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INSIDE *NIR*

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OIG Says Lab Processing and Registry Arrangement May Violate Anti-Kickback Law

The Department of Health and Human Services Office of Inspector General (OIG) June 25 warned clinical laboratories and physicians that providing remuneration to physicians to collect, process, and package patients' specimens and/or establishing databases to collect patient testing data could violate federal anti-kickback law.

In a special fraud alert on laboratory payments to referring physicians, the OIG said it is "concerned about the risks that Specimen Processing Arrangements and Registry Arrangements pose under the anti-kickback statute." The fraud alert "reiterates our longstanding concerns about payments from laboratories to physicians in excess of the fair market value of the physicians' services and payments that reflect the volume or value of referrals of Federal health care program business."

The OIG said the two arrangements "present a substantial risk of fraud and abuse under the anti-kickback statute."

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House Passes Reauthorization to Require Newborn Screening Tests, Expand Program

The House June 24 passed a bill to reauthorize a program aimed at preventing newborn deaths and severe disabilities through the increased use of comprehensive and standardized newborn screening tests.

The proposed Newborn Screening Saves Lives Reauthorization Act of 2014 (H.R. 1281) would extend for five years a program administered by the Health Resources and Services Administration in the Department of Health and Human Services (HHS) to provide screening, counseling, and other services related to heritable disorders. It also would expand the program to include evaluation of the treatment and follow-up care provided for newborns and their families after screening and diagnosis.

The bill would continue the Hunter Kelly Newborn Screening Program, which helps researchers at the National Institutes of Health to develop better detection, prevention, and treatment strategies. The program is named after the son of Pro Football Hall of Fame quarterback Jim Kelly, who died at age 8 in 2005 of a rare, fatal genetic disorder affecting the nervous system.

The House passed the bill though a voice vote.

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House Passes Reauthorization to Require Newborn Screening Tests, *from p. 1*

"By passing the Newborn Screening Saves Lives Reauthorization Act, the House has reaffirmed the importance of ensuring that babies continue to receive a comprehensive and consistent set of screening tests, and giving parents and professionals centralized access to newborn screening information," bill sponsor Lucille Roybal-Allard (D-Calif.) said in a June 24 statement.

Roybal-Allard also introduced the original legislation, the Newborn Screening Saving Lives Act of 2007 (Pub.L. 110-204). Before the original law was enacted in 2008, Roybal-Allard said, just 10 states and the District of Columbia required infants to be screened for a complete panel of recommended disorders, and there was no federal repository of information on the diseases. Today, she said, 44 states and the District require screenings for 29 of the 31 core treatable conditions, and parents and professionals have access to a central database of newborn screening information when a baby is diagnosed with one of these disorders.

The 2014 reauthorization bill would help provide states with the resources they need to improve their newborn screening programs and to uniformly test for all recommended disorders.

But Roybal-Allard said there are still discrepancies in the number of screening tests given from state to state, and about 1,000 infants face death or permanent disability each year as a result of what would have been treatable disorders. The 2014 reauthorization bill would help provide states with the resources they need to improve their newborn screening programs and to uniformly test for all recommended disorders. It also would provide states with assistance in developing follow-up and tracking programs, Roybal-Allard said.

The bill renews the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children, which advises the HHS secretary on universal newborn screening tests, technologies, policies, guidelines, and standards. The Senate Jan. 29 passed a companion bill (S. 1417), sponsored by Sens. Kay Hagan (D-N.C.) and Orrin G. Hatch (R-Utah).

Privacy Concerns Raised

The Citizens' Council for Health Freedom, a health freedom group based in St. Paul, Minn., described the legislation as supporting a "funding program that allows states to collect and store newborn DNA without parental consent."

"In the name of public health, this legislation continues a program that strips parents of their right to have a say in who holds their child's genetic code, strips children of their privacy and property rights, and institutionalizes national data-sharing among federal and state governments," Twila Brase, co-founder and president of the citizens' council, said in a June 23 statement.

"It's one thing for newborn blood samples to be tested for a specific set of newborn genetic conditions; it's entirely another for the government to grant itself the right to store that data and those DNA samples indefinitely, to use them for genetic research without parental knowledge or consent, and to place virtual tracking devices on every child by following their health history into adolescence. Yet, these are exactly what this bill does," Brase said.

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In response to a request for comment, Roybal-Allard said that newborn screening is voluntary. "Parents have the option of opting out of any tests that a baby may receive," Roybal-Allard said in her e-mail. "And individual state laws, not federal laws, determine specific policies regarding these specimens."

Natasha F. Bonhomme, vice president of strategic development at Genetic Alliance, which runs the newborn screening resource center (*http://BabysFirstTest.org*), said reauthorization of the Newborn Screening Saves Lives Act will ensure that federal programs can continue to support state public health departments in their efforts to improve screening for all children, expand education and awareness efforts for parents and health professionals, and promote laboratory quality improvement. Bonhomme added that each state has its own newborn screening program and has particular protocols regarding the parents' ability to opt out of screening, storage and use of residual specimens, and data-sharing.

"These practices aim to provide the highest quality of care, including the protection of privacy," Bonhomme said. "This act has supported multiple initiatives that have examined parent perspectives and preferences regarding screening across the country. State programs can now use these findings to improve how they communicate with and connect to families. This funding allows for the development of best practices for continued newborn screening program advancements and renews the commitment to improving and protecting the health of all newborns."

H.R. 1281 was received by the Senate for its consideration June 25.

Takeaway: Legislation reauthorizing a newborn screening program has met some resistance from privacy groups, which raise concerns about states being able to collect and store DNA without informed consent.

New Jersey Doc Sentenced to Prison in Lab Referral Scheme

A New Jersey doctor was sentenced by a federal court in Newark, N.J., July 7 to two years in prison for taking bribes from a clinical testing laboratory as part of a long-running scheme operated by the lab, its president, and a number of associates, announced U.S. Attorney for the Central District of New Jersey Paul J. Fishman (*United States v. Aponte*, D.N.J., No. 13-cr-464-SRC).

In addition to the prison term, Judge Stanley R. Chesler ordered physician Dennis Aponte to pay a $50,000 fine and forfeit $235,000.

Aponte was one of three doctors who pleaded guilty in July 2013 to one count of bribery in violation of the Federal Travel Act for accepting tens of thousands of dollars from Biodiagnostic Laboratory Services LLC (BLS) of Parsippany, N.J., in return for sending their patients' blood samples to BLS for testing.

The doctors participated in what the government has alleged was a scheme in which BLS, through its owners and sales representatives, paid physicians millions of dollars between 2006 and 2013 for referrals.

From October 2012 to March 2013, Aponte received about $3,000 a month in cash in return for blood specimens referred to BLS, according to federal prosecutors, who said the lab made more than $175,000 through testing on specimens referred by Aponte.

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focus on: Physician Fee Schedule

CMS Proposes Increase in FISH Payment, Review of LCD Process for Lab Tests

Independent clinical laboratories would see a 3 percent increase in their Medicare physician reimbursement under proposed changes to the Physician Fee Schedule (PFS) announced July 3. Pathologists, meanwhile, would see an overall increase of about 1 percent.

In terms of specific codes, most proposed payments for major codes are up 1 percent to 5 percent. Based on the initial proposed relative value units (RVUs) for fluorescence in situ hybridization (FISH), the technical component for both manual and automated is set to increase about 30 percent, yielding a total increase of 22 percent for both automated and manual FISH.

For labs that perform a great deal of FISH testing (such as NeoGenomics), this could have a significant positive impact on their bottom lines, according to analysts with William Blair, an equity research firm based in Chicago. "This should at least offset the impact of [National Correct Coding Initiative] edits made in 2014, which stated that only one FISH probe can be billed per procedure; previously, each probe has been billable," write the analysts in a research note July 7.

Key changes proposed in the rule are detailed below.

Local Coverage Determinations

The Centers for Medicare and Medicaid Services (CMS) notes that the Protecting Access to Medicare Act (PAMA), enacted earlier this year, requires Medicare Administrative Contractors to issue coverage policies with respect to clinical diagnostic laboratory tests in accordance with the process for making a local coverage determination (LCD). CMS says it will examine the current LCD implementation process.

In addition, CMS will examine the Molecular Diagnostic Services Program launched by Palmetto GBA in 2011. The agency notes that it believes the "pilot's designs and some of the lessons learned from the pilot can be applied to all diagnostic laboratory tests." Further, CMS says that it believes a process that ensures transparency and stakeholder participation can be achieved without utilizing the current LCD process in its entirety. "Some key aspects of the process should be maintained, such as allowing public comment on draft LCDs and requiring MAC responses to public comments," writes CMS.

Prostate Biopsy Codes

CMS is proposing to use only one code (G0416) to report prostate biopsy pathology services, regardless of the number of specimens. The agency proposed to require the use of the revised G0416 and deletion of the remaining prostate biopsy G codes. In addition, CMS believes that this service is potentially misvalued for 2015 and seeks public input on the appropriate payment level of G0416 for next year.

Transparency

CMS also proposes to enhance transparency in PFS rate setting. The agency says it intends to implement a process by 2016 to allow all misvalued code revisions to go

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through notice and comment rulemaking before being adopted. CMS proposes to do this by making all changes to RVUs made available in the proposed rule beginning in 2016 for codes that CMS receives Relative Value Scale Update Committee (RUC) recommendations on by Jan. 15 of the previous year. The agency will create G codes for codes that it does not receive RUC recommendations for in time, which would effectively delay changes to reimbursement for a year. The transparency enhancements may be due to pressure from Congress. In separate letters sent to the agency this year, members of the Senate and House had asked that CMS place information on modification of physician codes in the proposed fee schedule, rather than just in the final rule. CMS says the new process "will be more transparent and allow for greater public input prior to payment rates being set."

Linking Pathology Payment to HOPPS

CMS again discusses a proposal to link payments made under the PFS to those made in hospital outpatient settings. The agency last year had proposed to compare payment rates for anatomic pathology services under both the PFS and the hospital outpatient prospective payment systems (HOPPS) and set reimbursement according to whichever is lower. However, CMS decided not to finalize the proposal for 2014 and said it would take more time to fully consider all comments and develop an alternate proposal.

In this year's proposed rule, CMS references its expanded legal authority under the PAMA to review payments based on differences across sites of service. The agency is specifically seeking comments on utilizing hospital cost data for use in valuing the practice expense payment for physician services.

Misvalued Codes

CMS includes in the rule a new list of services that it plans to re-examine as part of its expanded authority in the "misvalued codes" initiative. Among the codes to be re-examined is CPT 88185, an add-on code used to bill the technical component of flow cytometry. The list also includes 80 codes from other specialties based on reviewing high-expenditure services.

New Quality Measures

CMS proposed to add three new pathology measures created by the College of American Pathologists (CAP) to the 2015 Physician Quality Reporting System (PQRS). Two of the pathology measures are related to lung cancer and the other is for melanoma. With the anticipated addition of the three measures, pathologists would have a total of eight PQRS measures in 2015.

Value-Based Modifiers

According to the proposal, the value-based modifier (VBM) penalty for unsuccessful participation in the PQRS will increase to 4 percent while the potential modifier bonus could be 4 percent or higher for high-quality, low-cost eligible professionals. The VBM would apply to all physicians, but groups with nine or fewer members will not be subject to a negative adjustment if they successfully participate in the PQRS. Groups with 10 or more are subject to quality tiering and may face penalties even when they do successfully participate in the PQRS. CAP has proposed that pathologists' VBM be tied to the performance of their hospitals in 2015 so that the modifier applied by CMS in 2017 better reflects the value pathologists bring to their patients.

Comments will be accepted on the proposed rule until Sept. 2. A final rule should be published by Nov. 1.

Takeaway: The proposed PFS rule for 2015 contains no major surprises. Some of the proposed changes may have a slightly positive effect on labs' and pathologists' bottom line.

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Lab Processing and Registry Arrangement, *from p. 1*

Physicians Also at Risk

Because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible kickback arrangement, physicians who enter into either arrangement also might be at risk under the statute, the alert said.

The OIG said specimen processing arrangements typically involve payments from laboratories to physicians for certain specified duties, which may include collecting the blood specimens, centrifuging the specimens, maintaining the specimens at a particular temperature, and packaging the specimens so that they aren't damaged in transport. Payments under specimen processing arrangements typically are made on a per-specimen or per-patient-encounter basis and often are associated with expensive or specialized tests, the alert stated.

The alert said these arrangements may violate anti-kickback law in several instances, including when:

- Payment is made directly to the ordering physician, rather than to the ordering physician's group practice, which may bear the cost of collecting and processing the specimen;
- Payment is made on a per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals; or
- Payment is made to the physician or the physician's group practice, despite the fact that the specimen processing is actually being performed by a phlebotomist placed in the physician's office by the laboratory or a third party.

"OIG's concerns regarding Specimen Processing Arrangements are not abated when those arrangements apply only to specimens collected from non-Federal health care program patients," the alert said. "Arrangements that 'carve out' Federal health care program beneficiaries or business from otherwise questionable arrangements implicate the anti-kickback statute and may violate it by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business."

Inducing More Tests

OIG said it also has become aware of arrangements under which clinical laboratories are "establishing, coordinating, or maintaining databases, either directly or through an agent, purportedly to collect data on the demographics, presentation, diagnosis, treatment, outcomes, or other attributes of patients who have undergone, or who may undergo, certain tests performed by the offering laboratories."

"Typically these are specialized and expensive tests paid for by Federal health care programs," the alert said.

Laboratories that participate in registry arrangements often assert that they are intended to advance clinical research to promote treatment, to provide physicians with valuable clinical knowledge for patients with similar disease profiles, and to provide other benefits to physicians or the health care industry, the OIG said.

But the alert said such arrangements may induce physicians to order medically unnecessary or duplicative tests, including duplicative tests performed for the purpose of obtaining comparative data, and to order those tests from laboratories that offer registry arrangements in lieu of other, potentially clinically superior, laboratories.

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Such arrangements may violate the anti-kickback statute in several instances, including when:

- ❑ The laboratory collects comparative data for the registry from, and bills for, multiple tests that may be duplicative (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information) or that otherwise aren't reasonable and necessary; or
- ❑ The laboratory offers registry arrangements only for tests (or disease states associated with tests) for which it has obtained patents or that it performs exclusively.

Takeaway: The OIG has concluded that specimen processing arrangements and registry arrangements between labs and physicians could violate the federal anti-kickback law.

Hospital Outpatient Prices Higher Than in Community Settings

Prices for services in a hospital outpatient department (HOPD) can be much higher than prices in a physician's office or other community-based setting, according to a June 26 study from the National Institute for Health Care Reform (NIHCR).

The study was conducted by researchers at the former Center for Studying Health System Change (HSC), using private insurance claims data from 2011 for about 590,000 active and retired nonelderly autoworkers and their dependents.

Researchers examined prices for forms of four common procedures—knee MRIs, colonoscopies, simple clinical laboratory tests, and physical therapy services—for the study "Location, Location, Location: Hospital Outpatient Prices Much Higher than Community Settings for Identical Services."

The study suggested that insurers can avoid the higher costs by using narrow networks that exclude higher-price providers, tiered networks with higher cost sharing for patients using higher-cost providers, or reference pricing that requires patients using a provider that charges over the reference price to pay the difference.

Are Higher Prices Justified?

"A key question is whether the higher cost for routine, nonemergency services in hospital outpatient departments is justified when the same services are widely available at much lower prices in community settings," Dr. James D. Reschovsky, co-author of the study and a former HSC senior fellow, said in a June 24 statement.

The NIHCR study found knee MRIs were over 50 percent more expensive in HOPDs, with an average price of $919, compared to $606 in community settings. Simple clinical laboratory tests were two to three times more expensive on average in HOPDs, the study said. Both the MRIs and the tests had prices that were much more skewed toward the high end in HOPDs than in community settings.

Hospitals say sicker patients and higher overhead costs due to emergency capacity and regulatory requirements account for the higher costs, the release said. However, the study found no difference in health status between the patients receiving knee MRIs and colonoscopies. The study found a health status difference for physical therapy services, likely due to hospital inpatient stays, and for the laboratory tests, but the difference should be irrelevant for the tests because the study looked at standardized services.

Takeaway: A new study explores the difference in pricing for services, including laboratory testing, provided in hospital outpatient settings compared to community-based settings.

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Senators Request Release of FDA Lab Test Guidance

A group of five Senate Democrats wants the White House to release a draft Food and Drug Administration (FDA) guidance that describes how the agency will regulate laboratory-developed tests (LDTs).

Signed by Sens. Edward J. Markey (D-Mass.), Richard Blumenthal (D-Conn.), Elizabeth Warren (D-Mass.), Sherrod Brown (D-Ohio), and Richard J. Durbin (D-Ill.), the letter said the White House Office of Management and Budget (OMB) has delayed the FDA's draft guidance on LDTs.

"The FDA has developed what the agency has referred to as 'risk based' draft guidance on how the agency will exercise its authority over LDTs, while recognizing the unique circumstances of the laboratory community," the letter said. "For years this draft guidance has languished at OMB causing continued unpredictability and uncertainty for industry, clinicians, patients, and the general public."

Potential changes to the regulation of LDTs by the FDA have pitted groups representing device and combination product manufacturers against clinical laboratories.

A citizen petition filed June 4, 2013, by the American Clinical Laboratory Association (ACLA) questioned the FDA's authority to regulate LDTs as medical devices (*NIR, June 10, 2013, p. 1*).

Expressing a different view, on May 15, the Combination Products Coalition sent a letter to the FDA to request that the agency decide whether it possesses the authority to regulate all LDTs as medical devices (*NIR, June 5, 2014, p. 1*). The coalition said at the time that the current system doesn't offer balance, because it treats two indistinguishable products—LDTs and in vitro diagnostics (IVDs)—completely differently, "and imposes a number of extra requirements on IVDs beyond those for LDTs."

Reactions Highlight Industry Divisions

The senators' letter drew support from the Advanced Medical Technology Association (AdvaMed), a devices industry group. Andrew Fish, the executive director of AdvaMed-Dx, said the group "thanks Sens. Markey, Blumenthal, Warren, Brown and Durbin for their leadership on this important issue. AdvaMed along with 24 patient groups have urged FDA to release its guidance on LDTs to clarify the regulatory requirements of these tests. The Senate letter follows a similar request from members of the U.S. House last year. We have long maintained that for the safety of public health all diagnostic tests should be held to the same regulatory requirement regardless of location of manufacture."

In a July 2 statement, Alan Mertz, president of the ACLA said that regulation of LDTs by the FDA "would be duplicative, contrary to the public health, stifling innovation and negatively impacting patient access to this critical category of diagnostic laboratory service." He added that, ACLA maintains the FDA does not have the authority to regulate laboratory developed tests. LDTs are laboratory services, not devices as defined by the Federal Food, Drug, and Cosmetic Act.

Takeaway: The clinical laboratory industry and the medical device industry remain divided on whether the FDA should regulate lab-developed tests. A group of senators is seeking to shake draft guidance on LDTs loose from the OMB.

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