G2 INTELLIGENCE

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Florida Law Curbs Lab Personnel Placement, Specimen Collection

State lawmakers enacted the curbs in response to allegations that placement of lab personnel in a physician's office and a lab's rental or lease of space in a physician's office constituted illegal kickbacks to induce test referrals and flouted state agency warnings against such behavior.

A new Florida law imposes new prohibitions on what an outside clinical laboratory can do within a physician's office and also stiffens the penalties on unlicensed clinical labs operating within the state.

The strictures are part of a broad bill that streamlines and clarifies regulatory issues affecting a variety of health care facilities, not just clinical labs (House Bill 787, which takes effect July 1, 2012).

But in signing the measure into law, Republican Gov. Rick Scott in an April 27 letter expressed concerns about the ban on lab operations within a physician's office, which amends Section 483.245 (1) of the Florida statutes.

That section already makes it "unlawful for any person to pay or receive any commission, bonus, kickback, or rebate, or engage in any split-fee arrangement in any form whatsoever with any dialysis facility, physician, surgeon, organization, agency, or person, either directly or indirectly, for patients referred to a clinical laboratory licensed under this part."

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New York Pathologists Seek Licensure for Out-of-State Lab Personnel

With almost $1.4 billion in New York patient laboratory work now sent to out-of-state or foreign laboratories, the New York State Society of Pathologists (NYSSP) is pushing for all out-of-state lab personnel working with patient specimens originating in the state to be licensed by the state of New York.

Since 2006, out-of-state lab personnel have been exempt from certain qualification standards for New York-based laboratories under regulations issued by the New York State Education Department. During this time, the amount of patient laboratory work flowing to out-of-state labs has increased from an estimated $794 million in 2005 to $1.395 billion this fiscal year, according to the New York State Department of Health.

The NYSSP views the lack of uniform personnel quality standards as not only providing out-of-state labs with a competitive advantage but also denying New York patients consistency in laboratory quality. "Over 30 percent of New York patient laboratory work is now being sent outside of the state," said NYSSP President David Crossland, M.D., FCAP. "These numbers confirm that the exemption of out-of-

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House Bill 787 adds the following language to the above section: "A clinical laboratory is prohibited from, directly or indirectly, providing through employees, contractors, an independent staffing company, lease agreement, or otherwise, personnel to perform any functions or duties in a physician's office, or any part of a physician's office, for any purpose whatsoever, including for the collection or handling of specimens, unless the laboratory and the physician's office are wholly owned and operated by the same entity.

"A clinical laboratory is prohibited from leasing space within any part of a physician's office for any purpose, including for the purpose of establishing a collection station.

"The Florida Agency for Health Care Administration (AHCA) shall promptly investigate all complaints of noncompliance with [the above] and shall impose a fine of $5,000 for each separate violation. In addition, the agency shall deny an application for a license or license renewal if the applicant, or any other entity with one or more common controlling interests in the applicant, demonstrates a pattern of violating [the above]. A pattern may be demonstrated by a showing of at least two such violations."

"A clinical laboratory is prohibited from leasing space within any part of a physician's office for any purpose, including for the purpose of establishing a collection station."

—House Bill 787

Taking a Further Look at the Language

In Gov. Scott's letter noted above, he acknowledges that "it is critically important for the state to maintain a strict prohibition against unlawful commissions, bonuses, kickbacks, rebates, or split-fee arrangements." He goes on, however, to note that "the current interpretation of the anti-kickback law as it relates to the use of trained specimen collectors and the lease of space in physician offices merits further scrutiny. To that end, I will direct the secretary of the AHCA to work with representatives of the clinical lab industry to examine this issue and develop alternative approaches to regulating this particular area of health care law."

Tougher Penalties for Unlicensed Labs

Further, Section 483.23 of the Florida statutes, which delineates unlawful conduct of clinical laboratories not licensed by the state, is amended to specify that this "constitutes a misdemeanor of the second degree" and the offending labs shall be referred by the AHCA to local law enforcement. "Additionally, AHCA may issue and deliver a notice to cease and desist from such conduct and may impose by citation an administrative penalty not to exceed $5,000 per act. Each day that unlicensed activity continues after issuance of a notice to cease and desist constitutes a separate act."

Some Perspectives on Florida's Action

NIR turned to attorney Robert E. Mazer, a principal of Ober/Kaler in Baltimore, for an assessment of how the new Florida curbs on labs mesh with similar actions by other large states. His comments are as follow:

"State laws can restrict arrangements that would not violate federal law. The New Jersey rule from July 2010 indicates that New York and Pennsylvania have prohibited

clinical laboratories from operating collection stations in physicians' offices, whether or not the labs pay rent. New Jersey did not prohibit those arrangements, but does not allow labs to pay rent to physicians for use of their office space for this purpose.

"There are also significant concerns under the federal anti-kickback statute (FAS). In a Special Fraud Alert issued in February 2000, the Health and Human Services Office of Inspector General cautioned that payments of rent for space that physicians have traditionally provided for free or for a nominal charge for the benefit of their patients may be disguised kickbacks."

—Robert Mazer, Esq.

"Some laboratories take the position that the federal Stark physician self-referral law permits them to lease space from physicians because the statute requires only that the agreement be commercially reasonable even if there were no 'referrals' between the parties. They claim that because 'referrals' include only requests for services covered under Medicare, the lease satisfies this requirement because it would be commercially reasonable for the laboratory to pay for use of space to collect specimens from individuals who are not Medicare beneficiaries.

"There's some question, however, whether the arrangement would satisfy other Stark law requirements, particularly that the leased space not exceed the amount required for legitimate business purposes and that rental charges not take into account referrals or business generated between the parties because the laboratory would not lease *any* space or agree to make *any* lease payments if it did not anticipate test orders from the physicians from whom the space would be leased.

"There are also significant concerns under the federal anti-kickback statute (FAS). In a Special Fraud Alert issued in February 2000, the Health and Human Services Office of Inspector General cautioned that payments of rent for space that physicians have traditionally provided for free or for a nominal charge for the benefit of their patients may be disguised kickbacks. These arrangements could fall within that category. In its July 2010 rule, the New Jersey Department of Health and Senior Services stated that arrangements for the lease of space in physician offices had increased in recent years but, even then, laboratories operating collection stations in physician offices paid rent less than one-half of the time.

"The arrangements also raise issues under the FAS safe harbor that are similar to those raised under the Stark law. Because the space is generally used only to collect specimens from patients of physicians who are part of the medical practice receiving the lease payments, there is a clear relationship between the lease payments and test orders from these physicians. Therefore, lease payments may not be unrelated to the volume or value of referrals or business generated between the parties. Similarly, it is questionable whether the space is reasonable and necessary to accomplish the 'legitimate business purposes' of the lease if the purpose of the arrangement is to obtain referrals from physicians from whom the space is leased." G2

focus on: *Pathologists and Accountable Care Organizations*

Pathologists Have Key Role to Play in Shared Savings Models

Pathologists have a key role to play in accountable care organizations (ACOs), according to a new white paper from the College of American Pathologists (CAP) that examines three ACOs and the ways in which pathologists are helping manage chronic illness among beneficiaries.

"This CAP white paper is a blueprint for ACOs, as well as institutions looking to form an ACO," said Kavita Patel, M.D., managing director for clinical transformation and delivery at the Brookings Engelberg Center for Health Care Reform. "The analysis makes clear the potential impact that pathology can have on how ACOs achieve their savings goals."

ACOs represent the most recent trend in trying to restrain the growth in U.S. health care spending, notes the paper. With an explicit goal of improving quality of care and health care outcomes, as well as restraining spending, ACOs are coordinated care systems in which providers are incentivized on the basis of outcomes rather than the number of services. The Patient Protection and Affordable Care Act allowed for the establishment of ACOs within Medicare, and ACOs and other coordinated care delivery systems already exist in the private sector.

"ACOs offer both challenges and opportunities for pathologists," says the white paper. "The challenges accrue from substantial changes that are associated with practicing in an ACO, in particular a movement away from traditional fee-for-service payment and from an individual approach of practicing toward being part of a care team. However, with its emphasis on health care quality and population health supported by electronic connectivity, the ACO model also offers opportunities for pathologists to apply their skills to help ACOs achieve their goals while finding new ways to show value in an environment where reimbursement rates are expected to continue their downward trend."

To better understand how some pathology practices have been able to take leading roles in ACOs, CAP visited three health care organizations representing diverse models of health care delivery: Geisinger Health System (Danville, Pa.); Accountable Care Alliance, Omaha, Neb.; and Catholic Medical Partners-IPA (CMP) in Buffalo, N.Y. For each of these organizations, the evolution to a coordinated care delivery model was more a function of natural outgrowth of existing business models than a reaction to health care reform or the Medicare Shared Savings Program in particular, notes the white paper.

In studying the three different organizations, CAP identified four examples of how pathologists and laboratory medicine have added value:

1 *Development of protocols for laboratory ordering*. One important way that pathologists in these institutions contribute to ACO goals is by setting up test ordering protocols for high-cost or high-volume tests. Officials and pathologists at the insti-

tutions CAP visited said that clinicians don't always know or understand which tests are appropriate for different conditions. "There is evidence that, in settings in which care is not coordinated, ordering protocols for the same condition are not always standardized—protocols can vary between sites or between physicians at the same site, and that the continuum of evidence behind those protocols can vary from being well investigated to being developed on an ad hoc basis," notes the paper. "Other studies point to the substantial effort needed to ensure that protocols are consistently updated to reflect medical advances and new information on clinical effectiveness."

2 *Population health management*. Pathologists are applying their expertise to help ACOs develop standards for identifying and managing chronic illness among the population enrolled in the system. Geisinger, for example, has implemented standards under its ProvenCare programs, which establish clinical guidelines and offer guarantees to patients and third-party payers that they would not have to pay for readmissions due to care that should not have been needed. As a result of laboratory standards for this program, Geisinger has reduced the median days it takes for renal patients on erythropoietin to reach a target hemoglobin level from 62.5 days to 35 days, at a savings of about $2,200 per patient per year.

3 *Improving physician access to actionable data from the laboratory*. Access to electronic patient data is a foundation of an ACO's ability to effectively coordinate care. As electronic health records (EHRs) and Health Information Exchanges (HIEs) become more common, a key role for pathologists is to design the format for lab results in the EHR and HIE, making the format as "actionable" as possible. Pathologists at CMP are working on how they can use data to improve care management. For example, they are looking at how to use the EHR to identify diabetic patients who had not been getting the HgA1cb tests that are needed to determine whether their disease is under control. The medical director of Univera Health plan, which covers many of the ACO members with which CMP has a contract, has expressed a desire for pathologists and the laboratory community to give extra help to primary care physicians and other ordering physicians on when follow-ups are needed.

4 *Greater collaboration with other clinicians*. Both pathologists and nonpathologists agreed that pathologist leadership and collaboration with other physicians and with ACO leaders are major contributors to their success. The opportunities for pathologists to collaborate are varied. Pathologists at the three institutions visited by CAP achieved their leadership roles by proactively asserting their ability to help the ACO meet its goals. In each organization, there is an established culture of pathologists working in a coordinated and integrated manner with other clinicians.

Despite their successes, pathologists in these organizations, as well as the organizational leadership, continue to face challenges related to achieving the greatest possible value from improving laboratory medicine, including payment, improving the capabilities of health information technology systems, and the difficulty of culture change. The white paper suggests some potential areas where public policy changes can establish an environment that would enhance opportunities for ACOs to be more effective. It also recommends ways in which pathologists can best avail themselves of the opportunity to be part of this new world.

The white paper, "Contributions of Pathologists in Accountable Care Organizations," is available online at www.cap.org/apps/docs/membership/transformation/new/initiatives_index.html.

New York Pathologists Seek Licensure, *from p. 1*

state clinical laboratories from the personnel quality standards of New York state makes no sense and should be modified to ensure consistency in quality for all New York state patients."

To correct this regulation, NYSSP—along with the College of American Pathologists—is supporting Assembly Bill 598/Senate Bill 3442, which would remove this exemption and require laboratory personnel to be licensed by the New York State Department of Health. Sponsored by Assemblywoman Ellen Jaffe (D-Sufern) and state Sen. Kenneth LaValle (R-Port Jefferson), the bill is also supported by the Service Employees International Union, which represents many laboratory workers in New York.

"New York state patients, laboratory physicians, and the personnel who work in New York laboratories have an interest in fixing this bureaucratic inconsistency to correct what has become a problem of growing dimension for the state," said NYSSP member Vernon Pilon, M.D., FCAP, director of Albany Memorial Hospital's clinical laboratory.

House Budget Committee OKs Replacement to Sequestration

The House Budget Committee late May 7 approved a pair of bills aimed at repealing part of the scheduled across-the-board $1.2 trillion spending cuts set to begin in 2013 and replace them with cuts to various social programs.

The sequester replacement bill, a compilation of spending cuts and revenue increases proposed by six House committees to meet directions contained in the House budget resolution (H. Con. Res. 112), was approved on a party-line vote of 21-9.

The bills face opposition from the White House and the Democratic-held Senate and, if approved by the House, are considered unlikely to see a Senate vote. Instead, they will most likely serve as a political marker for House Republicans headed into the fall election as an indication of how they would deal with the deficit.

The bill to partially repeal the sequester language (H.R. 4966) was approved by a 21-13 vote. Both bills are expected to be on the House floor May 10.

The measure would cancel cuts scheduled to begin Jan. 1, 2013, for the Department of Defense but leave intact a 2 percent Medicare spending reduction.

The bills face opposition from the White House and the Democratic-held Senate and, if approved by the House, are considered unlikely to see a Senate vote. Instead, they will most likely serve as a political marker for House Republicans headed into the fall election as an indication of how they would deal with the deficit.

Symbolic Democratic Motions Fail

Under the rules governing consideration of bills put together to meet reconciliation instructions, the Budget Committee is unable to make substantive changes to the product of the other committees.

Instead, Democrats offered several largely symbolic motions to have the committee instruct the chairman to request that the Rules Committee, which can make changes

to the bill, allow certain changes. Those motions, which were all defeated, included one to eliminate a section in the reconciliation bill that repeals the "maintenance of effort" requirement for states for children's health insurance and Medicaid and to eliminate a provision repealing the preventive health program in the health care reform law.

While the bill to replace the sequester is treated as a reconciliation bill under House rules, it would not enjoy the usual filibuster protection granted those kinds of bills in the Senate because the House and Senate have not agreed to budget resolution.

CMS to Delay Issuing Final Sunshine Payments Rule; No Data Collected Until 2013

Despite pressure from lawmakers, the Centers for Medicare and Medicaid Services (CMS) says it will delay implementing the Physician Payments Sunshine Act and will not begin collecting data until 2013.

In a May 3 post on the CMS blog, the agency said it is delaying collecting data from drug and medical device manufacturers in order to "provide time for organizations to prepare for data submission and to sufficiently address the important input we received during the rulemaking process."

The Physician Payments Sunshine Act was included in the health care reform law and requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) to report annually to the secretary of health and human services certain payments or transfers of value to physicians or teaching hospitals.

Companies would have to begin disclosing all physician payment data 90 days after a final rule is published. The proposed rule was published in the Dec. 19, 2011 *Federal Register.*

Lawmakers Push for Implementation

The authors of the sunshine law, Sens. Herb Kohl (D-Wis.) and Chuck Grassley (R-Iowa), recently sent a letter urging CMS to issue a final rule by June so that data collection could begin this year.

The lawmakers in the letter said the final rule governing the sunshine law should clarify several issues raised in the proposed rule, including a more precise definition of payment categories "so that all stakeholder[s] are operating under the same assumptions."

However, associations representing drug and medical device manufacturers urged CMS to delay final implementation of the rule by at least 180 days following publication of a final rule, according to comment letters.

The Advanced Medical Technology Association said it was "pleased CMS is carefully reviewing the many comments submitted on this important issue." The group said it shares CMS's commitment to successful implementation of the sunshine reporting.

CMS in the May 3 post said it still intends to release the final rule later this year. "This timing will provide CMS with additional time to address operational and implementation issues in a thoughtful manner, and the ability to ensure the accuracy of the data that is collected," the agency said.

Palmetto's MolDx Program Now in Effect

Palmetto GBA's new Molecular Diagnostic Services Program (MolDx) is now in effect and all laboratories performing molecular diagnostic testing and billing in the J1 Region must now apply for a unique identifier for each assay in order to be paid.

The MolDx program became effective May 7 for all claims for molecular tests in Medicare's J1 Part B region, which covers California, Nevada, Hawaii, and the U.S. Pacific territories of Guam, American Samoa, and the Northern Mariana Islands. Under the program, Palmetto is requiring that all labs that perform molecular diagnostic testing and bill Medicare in the J1 region obtain either a McKesson Z-Code or a Palmetto Test Identifier to identify each molecular diagnostic test for which it is seeking coverage and reimbursement.

Labs are required to submit test information and supporting evidence for each test, which then will go through a technical assessment process in which subject matter experts from academia and industry will assess the scientific literature and determine coverage. In addition to the published requirements, experts may consider retrospective studies, white papers written by national societies and recognized experts, virtual or theoretical models that have been vetted in the scientific literature, and abstracts.

Upcoming G2 Events

Webinar (2 p.m. – 3:30 p.m. Eastern)

May 31

The End of the Pathology Grandfather: Strategies for Negotiating TC Payments with Hospitals

Featured Speakers:
Jane Pine Wood, Esq., Member, McDonald Hopkins LLC

Stewart Adelman, CEO, Puget Sound Institute of Pathology

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