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CCLA Sues HHS Over Noncoverage of Lab Tests, Seeks to Have LCDs Declared Invalid

Frustrated by Medicare local coverage determinations (LCDs) that effectively deny patients access to critical lab testing, the California Clinical Laboratory Association (CCLA) on April 18 filed a lawsuit against the Department of Health and Human Services (HHS) asking that the LCD process and resulting LCDs for laboratory services to be declared invalid and unenforceable.

The complaint, filed by the law firm of Hooper, Lundy, and Bookman PC (Los Angeles) on behalf of CCLA and an unnamed beneficiary, charges that Medicare Administrative Contractors (MACs) continue to develop and apply local coverage determinations that result in policies depriving Medicare beneficiaries throughout the country of critically necessary clinical laboratory services.

"Today the MACs have a stranglehold on critical, cost-effective innovation," said Patric Hooper, the lead attorney for the plaintiffs. "Our clients have been forced to bring this lawsuit to bring attention to, and change, the current practice of denying coverage for critically

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HOPPS Lab Test Packaging Policy Anything but Clear

A new policy on packaging of laboratory tests provided to hospital outpatients is creating confusion among laboratories as directives from the Centers for Medicare and Medicaid Services (CMS) explain the new policy using different terms.

Under the new packaging policy, which went into effect Jan. 1, 2014, certain clinical laboratory tests are to be packaged (or bundled) into the payment for the primary service performed in a hospital outpatient setting.

According to the final Hospital Outpatient Prospective Payment System (HOPPS) rule issued last December, the Centers for Medicare and Medicaid Services (CMS) will package laboratory tests "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 would 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. Molecular pathology tests are exempt from this packaging policy.

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CMS issued instructions to contractors on Dec. 27, 2013, and followed it with an *MLN Matters* (*MLN*) shortly thereafter. The problem, says Robert Mazer, an attorney with Ober | Kaler (Baltimore) is that there are inconsistencies in the instructions regarding which laboratory services have to be packaged by the hospital and which services can be billed individually under the Clinical Laboratory Fee Schedule. In addition, neither adequately explains when a laboratory test must be billed by the hospital, particularly when the test is performed by a lab that is not part of the hospital.

Instructions to Contractors

According to *MLN* article SE1412, effective Jan. 1, 2014, packaged payment would apply to all lab tests (other than molecular pathology) billed by OPPS hospitals on a 013X type of bill (TOB; hospital outpatient). Initially, CMS said that in limited exceptions, hospitals could use the 014X TOB (hospital nonpatient) to obtain separate payment in only the following circumstances:

1. Nonpatient (referred) specimen;
2. A hospital collects specimen and furnishes only the outpatient labs on a given date of service; or
3. A hospital conducts outpatient lab tests that are clinically unrelated to other hospital outpatient services furnished the same day. "Unrelated" means the laboratory test is ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services, for a different diagnosis.

However, since the release of Change Request 8572, some hospitals expressed concern that submitting a 014X TOB could violate the Health Insurance Portability and Accountability Act. The National Uniform Billing Committee definition approved in 2005 for the 014X TOB for billing of lab services provided to nonpatients means referred specimen, where the patient is not present at the hospital.

To alleviate this concern, CMS is implementing a new modifier that will be used on the 013X TOB (instead of 014X TOB) when nonreferred lab tests are eligible for separate payment under the Clinical Laboratory Fee Schedule (CLFS) for exceptions 2 and 3 listed above. The 014X will only be used for nonpatient, referred laboratory specimens (exception 1 above) and will not include this new modifier. The new modifier will be effective for claims received on or after July 1, 2014, and retroactive for dates of service on or after Jan. 1, 2014. Until July 1, 2014, providers can continue to use the 014X TOB.

According to CMS, it will continue to be the hospital's responsibility to determine when laboratory tests qualify to receive separate payment. Starting with claims received after July 1, 2014, when a hospital appends the new modifier to the laboratory service, the provider is attesting that exception 2 or 3 listed above is met. The requirement for all OPPS services to be submitted on a single 013X claim (other than recurring services) continues to apply.

Potential Inconsistencies

One issue that remains confusing is what tests are required to be billed by the hospital when the tests are performed by another laboratory, says Mazer. For example, is a hospital responsible for billing for a diagnostic test if a hospital patient leaves the hospital and goes elsewhere to obtain the test? And what about cases where the hospital has outsourced lab services to freestanding providers furnishing services on hospital grounds or the patient elects to receive services from a lab that is not part of the hospital?

In the preamble to the final HOPPS rule, CMS stated that a freestanding entity (one that is not provider-based) may bill for services furnished to beneficiaries who do not meet the definition of a hospital outpatient at the time the service is furnished. The bundling or packaging requirement, said CMS, applies to services furnished to a "hospital outpatient" during an "encounter" as defined by the Medicare regulations. Implementing instructions, however, require hospitals to bill for diagnostic services that are ordered during or as a result of an encounter that occurred while the individual was an outpatient. The hospital is required to bill if the patient is directed to another entity for testing. Instructions are intended to be consistent with related regulations, so they should not generally be disregarded. The differences in terminology, notes Mazer, could lead to different interpretations and different results.

Mazer advises hospitals to make appropriate efforts to ensure that they are billing for all tests for which Medicare will pay only the hospital and to make certain that payment is not being claimed for those services by another entity, such as a lab that may have performed outpatient reference tests.

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Is Packaging Optional?

Another source of confusion is a note in *MLN* article 1412, which states:

> Under the CY 2014 OPPS final rule, it is optional for OPPS hospitals to seek separate payment under the CLFS for a given outpatient lab test. To minimize administrative burden, OPPS hospitals are not required to distinguish related and unrelated outpatient lab tests and may bill "unrelated" outpatient labs on the 013X TOB prior to July 1, 2014, or on the 013X TOB without the new modifier on or after July 1, 2014, to receive packaged payment under the OPPS.

Mazer believes that the only reasonable interpretation for this statement is that hospitals have the option *not to seek* separate payment under the CLFS for an outpatient lab test for which such payment is available. "Hospitals *are not* afforded, however, the option of disregarding the packaging requirements where applicable and claim separate payment for lab tests under the CLFS," he writes in a *Payment Matters* article distributed to clients.

Sole Community Hospitals

Sole community hospitals (SCHs) are paid under the OPPS. However, SCHs with qualified laboratories continue to be eligible for the 62 percent CLFS payment amount described in the Medicare Claims Processing Manual when they furnish outpatient lab tests that are separately payable under exception 2 and 3 listed above. The 014X TOB does not provide differential CLFS payment rates for SCHs with qualified labs and other OPPS hospitals. Thus, qualified SCHs must submit a 013X TOB with the new modifier appended to separately payable outpatient lab services in order to obtain the 62 percent CLFS payment amount provided in current manual instructions. CMS is permitting SCHs to wait until the new reporting methodology goes into effect on July 1, 2014, to submit claims for payment.

Review of Claims Data

CMS will be reviewing claims data for 2014 for potential unbundling of laboratory services under the new OPPS packaging policy. As stated in the OPPS final rule, CMS does not expect changes in practice patterns under the new policy. Hospitals may not establish new scheduling patterns in order to provide laboratory services on separate dates of service from other hospital services for the purpose of receiving separate payment under the CLFS, says CMS.

Takeaway: Implementing instructions for Medicare's new policy under which lab tests provided to hospital outpatients are packaged with payment for a primary service are anything but clear.

Industry Groups Applaud New CBO Score On Closing Stark Loophole

Laboratory and pathology groups are applauding the latest scoring of potential Medicare savings that could be achieved if lawmakers exclude anatomic pathology (AP), advanced diagnostic imaging, physical therapy, and radiation therapy from the in-office ancillary services (IOAS) exception to the federal self-referral statute.

The Congressional Budget Office (CBO) estimates that excluding these services from the IOAS exception would generate $3.4 billion in savings for the Medicare program, an increase of $1.6 billion from an earlier score of $1.8 billion. The latest figure is included in the April 17 CBO score of President Obama's 2015 budget proposal.

The Alliance for Integrity in Medicare (AIM), which includes the American Clinical Laboratory Association and the College of American Pathologists (CAP), said in a statement released the same day that it commends the administration not only for including IOAS reform for a second year in its budget proposal, but also for adding AP services to the proposed list of excluded services in fiscal 2015.

"The savings estimate released by CBO for narrowing the IOAS exception definitively validates that unnecessary expenditures by the Medicare program would be reduced if Congress would enact the President's recommendation," said the statement.

Several studies from the Government Accountability Office and independent research have shown that the existing IOAS physician self-referral loophole results in increased spending and unnecessary utilization. AIM is urging lawmakers to pass legislation such as H.R. 2914 that would remove AP, advanced diagnostic imaging, radiation therapy, and physical therapy from the IOAS exception.

Separately, a coalition of 31 provider associations has called on Congress to keep the exception the way it is, arguing that any limits would force patients to receive ancillary services in a new and unfamiliar setting, increase inefficiencies, and present significant barriers to appropriate screening and treatment.

Lab and pathology groups have long been at odds with physician specialists over the IOAS exception. CAP has argued that the exception was never intended to include AP services that involve a complex multistep process and analysis of a tissue specimen produced as part of a procedure to diagnose cancer or other diseases and conditions.

Takeaway: The latest scoring by the Congressional Budget Office of savings associated with removing anatomic pathology and other services from the in-office ancillary services exception helps support arguments made by lab and pathology groups that the exception should be narrowed.

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important laboratory services. In addition, the same private insurers who make determinations for Medicare also make determinations in the private market, so the entire population is affected."

At issue are coverage policies determined by MACs without any input from the laboratory community or beneficiaries. In many instances, lab tests are denied Medicare coverage despite the fact that the secretary of HHS has failed to implement the statutory procedures required by Congress, including a procedure for ensuring the nationwide consistency of LCDs and a mediation process mandated by law. What's more, HHS has "eliminated any meaningful opportunity for laboratories to administratively appeal the application of LCDs to laboratory services by unilaterally suspending the only portion of the administrative appeal process where laboratories have any chance of avoiding the impact of adverse LCDs and of obtaining coverage for a laboratory service for a particular Medicare claim," said the complaint, filed in federal district court in the District of Columbia.

In many instances, lab tests are denied Medicare coverage despite the fact that the secretary of HHS has failed to implement the statutory procedures required by Congress, including a procedure for assuring the nationwide consistency of LCDs and a mediation process mandated by law.

Of particular concern are noncoverage policies issued by MACs of molecular diagnostic tests, which often enable personalized protocols for treatments such as chemotherapy. The complaint cites as an example an LCD issued by Palmetto in 2011 that "drastically changed the standard for coverage for molecular diagnostic testing. Under this LCD . . . Palmetto confirmed its policy of 'noncoverage' for all molecular diagnostic tests that are not explicitly covered by [a national coverage decision], an LCD, or a coverage article published by Palmetto." In January 2014, despite opposition from lab and pathology groups, Palmetto finalized another LCD stating that unless a molecular diagnostic test is expressly approved by Palmetto, it would be considered noncovered.

Drug Testing Also an Issue

The laboratory LCDs are not limited to molecular diagnostic testing. The complaint notes that MACs have issued LCDs affecting coverage of laboratory testing for drugs of abuse, with different MACs developing different coverage policies for such testing over the objections of various stakeholders. Proposed LCDs will disallow coverage for all confirmatory drug testing ordered by physicians by patients suspected of using illicit drugs if a less comprehensive screening test showed negative results for drug use.

"This policy is inconsistent with the standard of medical practice regarding testing for drug abuse," says the complaint. "In fact, the Florida and Kentucky Attorneys General and the Florida Assistant Secretary for Substance Abuse and Mental Health submitted comments to the MAC about how destructive this policy will be to efforts throughout the country to stop the abuse of heroin and prescription pain medications and 'would walk the science back' by disallowing confirmatory quantitative laboratory testing of the less sensitive cup tests as physicians attempt to combat prescription drug abuse."

Specifically, the complaint asserts that:

- ❑ Congress has unlawfully delegated regulatory power to the MACs;
- ❑ MACs have implemented Medicare policy without following required federal rulemaking requirements;
- ❑ MACs have developed LCDs based on criteria they are not permitted to consider;

- HHS has eliminated any meaningful opportunity for laboratories to administratively appeal the application of LCDs and has not established a required mediation process; and
- HHS has not developed an effective plan to evaluate the appropriateness of adopting new LCDs nationally, as noted recently by the Office of Inspector General.

Takeaway: A lawsuit filed by the California Clinical Laboratory Association seeks to have the current system used by Medicare contractors to develop local coverage policies declared invalid. G2

OIG Terminates Earlier Opinion on EHR Referral Fee, Concludes Fee Could Generate Improper Referrals

The Department of Health and Human Services Office of Inspector General (OIG) April 8 terminated a December 2011 advisory opinion (No. 11-18) that found a low risk of improper inducement of referrals from a fee arrangement in an electronically facilitated patient referral service.

The OIG previously said the requesting service provider's proposed fee discount of up to $1 for referrals to providers within its network (called "trading partners") was too small to cause any improper referral inducement. Although the OIG redacts its opinions, athenahealth Inc. announced separately it had requested the opinion.

The laboratory testing company said that it received feedback from some of its physician clients that explicitly stated they would only continue to use the requestor's services with their normal frequency if the laboratory testing company became an athenahealth trading partner.

The electronic referral service created by athenahealth allows physicians to make referrals directly through athenahealth's electronic health record (EHR) service and receive patient results automatically through an EHR as well.

The OIG's notice of termination said it reconsidered its stance, saying the discount could create an improper incentive for physicians to make federal health care program referrals to athenahealth trading partners over nontrading partners for certain high-volume referral services such as laboratory testing.

Related Laboratory Service Opinion

The OIG also released a related advisory opinion (No. 14–03) concerning the fee arrangement that was requested by an unnamed laboratory testing company that entered into a trading partner arrangement with athenahealth.

The OIG indicated that the fee arrangement could potentially generate compensation prohibited under the anti-kickback law. The OIG said physicians referring laboratory testing work through athenahealth's service could avoid paying the fee if they referred service to a trading partner like the laboratory testing company that requested the opinion but were responsible for the fee themselves if they referred the tests to a nontrading partner. The OIG said this fee structure "could potentially influence" physician referrals "in a material way."

The OIG said that the arrangement "appears to permit Requestor to do indirectly what it cannot do directly; that is, to pay compensation to the Referring Physicians" in the form of the fee discount in exchange for laboratory testing service referrals. The OIG said "there appears to be no reason for [the requestor] to pay the Per-Order Fees other than to secure referrals."

The laboratory testing company said that it received feedback from some of its physician clients that explicitly stated they would only continue to use the requestor's

services with their normal frequency if the laboratory testing company became an athenahealth trading partner. The OIG cited this feedback in reiterating its concern that the fee would prove to be an inducement of provider referral choice for high-volume referral services like the requestor's laboratory testing services.

athenahealth Responds

In an April 8 statement, athenahealth Executive Vice President and Chief Operating Officer Ed Park called the OIG's termination of its earlier advisory opinion a "setback" that "closes one promising path forward to a functioning, sustainable economic model for health information exchange."

Dan Haley, athenahealth's vice president of government and regulatory affairs, said that the termination notice wouldn't have any immediate impact on providers using its referral service. Haley said athenahealth was working on modifications to its service that made sure "we and our clients comply with the letter and the spirit of the law." He also said the changes were being made to minimize impact on clients and to preserve "the progress we've made toward building a national care coordination network."

Haley took issue with the OIG's rejection of its prior analysis over physician inducement concerns. Haley said "[t]hat concern was fully analyzed in the original advisory opinion" and that the OIG's original analysis "remains valid and convincing."

Referring specifically to the assertion made in the advisory opinion about physicians redirecting referrals from the requesting laboratory service, Haley said they were "anecdotal inputs from a commercially interested actor." He said athenahealth had not heard of any similar statements from physicians and that while "we have no reason to believe those anecdotal representations are accurate," athenahealth had no way to assess their veracity.

Park defended the fee discounts as simply the cost of facilitating the exchange of patient information between providers. Park likened the fee difference for trading partners and nontrading partners to the fees some banks charge to ATM customers from other banks.

The OIG said in both its termination notice and newly issued advisory opinion that it believed "the efficient exchange of health information between health professionals is a laudable goal." However, the OIG said the fee structure "includes potentially problematic financial incentives" and has "more than a minimal risk of fraud and abuse under the anti-kickback statute."

Possible Legislative, Regulatory Action

Haley said that athenahealth's goal was to create a nationwide market that other actors could participate in as well and that ultimately regulatory or legislative action would be necessary to achieve that goal.

"The safe harbor that the OIG opinion created for us [under the anti-kickback law] is precisely the same safe harbor that is applied by regulation and statute in any context where the goal is care coordination," Haley said.

Haley said OIG's actions "handed us a really good argument for why it is that a fundamental paradigm shift can't come from an advisory opinion, because it's too uncertain a foundation on which to build a new model." Haley said there has been significant interest from legislators in both parties and he "would not be surprised to see" some formal action this year in expanding the network model.

Takeaway: The OIG says that an electronic referral service fee could potentially generate improper referrals, especially for high-volume services such as laboratory testing.

Hospitals Sue CMS Over 'Two-Midnight' Rule

In two related lawsuits filed April 14, the hospital industry challenged the Department of Health and Human Services' (HHS's) "two-midnight" rule for inpatient admissions, which the industry says imposes regulatory burdens that could compromise care for seniors.

In one complaint filed in the U.S. District Court for the District of Columbia, the American Hospital Association (AHA), other groups, and individual hospitals challenged an August 2013 HHS policy for determining when a patient is an "inpatient" for purposes of Medicare reimbursement (*Am. Hosp. Ass'n v. Sebelius*, D.D.C., No. 1:14-cv-609, *filed* 4/14/14).

The AHA's filing said that this "new rule provides that a Medicare beneficiary is not an 'inpatient' unless the admitting physician expects that beneficiary to need care in the hospital for a period spanning two midnights." The August 2013 rule was scheduled to apply to fiscal year 2014 payments.

In a statement from the AHA, the plaintiffs said hospitals "take issue with the wholly arbitrary requirement that a physician must certify at the time of admission that a Medicare patient is expected to need care in the hospital for a period spanning two midnights to be considered an inpatient."

Series of Delays

The final two-midnight rule, promulgated because of concerns that hospitals were overusing observation status, has been controversial from its inception, with hospitals and lawmakers seeking implementation delays and reconsideration immediately after the rule was first issued in final form.

The rule was scheduled to take effect on Oct. 1, 2013, but enforcement has since been delayed on multiple occasions. The Centers for Medicare and Medicaid Services (CMS) initially gave affected providers a three-month grace period and thereafter extended the audit-free transition period through March 31. Another delay, announced Jan. 31, extended the enforcement delay through Sept. 30.

Only weeks ago, Congress passed and President Barack Obama signed a law that extended the enforcement moratorium on the two-midnight rule through March 2015. With the extension, and on top of the delays already implemented, Medicare Recovery Audit Contractors (RACs) won't be able to audit inpatient hospital claims from Oct. 1, 2013, through March 31, 2015.

Although implementation of the two-midnight rule has now been delayed, an AHA spokeswoman said the delay does not resolve the issues raised in their lawsuits. Although RACs will not conduct patient status reviews for dates of admission between Oct. 1, 2013, through March 31, 2015, during this time CMS will conduct limited prepayment "Probe and Educate" audits to determine a provider's compliance with the requirements of the two-midnight rule, the spokeswoman noted. "Essentially, this means that hospitals must now comply with the requirements of the rule," she said.

Takeaway: Hospital groups believe HHS's "two-midnight" rule for inpatient admissions undermines patient care.

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