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INSIDE *NIR*

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Labs Advised Not to Delay Release of Test Results Under Patient Access Rule

While laboratories will have up to 30 days to provide patients with completed test reports following a request under the so-called "patient access rule," officials with the Centers for Medicare and Medicaid Services (CMS) say they expect that labs will deliver results as soon as the final report is available.

"Patients should be able to get their results immediately," says Karen Dyer, deputy director of CMS's Division of Laboratory Services, Survey and Certification Group. "Labs can't delay sending results."

According to the final rule giving patients access to their test reports, laboratories will be required to provide individuals with access to their laboratory reports within 30 days of the request. However, "with a very limited exception, covered entities may not deny an individual access to his/her health information based on the information's sensitive nature or potential for causing distress to the individual," says Dyer.

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Groups Weigh In on PFS; LCDs, 88185, Prostate Biopsy Code Among Concerns

Laboratory and pathology groups weighed in recently on proposed changes to the Physician Fee Schedule (PFS) for 2015. Chief among their concerns are proposed changes to the local coverage determination (LCD) process for lab tests, a proposal to use a single code for prostate biopsies, and plans to revalue CPT 88185 (flow cytometry, each additional marker).

In the rule issued July 3, the Centers for Medicare and Medicaid Services (CMS) proposed several significant changes to the LCD process for all clinical laboratory tests, including shortening the comment period, changing the requirement for a carrier advisory committee (CAC) meeting, specifying a timeline for publication of a final LCD, and changing timing of a new LCD taking effect.

Both the American Clinical Laboratory Association (ACLA) and the College of American Pathologists (CAP) oppose shortening the comment period on draft LCDs from 45 days to 30 days, saying that the current allotment of 45 days is often insufficient given that each of the

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Labs Advised Not to Delay Release of Test Results, *from p. 1*

Dyer's comments came in response to an article published in the August issue of *National Intelligence Report* detailing practical strategies that labs are planning to use to comply with the Oct. 6, 2014, compliance date for the patient access rule. The article was based on a July 31 webinar sponsored by G2 Intelligence.

During the webinar, Marguerite Busch, vice president and chief compliance officer for PAML, a large reference laboratory based in Spokane, Wash., suggested that labs consider delaying release of results to patients for 48 hours (or other time frame) after the ordering provider would have received the results. In the case of sensitive tests, Busch suggested that labs may want to delay release of results for 21 days. In both cases, the goal of the delay would be to give the referring physician time to discuss results with patients prior to their receiving the results.

While both of these scenarios technically fall within the requirements of the final rule, Dyer and Judy Yost, director of the Division of Laboratory Services at CMS, tell *NIR* that they do not comport with the "intent" of the rule, which is that patients receive results as quickly as possible. Dyer and Yost advise that labs not delay release of test results to patients for any reason.

CMS also clarified a statement made by *NIR* that labs must be prepared to e-mail test results upon request. "The HIPAA Privacy Rule does not require that a HIPAA-covered laboratory have the capability to produce a copy of a completed test report in whatever electronic format or manner the individual requests," the agency said in a statement. "The Rule allows a covered laboratory to make some other agreement with individuals as an alternative means to provide a readable electronic copy to the individual where the covered laboratory is not able to readily provide the form of electronic copy requested. If the individual declines to accept any of the electronic formats that the laboratory can produce, the laboratory must provide a hard copy as an option to fulfill the request."

For specific requirements under the new mandate, labs are advised to see the final rule, published in the Feb. 6, 2014, *Federal Register*.

CAP Opposes Proposals to Package Ancillary Services

The College of American Pathologists (CAP) has serious concerns with proposals by the Centers for Medicare and Medicaid Services (CMS) to package payment for certain pathology services into ambulatory payment classifications (APCs) under the Hospital Outpatient Prospective Payment System (HOPPS).

Under a rule released July 14, 2014, CMS is proposing to conditionally package payment for ancillary services which have a geometric means cost of $100 or less. This would include APC 0342, Level I pathology services. APC 0345, Level 1 transfusion laboratory services, and APC 0433, Level II pathology procedures. The agency is also proposing to package certain add-on services and certain pathology professional services.

In comments to the rule submitted Aug. 29, CAP says it believes that "CMS is again proposing an unwarranted and untested expansion of bundling without first taking adequate steps to define the proposals in sufficient detail to engage with stakeholders to understand the impact of the proposal on affected groups,

or to anticipate possible consequences that could adversely affect quality of care and access to services."

Specifically, CAP notes that CMS is proposing to package the technical components of more than 215 physician services, including more than 30 pathology physician services, without any way of determining whether these services will be appropriately reimbursed or if physicians will receive payment for their services at all in 2015.

"It is important to recognize that any of these services may often be medically necessary multiple times each day per primary service," the college writes. "Each of these services has different medically necessary utilization patterns based on each particular patient's specific conditions. To establish and apply a packaged reimburse rate that includes such services is likely to result in inaccurate and therefore, sometimes inadequate, compensation for services delivered."

CAP also noted that the packaging policies create significant administrative burden for pathology practices and would necessitate that many pathology practices receiving specimens from hospitals renegotiate their hospital contractual arrangements, which could result in another very substantial impact on the reimbursement of laboratory tests.

The college also opposes plans by CMS to package all add-on codes furnished as part of a comprehensive service as well as plans to reimburse Current Procedural Terminology codes 88187, 88188, and 88189 under the HOPPS schedule. "We are unclear why these services are included in the [H]OPPS as they relate to the physician's professional service of interpretation of flow cytometry," writes CAP. "These codes are generally billed by physicians rather than by facilities."

In addition, CAP questions the inclusion of the following three codes as unconditionally packaged under the proposed rule: 88380 (microdissection laser), 88381 (microdissection manual), and 88387 (tissue exam molecular study). "Other services in the molecular space that are packaged are on the clinical laboratory fee schedule while these services . . . are on the physician fee schedule."

Takeaway: The College of American Pathologists opposes proposals by Medicare to package payment for additional pathology services under the Hospital Outpatient Prospective Payment System.

Medicare Payments to Hospital Outpatient Labs Showing Huge Shift

Medicare payments to hospital outpatient laboratories made under the Clinical Laboratory Fee Schedule (CLFS) are expected to decline by more than 60 percent in 2014 as a result of many lab tests being bundled into hospital outpatient payment.

According to the Centers for Medicare and Medicaid Services' (CMS) 2014 Medicare Trustees Report, CLFS payments to hospitals will drop to $1.837 billion this year, down significantly from 2013 levels of $4.63 billion. However, Barry Portugal, president of Health Care Development Services Inc., notes that this is not a

real decline in payments but simply a shift from one Medicare bucket to another. Payments that previously had been made under the CLFS are now being bundled into ambulatory payment classifications (APCs) under the Hospital Outpatient Prospective Payment System.

"Our clients have reported that there is no appreciable drop in Medicare payment to outpatient labs," says Portugal.

Effective Jan. 1, 2014, CMS is packaging lab tests into outpatient payment "when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting." To be packaged, the lab tests have to be provided on the same date of service as the primary service and ordered by the same practitioner who ordered the primary service.

While Part B payment to hospital labs is expected to decline, Part B payment to hospitals is actually expected to increase from $37.217 billion in 2013 to $40.767 billion in 2014. Part of that increase is likely due to an increase in hospital outpatient payments.

Medicare Part B Spending on Lab Services (in billions)				
	2014*	***2013***	***2012***	***2011***
Hospital labs (intermediary)	$1.837	$4.630	$4.675	$4.420
Independent, POLs (carrier)	5.277	5.116	5.102	4.579
*Source: 2014 Medicare Trustees Report. *Estimated.*				

In terms of incurred reimbursement amounts per fee-for-service enrollee for intermediary services, outpatient lab payment is expected to drop from $129.97 per enrollee in 2013 to $47.11 per enrollee in 2014. On the flip side, however, outpatient hospital payment per enrollee is expected to increase from $1,057.88 per enrollee in 2013 to $1,190.53 per enrollee in 2014.

In a footnote for both categories, CMS notes that a large portion of outpatient laboratory services is now bundled into the Outpatient Prospective Payment System, one more indication that the money is simply being shifted from one bucket to another.

Part B spending for lab tests performed by independent labs and physician offices is expected to total $5.277 billion in 2014, up about 3.1 percent from 2013 levels of $5.116 billion. Altogether, Medicare Part B payment for lab services is estimated at $7.114 billion in 2014.

Total Medicare spending in 2014 is expected to increase by 4.9 percent to $611.7 billion when compared to 2013's spending of $582.9 billion. Lab spending as a percentage of Medicare is estimated at 1.2 percent in 2014, down from 1.7 percent in 2013 and 2012.

In 2014, the number of new Medicare beneficiaries increased by 3.3 percent to 54 million.

Takeaway: While Medicare Part B payment made to hospital outpatient labs under the CLFS is expected to drop significantly in 2014, the decline is being offset by an increase in payment to these labs under the Hospital Outpatient Prospective Payment System.

Groups Weigh In on PFS, *from p. 1*

Medicare administrative contractors (MACs) posts draft LCDs in a different place and communicates with stakeholders in a different manner, making it difficult for labs and other stakeholders to keep abreast of all the various proposals and develop comments within 45 days.

But ACLA and CAP differ on whether they think LCDs should become effective immediately upon publication. "Making the LCD effective immediately upon publication is a 'double edged sword,'" notes ACLA. While having an immediate effective date would make tests available to beneficiaries more quickly, in cases where a noncoverage determination is announced, "it can be difficult for laboratories offering the test to respond to such an abrupt policy change," says ACLA, which recommends that changes in coverage conditions continue to be effective 45 days after a final decision is made.

CAP, however, supports making the final LCD effective immediately upon publication "assuming that the agency does not shorten the current 45-days LCD comment period and provides adequate process transparency."

Currently, MACs are required to hold both open public meetings to discuss draft LCDs with interested parties and also to present the draft policy to the CAC. CAP opposes plans to have the sole authority to determine the necessity of a CAC meeting rest with a MAC, as the new rule proposes. ACLA suggests that CMS provide MACs with more guidance about the circumstances under which the CAC should be involved. At a minimum, CACs should be consulted on noncoverage LCDs and on LCDs that restrict coverage, it says.

Any changes to the LCD process for clinical laboratory tests should be consistent with Congress's goals in enacting the LCD provision in the Protecting Access to Medicare Act (PAMA), stresses ACLA, noting that CMS does not state whether or not articles may be used in lieu of LCDs to announce noncoverage of clinical laboratory tests. This has been a source of contention between MACs and labs for some time, especially as it relates to coverage decisions made by Palmetto under the Molecular Diagnostics Services Program.

Given the attention that Congress has paid to this issue, it is somewhat surprising that CMS would propose changes to the LCD process that reduce the procedural protections that currently apply to clinical laboratory LCDs, says ALCA.

"Articles are not subject to the same requirements as LCDs; therefore, when a contractor issues an article that effectively denies coverage for a test, affected laboratories do not have the same ability to comment or submit information on the test at issue," says ACLA. Section 216 of PAMA requires that for LCDs issued on or after Jan. 1, 2015, "a Medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination . . . including the appeals and review process for local coverage determinations."

Given the attention that Congress has paid to this issue, it is somewhat surprising that CMS would propose changes to the LCD process that reduce the procedural protections that currently apply to clinical laboratory LCDs, says ALCA. The association urges CMS to make clear in the final rule that articles may not be used to announce noncoverage decisions in lieu of an LCD.

Prostate Biopsy Code

CMS is proposing to use just one Healthcare Common Procedure Coding System (HCPCS) code—G0416—to describe all prostate needle biopsy procedures regardless of the number of specimens and regardless of the methodology (standard prostate

biopsy versus saturation prostate biopsy). It proposed to delete G0417, G0418, and G0419. CMS also is proposing G0416 as a potentially misvalued code and seeks input on the appropriate work relative value units, work time, and direct practice expense inputs.

"CMS continues to be completely misguided in its approach to these codes," says ACLA. "As we have discussed with the agency repeatedly, HCPCS codes G0416 through G0419 originally were developed to apply to a relatively rare procedure, prostate needle biopsies, which are done under general anesthetic and involve biopsy of the entire prostate in order to determine if previously diagnosed prostate cancer is spreading.

CAP also believes CMS should use CPT 88305 for prostate biopsies, urging the agency to withdraw its proposal to use G0416 for the pathology of all prostate specimens.

"However, last year, CMS decided to apply these codes to a standard biopsy, which is a far more common procedure, done under local anesthetic, and which involves taking fewer biopsies to determine if cancer could be present in the first instance," ACLA continues. "These latter types of procedures always previously were billed under CPT 88305. It is inappropriate for CMS to treat these two vastly different procedures as the same and to include them under the same HCPCS code."

ACLA also argues that the code should not be considered a misvalued code. CMS notes that most prostate biopsies are billed for 10 to 12 biopsies. The current rate for the G code is $651.26, or about $54.25 per specimen, for a standard 12-biopsy specimen. The reimbursement rate already is almost 30 percent below the level that ACLA believes is appropriate, which would be 12 units of 88305, or approximately $847, the association says.

"CMS has failed to explain why it believes that a significant reduction in HCPCS code G0416 may be appropriate when it bundles the codes together," writes ACLA. "Moreover, CPT 88305 itself was significantly reduced several years ago, on the basis that is was misvalued; therefore, to reduce the payment even further below the current levels seems unwarranted."

CAP also believes CMS should use CPT 88305 for prostate biopsies, urging the agency to withdraw its proposal to use G0416 for the pathology of all prostate specimens. "We believe that the additional revaluation and scrutiny finalized by the agency in the 2014 final rule for surgical pathology code 88305, together with greater granularity in payment, addresses the agency's intent to establish straightforward coding and accurate payment for these services," says the college in its comments.

CPT 88185

CMS says it intends to revalue CPT 88185. ACLA is calling on CMS to withdraw its proposal to review 88185 as a potentially misvalued code, arguing that the agency has not said why it thinks the code is misvalued other than it is one of the "top 20 codes by specialty in terms of allowed charges." If CMS does intend to adopt a new valuation for 88185, "despite its inappropriate selection as a potentially misvalued code, it should do so using the process it is proposing for valuation of new, revised, and potentially misvalued codes," says ACLA. The new valuation should be published for comment in the 2016 PFS proposed rule, rather than in the 2015 PFS final rule.

The final PFS rule for 2015 is expected to be published on or around Nov. 1, 2014.

Takeaway: Industry groups oppose several proposed changes to Medicare policies for 2015, including policies that govern the way LCDs are issued and challenged.

Texas Lab Must Repay Government $10.6 Million for Illegal Travel Expenses

A Texas laboratory must pay the federal government more than $10.6 million in travel expenses for which it illegally billed the Medicare program but that didn't incur, the U.S. District Court for the Southern District of Texas ruled Aug. 21 (*United States ex rel. Drummond v. BestCare Lab. Servs. LLC*).

The court granted partial judgment to the United States in a whistleblower action brought by a competitor of the defendant laboratory under the False Claims Act and the Texas Medicaid Fraud Prevention Act.

Under Medicare billing provisions, the court explained, laboratories may bill the United States $1 per mile that their workers travel to collect specimens from patients. The fee covers "the transportation and personnel expenses" for a worker to travel to the patient to collect the sample and return. The amount is based on the number of miles traveled and personnel costs associated with collection.

Defendant BestCare Laboratory Services LLC operates a diagnostic laboratory in Webster, Texas, a suburb of Houston, where it tests specimens, primarily from disabled and elderly patients. It took advantage of this Medicare billing provision by sending specimens from its branches in Dallas, San Antonio and El Paso, Texas, to Houston for testing. BestCare's workers didn't travel from these cities to Webster with the specimens.

They shipped the specimens on flights to Houston for roughly $100 per batch. A different worker from the Webster laboratory retrieved the batches from Houston's airport.

Workers Didn't Travel

Despite the fact that BestCare's workers didn't accompany the specimens to Webster, the company billed Medicare as if they had, in one instance billing Medicare $1,500 in travel expenses for a $43 blood test.

BestCare also billed for each specimen separately by calculating the maximum number of miles that its worker could theoretically have driven to retrieve them. In reality, the worker retrieved many specimens in a single trip and didn't travel back to the laboratory after collecting each specimen.

The court rejected BestCare's contention that the rule doesn't say that the sample has to be conveyed by a person, calling it "an argument that would embarrass a middle-school debater."

BestCare argued that the Medicare third-party contractors—hired by the United States to administer Medicare—approved and paid the claims.

"That is true," the court said. "That they erred does not excuse BestCare's dishonest predicate to their error. Bad advice from a Medicare contractor does not bind the people of the United States."

The manuals that Medicare contractors gave BestCare stated that it couldn't bill for these expenses, the court said, and they explained that the travel allowance is intended to cover the "estimated travel cost and technician's salary associated with collecting the specimen."

A 2007 addition to the manual specifically states that laboratories can't bill "for miles not actually traveled by the laboratory technician," the court emphasized.

Takeaway: Laboratories cannot bill Medicare for miles that lab technicians did not actually travel. Doing so can result in significant penalties.

FDA Official Defends Plan to Issue Guidance for LDTs

Jeffrey Shuren, director of the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH), this week defended the agency's plans to issue draft guidance on laboratory-developed tests (LDTs).

A Sept. 9 hearing of the House Energy and Commerce Health Subcommittee regarding the FDA's intention to issue draft guidance on LDTs turned somewhat testy, as some Republican members accused the FDA of trying to sidestep the formal rulemaking process.

Shuren faced questions from several Republican members about the FDA's intention to release draft guidance that will describe the agency's plans to oversee and regulate diagnostic tests manufactured by clinical laboratories and medical device companies.

Rep. Michael C. Burgess (R-Texas), along with other members of his party, asked Shuren if the FDA held the authority to now propose new LDT regulations without going through the formal rulemaking process. Shuren said that the changes proposed to the LDT regulations don't require the agency to follow the formal rulemaking process and that the FDA will release the draft guidance within 30 days.

Shuren Defends Guidance

Shuren spent a large part of his testimony defending the agency's decision to issue guidance instead of a formal rule. While questioning Shuren, Rep. Joe Pitts (R-Pa.), the Health Subcommittee chairman, said the guidance marks a significant change of policy regarding LDTs and asked the CDRH director why the agency didn't need to follow the Administrative Procedure Act when it announced its intention to regulate tests made by clinical laboratories.

According to Shuren's testimony, all diagnostic tests have been subject to FDA regulation since the passage of the Medical Device Amendments in 1976. However, Shuren said that since 1976, the agency exercised "enforcement discretion" of LDTs—that is, the FDA generally didn't enforce applicable requirements for the tests—as they were limited in number, were relatively simple tests, and typically were used to diagnose rare diseases and uncommon conditions. Shuren testified that the agency doesn't need to complete formal rulemaking because the FDA is only changing its enforcement policies for LDTs.

Several subcommittee members of both political parties asked Shuren to comment on the guidance's potential to discourage investment in diagnostic tests. Shuren responded that the FDA will continue to use its enforcement discretion and will only regulate tests that carry the highest risk.

In written testimony, Shuren said, "FDA intends to continue to exercise enforcement discretion for many LDTs—including those that are low risk, for rare diseases, and for unmet medical needs," adding, "Our upcoming proposal would incentivize innovation, and would also support the advancement of personalized medicine by assuring that patients and their physicians can rely on LDT results for making major medical decisions."

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