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INSIDE *NIR*

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Congress Likely to Approve New System for Tests Paid Under CLFS; Bill Would Also Extend SGR Patch, Delay ICD-10 Implementation

Legislation designed to extend current Medicare payment for physicians for one year also contains good news for clinical laboratories: A new market-based system for Medicare payments for tests paid under the Clinical Laboratory Fee Schedule (CLFS).

Laboratory groups are applauding the provision, which would repeal authority by the Centers for Medicare and Medicaid Services (CMS) to make changes to the CLFS based on technological changes and replace it with a process to adjust reimbursement based on market rates. The bill would also provide a temporary patch to the system used to pay physicians and delay implementation of the ICD-10 code set for one year. The House approved the measure March 27; the Senate is expected to follow.

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ACLA Seeks Reversal of NCCI Edit Limiting FISH Reimbursement

A new policy issued by the Centers for Medicare and Medicaid Services (CMS) limiting reimbursement for fluorescence in situ hybridization (FISH) testing to just one procedure regardless of how many probes are used would result in underpayment to clinical and anatomic pathology laboratories, says the American Clinical Laboratory Association (ACLA) in a letter to CMS officials.

The letter refers to a change in the National Correct Coding Initiative (NCCI) policy manual that limits reimbursement for FISH testing to one unit of service. Effective Jan. 1, 2014, the NCCI manual states:

> The unit of service for in situ hybridization reported as CPT codes 88365, 88367, or 88368 is each probe staining procedure per specimen. If a single probe staining procedure for one or more probes is performed on multiple blocks from a surgical specimen, multiple slides for a cytological specimen, or multiple slides from a hematological specimen, only one unit of service may be performed for each separate specimen. Physicians should not report more than one unit of service for CPT codes 88365, 88367, or 88368 per specimen for a probe staining procedure even if it contains multiple separately interpretable probes.

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Congress Likely to Approve New System for Tests Paid Under CLFS, *from p. 1*

"We are pleased that Congress listened to and included many of our key priorities in this proposal for modernizing how Medicare reimburses clinical laboratories," said Alan Mertz, president of the American Clinical Laboratory Association. "If adopted, this proposal would preserve seniors' access to diagnostic testing by avoiding another potential round of indiscriminate across-the-board payment cuts, bringing some much-needed predictability in reimbursement over the next several years. This legislation will provide more transparency and more time for laboratories and other stakeholders to prepare for changes. It will also provide more opportunity for stakeholders to work with CMS on implementing these important reforms."

Section 216 of the bill, "Improving Medicare Policies for Clinical Diagnostic Laboratory Tests," would add a new section to the Social Security Act that would use rates paid to laboratories by private payers to determine Medicare rates for laboratory tests. The Congressional Budget Office estimates that this would save Medicare $2.5 billion over 10 years.

Under this new system of adjusting CLFS payment, there would be no cuts in 2015 and 2016. For years 2017 through 2019, cuts would be capped at 10 percent per code per year. For years 2020 through 2022, the cuts would be capped at 15 percent.

Labs Would Report Payment Rates

Beginning Jan. 1, 2016, and every three years thereafter, laboratories that receive a majority of their revenues under the CLFS or the Physician Fee Schedule, would be required to report to the Department of Health and Human Services (HHS) (1) the payment rates paid by each private payer during the specified reporting period, and (2) the volume of such tests for each payer for the period. If a lab has different payment rates for the same payer, or different rates for different payers for the same test, it would be required to report all rates.

Section 216 also creates a new system for establishing payment for "advanced diagnostic laboratory tests" that have not previously been paid under the CLFS. Essentially, initial Medicare payment for these tests would be the publicly available list price. After reporting private payer rates, the pricing would be determined under the same system using private-payer weighted median prices as used for other tests paid under the CLFS.

If HHS determines that the amount paid for an advanced diagnostic laboratory test during the initial period is greater than 130 percent of the private payer-based payment amount, HHS would recoup the different between the two payment amounts.

Between enactment of the measure and Dec. 31, 2016, HHS would use methodologies for pricing, coding, and coverage that are currently in effect.

While this new system could potentially result in some reductions in lab payment, the reductions are likely to be much less than the alternative being considered by Congress: continuation of the 1.75 percent across-the-board cut to the CLFS. That measure, included in President Obama's proposed budget for 2015, would have resulted in cuts of $7.9 billion over 10 years. In addition, CMS's plan to revalue tests paid under the CLFS could have resulted in further cuts on top of that.

Takeaway: Labs are likely to see enactment of a new system used to adjust payment for tests paid under the Clinical Laboratory Fee Schedule beginning in 2017. G2

FDA Updates 2008 Guidance on Categories of Lab Testing

The Food and Drug Administration (FDA) released March 12 an updated guidance on categorization of laboratory tests.

The document, "Administrative Procedures for CLIA Categorization: Guidance for Industry and Food and Drug Administration Staff," replaces a document issued in May 2008. CLIA refers to the Clinical Laboratory Improvement Amendments of 1988.

The FDA noted that the CLIA law requires that clinical laboratories obtain a certificate before accepting materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or the impairment of or assessment of the health of human beings. "The type of CLIA certificate a laboratory obtains depends upon the complexity of the tests it performs," the FDA said, adding that CLIA regulations describe three levels of test complexity: waived tests, moderate-complexity tests, and high-complexity tests.

Categorization, Waivers

The new guidance covers procedures for determining CLIA categorization, as well as CLIA waiver protocols and applications.

The new guidance also directs readers to a January 2008 FDA guidance, "Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices." That guidance is available at www.fda.gov/MedicalDevicesDeviceRegulationandGuidance/GuidanceDocuments/ucm079632.htm.

In the first area, the agency said that categorization of in vitro diagnostic tests is determined "at the time of review of a premarket notification submission (510(k)) or a premarket approval application (PMA) under the Federal Food, Drug, and Cosmetic Act." In those cases when a 510(k) or PMA isn't needed but CLIA categorization still is appropriate (the agency gave as an example the devices exempt from premarket notification), manufacturers should submit a request for CLIA categorization, including a copy of the test package insert with test instructions, to the Center for Devices and Radiological Health Document Control Center. And to expedite review, the FDA "strongly encourages" submission of an eCopy.

In the second area, involving waivers, the guidance said that a test initially categorized as moderately complex might meet the statutory criteria for a CLIA waiver "if the device is simple to use and the sponsor demonstrates in studies conducted at the intended use sites that the test is accurate and poses an insignificant risk of erroneous results." The agency guidance said that if a company whose test is categorized as moderate complexity believes the test meets the statutory criteria for CLIA waiver, it may submit a CLIA "waiver by application" to request categorization of the test system as waived.

The agency said that under the medical device user fees law known as MDUFA, from fiscal years 2013 through 2017 the agency made commitments for review times of CLIA waiver by applications. For a substantive interaction, which may be a request for additional information (via letter or e-mail), the review time (measured in FDA days) is 90 days. For a final decision on the waiver, the times under the user fees law are 180 days (with no panel), 330 days (with a panel), and 210 days for a dual 510(k) and CLIA waiver by application.

The text of the new guidance document is at *www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070889.pdf*.

Takeaway: FDA's updated guidance on categorization of laboratory tests should not have a major impact on clinical laboratories. G2

focus on: *Patient Access to Lab Test Results*

Labs Have Flexibility in Developing Policies Under New Access Rule

Clinical and anatomic pathology laboratories have flexibility as to how to set up policies and procedures to respond to patient requests under a new rule requiring labs to provide patients with access to their completed test reports, say industry experts.

In a March 25, 2014, webinar co-sponsored by G2 Intelligence and the American Clinical Laboratory Association (ACLA), a key staff person from the Centers for Medicare and Medicaid Services (CMS) and the legal counsel to ACLA addressed key issues raised by the new rule.

The new rule becomes effective April 7, though laboratories will not be required to comply until Oct. 6, 2014. As of April 7, a lab subject to the Clinical Laboratory Improvement Amendments *may* provide patients with a copy of a completed test report. As of Oct. 6, a lab that is subject to the rule *must* do so.

Labs must provide individuals with a copy of their test reports in the form or format that the individual requests if a copy in that form is readily producible.

The rule applies to laboratories that are considered "covered entities" under the Health Insurance Portability and Accountability Act (HIPAA)—in other words, any labs that performed covered electronic transactions, such as transmitting health care claims to a health plan, according to Karen Dyer, MT(ASCP), deputy director of the Division of Laboratory Services at CMS. The rule is expected to apply to almost all laboratories.

The new rule preempts contrary state law that prohibits providing individuals with access to their test results, although HIPAA-covered laboratories must continue to abide by state law that provides "more stringent" access to protected health information (PHI). More stringent means greater right of access.

Test reports maintained by or for a covered laboratory are considered part of a "designated record set," and the patient has the right to all PHI in that record set for as long as the information is maintained by the laboratory. There is no time limit on requests, so patients can request completed test reports from previous years and the lab must provide those reports if they still have them.

Labs must provide individuals with a copy of their test reports in the form or format that the individual requests if a copy in that form is readily producible. If the test report is not readily producible in that specific format, the copy must be either a readable hard copy or other form or format agreed upon by the individual and lab.

If the lab maintains requested information electronically, the lab must have the capability of providing some form of electronic copy of the test report, such as a PDF sent through e-mail or on a CD. The lab is not required to purchase new software or systems to accommodate a request for an electronic copy in a form that it cannot produce, explains Dyer.

Concerns About Rule

Dyer addressed a number of concerns that have been raised by laboratories about compliance with the rule:

1 Since patients have access to test results without the benefit of provider interpretation, there is a potential for them to panic and act upon results that appear

to be abnormal. Dyer notes labs will not be required to interpret test results for patients and should continue to refer patients back to the referring physician for interpretation. Peter Kazon, Esq., senior counsel with Alston & Bird, suggests that labs have a policy that results not be released to the patient any sooner than 48 hours after they have been sent to the physician. This gives the physician a chance to address any potential concerns about abnormal results before the patient receives the results.

2 Reference laboratories do not have contact with the patient, and many feel this rule should not apply to them. According to Dyer, reference labs that are covered entities under HIPAA will be require to provide access to completed test reports.

3 Labs have 30 days to respond to a request, but in some cases, it may not be possible to meet that time frame (i.e., testing takes longer or labs have to retrieve archived records). Dyer notes that labs may request, in writing, a one-time 30-day extension and the request must provide the patient with a reason for the delay. In rare cases when tests will not be completed and available within the time frame and the individual still wants the report, the lab must provide access to the existing information in its designated record set at the time, minus the test report requested. Test reports are not considered part of the designated record set until they are complete.

4 Under HIPAA, individuals have a broad right of access to any or all of their information contained in a designated record set with a very limited exception. There is an exception if a licensed health care professional has determined, based on professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person.

Authentication

Laboratories are required under the HIPAA privacy rule to verify both the identity and authority of the person to have access to the individual's PHI. Laboratories are required to abide by an individual's request to have the lab transmit the copy of the person's PHI to another person or entity designated by the individual (i.e., a different doctor for a second opinion).

Labs are required to take reasonable steps to verify the identity of the individual making a request for access, but labs can't impose unreasonable verification measures as a means to avoid having to provide access. No particular form of verification is mandated by the rule; Kazon suggests the labs require the individual to supply some mix of specific data elements that only that person would know, which could include name, date of birth, the last four digits of their Social Security number, date of service, test name, address, insurance ID, ordering physician name and address, and billing statement number.

Essentially, there are two parts to the authentication: Does the person have the right to the information and, if so, is this the right information for this person? The lab will need to set up internal verification processes. While a request does not have to be made in writing, both Dyer and Kazon recommend that labs develop a request form that individuals complete and sign. This ensures that the lab has documentation and will help protect the lab from potential liability.

Takeaway: Laboratories have a fair amount of flexibility in how they handle patient requests for test information under the new rule. As of Oct. 6, 2014, labs must be prepared to provide access to all completed test reports, even those from previous years.

Editor's note: See the next issue of National Intelligence Report *for more on complying with the patient access rule.*

ACLA Seeks Reversal of NCCI Edit, *from p. 1*

According to Joanne Glisson, ACLA vice president, reimbursing a laboratory for one procedure, regardless of how many probes must be used for a test, results in inadequate compensation compared to the costs and fails to account for the resources associated with preparing and analyzing each probe in a properly conducted FISH test.

"As is reflected in the CPT code descriptors for FISH tests, there is a cost associated with preparation of each individual probe and with the preparation of each slide, both in terms of the technologist's time and the required materials," writes Glisson in a March 19 letter. "Purchasing two probes, even if they come together in one vial, typically costs double what it costs to purchase a single probe.

CPT Codes and Descriptors for FISH Tests

88365—In situ hybridization (e.g., FISH), each probe (do not report 88365 in conjunction with 88367, 88368 for the same probe).

88367—Morphometric analysis, in situ hybridization (quantitive or semi-quantitative), each probe; using computer-assisted technology.

88368—Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), each probe; manual.

"A pathologist or geneticist must analyze each fluorescent probe using single pass filters to determine the number of gene 'signals' in each cell; since each probe must be viewed individually, there are no efficiencies to be gained by analyzing all probes at once when the procedure is performed properly," she continues. "A pathologist or geneticist must then view all of the probes in concern through a filter that can detect all of the relevant colors in order to look for chromosomal abnormalities, interpret the findings, and issue a report."

ACLA is requesting that CMS rescind the NCCI policy, noting that when conducting FISH tests, two or more probes must be used for virtually all patient specimens. Multiple probes are necessary to see almost all chromosomal translocations, duplications, deletions, amplifications, and inversions, says Glisson. Additionally, for some disease tests, multiple probes must be performed on a series of slides due to limitations in the number of fluorophores available.

"We understand CMS's concerns about appropriate utilization of molecular diagnostic tests, and we would not oppose implementation of a reasonable edit that identifies claims submissions for FISH tests that clearly are wrong," writes Glisson. "However, the NCCI policy is too blunt an instrument for this kind of test, especially because multiple probes are essential to practically all FISH testing."

Takeaway: New NCCI edits limiting Medicare payment for FISH testing to one unit of service results in underpayment and should be replaced with more reasonable edits.

Coalition of Provider Organizations Urges Congress To Keep Stark In-Office Exception

A coalition of 31 provider associations March 18 called on Congress to keep the Stark law's in-office ancillary services exception (IOASE), which would be limited under the Obama administration's fiscal year 2015 budget proposal, according to a letter sent to the Senate Finance and House Ways and Means and Energy and Commerce committees.

"Limiting the IOASE would force patients to receive ancillary services in a new and unfamiliar setting, increase inefficiencies, present significant barriers to appropriate screenings and treatments, and make health care both less accessible and less affordable," said the letter, which was signed by the American Medical Association, the American College of Surgeons, and the American College of Cardiology, among other groups.

The Stark law, also known as the physician self-referral law, prevents Medicare self-referrals, which occur when a provider refers Medicare patients to entities with which the provider or his or her immediate family members have a financial relationship.

The IOASE allows physicians to provide certain services in their offices that normally would be prohibited under the Stark law, including imaging and physical therapy.

The administration's FY 2015 budget proposal carried over a provision from the FY 2014 budget proposal that would exclude certain services from the IOASE, including radiation therapy, therapy services, advanced imaging, and anatomic pathology (AP) services.

Along with the administration's proposal, Rep. Jackie Speier (D-Calif.) introduced a bill in August 2013 that would remove advanced imaging, anatomic pathology, radiation therapy, and physical therapy from the IOASE.

In December 2013, four Republican senators said the IOASE shouldn't be limited, according to a letter sent to Senate leaders.

However, the College of American Pathologists (CAP) supports removing AP services from the exception, noting that the IOASE was created to ensure patients could have easy access to a range of medical tests or services that inform diagnosis and treatment during the time of their physician visit, such as strep and glucose testing. However, CAP believes it was never intended to include AP services that involve a complex multistep process and analysis of a tissue specimen procured as part of a procedure to diagnose cancer or other diseases and conditions.

Coordinated Care

The provider coalition's letter said limiting the IOASE would reduce efforts to coordinate patient care and might lead to higher Medicare payments. "Legislatively prohibiting integrated practices from offering these ancillary services will only drive this care into the more expensive hospital setting," the letter said. For example, Medicare pays the same or more for advanced imaging provided by a hospital than for advanced imaging provided in a physician's office, the letter said.

The proposed IOASE limitations might also lead to more physician practices being purchased by hospitals, which might lead to higher costs. "Reducing the viability of the full spectrum of care being delivered in an independent outpatient setting will most likely centralize care around a few dominant hospital systems, which will undermine competition and in turn raise costs to the entire health care system over the long-term," the letter said.

It said utilization of radiation therapy, therapy services, advanced imaging, and AP services has decreased or plateaued over the past few years, meaning these services shouldn't be excluded from the IOASE.

Advanced imaging in physician offices experienced negative growth in 2012, the letter said, and Medicare payments for outpatient therapy in physician offices dropped from 9 percent of all outpatient therapy in 2002 to 4 percent in 2011.

Takeaway: Physician groups are fighting efforts by many lawmakers and pathologists to exclude anatomic pathology services from the in-office ancillary services exception to the Stark rule. G2

CMS Announces New Medicare Trip Fees for 2014

In a March 14 transmittal to local Medicare contractors, the Centers for Medicare and Medicaid Services (CMS) has set new allowances that clinical laboratories must use for reimbursement of travel to collect specimens from nursing home and homebound beneficiaries.

The travel codes allow for payment on either a per-mileage basis (P9603) or on a flat-rate per-trip basis (P9604). The travel allowance is intended to cover the estimated travel costs of collecting a specimen, including the laboratory technician's salary and travel expenses. Contractor discretion allows the contractor to choose either 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 contractors established local policy to pay based on a flat-rate basis only.

Under either method, when one trip is made for multiple specimen collections (e.g., 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 same time the claim is submitted by the laboratory or when the flat rate is set by the contractor.

Travel code P9603, paid on a per-mile basis where the average trip exceeds 20 miles, is 56 cents per mile, plus an additional 45 cents per mile to cover the technician's time and travel costs. Contractors have the option of establishing a higher per-mile rate in excess of the minimum $1.01 per mile if local conditions warrant it.

Travel code P9604, paid on a flat-trip basis, is $10.10. The flat-rate travel allowance is to be used in areas where average trips are less than 20 miles round trip. The specimen collection fee will be paid for each patient encounter. This rate is based on an assumption that a trip is an average of 15 minutes and up to 10 miles one way. It uses the federal mileage rate and a laboratory technician's time of $17.66 an hour, including overhead. While the new rates are effective as of Jan. 1, 2013, the implementation date is June 16, according to CMS Change Request 8641.

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