QW modifier. This enables your local Medicare contractors to recognize the code as waived.

The April update, plus a complete list of CLIA-waived tests and devices, can be found in Transmittal 2919 (Change Request 8705) at *www.cms.gov* under "Transmittals." The implementation date is July 7, 2014. G2

CPT CODE	EFFECTIVE DATE	DESCRIPTION
87880QW	July 29, 2013	Poly Stat Strep A Flip Test
G0434QW	Aug. 1, 2013	Alere iScreen DX Multi-Drugs of Abuse Dip Test
G0434QW	Sept. 10, 2013	Alere iScreen DX Single Dip Card
85018QW	Dec. 12, 2013	Alere HemoPoint H2 System
87804QW	Dec. 13, 2013	Sofia Analyzer and Influenza A+B FIA
G0434QW	Feb. 21, 2014	Ultimate Analysis Cup Inc. UA Cups Test Cards
G0434QW	Feb. 21, 2014	Ultimate Analysis Cup Inc. UA Cups
83516QW	Feb. 27, 2014	Rapid Pathogen Screening Inc. InflammaDry

Quest, LabCorp Among Largest Recipients of Medicare Dollars

Quest Diagnostics and Laboratory Corporation of America each received hundreds of millions of dollars from Medicare in 2012, according to new payment data released by the government. Multiple entities with Quest Diagnostics in their name collected a total of $669 million, while listings for LabCorp totaled $717 million.

The disclosures were gleaned from $77 billion in payment data released by the government April 9 that provide the first look at Medicare payments to health care providers in more than three decades.

Medicare paid almost 4,000 doctors and medical professionals more than $1 million apiece in 2012, including seven who received more than $10 million. Eye doctors were among the highest compensated, including one Florida ophthalmologist paid $21 million in 2012.

Making the data available may allow the public and researchers to better identify fraud and waste by doctors in the $604 billion Medicare system.

The data file covering 880,000 providers showed a concentration at the top, with the doctors over $1 million receiving at least 13 times the $77,000 average paid by the program. The data showed that cancer doctors specializing in blood work and radiation are those best compensated by Medicare, each averaging over $360,000 in annual payments from the program for the elderly and disabled, which is the largest health care payer in the United States.

While drug and hospital costs have been scrutinized, less attention has been paid to doctors' fees, which accounted for about 12 percent of Medicare's budget in 2012. Making the data available may allow the public and researchers to better identify fraud and waste by doctors in the $604 billion Medicare system.

More Scrutiny

The data could also bring more scrutiny on doctors who engage in self-referral—ordering tests and procedures that are performed in their own clinics or in those in which they have a financial interest.

The data release has been lauded by consumer groups seeking to spotlight possible fraud or overuse and criticized by physicians, including the American Medical Association, whose president has said misinterpretation could ruin doctors' careers.

California and Florida received the largest payments, with each getting more than $7 billion from Medicare, followed by Texas and New York, with $5 billion a piece. The Centers for Medicare and Medicaid Services is hoping that by releasing the data it can help cut waste from the Medicare system and improve cost-effectiveness, agency Deputy Administrator Jonathan Blum said last week in a blog post on the decision.

"Data like these can shine a light on how care is delivered in the Medicare program, Blum said. "Businesses and consumers alike can use these data to drive decision-making and reward quality, cost-effective care."

However, speaking to reporters after the data were released, Blum cautioned against drawing immediate conclusions about potential fraudulent or wasteful activities by providers who received particularly high levels of Medicare reimbursement.

Takeaway: Release of new Medicare data by the government may shine a light on how care is delivered and ways to cut waste in the system.

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