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INSIDE *NIR*

Free Urine Testing Supplies Might Violate Stark, Anti-Kickback Laws

A federal district court in Florida handed down a split summary judgment ruling May 5 in litigation between two competing clinical laboratories on whether the provision of free urine drug screening cups that include testing strips in the cups violates the Stark self-referral and anti-kickback laws (*Ameritox, Ltd. v. Millennium Labs., Inc.*, 2014 BL 124965, M.D. Fla., No. 8:11-cv-00775-SCB-TBM, 5/5/14).

The U.S. District Court for the Middle District of Florida said the issue of whether the free point-of-care testing (POCT) cups provided by defendant Millennium Laboratories Inc. violated the Stark and anti-kickback laws turned on whether the free cups constituted remuneration. Judge Susan C. Bucklew said there was a genuine issue of material fact as to whether the free POCT cups were remuneration for physicians who agreed not to bill for preliminary test results that the POCT cups provide, and she denied summary judgment to plaintiff Ameritox on that specific issue.

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Hospitals Urge FDA to Delay Final Guidance On Blood Glucose Monitoring Systems

The American Hospital Association (AHA) in a recent comment letter criticized a Food and Drug Administration (FDA) draft guidance on prescription point-of-care (POC) use blood glucose monitoring systems.

The AHA said it was concerned the draft guidance would have serious unintended consequences for patients and hospitals, including placing patients at unnecessary risk.

Nova Biomedical, a manufacturer of POC blood glucose systems, also warned the FDA about potential unintended consequences of specific areas of the guidance document but stopped short of calling for an enforcement delay. Nova Biomedical Corp. is based in Waltham, Mass.

The FDA Jan. 6 issued two separate draft guidances, describing what manufacturers should include when they submit 510(k) premarket notifications for self-monitoring blood glucose test systems for POC use as well as over-the-counter (OTC) use. In April, comments were extended from their original due date until May 7.

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Hospitals Urge FDA to Delay Final Guidance, *from p. 1*

Nova Biomedical told the agency that issuing two separate draft guidances "will improve the safety and effectiveness of the devices used in POC settings."

The AHA, however, urged the FDA to delay issuing final guidance until it consults with stakeholders to consider alternatives "that do not have the unintended consequences of inappropriately limiting proper use of glucose meters in hospitals and in other health-care settings." The hospital group wants the agency to convene a workshop with hospitals, device makers, and other interested parties before the FDA makes the guidance final.

Historically, the FDA said it hasn't recommended different types of information in 510(k)s for blood glucose meters used by medical professionals as compared to OTC self-monitoring devices intended for lay users. In recent years, however, concerns have been raised, including infection-control issues related to POC glucose meters, the agency said in the draft guidances. As a result, the FDA proposed different accuracy and study requirements for each environment that reflect the intended use of the devices.

Regulation Level

The AHA in its comments expressed concern that the guidance essentially deems hospital blood glucose testing an "off-label" use, which effectively nullifies the automatic waiver status from the Clinical Laboratory Improvement Amendments (CLIA) that OTC blood glucose meters currently in use have been granted in hospital settings.

According to the AHA, under the CLIA law, tests, including meters, approved by the FDA for OTC "home use" are automatically categorized as waived tests, which are then subject to the lowest level of CLIA regulatory requirements. This waiver allows hospitals to use these meters for convenient, rapid, and real-time bedside testing.

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But if the FDA policy change deems hospital use as off-label, the AHA said, the meters would be subject to the highest level of regulation under CLIA as "high complexity" testing, which could be detrimental to patient care. This is because hospitals would have to abandon bedside testing in favor of central lab testing, which the hospital industry said would delay care for patients.

The FDA in the draft said it expects that prescription-use blood glucose monitoring devices generally will be categorized upon clearance as "moderate complexity" and encouraged manufacturers to apply for a CLIA waiver determination if they were interested in being considered for a waiver.

In addition, the hospitals noted that New York state regulators already have issued a letter to hospital labs citing the FDA draft and saying that the hospitals using glucose meters in populations for which the device wasn't approved would be engaging in off-label use.

Given the concerns, the AHA recommended that the FDA immediately issue a statement clarifying that its draft guidance "should not be used by state or federal regulatory agencies as a tool to enforce new restrictions and requirements on the use of blood glucose meters in hospitals or in other health care settings."

Clinical Trial Expansion

Manufacturer Nova Biomedical, which produces the Nova StatStrip and StatStrip Xpress systems, said it supports the FDA's intent to increase the number of subjects per specimen type to optimize the confidence level within a clinical study.

However, the company said the requirement should be the same for all POC devices in professional health care settings, not just blood glucose test strip systems.

Nova Biomedical also said it was "strongly concerned that the proposed guidance document provides an easy pathway for manufacturers to make claims for populations that are particularly vulnerable to potential interferences" based on the number of patients allowed from different sites of care.

"The outcome of this proposed guidance document is that a new device would be cleared with an indication for use claim that includes MICU and SICU based upon a total of only 100 specimens," Nova Biomedical told the FDA. "The unintended outcome of this new labeling claim would be that health-care facilities and inspectors may interpret this indication for use to mean the new device is cleared for use with critically ill patients within these settings. We do not believe this is FDA's intent."

The company said the FDA "should clarify this point within the guidance document to ensure this Indication for Use would not lead health-care facilities and inspectors to interpret the device as safe and effective for use with critically ill patients."

Takeaway: Recent draft guidance issued by the Food and Drug Administration on prescription point-of-care use blood glucose monitoring systems would have serious unintended consequences for patients and hospitals, believes the American Hospital Association.

AMP Expresses Concerns About Product Labeling in Letter to FDA

The Association for Molecular Pathology (AMP) has requested that the Food and Drug Administration (FDA) prohibit the inclusion of patient management instructions or other medical recommendations in the product labeling for in vitro diagnostic tests.

In a May 13 letter to Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health, AMP noted that while it supports the use of HPV testing as a first-line primary cervical cancer test, it is concerned about the inclusion of medical practice recommendations in the revised "Indications for Use." The letter, signed by Elaine Lyon, M.D., AMP president, refers to FDA's recent approval of the Roche cobas HPV test.

The approval letter, dated April 24, 2014, includes the following in indication 5:

"Women who test positive for HPV genotypes 16 and/or 18 by the cobas HPV Test should be referred to colposcopy. Women who test high risk HPV positive and 16/18 negative by the cobas HPV Test (12 other HR HPV positive) should be evaluated by cervical cytology to determine the need for referral to colposcopy."

Lyon writes that although these recommendations are consistent with current clinical practice guidelines, such guidelines "are and should be established by relevant professional societies, and they often change over time." The FDA has acknowledged that the Federal Food, Drug, and Cosmetic Act was not intended to regulate the practice of medicine and has stated that "Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics, and devices according to their best knowledge and judgment."

"However, including medical practice recommendations in a device product label, even when consistent with accepted clinical practice, violates these principles by making FDA an arbiter of medical decision-making," writes Lyon.

Takeaway: Molecular pathologists are urging the FDA to refrain from making medical practice recommendations on in vitro diagnostic product labels, noting that such recommendations should be established by relevant professional societies.

focus on: Electronic Health Records

Laboratory Professionals Have Key Role to Play In Developing Safer EHR Systems

Laboratory professionals can contribute to the development of safer electronic health record (EHR) systems through engagement, data integrity and usability, and innovation, according to a new white paper from the Centers for Disease Control and Prevention (CDC).

The development of EHR systems and other health information technologies (HITs) is changing how laboratory data are transmitted and displayed throughout the health care system. Thoughtfully designed and rigorously tested EHR systems improve patient care by making it easier to collect, share, and interpret patient data, notes the CDC in the paper, "The Essential Role of Laboratory Professionals: Ensuring the Safety and Effectiveness of Laboratory Data in Electronic Health Record Systems." Examples of preventable safety risks include misdiagnosis, delays in treatment, and inappropriate treatment.

As the percentage of providers using EHR systems has significantly increased over the last decade, there is concern that EHR system-related events may also be on the rise

Nationwide efforts are under way to implement EHR systems that can seamlessly exchange health information to improve patient care and, ultimately, health outcomes. The Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services are promoting this development through two sets of regulations: the ONC's EHR Standards and Certification Criteria and the Medicare and Medicaid EHR Incentive Program.

As the percentage of providers using EHR systems has significantly increased over the last decade, there is concern that EHR system-related events may also be on the rise. While it is hard determine the extent of the risks to patient safety, several patient safety events related to the use of laboratory data in EHR systems are identified in the Food and Drug Administration's Manufacturer and User Facility Device Experience database.

The concerns for potential and real harm as shared by individual experts, the Clinical Laboratory Improvement Advisory Committee, and patient safety organizations (PSOs) prompted CDC to develop the white paper identifying examples of safety risks and highlight how lab professionals' experience can contribute to the development of safer EHR systems. The CDC proposes three focus areas where lab professionals can help address patient safety concerns. The three areas are discussed below.

Engagement

Laboratory professionals can provide lab expertise for HIT decisionmaking in the design, development, and implementation of EHR systems at both national and local levels. Given the complexity of EHR systems, expert consultation with lab professionals, as well as clinicians who use lab data, is critical to bridging the knowledge gap between clinical practice and EHR system technology design and implementation.

Among engagement strategies suggested by CDC:

- ❑ Serve on policy and standards federal advisory committees and the numerous workgroups that support the ONC health care initiatives.

- ❑ Monitor and submit comments on proposed rules and guidelines related to EHR implementation.
- ❑ Work with ONC, National Institute of Standards and Technology, and the Healthcare Information and Management Systems Society and other policy, certification, and standards development organizations to determine opportunities for collaboration.

Data Integrity and Usability

Laboratory professionals can guide and maintain data integrity and usability to ensure that laboratory data are accurately presented in the EHR and available at the point of care. The CDC cites the case of a young woman whose abnormal Pap smear results went undetected for years due to a usability issue with the physician's EHR system. Due to a default setting, the system presented the physician with the patient's previously normal laboratory result and the most recent abnormal result went unnoticed. The young women's advanced cervical cancer was only detected when she sought treatment for other symptoms that had developed. As a result of the delay in diagnosis and treatment, the young woman had a hysterectomy.

The CDC notes there are opportunities for lab professionals to have an impact on data integrity and usability, including these:

- ❑ Engage with EHR developers on the development and design of laboratory-related EHR system features, such as critical results alerts.
- ❑ Provide laboratory expertise for assessing and improving the interoperability and usability of EHR systems at both organizational and national levels.
- ❑ Facilitate rigorous assessment of the usability of laboratory test ordering and reporting functions in the EHR for high-risk patient testing.

Innovation

Laboratory professionals can partner with stakeholders to stimulate innovation in EHR technology and usability to reduce laboratory data-related errors attributed to the use of EHR systems. Innovative clinical decision support (CDS) tools can be created to analyze patient records automatically when new information is received in the EHR. If such CDS tools existed, the reduction in time to diagnosis and treatment for an acute condition could be lifesaving, says the white paper. Emergent conditions such as sepsis can be detected earlier, prompting clinicians to further evaluate the patient.

Among innovation strategies recommended by the CDC for lab professionals and organizations are these:

- ❑ Champion collaborative efforts and support research agendas to provide more detail on laboratory data-related patient safety concerns in the EHR.
- ❑ Collaborate with human factor engineers, EHR system interface designers, and others to advance innovation and the usability of laboratory data displays.
- ❑ Encourage participation in EHR system assessments and voluntary reporting of EHR-related issues to PSOs.

The CDC white paper is available at *www.cdc.gov/labhit/paper/Laboratory_Data_in_EHRs_2014.pdf*.

Takeaway: Lab professionals have a role to play in helping develop safer electronic health record systems.

Free Urine Testing Supplies, *from p. 1*

Bucklew said, however, that physicians not billing for preliminary results for reasons other than an agreement with Millennium in exchange for free POCT cups were receiving remuneration for purposes of the Stark and anti-kickback laws and granted that portion of Ameritox's summary judgment motion. Bucklew also rejected Millennium's contention that the POCT cups fell within a Stark law remuneration exception for testing supplies.

Free Supplies, Unfair Competition

Ameritox's lawsuit alleged that Millennium's nationwide marketing strategy for its urine drug testing practices violates the Lanham Act and state unfair competition laws through the provision of illegal financial inducements to health care providers, including free POCT cups.

Ameritox alleged that Millennium gave physicians the free POCT cups on the condition that they wouldn't bill for the preliminary results that the POCT cups provided on the spot but would send them to Millennium for confirmation testing and could bill for that service. According to Ameritox, the POCT cups normally cost about $5, and a physician can bill $20 for the preliminary test results. Ameritox claimed that a physician can receive reimbursement of $180 from confirmation testing sent to a lab like Millennium.

The court said that the POCT cups aren't used solely to collect and transport urine specimens because they also provide the physician with a preliminary testing result.

Ameritox alleged that physicians receiving Millennium's free POCT cups were receiving benefits in the form of a free sample cup and the ability to provide patients with preliminary test results. Ameritox said that although physicians wouldn't be able to bill for the preliminary test results with Millennium's free POCT cups, they would be able to bill for the higher reimbursement lab confirmation test using the specimen from the POCT cup.

Value of POCT Cups Disputed

Millennium argued that its POCT cups weren't remuneration because the physicians couldn't bill for the preliminary test results and therefore provided the physicians with no financial value.

Millennium also argued that two exceptions to the Stark law's definition of remuneration applied to the POCT cups: the provision of items used solely to collect, transport, or store specimens by the entity providing the item (42 U.S.C. §1395nn(h)(1)(C)(ii)(I)) and the provision of an item used solely to communicate testing results from a specimen by the providing entity (42 U.S.C. §1395nn(h)(1)(C)(ii)(II)).

Bucklew said a jury would have to decide whether a physician who could bill for preliminary urine testing, but gives up the $20 reimbursement potential because of an agreement with Millennium to receive free POCT cups, received remuneration. Bucklew said that physicians who wouldn't bill for preliminary testing for reasons other than an agreement with Millennium were clearly receiving remuneration under the Stark law through free POCT cups they otherwise would have to purchase and that Ameritox was entitled to summary judgment on that issue.

The court said its analysis of whether the free POCT cups constituted improper remuneration under the Stark law was applicable in the same manner to whether the free POCT cups were improper remuneration under the anti-kickback law.

The court held, however, that neither Stark remuneration exception applied to Millennium's provision of the free POCT cups.

The court said that the POCT cups aren't used solely to collect and transport urine specimens because they also provide the physician with a preliminary testing result. Further, the POCT cups don't communicate the results to Millennium, the providing entity, but to the physician administering the test.

Takeaway: A split ruling on whether free urine testing supplies violate the Stark law and anti-kickback statute further complicates the issue of when labs are allowed to provide free supplies to referring physcians. G2

Feds Charge 90 With Health Fraud in Latest Strike Force Takedown

A nationwide takedown by Medicare Fraud Strike Force operations in six cities has resulted in charges against 90 individuals, including 27 doctors, nurses, and other medical professionals, for their alleged participation in Medicare fraud schemes involving approximately $260 million in false billings.

The coordinated takedown is the seventh national Medicare fraud takedown in strike force history. Strike force operations are part of the Health Care Fraud Prevention and Enforcement Action Team, a joint initiative announced in May 2009 between the Department of Justice and the Department of Health and Human Services (HHS) to focus their efforts to prevent and deter fraud and enforce current anti-fraud laws around the country.

Since its inception in March 2007, strike force operations in nine locations have charged almost 1,900 defendants who collectively have falsely billed the Medicare program for almost $6 billion. In addition, the Centers for Medicare and Medicaid Services, working in conjunction with HHS Office of Inspector General, has suspended enrollments of high-risk providers in five strike force locations and has removed over 17,000 providers from the Medicare program since 2011.

The defendants are accused of various health care fraud-related crimes, including conspiracy to commit health care fraud, violations of the anti-kickback statutes, and money laundering. The charges are based on a variety of alleged fraud schemes involving various medical treatments and services, including home health care, mental health services, psychotherapy, physical and occupational therapy, durable medical equipment, and pharmacy fraud.

This latest takedown is indicative of aggressive health care enforcement efforts by the federal government. While clinical laboratories were not implicated in this latest round of charges, there are many instances where labs have paid millions of dollars to settle alleged kickbacks and false claims.

Takeaway: Clinical laboratories need to be aware of aggressive enforcement efforts being used by federal agencies and ensure they comply with all relevant laws and regulations. G2

Court Dismisses Lawsuit Against LabCorp . . . Again

The U.S. District Court for the Eastern District of Virginia has once again dismissed a lawsuit filed against Laboratory Corporation of America (LabCorp) by Chris Riedel, former chief executive officer of Hunter Laboratories.

The case, originally filed in 2007, was unsealed last year and dismissed by the court in November 2013. The lawsuit alleged that LabCorp violated the Virginia Fraud Against Taxpayers Act by overcharging the state Medicaid program and providing kickbacks to health care providers to induce the referral of Medicaid business. The lawsuit was originally filed against LabCorp, Quest Diagnostics, and Specialty Laboratories. In between filing the motion to amend and filing the amended complaint, the relators reached a provisional settlement with Quest and Specialty, which has since been stayed.

In dismissing the case against LabCorp for the second time, the court ruled that Hunter Laboratories and the former owner Riedel failed to identify a single false claim. The court dismissed the case with prejudice, meaning it cannot be amended and refiled.

In filing the lawsuit, Hunter and Riedel alleged that LabCorp violated the law by charging the state Medicaid program higher rates than non-Medicaid customers and offering discounts to providers to induce referrals. While the plaintiffs provided specific examples of LabCorp's "usual and customary" prices and "specific, particular examples of below-cost discounts," they did not identify specific false claims, said the court.

"The falsity of LabCorp's conduct lies not in the prices it charged or discounts it provided but in the claims it submitted to [Medicaid]," the court wrote. "Thus, it is the claims which must be alleged with particularity. Additionally, Rule 9(b) does not require identification of all false claims. It requires only the identification of *some* representative claims."

Usual, Customary, and Reasonable

The court also ruled that LabCorp was not required to charge the Virginia Medicaid program its lowest price. Rather, under the participation agreement, "[t]he provider agrees that charges submitted . . . will be based on the usual, customary, and reasonable concept and agrees that all requests for payment will comply in all respects with the policies of the [Virginia Medicaid Independent Laboratory Participation Agreement]."

Essentially, the court disagreed with the plaintiff's argument that labs are required to charge Virginia Medicaid the lowest rate they charge nongovernment payers. Rather, Virginia Medicaid is simply required to pay the lowest rate.

Riedel has pursued Quest, LabCorp, and other labs for years, alleging that they are overbilling state Medicaid programs. In 2005, Riedel won a settlement against the two big labs in California. Quest and LabCorp eventually settled the lawsuit for a combined $290.5 million.

Riedel reportedly has additional whistleblower lawsuits pending in Georgia, Massachusetts, Michigan, and Nevada.

Takeaway: LabCorp has won at least one fight in its battle with Chris Riedel, former CEO of Hunter Laboratories, as a court in Virginia dismisses a lawsuit filed by Riedel alleging that LabCorp overcharged the state Medicaid program.

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