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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

New OIG Compliance Guidance Places Emphasis on Individual Risk Assessment

New general compliance guidance released by the Health and Human Services Office of Inspector General (HHS OIG) places emphasis on individual risk assessment and signals the agency's increased interest in private equity investment in healthcare. The OIG is expected to issue industry-segment-specific compliance program guidance beginning next year, addressing various healthcare providers, including clinical laboratories. *More on page 2.*

Best Practices for Specialty Labs Contracting for Specimen Collection

A subscriber recently wrote to *LE Compliance & Policy Report* asking for best practices for a specialty laboratory contracting with other labs, health systems or doctors' offices to collect blood specimens for their specific, proprietary lab test. We posed this question to Melissa Bell, DCLS, MS, BS, MLS(ASCP), an independent laboratory consultant in Lubbock, Texas. Bell shares her thoughts on this issue although she advises that the lab posing the scenario should consult with legal counsel for a full analysis. *Continued on page 4.*

What's on the Government's Radar for Labs in 2024?

Each year government agencies with oversight of clinical and anatomic pathology laboratories give some indication of what areas they will focus on in the coming months. *Laboratory Economics Compliance & Policy Report* recently spoke with Elizabeth Sullivan, Chair of McDonald Hopkins's Healthcare Practice Group (Cleveland) about what she sees as lab enforcement trends in the coming year. *Details on page 6.*

Female Pathologists Sue Iowa Pathology Associates for Discrimination

Two female pathologists are suing Iowa Pathology Associates (IPA) and Regional Laboratory Consultants (RLC), alleging they were discriminated against on the basis of sex, age and pregnancy and that they faced harassment and retaliation. Their complaint follows a lawsuit filed last year by Iowa Pathology, accusing them and two other doctors of breach of contract [for details on the earlier lawsuit, see the January 2023 issue of *Laboratory Economics*]. *Details on page 8.*

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New OIG Compliance Guidance Places Emphasis on Individual Risk Assessment

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The release of the General Compliance Program Guidance (GCPG) on Nov. 6, 2023, marks the OIG's attempt to modernize its approach to compliance, including the accessibility and usability of its resources. Rather than publish new guidance in the Federal Register, the agency will publish compliance program guidance on its website at www.oig.hhs.gov. Eventually, current compliance program guidance—issued in the late 90s and early 2000s—will be replaced with newer versions.

"There's nothing revolutionary about what they've included—it's largely a collection of what's already out there," says Judith Waltz, a partner with Foley & Lardner (San Francisco). "However, the OIG did emphasize that it is really focusing on risk-based compliance instead of checkbox compliance. It really wants for each provider to identify its own risks and develop a compliance plan around them."

Judith Waltz

The GCPG includes an overview of relevant laws and legal frameworks, such as the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark) and the False Claims Act. The guidance also covers the seven core elements of an effective compliance program (see box, page 3).

The OIG says that while identifying and addressing risk have always been at the core of compliance programs, in recent years the agency has "come to recognize and place increasing emphasis upon the importance of a formal compliance risk assessment process as part of the compliance program."

Although the guidance is voluntary and nonbinding, Waltz advises that healthcare providers take the guidance seriously and follow it to the extent possible. If an organization decides not to follow a suggestion in the guidance, it should document why that decision was made and by whom.

Assessing Lab Risks

Waltz advises that clinical and anatomic pathology laboratories continually assess their specific risk areas and address them in their compliance programs.

"For labs, the risks are different than for other healthcare providers," she says. "Establishing medical necessity is a big risk for labs because they don't have access to the full medical record. They have to rely on physicians to ensure the tests ordered are medically necessary."

Sales is another significant risk area for labs as federal law highly regulates what salespeople are allowed to do to obtain new clients, says Waltz, noting that sales by its very nature is high risk. Lab sales and marketing people should be familiar with the AKS, the Stark Law and the Eliminating Kickbacks in Recovery Act (EKRA) and should ensure that their activities and compensation structures are in full compliance with these laws, she advises.

Other Compliance Considerations

Quality and patient safety. In its discussion of other compliance considerations, the OIG notes that while quality and patient safety are often treated as wholly separate and distinct from compliance, they are actually key components of compliance. Entities should incorporate quality and patient safety oversight into their compliance programs.

"Integrating quality and patient safety oversight into compliance processes can alert the entity of quality and patient safety concerns and enable the entity to mitigate the risk of patient harm," the OIG says. "Besides patient harm, quality and patient safety concerns, such as excessive services and medically unnecessary services, can lead to overpayment and may cause False Claims Act liability."

Previous OIG guidance "Corporate Responsibility and Health Care Quality: A Resource for

Health Care Boards of Directors," contains a helpful question-and-answer section on quality and compliance that entities and their boards may find useful in structuring board oversight, the GCPG notes.

Waltz notes that while quality and patient safety have been a topic of discussion among compliance professionals for two decades, many healthcare compliance programs still do not include them as meaningful components. She advises that all healthcare providers ensure these topics are addressed in their compliance programs.

New entrants in the healthcare industry. The healthcare sector is seeing an increasing number of new entrants, including technology companies, new investors and organizations providing non-traditional services in healthcare settings (such as social services, food delivery and care coordination services), notes the OIG. New entrants are often unfamiliar with the unique regulations and business constraints that apply in the healthcare industry, as well as the range of federal and state government agencies that regulate healthcare and enforce fraud and abuse laws.

"Simply put, business practices that are common in other sectors create compliance risk in healthcare, including potential criminal, civil and administrative liability," says the OIG. "New entrants should take steps to ensure that they and any business partners possess a solid understanding of the federal fraud and abuse laws, in addition to other applicable laws and they possess an understanding of the critical role an effective compliance program plays in preventing, detecting and addressing potential violations."

Financial incentives. Noting that one of the best ways to identify fraud and abuse risks is to follow the money, the OIG says that understanding how funds flow through business arrangements and the varying incentives created by different types of funding structures is key to unearthing potential compliance issues, implementing effective monitoring and identifying preventive strategies.

The growing prominence of private equity and other forms of private investment in healthcare raises concerns about the impact of ownership incentives (e.g., return on investment) on the delivery of high quality, efficient healthcare, says the OIG.

Seven Elements of an Effective Compliance Program

1. Written policies and procedures
2. Compliance leadership and oversight
3. Training and education
4. Effective lines of communication with the compliance officer and disclosure programs
5. Enforcement of standards, including consequences and incentives
6. Risk assessment, auditing and monitoring
7. Responding to offenses and corrective action, including investigations and reporting

"Healthcare entities, including their investors and governing bodies, should carefully scrutinize their operations and incentive structures to ensure compliance with the federal fraud and abuse laws and that they are delivering high quality, safe care for patients," it notes. "An understanding of the laws applicable to the healthcare industry and the role of an effective compliance program is particularly important for investors that provide management services or a significant amount of operational oversight for and control in a healthcare entity."

In particular, compliance officers should be attuned to the varying risks associated with the payment methodologies through which healthcare entities are reimbursed for the items and services they provide. In addition, given the significant number of transactional agreements in healthcare, organizations should have a tracking system to ensure that proper supporting documentation is maintained, regular legal reviews are conducted and fair market value assessments are performed.

Best Practices for Specialty Labs Contracting for Specimen Collection

(*cont'd from page 1*)

Determine What Agreements Are in Place

Before contracting with another lab, health system or doctor's office for specimen collection, ensure that your lab will not be violating any agreements those providers already have in place, such as contracts with larger reference laboratories.

"I worked with a large health system that had 25 to 30 physicians on staff," says Bell. "Sales reps would come in and talk with them and before you knew it, orders were coming in for a particular test. Physicians may not know what agreements are in place. The lab salesperson should talk to the lab director or the executive who is over laboratory services to ensure there is no conflict."

Melissa Bell

Bell notes that there may be cases where a lab is owned by a large national laboratory, and that lab might not be allowed to send specimens to a specialty lab. However, the same restrictions should not apply to a physician-office laboratory. Specific insurance companies might also have restrictions on what lab must be used to process specimens, she adds.

"You need to know what restrictions might already be in place before you contract with a particular provider to collect specimens for your proprietary test," she advises.

Be Aware of AKS and Stark Restrictions

Sales representatives can make recommendations on particular tests and explain how they would benefit patients. However, there are limitations on what sales reps can do to convince providers to order a particular test, notes Bell.

"Things get blurry when lab sales reps are trying to convince providers by providing meals or other items that might be considered inducements," she says. "You must be aware of the limits on non-monetary compensation and have a system in place for tracking these items."

The federal Anti-Kickback Statute (AKS) prohibits the knowing and willful solicitation, offer, payment or receipt or any remuneration, whether direct or indirect, in cash or in kind, to induce or in return for referrals for items or services covered by a federal healthcare program.

The Stark law prohibits a physician from making a referral for certain designated health services (including clinical laboratory and anatomic pathology services) for which payment may be made under the Medicare or Medicaid program if the physician or an immediate family member has a financial relationship with the entity that provides the designated health services. The Stark law was last updated in December 2020.

> *"Things get blurry when lab sales reps are trying to convince providers by providing meals or other items that might be considered inducements. You must be aware of the limits on non-monetary compensation and have a system in place for tracking these items."*

The Stark law contains limited exceptions, such as an exception for non-monetary compensation. This exception permits a lab to provide certain non-monetary compensation to referring physicians. In 2023, the limit is $489 per physician. That means a lab salesperson could provide food gifts, coffee mugs, pens and other small items to a provider or their staff as long as the cost of the items does not exceed $489 per physician.

In guidance, the government has also said that low-cost supplies used solely to collect specimens for the laboratory may be provided without charge to a physician. However, higher-cost items used by the physician to perform the underlying surgical procedure, such as biopsy needles and snares, could violate the law.

Phlebotomist in Office

Another compliance concern for specialty laboratories is the placement of phlebotomists in a physician office. According to the Health and Human Services Office of Inspector General (HHS OIG), the mere placement of a laboratory in a physician's office would not necessarily serve as an inducement prohibited by the AKS, but the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff. This can include taking vital signs or other nursing functions, testing for the physician's office laboratory or performing clerical services.

When the phlebotomist performs a clerical or medical function not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referral to the laboratory, says the OIG in a 1994 special fraud alert.

"It needs to be clear that the phlebotomist is an employee of the lab, not the physician office," says Bell. "Lines can easily get blurred. Physicians sometimes will ask the phlebotomist to help out in ways they are not authorized to do. We see this mostly in rural places or private practices. It's a very tricky area."

Ensure Compliance with EKRA

All clinical laboratories must also ensure compliance with the Eliminating Kickbacks in Recovery Act of 2018 (EKRA), says Bell. While EKRA initially targeted patient brokering and kickback schemes within the addiction treatment and recovery spaces, it does apply more broadly to all clinical laboratories.

EKRA prohibits the payment of remuneration in return for referring a patient to a recovery home, clinical treatment facility or laboratory. A common issue related to the interpretation of EKRA is how it applies to employee compensation. In contrast to the AKS, which has both a statutory exception for payments made to employees and a separate regulatory safe harbor governing employment agreements, EKRA's provision is drafted ambiguously.

Because HHS and the Department of Justice (DOJ) have not provided any guidance or clarity regarding the statute, clinical laboratories have had difficulty determining what compensation structure or marketing and sales activities are appropriate and what constitutes a referral under the statute. As a result, labs must look to recent enforcement actions to glean what is and is not allowed under EKRA. [For a more in-depth discussion of EKRA, see the April 2023 issue of *LECPR*, p. 1].

Bell notes that EKRA not only applies to Medicare and Medicaid, but also to private health insurance plans, making its reach a lot more expensive than the AKS. EKRA also has fewer exemptions (regulatory safe harbors) than the AKS, and conduct that was once exempt by AKS is prohibited by EKRA.

Given the uncertainty regarding EKRA, labs should absolutely consult their legal counsel to ensure their policies are in compliance with the law, says Bell. Counsel should conduct a full analysis of all marketing arrangements and compensation structure to ensure compliance.

WHAT'S ON THE GOVERNMENT'S RADAR FOR LABS IN 2024? (*cont'd from page 1*)

What do you expect to see in terms of enforcement next year?
We are expecting increased enforcement, which is likely not a surprise to anyone in the lab industry. The OIG [Health and Human Services Office of Inspector General] has indicated through recent advisory opinions and its work plan that labs will continue to be highly scrutinized. The themes are not new – fraud and abuse and false claims, particularly kickback issues in business arrangements and medically unnecessary testing.

In late September, the OIG released an advisory opinion that took a negative position on a purchased services arrangement for the technical component of anatomic pathology. Typically, we see more scrutiny concentrated on clinical laboratories than on anatomic pathology labs, but this opinion underscores that the OIG is looking at both clinical and anatomic labs.

Medical necessity, especially for molecular testing, continues to be on the OIG's radar. We expect continued scrutiny for molecular laboratories, particularly those that expanded with the use of telehealth during the Covid Public Health Emergency (PHE). An independent, but related focus that we anticipate is testing ordered via telemedicine. The flexibilities that were offered during the PHE drove wider telehealth adoption. Because telehealth providers did not necessarily need to establish or maintain a traditional patient relationship during the PHE, it allowed telehealth providers to serve and order testing for an expanded population. The flexibility to order testing and in turn, for labs to be reimbursed for such testing, without an established patient relationship is no longer permissible. The government's concern for testing originating from telehealth arrangements is in part the result of arrangements they have already uncovered relating to genetic testing ordered via telehealth where the ordering clinician didn't have a treating relationship with the patient. While appropriate models exist, the government has identified this as an area where improper ordering could result in medically unnecessary testing, particularly in the genetic testing space. Labs that are accepting test requisitions from telehealth providers need to understand how those arrangements are structured and ensure that they are appropriate.


Liz Sullivan

Is Covid testing still on the government's radar?
Yes. One of the items in the OIG's workplan is increased payment for expedited results for Covid testing. During the PHE, Medicare paid additional reimbursement for expedited results. Labs that billed the add-on for expedited results should be aware that the government will likely be auditing to ensure that increased payments were properly paid. Now that the PHE is over, I expect to see increased audits of labs that were performing Covid testing if nothing else, due to the sheer amount of money disbursed as payment for Covid testing.

The OIG recently released new general compliance program guidance and said it would be issuing industry-specific guidance beginning in 2024. Any idea when the guidance for laboratories will be released?
It is difficult to anticipate exactly where the OIG will focus, but considering the level of risk that the OIG perceives with respect to lab providers, lab guidance may be a priority. Until the new guidance comes out, labs should revisit the existing program guidance. Although there is no clear penalty for failure to maintain a compliance program, programs are mandatory. The value of having a compliance program is twofold—first, it allows providers to catch issues earlier, placing them in a better position than if a regulator identifies a problem—and two, having an active compliance plan and using it effectively can be a mitigating factor in a government investigation. If your lab is investigated, and you don't have an active compliance program, it could be harmful.

Our impression has been that there isn't a high adoption rate for a formal, written, active compliance plan within the lab industry. Many labs don't have a compliance committee or conduct

regular internal audits. We see many labs with pieces and parts of a program, but not many in the industry have that formal, written, regularly functioning compliance program. While large organizations typically have robust programs, smaller labs don't always have the resources to support them.

What do you expect the Department of Justice (DOJ) to focus on in the coming year?
We expect to see more enforcement of kickback and EKRA (Eliminating Kickbacks in Recovery Act) activity. Our observation is that the DOJ is taking the lead on these investigations. We have seen significant enforcement relating to independent contractor sales and marketing arrangements pursuant to the Federal Anti-Kickback Statute (AKS). Under EKRA, labs have been moving away from independent contractor arrangements and have brought sales and marketing representatives in-house as employees. While this is intended to satisfy the AKS bona fide employee safe harbor, there is no equivalent under EKRA. It's possible that the government will continue investigating lab sales and marketing arrangements pursuant to AKS and EKRA.

We understand there is continued advocacy within the lab industry to clarify the application of EKRA and/or to create an employee exception under EKRA similar to the AKS bona fide employee safe harbor.

At this time, there is little regulatory guidance or case law to help us better understand how the government will apply EKRA. There have been a couple of cases that give us some idea and it appears that the DOJ will apply EKRA broadly relating to laboratory business arrangements, but we don't know for certain how DOJ enforcement will evolve in the future.

We have some clients that have moved to a flat salary for their sales and marketing people in response to EKRA, and those that have established alternative bonus structures, for example, a bonus tied to the overall success of the business; however, these alternatives can create business challenges. Labs continue to approach EKRA in different ways.

What other areas do you anticipate that the government will focus on?
Digital pathology seems to be one area that is prime for scrutiny. There are two areas that we are watching. First, the platforms are very expensive, and there are a lot of vendors working with pathology groups and labs to set up the technology. In some cases, the vendor is also potentially generating work for the group. In instances where the group is going to pay for digital pathology services on a volume basis, there may be an argument that such an arrangement is an inadvertent sales and marketing arrangement.

The other area applies to in-office arrangements. During the Covid PHE, Stark Law [Federal Physician Self-Referral Law] blanket waivers allowed ordering physician groups to have certain designated health services, such as pathology and radiology, performed remotely and still comply with applicable Stark Law requirements. When the PHE ended in May, that waiver expired; however, many physician groups are unaware that the flexibility is no longer available.

We are seeing digital pathology platforms indicate that physician groups can continue to maintain remote arrangements with pathologists, but the regulations don't permit such arrangements. It is unclear if the government would agree with arguments relating to remote presence. Any pathology group that set up an arrangement for remote reads during Covid should review the compliance of such arrangements with counsel.

What is your overall advice for clinical and AP labs in 2024?
Stay dialed in to the OIG's new compliance program guidance. If you have an active compliance plan, you are more likely to catch problems. Relatedly, if you don't currently have a plan for billing and compliance audits, you should. They can go a long way in helping you identify patterns and practices that might create vulnerabilities and demonstrate a commitment to compliance. Scrutinize business arrangements – what kind of arrangements do you have with referral sources?

Female Pathologists Sue Iowa Pathology Associates for Discrimination

(*cont'd from page 1*)

Tiffani Milless and Caitlin Halverson filed a complaint on Nov. 2, 2023, in the Iowa District Court for Polk County against IPA, RLC, Executive Director Scott Denker, Jacob Sramek and Larry Anderson. The complaint alleges that both women were paid hundreds of thousands less than their male counterparts with similar or lesser qualifications. Both received a starting salary of $200,000, with annual increases of $50,000 in years two and three. Milless and Halverson allege that a male doctor hired in 2007 started at $225,000 and earned more than $350,000 than they did in his first three years. Another male doctor, hired in 2022, started at $600,000 and received additional bonuses. Both women say they were told when hired that associate pay was fixed, with no room for negotiation.

Iowa Pathology specializes in providing diagnostic lab services for other medical practices and facilities, including major central Iowa hospitals and health networks. Milless joined the practice in 2013, and Halverson joined in 2015. Both are board-certified pathologists.

Unequal Treatment

Milless and Halverson also allege that they were treated differently than their male counterparts in other ways as well. While they both became "shareholders" in the practice, they say they had little or no management authority. To be better able to take on corporate leadership at IPA and RLC, Milless and Halverson personally paid to attend national training offered by the College of American Pathologists (CAP). Milless says she repeatedly requested informal mentoring in leadership and business management so she could gain experience and learn from her colleagues, but she was rebuffed by her colleagues.

The complaint alleges that the defendants repeatedly denied Milless and Halverson business information to which they were legally entitled, such as financial statements, billing contracts, accounting records and documents reflecting the productivity of each doctor. Only male shareholders were involved in managing the business or making high-level decisions, the women say.

Harassment and Retaliatory Treatment

The plaintiffs in their lawsuit describe being subjected to a variety of sexual situations at Iowa Pathology, ranging from flirting by their decades-older executive director to raunchy jokes about female newscasters to male colleagues who watched pornography on work computers.

According to the complaint, Denker sometimes treated Milless as if she were his administrative assistant. He repeatedly asked Milless to order lunch for partnership meetings, pick up pastries for staff, facilitate Zoom calls, create PowerPoint presentations and manage the laptop for such presentations, they allege, noting that no male doctors were ever asked to perform such tasks.

The defendants allegedly referred to Milless and Halverson as "girls," dismissed their input and told the women that they needed to "let people who know what they are doing" handle things. Milless and Halverson also alleged that an area where they often were assigned to work contained an image of Miley Cyrus in a white bikini leaning back provocatively atop a Christmas ornament. Another area contained a large photograph of a bare-breasted women.

The complaint details numerous other instances in which they were demeaned and where complaints to the company's leaders were ignored or brushed aside. The women also allege a pattern of retaliation by Executive Director Scott Denker and others toward them. The complaint also alleges that the defendants failed to provide Milless and Halverson with up to eight weeks of medically necessary maternity leave in violation of the Iowa Civil Rights ACT.

"Defendants excluded Dr. Milless and Dr. Halverson from ownership activities and treated them

with outright hostility and distrust," the complaint says. "The hostile work environment was exhausting, humiliating and belittling."

The plaintiffs are seeking lost wages, as well as damages for their emotional distress and loss to reputation, according to Page Fiedler, an attorney with Fiedler Law Firm, P.L.C., which is representing the women. The amount has not yet been determined, but it will be significant, she tells *LECPR*.

IPA Sues Departing Pathologists

In 2022, Halverson, Milless and two other shareholders left Iowa Pathology to start a competing practice, Goldfinch Laboratories. In the complaint, they describe their decision to leave Iowa Pathology as "due to the pervasive harassment, discrimination and retaliation."

In December 2022, Iowa Pathology sued the departing shareholders, accusing them of breach of contract. IPA alleged that the four pathologists began conspiring to form a competing dermatopathology lab sometime in 2021, when they were still under contract with the group. The contracts required that the pathologists devote their full time and best efforts to IPA and not engage in the practice of medicine except on the behalf of IPA. A judge granted an injunction preventing them from promoting Goldfinch until February 2023. The Goldfinch partners filed counterclaims, and the case is pending.

In their new complaint, Milless and Halverson describe the lawsuit against them and their partners as an "intimidation tactic" meant to pressure them not to pursue their civil rights claims against Iowa Pathology.

Healthcare Fraud Program Notches Hundreds of Criminal, Civil Actions

During fiscal year 2022, civil healthcare fraud settlements and judgments under the False Claims Act exceeded $1.6 billion, according to a new report on the Healthcare Fraud and Abuse Control Program, a joint effort between the Health and Human Services Office of Inspector General (HHS OIG) and the Department of Justice (DOJ).

In addition, the DOJ opened more than 809 new criminal healthcare fraud investigations and filed criminal charges in 419 cases involving at least 680 defendants. In civil matters, the DOJ opened more than 774 new civil healthcare fraud investigations and had more than 1,288 civil healthcare fraud matters pending at the end of the fiscal year. Federal Bureau of Investigation (FBI) investigative efforts resulted in 499 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 132 healthcare fraud criminal enterprises.

In FY 2022, investigations conducted by the HHS OIG resulted in 661 criminal actions against individuals or entities that engage in crimes related to Medicare and Medicaid, and 726 civil actions, which include false claims, unjust-enrichment lawsuits filed in federal district court and civil monetary penalty (CMP) settlements. The OIG excluded 2,332 individuals and entities from participation in Medicare, Medicaid and other federal healthcare programs. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (983) or to other healthcare programs (433), for beneficiary abuse or neglect (305) and as a result of state healthcare licensure revocations (372).

Diagnostic Testing Enforcement

In October 2021, Nevada-based MD Spine Solutions (MD Labs) and two of its owners agreed to pay up to $16 million to resolve civil FCA allegations that it submitted false claims for medically

unnecessary urine drug testing. Under terms of the settlement, MD Labs and the owners will pay the government and various states no less than $11.6 million and up to $16 million.

In February 2022, a Detroit man was convicted of one count of healthcare fraud for operating a kickback scheme for a clinical laboratory, in which he paid marketers to solicit urine samples from physicians for comprehensive urine drug testing. The fraudulent conduct resulted in $28.2 million worth of improper claims being submitted to Medicare, for which Medicare paid the lab $2.1 million. The defendant is awaiting sentencing.

In March 2022, Radeas LLC, a North Carolina-based clinical laboratory, agreed to pay $11.6 million to resolve civil FCA allegations that it submitted false claims to Medicare for medically unnecessary urine drug testing (UDT). Radeas also admitted to compensating sales organizations on a commission basis for their referrals of UDT to the company, from May 10, 2013, through April 30, 2021.

In May 2022, the CEO of Northwest Physicians Laboratory was sentenced to serve 24 months in prison and ordered to pay $7.6 million in restitution for conspiracy to solicit kickbacks from medical testing labs in exchange for referring government testing business to the labs. To date, the lab and individuals involved in this investigation have agreed to pay more than $14 million t o settle related civil allegations.

In FY 2022, investigations conducted by the HHS OIG resulted in 661 criminal actions against individuals or entities that engage in crimes related to Medicare and Medicaid, and 726 civil actions, which include false claims, unjust-enrichment lawsuits filed in federal district court and civil monetary penalty (CMP) settlements.

In July 2022, Metric Lab Services LLC and Metric Management Services LLC, Spectrum Diagnostic Labs LLC, clinical laboratories in Mississippi and Texas, respectively, and two of their owners and operators agreed to pay $5.7 million to resolve allegations that they caused the submission of false claims to Medicare by paying kickbacks in return for genetic testing samples.

In July 2022, an owner and operator of a youth mentoring program known as Do-It-4-The-Hood Corporation (D4H) was sentenced to 70 months in prison and two years of supervised release and ordered to pay restitution for his part in defrauding Medicaid programs in North Carolina, South Carolina and Georgia of more than $5 million through a scheme in which the program required children enrolled to submit urine specimens for drug testing. The defendant then conspired with labs in Georgia, North Carolina and Virginia to perform medically unnecessary drug testing on the enrolled children's urine specimens and received kickbacks once the labs were reimbursed by the state Medicaid programs.

In July 2022, Inform Diagnostics Inc., a clinical laboratory headquartered in Irving, Texas, agreed to pay $16 million to resolve civil FCA allegation that it submitted false claims for payment to Medicare and other federal healthcare programs. According to the settlement, Inform admitted that between 2013 and 2018, it routinely and automatically conducted additional tests on biopsy specimens prior to a pathologist's review and without an individualized determination regarding whether additional tests were medically necessary.

In July 2022, the owner of a diagnostic laboratory was convicted of one count of conspiracy to pay and receive for this role in an illegal kickback scheme involving medically unnecessary genetic testing in which Medicare was billed at least $7.9 million and paid $4.7 million for kickback-tainted genetic testing. The defendant awaits sentencing.

COMPLIANCE 101:

Clinical Laboratory Notices to Physicians

According to the Health and Human Services Office of Inspector General (HHS OIG) Compliance Program Guidance for Clinical Laboratories, all laboratories should provide all of their clients with annual written notices that set forth:

1. The Medicare medical necessity policy;
2. The individual components of every laboratory profile that includes a multichannel chemistry test result or other automated multiple test result;
3. The CPT or HCPCS codes that the laboratory uses to bill the Medicare program for each such profile;
4. The Medical National Limitation Amount for each CPT or HCPCS code used to bill Medicare for each profile and its components; and
5. A description of how the laboratory will bill Medicare for each profile.

If the laboratory engages a physician clinical consultant, the notice also should provide the phone number of the physician clinical consultant and advise of his or her availability to discuss appropriate testing and test ordering.

In addition to the general notices above, laboratories offering clients the opportunity to create customized profiles should provide all clients who request customized profiles with annual notices that:

1. Explain the Medicare reimbursement paid for each component of each such profile;
2. Encourage physicians who are ordering tests for which Medicare reimbursement will be sought to order only tests that are medically necessary for each patient;
3. Inform physicians that using a customized profile may result in the ordering of tests for which Medicare may deny payment; and
4. Inform physicians that the OIG takes the position that a physician who orders medically unnecessary tests for which Medicare reimbursement is claimed may be subject to civil penalties.

Physician Acknowledgements

Laboratories that agree to customize profiles in response to physician requests should require such requesting physicians to sign a Physician Acknowledgement. By signing the Physician Acknowledgement, the physician would affirm that:

1. The physician has requested the creation of a custom profile that includes the tests listed on the acknowledgement;
2. The physician has been informed of the reimbursement amount that Medicare (and, where appropriate, Medicaid) will pay for each test included in each customized profile;
3. The physician understands that when ordering tests for which Medicare reimbursement will be sought, the physician should only order those tests which the physician believes are medically necessary for each patient;
4. The physician knows that using a customized profile may result in the ordering of tests for which Medicare or other federally funded healthcare programs may deny payment;
5. The physician will order individual tests or a less inclusive profile when not all of the tests included in the customized profile are medically necessary for an individual patient;
6. The physician has been informed that the OIG takes the position that a physician who orders medically unnecessary tests may be subject to civil penalties; and
7. If appropriate, the physician is aware that the laboratory makes available the services of a clinical consultant to assist the physician in ensuring that appropriate tests are ordered.

In Brief

Congress Delays Medicare Cuts to Clinical Laboratories

Congress has once again delayed Medicare cuts to clinical laboratories mandated by the 2014 Protecting Access to Medicare Act (PAMA). The cuts of up to 15% would have affected about 800 clinical laboratory services. The delay, included in a short-term spending package passed by Congress November 15, is now extended to January 2025.

Susan Van Meter, president of the American Clinical Laboratory Association (ACLA), praised the move and said ACLA would continue working with 70 patient and provider organizations and bipartisan champions of the Saving Access to Laboratory Services Act (SALSA), which would revise how lab data is collected to determine Medicare payment rates. SALSA would ensure that true private market rates are included and would provide a much-needed reduction in the reporting burden.

CDC Recommends HCV Testing of Perinatally Exposed Infants and Children

The CDC is recommending hepatitis C virus (HVC) testing for all perinatally exposed infants and children. Infants and children testing positive should be referred to appropriate care and receive curative treatments that are approved for children as young as three years. Four new recommendations were issued to address a greater than three-fold increase in HCV incidence among persons of reproductive age during the period 2010-2021 and the 6% to 7% of perinatally exposed infants and children who acquired HCV infection.

Chief Compliance Officer Sentenced in $50 Million Fraud Scheme

A Florida man was sentenced Nov. 16, 2023, to four years and six months in prison and ordered to pay $21.7 million in restitution for his role in a healthcare fraud and wire fraud conspiracy that resulted in more than $50 million in false and fraudulent claims being submitted to Medicare. Steven King, 45, of Mirimar, was the chief compliance officer of a pharmacy holding company that fraudulently billed Medicare for dispensing lidocaine and diabetic testing supplies that Medicare beneficiaries did not need or want.

Jondavid Klipp, Publisher Kimberly Scott, Editor Jennifer Kaufman, Chief Copy Editor