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INSIDE *NIR*

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CMS Reaches Different Conclusions on Provision of Pap Smear Collection Supplies

In two separate advisory opinions issued in October, the Centers for Medicare and Medicaid Services (CMS) reached different conclusions regarding the provision of liquid-based Pap smear collection kits and biopsy brushes by laboratories to referring physicians.

In one opinion (AO-2013-02) CMS says it is a violation of Stark law for a laboratory to provide free disposable cervical biopsy brushes to referring physicians. In another opinion (AO-2013-01) the agency says it is legal for a lab for provide free Pap smear collection kits to clinicians.

Requestors in both cases certify that the items provided are used solely to collect Pap smears and that they have procedures in place to monitor the number of items provided and the number of Pap smears received to ensure they are not providing excessive supplies the physician can use for other purposes.

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Court Dismisses Lawsuit Against Quest, LabCorp

The U.S. District Court for the Eastern District of Virginia has dismissed a whistleblower lawsuit filed against Quest Diagnostics and Laboratory Corporation of America by Hunter Laboratories, saying that Virginia law does not require laboratories to charge Medicaid their lowest rates.

The lawsuit, *Hunter Labs LLC v. Quest Diagnostics*, was originally filed in 2007 but was only recently unsealed. Hunter Labs and former Chief Executive Officer Chris Riedel have pursued complaints against the large national laboratories in several states. Riedel won a settlement against Quest and LabCorp in 2005, claiming they overbilled California's Medicaid program. The two labs eventually settled the suit for a combined $290.5 million.

Hunter Laboratories is now owned by Bio-Reference Laboratories (Elmwood Park, N.J.). Riedel is now CEO of HunterHeart Inc.

In the Virginia case, Hunter alleged that Quest and LabCorp violated the Virginia Fraud Against Taxpayers Act by billing the state Medicaid program at rates above the maximum allowed under Virginia regulations. The relator also alleged that the defendants violated the federal anti-kickback statute (AKS) by offering illegal discounts on rates for private-pay patients in order to "pull through" Medicaid business.

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CMS Reaches Different Conclusions, *from p. 1*

Collection Kit OK

In the first advisory opinion, the requestor states that it creates a Pap smear collection kit by packaging one or two collection tools with a vial of fixative and labeling the kits with the lab's name and brand. All components of the kit are Food and Drug Administration (FDA)-cleared, disposable, single-use instruments used to collect specimens for Pap smear examination or liquid-based cytology. Under the proposed arrangement, the lab would provide the kits to referring physicians at no charge.

In its analysis, CMS concludes that the collection kits are not "surgical items, devices, or supplies" for purposes of the physician self-referral law. Information publicly available from the manufacturers of the component parts of the kits indicates that the collection tools are all disposable and intended for a single use only, the agency notes.

In its analysis, CMS concludes that the collection kits are not "surgical items, devices, or supplies" for purposes of the physician self-referral law.

Based on the specific facts provided by the requestor, CMS concludes that the arrangement would not result in remuneration to referring physicians and therefore would not violate the physician self-referral law. However, CMS also notes that the provision of a kit containing a collection tool that is not a "single-use" item could result in a different conclusion.

Biopsy Brush Not OK

In the second advisory opinion, the requestor is a lab that provides a patented, sterile, disposable, single-use biopsy brush used to obtain tissue from areas of the cervix appearing to be abnormal during vaginal examinations. The device is intended as an alternative to the traditional punch biopsy, which pierces and removes tissue to obtain a sample for testing.

The requestor certified that the CPT code reported to document the collection of specimens using the biopsy brush is the same as that used to document collection via punch biopsies (CPT 57454). According to the requestor, when the device is used, its tip is broken off and sent to the laboratory in a small specimen bottle with formalin to preserve the specimen. The device cannot be reused.

In its analysis, CMS concludes that the biopsy brush is a "surgical item, device, or supply." According to CMS, the FDA defines a "manual surgical instrument for general use" as a nonpowered, handheld, or hand manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. Under the relevant provision, the FDA lists approximately 50 types of devices intended for use in various surgical procedures, including a biopsy brush.

In reaching its conclusion, CMS also considered the intended purpose of the device and whether it is "routinely used as part of a surgical or medical procedure." Because all biopsies are categorized by the American Medical Association as surgical procedures, and in light of the agency's review of the 510(k) premarket notification, CMS concludes that the biopsy brush is routinely (if not predominantly) used as part of a surgical procedure.

Based on the facts presented, CMS concludes that the proposed arrangement would result in remuneration to referring physicians and thereby create a "compensation arrangement" that implicates the physician self-referral law.

'Rumeneration' Definition Key

Robert Mazer, Esq., an attorney with Ober | Kaler (Baltimore), says that even though CMS reached different conclusions in the advisory opinions, they are not neces-

sarily inconsistent with one another under the definition of "remuneration" under the Stark regulations.

"The opinions indicate that there may be no 'one size fits all' rule as to whether a particular item, device, or supply that may be used to obtain a laboratory specimen can be given to physicians"
—Robert Mazer, Esq., Ober|Kaler

The Stark statute excludes from the definition of remuneration items, devices, or supplies that are used solely to collect specimens for the entity providing them to the physician. The definition of remuneration in the Stark regulations is similar, with one significant exception, notes Mazer. The regulations specifically state that "surgical items, devices, or supplies" can not be excluded from the definition of remuneration.

"The opinions indicate that there may be no "one size fits all" rule as to whether a particular item, device, or supply that may be used to obtain a laboratory specimen can be given to physicians," says Mazer. "Instead, laboratories will be required to analyze the particular use of the item, device, or supply and how related procedures are coded by physicians who use them. This may require knowledge regarding medical procedures other than pathology, which a laboratory may or may not have in-house."

Takeaway: Laboratories may provide referring physicians with Pap smear collection kits without fear of violating the physician self-referral law, but provision of biopsy brushes would implicate the law. Labs need to evaluate provision of supplies to physicians on a case-by-case basis.

Doc Fix Proposal Pushes Electronic Health Records

Leaders of the Senate Finance Committee and the House Ways and Means Committee have released a discussion draft of a bill that would replace the sustainable growth rate (SGR) formula, which was intended to control the growth of payments to physicians under Medicare.

It is the second major proposal this year that would repeal the SGR and the second such effort that omits a means of paying for it. Passage of an SGR repeal would remove the need for the frequent legislative "doc fixes" that have been a short-term patch preventing SGR-mandated cuts to Medicare physician payments.

Unlike preceding bills that would end the need for annual doc fix legislation, one of the distinguishing features of this proposal is its focus on using adoption of electronic health records (EHRs) systems as an incentive.

Under the proposal, up to one-quarter of the score used to adjust payments to Medicare providers would be based on how well a provider meets certain standards for meaningful use of EHRs. Meaningful use requirements range from maintaining basic information on patient demography and vital signs to ensuring electronic access to external and internal drug formularies.

Such a requirement could be a problem for pathologists, who have limited direct interaction with patients and generally use laboratory information systems, not EHRs. The College of American Pathologists previously urged the Centers for Medicare and Medicaid Services (CMS) to grant pathologists a full five-year exception from meeting current meaningful use requirements of EHRs. CMS has granted pathologists a hardship exception from penalties in 2015, but the exception is only for one year at a time, up to five years.

Through September, CMS spent nearly $3.95 billion on incentive payments to Medicare providers to encourage adoption of EHRs. The House-Senate bill is clearly trying to leverage this investment.

The latest doc fix proposal has the potential to boost growth and solidify market share in the EHR market for vendors with proven track records of achieving meaningful use for their clients.

Nearly 53 percent of the physicians who have received meaningful use incentive payments use software from five companies: Epic Systems Corp., Allscripts Healthcare Solutions Inc., eClinicalWorks LLC, NextGen Healthcare Information Systems Inc., and General Electric Co.

Previous Legislation

Like H.R. 2810, a proposal approved earlier this year by the House Energy and Commerce Committee, the House-Senate proposal includes no plans for how to pay for the repeal of the SGR.

In September, the Congressional Budget Office (CBO) scored the costs of H.R. 2810 at $175.5 billion from 2014 through 2023.

CBO's score of H.R. 2810 offers some hints at how a score of the new proposal could look. In that estimate, CBO indicated that the 10-year cost of the automatic annual updates to physician payments would be $63.5 billion, more than 36 percent of the total estimate.

The new House-Senate proposal does not provide for any annual updates. Without an automatic update provision, H.R. 2810 would have scored at $112 billion over 10 years. This suggests that this newest proposal could be less costly than the House-passed bill.

The Medicare Payment Advisory Commission (MedPAC) testified in May before the Senate Finance Committee on replacing the SGR. In its testimony, MedPAC resubmitted its 2011 recommendations on how to pay for a replacement of the SGR. Under MedPAC's framework, drugmakers and physicians would shoulder the majority of the burden of paying for the repeal and replacement.

What's Ahead

The committees requested public comments on their proposal by Nov. 12. The bipartisan, bicameral nature of this proposal, in addition to the existence of a previous bipartisan bill in the House, gives it a better chance at passage than most other proposals.

Further, while a "grand bargain" budget deal seems unlikely, based on the comments of House and Senate budget conferees, it is possible that a smaller agreement on the budget could include a deal to repeal and replace the SGR.

However, until a concrete proposal is unveiled to pay for this legislation—which could cost as much as $200 billion—the bill will not proceed and lawmakers will face another doc fix in December.

Takeaway: A new proposal to replace the sustainable growth rate formula used to determine Medicare payment for physicians would include electronic health record adoption as an incentive, which could be a problem for pathologists who generally don't use EHRs.

Court Dismisses Lawsuit Against Quest, LabCorp, *from p. 1*

In its motion to dismiss, the district court seemingly accepted Quest's argument that the relator's allegations were based on regulations that governed the payments from Virginia's Medicaid program and not the charges that providers bill to Medicaid.

The court stated that applicable law does not require laboratories to charge Medicaid their lowest rates and found that the whistleblower failed to identify a specific false claim that the defendants submitted to Medicaid or to show how the defendants' claims for reimbursement violated Virginia or federal law.

Second Circuit Affirms Dismissal of False Claims Case Against Quest

In a second lawsuit involving Quest Diagnostics, the Second Circuit on Oct. 25 affirmed dismissal of a False Claims Act (FCA) case brought by the former general counsel for Unilab, a Quest subsidiary.

Fair Laboratory Practices Associates (FLPA) filed the lawsuit in 2005 in the Southern District of New York against Quest and Unilab. FLPA is a general partnership formed by three former Unilab executives, including Mark Bibi, who was Unilab's general counsel from 1993-2000. As general counsel, Bibi advised the company on a variety of matters, including its contracts, and handled all of the company's litigation.

According to Sidley Austin LLP, the law firm representing Quest, after the defendants learned that one of FLPA's members was Unilab's former general counsel, the district court permitted limited discovery to determine whether Bibi and FLPA had improperly used or disclosed Unilab's confidences in bringing the lawsuit.

Following discovery, the defendants moved to dismiss on grounds that Bibi had breached his ethical obligations to his former client by using and disclosing Unilab's client confidences for his own financial benefit, thereby tainting the entire proceeding. The district court agreed and dismissed FLPA's action. A few months later, the United States gave notice that it was declining to intervene.

In the Second Circuit, FLPA contended that the district court erred in dismissing the case, arguing that deference to state ethical rules would undermine federal policy that uses whistleblower rewards as a vehicle for rooting out fraud. FLPA also disputed that Bibi violated New York's ethical rules, maintaining Bibi was permitted to disclose Unilab's confidences because he reasonably believed that the defendants were committing a crime.

A unanimous three-judge panel affirmed the district court's decision. Writing for the court, Judge José Cabranes explained that, first, the FCA does not preempt state ethical rules. "Nothing in the False Claims Act envinces a clear legislative intent to preempt state statutes and rules that regulate an attorney's disclosure of client confidences," he wrote. Furthermore, although the FCA permits relators to bring qui tam suits, "it does not authorize that person to violate state laws in the process."

The court also agreed that Bibi violated New York's ethical rules by disclosing confidential information beyond what was "necessary" as required by those rules. While FLPA claimed that disclosures were necessary because the FCA requires relators to provide a "written disclosure of substantially all material evidence and

information the person possesses to the government, the court agreed that Bibi had means of exposing the alleged fraud other than using client confidences in an FCA suit against his former client.

The Second Circuit's decision has significant implications, notes Sidley Austin, particularly in the health care industry, where companies rely heavily on their counsel—both in-house and external—to navigate increasingly complicated fraud and abuse laws.

"The ruling shows that the federal interest in identifying fraud is not limitless, but rather gives way to ethical obligations that otherwise would prevent an attorney's participation as an FCA relator," notes the firm.

Takeaway: Former advisers are not free to parlay a client's candor into a False Claims Act lawsuit against the client.

NEJM Report Adds Fuel to Efforts to Ban Self-Referral

A new study published in the Oct. 24 issue of the *New England Journal of Medicine (NEJM)* concludes that urologists with an ownership interest in intensity-modulated radiation therapy (IMRT) for prostate cancer had a higher treatment rate than those without an ownership interest.

The study corroborates the increased IMRT treatment rates among self-referrers reported by the Government Accountability Office (GAO) in its August 2013 report, "Medicare: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny."

The study, authored by Jean Mitchell, Ph.D., an economist and professor at the McCourt School of Public Policy at Georgetown University, reviewed Medicare claims for more than 45,000 patients from 2005 through 2010 and found that nearly all of the 146 percent increase in IMRT among urologists with an ownership interest in treatment was due to self-referral.

The *NEJM* report concludes that "men treated by self-referring urologists, as compared with men treated by non-self-referring urologists, are much more likely to undergo IMRT, a treatment with a high reimbursement rate, rather than less expensive options, despite evidence that all treatments yield similar outcomes."

The physician self-referral law prohibits physicians from referring a patient to a medical facility in which he or she has a financial interest. However, the law includes an exception that allows physicians to refer for so-called "ancillary services," including radiation therapy, anatomic pathology (AP) services, and physical therapy. To date, the GAO has issued three reports in a four-part series on physician self-referral. The final report, expected by the end of this year, will detail self-referral for physical therapy services. A report issued July 16 by the GAO estimated that in 2010, providers who self-referred AP services cost Medicare about $69 million.

Legislation introduced in early August to close the in-office ancillary services (IOAS) exception to the Stark law would exclude AP, advanced diagnostic imaging, physical therapy, and radiation services from the IOAS exception. If passed, the measure could save the federal government almost $7 billion over a 10-year period.

Takeaway: Multiple reports from the government and medical societies conclude that physician self-referral is driving up medical costs and provide ammunition for the fight to close the so-called self-referral loophole.

Lab Claims With Incomplete NPI Info at Risk for Denial

Laboratory claims with missing or incorrect National Provider Identifier (NPI), or missing or incorrect identification information about the referring or ordering provider, are at risk of denial effective Jan. 6, 2014, according to a Nov. 6 announcement from the Centers for Medicare and Medicaid Services (CMS).

The Affordable Care Act requires physicians or other eligible providers to be enrolled in the Medicare program to order or refer items or services for Medicare beneficiaries. Physicians and suppliers that bill Medicare must show their NPI on a claim. CMS implemented edits on ordering and referring providers when they are required to be identified in certain Part B claims, including those for clinical laboratory services.

In Phase 1, which began Oct. 5, 2009, providers received an information message alerting them that the identification of the referring provider is missing, incomplete, or invalid. During this phase, claims were not denied but certain specific reason and remark codes were included to help providers or suppliers identify claims that were problematic.

In Phase 2, which becomes effective Jan. 6, 2014, CMS will turn on the edits to deny Part B claims that fail to identify the ordering provider and that fail to have the required NPI. If the referring provider is listed on the claim, the edits will verify that the provider is enrolled in Medicare and will compare the first four letters of the last name.

Claims from billing providers and suppliers that are denied because they failed the ordering or referring edit will not expose a Medicare beneficiary to liability. Therefore, an advance beneficiary notice is not appropriate in this situation.

Details on Phase 2 are contained in a revised *MLN Matters* article, SE1305, released Nov. 6, 2013. The article is available at *www.cms.gov*.

Takeaway: Laboratory claims must contain correct national provider identifiers and correct information about referring providers in order to be paid beginning Jan. 6, 2014.

Medicare *Claims Advisory*

Interest Rate Declines for Overpayment, Underpayment

The rate of interest that Medicare will pay you for claims that were underpaid, or collect from you from claims that were overpaid, has dropped to 10.125 percent, effective Oct. 18, 2013, down from the 10.375 percent that has been in effect since July 17, 2013.

The Centers for Medicare and Medicaid Services (CMS) announces the latest update in Transmittal 229, Change Request 8516. Medicare Regulation 42 CFR 405.378 provides for the assessment of interest at the higher of the current value of funds rate (1 percent for calendar year 2013) or the private consumer rate as fixed by the Department of the Treasury.

The highest interest rate in the past decade was in early 2001, when it was 14.125 percent, but for most of the years since, the rate has hovered between 10.5 percent and 12 percent.

The interest rate fluctuations have taken on even greater importance to clinical laboratories, pathology practices, and other Medicare providers because their period of exposure to attempts by CMS to recover any overpayments plus interest has been extended from three years to five years, effective Jan. 2, 2013.

Are Labs to Blame for a $1,000 Pap Smear?

A recent editorial in the *New England Journal of Medicine* about a "$1,000 Pap smear" has generated a great deal of discussion in the laboratory community.

The Oct. 17 editorial, written by Cheryl Bettigole, M.D., a New Jersey-based family practitioner, states that laboratories sometimes charge her patients $1,000 or more for a Pap smear that until recently cost only $20 or $30. The high charges are mostly due to "add on" tests, such as those for HPV and sexually transmitted diseases, as well as sophisticated lab tests for a variety of yeasts.

While Bettigole says clinicians deserve much of the blame for ordering unnecessary tests, she believes that labs are also to blame, arguing that labs have learned that one easy way to increase revenue is to make it easy for clinicians to order more tests.

"In the past year, I have been visited by multiple laboratory representatives touting 'improved' tests, virtually all of which involve combination panels that can be easily ordered and that contain extensive lists of fairly esoteric tests," she writes. "The single-vial women's health test is being heavily marketed by multiple laboratories. It includes not only the Pap and HPV tests but also tests for multiple infections—including some we would rarely have tested for in the past—for which we often have no evidence of benefit."

"The final step in creating these astronomical bills for women without health insurance is that some laboratories charge uninsured women vastly inflated amounts, while offering insurers steep discounts from these 'usual fees,'" she continues. "Although some laboratories offer discounts to uninsured patients, others do not, leading to the phenomenon well documented in other areas of medicine in which the uninsured pay premium rates, often having to set up multiyear payment plans for services for which a health maintenance organization would have paid a fraction of the charges."

Scott McGoohan, vice president of reimbursement and scientific affairs for the American Clinical Laboratory Association (ACLA), argues that the decision about which tests to order lies with the referring physician and labs should not be blamed for overtesting.

"ACLA supports the medically reasonable and necessary use of diagnostic testing, and precisely which diagnostic tests are ordered is a matter of physician judgment in a given clinical scenario," he says. "Laboratories are not responsible for the ordering of laboratory tests, nor can they receive reimbursement from the government for testing which is not deemed to be medically reasonable and necessary."

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