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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

How to Navigate the Challenge of Paying Lab Sales Reps: Q&A with David Gee

Since the Eliminating Kickbacks in Recovery Act (EKRA) became law in 2018, clinical laboratories have struggled with how to pay their sales and marketing professionals without violating the law. While the Anti-Kickback Statute (AKS) has clear safe harbors for employed sales and marketing professionals, exceptions under EKRA do not line up with the AKS, making it difficult to know when an arrangement is compliant. *Laboratory Economics Compliance & Policy Report* recently spoke with David Gee, a partner with Davis Wright Tremaine LLP (Seattle) about how labs can navigate this bumpy road. *See page 2 for the first of our two-part conversation.*

Top Five Common Pathology Coding Errors and How to Fix Them

Common pathology coding errors can cost clinical and anatomic pathology (AP) laboratories significant lost revenue, according to coding specialists with Lighthouse Lab Services (LLS). The top five most common coding errors involve immunohistochemistry (IHC) stains, special stains, fine needle aspirate adequacy interpretation, specimen level and comingled tissues, say Billie Mildenberger, director of audit services, and Holly Wolford, lead revenue cycle management and coding specialist. *Continued on page 5.*

Provista Health, Owner Ordered to Pay $26 Million Over Unnecessary RPP Tests

Patrick Britton-Harr and multiple laboratory companies owned by him will have to pay the U.S. government more than $26 million for violations of the False Claims Act (FCA). The default was ordered by the U.S. District Court for the District of Maryland on July 18 after Britton-Harr and his companies failed to defend against the United States' allegations. *More on page 9.*

Three Florida Labs to Pay Almost $2.5 Million Over Manipulated Diagnosis Codes

Three clinical laboratories based in Clermont, FL, have agreed to pay almost $2.5 million to settle allegations that they violated the False Claims Act (FCA) by submitting claims to Medicare and Medicaid that contained manipulated diagnosis codes. *Details on page 9.*

CONTENTS

How to Navigate the Challenge of Paying Lab Sales Reps: Q&A with David Gee (*cont'd from page 1*)

What kind of enforcement activity are you seeing in regard to compensation for sales and marketing representatives for clinical laboratories?

Although EKRA was enacted more than five years ago, in October 2018, we have seen relatively few (published) efforts by the Department of Justice (DOJ) to employ EKRA to regulate compensation to sales and marketing representatives for promoting laboratory lab testing. Only two cases come to mind and only one of those involved the DOJ: The first, the *Graves* case, was a breach of contract case by a sales rep against his lab employer, decided in October 2021 by the US District Court in Hawaii. The court ruled that a lab's contract to pay commissions to a sales employee for marketing lab testing to physician customers who order the testing did not violate EKRA. Therefore, the contract was legal and enforceable by the sales representative. The second, the *Schena* case, was a criminal case against a lab owner, in which the US District Court for the Northern District of California issued an order in May 2022. It expressly rejected the result and reasoning of the *Graves* court and ruled that EKRA does restrict payments by a lab to marketers to secure referrals through physicians. The defendant in the *Schena* case eventually was convicted and sentenced to prison for violation of EKRA as well as for securities fraud and other healthcare fraud.

David Gee

Instead of EKRA enforcement over the past several years, we have seen an increasing focus by the government on alleged violations of the AKS by labs in paying percentage-based compensation to independent sales contractors and distributors. The government has become insistent that the practice of paying contract marketers on a percentage basis is a reason for investigation and prosecution under the AKS and likely the False Claims Act (FCA). This emphasis comes in the wake of the government's successful investigation and prosecution of Health Diagnostics Laboratory (HDL), resulting in HDL's $47 million settlement in 2015 for paying physicians allegedly illegal processing and handling fees (P&H payments) in violation of the AKS and the FCA. This was followed by the $114 million jury verdict and judgment in 2018 against HDL's former CEO, Latonya Mallory, and HDL's exclusive contract marketing company, BlueWave Healthcare Consultants, and its principals.

Significantly, the government's case against BlueWave, in addition to P&H Payments, included claims that they violated the AKS and FCA by receiving percentage-of-revenue-based sales commissions. In 2021, the Fourth Circuit Court of Appeals upheld the jury verdict, in an opinion that focuses on and supports the government's case that paying contract marketers on a percentage basis violates the AKS.

The *Genotox* case from April 2023 is a second example of AKS enforcement in sales and marketing. [Genotox Laboratories of Austin, Texas, agreed to pay at least $5.9 million to resolve FCA allegations that it paid volume-based commissions to third-party marketers in violation of the AKS.]

Another example is the January 2024 settlement by RDx Bioscience. [The clinical laboratory agreed to pay over $13 million to resolve allegations of illegal kickbacks and medically unnecessary laboratory testing. One of the charges was that RDx paid independent contractor marketers commissions that were based on the volume and value of healthcare providers' Medicare and Medicaid lab referrals to RDx.]

Significantly, the DOJ's recently issued 2024 digest of actions includes multiple new criminal cases brought by the government against lab owners and contract marketers allegedly paid on a percent-

age basis in violation of the AKS. For example, in June 2024 the government charged the owner of two Houston-area labs, Bio Choice and Bios Scientific, as well as the labs' principal contract marketer, with conspiracy to commit healthcare fraud and conspiracy to defraud the United States and pay and receive kickbacks "in connection with a $359 million scheme to bill Medicare for medically unnecessary genetic tests that were induced by kickbacks."

The government has alleged, among many other claims, that the lab owner "negotiated illegal kickback and bribe arrangements with marketers, including [the principal contract marketer], and knowingly and intentionally disguised the nature and source of these illegal kickbacks and bribes through sham contracts … that purported to pay marketers on a 'flat fee' or hourly basis for legitimate marketing services." Instead, the contracts allegedly were based on the volumes or expected volumes of DNA samples and signed doctor's orders for genetic testing that the contract marketers referred or caused to be referred to the labs.

When laboratories or hospitals or other types of healthcare providers engage someone other than a bona fide employee for marketing, there is a high risk that the arrangement will not fit within a safe harbor and will be viewed as being inappropriate under the Anti-Kickback Statute.

In another criminal indictment filed in Texas in June 2024, the government has alleged that the owner of two Texas clinical laboratories, Axis Professional Labs and Kingdom Health Laboratory, offered and paid kickbacks to contract marketers, including its primary contract marketer in Indiana, "in exchange for their referral to Axis and Kingdom of Medicare beneficiaries' DNA samples, personally identifiable information (including Medicare numbers), and signed doctors' orders authorizing medically unnecessary cardio genetic testing. As part of the scheme, the marketers engaged other companies to solicit Medicare beneficiaries through telemarketing and to engage in 'doctor chase,' i.e., to obtain the identity of beneficiaries' primary care physicians and pressure them to approve genetic testing orders for patients who purportedly had already been 'qualified' for the testing."

The government has also alleged in this case that the lab owner and contract marketers "concealed and disguised the scheme by, among other things, (1) creating and causing the creation of a sham contract that falsely described [the contract marketer's] duties as marketing and advertising Axis' services; (2) creating and causing the creation of sham invoices … that identified the kickback and bribe payments as payments for marketing services at an hourly rate, when in truth and in fact the payments were based on per-sample fees." According to the government, Medicare paid Axis and Kingdom at least $54 million during the course of the arrangement.

In addition, we have seen the government routinely making inquiries about sales and marketing in subpoenas and civil investigative demands that appear on the surface focused more generally on billing or other practices by the laboratory. Invariably, this can lead to questions about whether a lab is using contract marketers and how the lab is compensating them.

What advice do you give to laboratories in terms of hiring contract marketers or (1099) salespeople?

I advise them to avoid any type of percentage-based compensation in relation to any type of contract marketer or distributor, even though I recognize there are often compelling business reasons for a lab company, especially a start-up, to prefer that option over recruiting and hiring the sales

team as employees. That has been my practice for many years, especially after I reviewed the government's pleadings and briefings as they were filed in the BlueWave case.

When laboratories or hospitals or other types of healthcare providers engage someone other than a bona fide employee for marketing, there is a high risk that the arrangement will not fit within a safe harbor and will be viewed as being inappropriate under the Anti-Kickback Statute. As explained earlier, the government views this type of arrangement as a "red flag." As early as 1989, the government has resisted creating a safe harbor for independent contractors paid on a commission basis, citing "many examples of abusive practices by sales personnel who are paid as independent contractors."

At the end of the day, I advise labs and other healthcare providers that the best and safest course to avoid investigation or prosecution under the AKS, if they want to pay sales representatives on the basis of the amount of business they generate, including Medicare and Medicaid business, is to hire and pay their sales representatives as W-2 employees.

It was the government's stated view at the time that if healthcare entities wish to pay sales representatives on the basis of the amount of business they generate, they "should make these salespersons employees" to avoid "civil or criminal prosecution." The government likely would point to its recent Texas indictments and the BlueWave case and others as strong validation of its longstanding concerns about "the existence of widespread abusive practices by salespersons who are independent contractors."

One further explanation offered by the government is that independent contractor sales representatives are less accountable to the healthcare provider that engages them than sales representatives hired as employees. In my experience, this observation has proven to be true. I have seen it over and over again during my career in the lab industry.

Ultimately, however, the legal and practical tension with contract marketing arrangements under the AKS is that labs and other healthcare entities want to pay sales representatives on the basis of the amount of business they generate in order to align risks and rewards, and motivate performance. However, the AKS safe harbor rule applicable to personal services and management contracts, even as loosened slightly by regulatory changes in 2020, simply cannot protect the contract relationship unless the methodology for determining the compensation paid to the contract marketer over the term of the contract is set in advance, is consistent with fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other federal healthcare programs. And AKS safe harbor protection is afforded only to arrangements that precisely meet all of the conditions of the safe harbor.

What is the safest type of sales compensation arrangment?

At the end of the day, I advise labs and other healthcare providers that the best and safest course to avoid investigation or prosecution under the AKS, if they want to pay sales representatives on the basis of the amount of business they generate, including Medicare and Medicaid business, is to hire and pay their sales representatives as W-2 employees. That will allow them to enjoy protection of the AKS employee safe harbor rule and statutory exception, which protects the amount paid by an employer to a bona fide employee even if the payments are calculated based on the volume or value of the business they generate, including Medicare and Medicaid business.

I should add one specific caution here, especially in light of the recent Texas lab owner indictments I mentioned where the government has called out "sham" arrangements, namely, it is important that if you want the protection of the employment safe harbor, the relationship must be a bona fide employment relationship—one in which you as the employer exercise control over the way the sales team operates and you also insist on a meaningful level of accountability from each sales representative. By contrast, I am aware of situations in which labs have hired and paid sales representatives on a part-time or other non-exclusive basis, and the sales representatives would also offer their marketing services to one or more other laboratories (even competing labs). The reps then offer existing and prospective physician customers lab services from among the rep's multiple employers based on what the physician wanted or the amount of sales commissions to be paid by that lab employer.

I also have advised a number of labs and other healthcare clients who feel an employment relationship would not work for their business reasons that there are alternative compensation models, in which compensation is not tied to the volume or value of referrals, that can be structured with an independent contractor to fit within the AKS personal services and management contracts safe harbor.

That type of "sham" arrangement has been questioned by the government, particularly when the physician customers didn't even know what lab they were using because the customer's relationship was primarily with the sales representative. Indeed, in that type of situation, the government might question or challenge whether the employee is in fact your bona fide employee despite receiving a W2 from you. Some tell-tale indicators include what types of business cards and email addresses the sales reps use.

What other problems do these kind of arrangements present?
These arrangements also can expose your lab to vicarious liability for the improper and illegal practices of the sales representatives, even when those practices are condoned or encouraged by the reps' other employer lab(s) and not by your lab. Labs also should recognize that even if this type of arrangement escapes government scrutiny, the value and sustainability of the business generated by such sales representatives are likely to be highly transitory.

Finally, I also have advised a number of labs and other healthcare clients who feel an employment relationship would not work for their business, explaining that there are alternative compensation models, in which compensation is not tied to the volume or value of referrals, that can be structured with an independent contractor to fit within the AKS personal services and management contracts safe harbor.

Specifically, there are other metrics besides the volume or value of federal payer business generated between the parties, including even something as simple as the number of contracts signed with lab customers or specific types of lab customers (i.e., physician specialties), or the successful opening of targeted new service territories. Other models could include appropriate equity arrangements and proper joint ventures. In any case, however, given the heightened risk, labs are well advised to seek experienced legal counsel in this area.

See the September issue of LECPR for the second part of our discussion with David Gee.

Top Five Common Pathology Coding Errors and How to Fix Them

(*cont'd from page 1*)

Billie Mildenberger

Holly Wolford

Common errors when billing for immunohistochemistry stains include billing per block, miscounting stains and billing the improper CPT code based on results and methodology, says Mildenberger.

"Comprehensive documentation is essential for selecting the appropriate CPT code for IHC stains," she says. "The method (manual versus computer-assisted) and results significantly influence the code determination. In addition, listing each antibody along with its corresponding result supports accurate billing. Remember to bill IHC stains per specimen, not per block. That's different than for special stains, where it should be per block, not per specimen."

Qualitative IHC stains, whether positive or negative, should be reported per specimen, not per block, using codes such as 88342 for the initial single antibody stain and 88341 for each additional single antibody stain. Quantitative or semi-quantitative IHC stains, whether using a scoring system or percentage result, should be reported with codes 88360 (manual) or 88361 (computer-assisted), advises Wolford.

IHC Coding Example

The lymph node is largely replaced by tumor cells, which are positive for ER and GATA3, but negative for CK7, CK20, TTF-1 and CDX2. The overall findings are consistent with adenocarcinoma of breast origin.

Immunohistochemical stains are performed on block A1.

Result: Estrogen Receptor (CLONE SP1).

Positive. Nuclear staining is seen in 95% of infiltrating tumor cells.

Intensity of nuclear staining is strong.

✗ Incorrect Code Selection:

- 88342 (GATA3), 88341x5 (CK7, CK20, TTF-1 & CDX2, ER), 88360 (ER).

✓ Correct Code Selection:

- 88342 (GATA3), 88341x4 (CK7, CK20, TTF-1 & CDX2), 88360 (ER).
- ER cannot be reported as 88341 since being billed as 88360.

Special Stains

Common errors include not reporting per block and not documenting what block the special stain was performed on to support multiple units. Thorough documentation is crucial for determining the correct CPT code for special stains, says Mildenberger. The distinction between Group I and Group II stains significantly influences code selection.

"Additionally, listing each stain alongside its corresponding result ensures accurate billing," she adds. "As new Medicare LCDs take effect next month, this practice becomes even more important. Remember to bill one unit for each special stain on every surgical pathology block."

Special stains should be reported per block, with clear documentation of each block stained. Use CPT codes 88312 for Group 1, microorganisms, and 88313 for Group II, all other stains.

Fine Needle Aspirate (FNA) Adequacy Interpretation

Common errors include documentation not supporting the evaluation episode or not supporting the time necessary for the charge.

"Supporting documentation for the 88177 CPT code often presents challenges," says Mildenberger. "There are numerous variations in the documentation for this charge, and it is common to find that the provided documentation does not substantiate the billed charges."

Documentation for 88177 must include the evaluation episode or the time to support the charge. This code is used for each separate additional evaluation episode after the initial evaluation on the same site.

FNA Adequacy Example

☒ Incorrect Documentation:

IMMEDIATE SMEAR EVALUATION.

- 11R-1st Pass: Blood Elements and Rare Bronchial Cells.
- 11R-2nd Pass: Blood Elements and Bronchial Cells.
- 11R-3rd Pass: Blood Elements.
- 11r-4th Pass: Blood Elements.
- 11R-5th Pass: Blood Elements.
- 11R-6th Pass: Blood Elements and Bronchial Cells.
- 11R-7th Pass: Blood Elements and Bronchial Cells.
- Lung, Right Upper Lobe-1st Pass: Malignant Cells Present.
- Lung, Right Upper Lobe-2nd Pass: Inflammatory Debris and Possible Tumor.

Code: CPT 88172x2, 88177x7.

☑ Correct Documentation:

RAPID PRELIMINARY INTERPRETATION

- Rapid on-site evaluation was performed in five separate evaluation episodes.
- Evaluation episode 1: Bronchial epithelial cells.
- Evaluation episode 2: Bronchial epithelial cells.
- Evaluation episode 3: Single granuloma.
- Evaluation episode 4: Rare possible granulomas.
- Evaluation episode 5: Granulomas.

Code: CPT 88173, 88172, 88177x4

In the incorrect example, Wolford notes that it is unclear whether each pass was done separately or whether they were given to the pathologist all at once. In the correct example, it is clear that each evaluation was done at separate times, which supports the coding, says Wolford.

Specimen Level

Another common mistake is general miscoding of surgical specimens, says Mildenberger, who explains that properly selecting the correct CPT codes for pathology surgical specimens can be challenging.

Specimen Level Example

☒ Incorrect Code Selection:

Final Diagnosis: Right breast accessory breast tissue: Skin and breast tissue with no pathological diagnosis, compatible with accessory breast tissue.

Gross Description: Received is an ovoid shaped fragments of yellow smooth rubbery soft tissue measuring 1.9 cm. Outer surface is inked black. Cut surface white and smooth. Specimen is submitted entirely.

Code: CPT 88307

☑ Correct Code Selection:

Gross Description

A. Received in formalin, labeled with the patient's barcode and "breast, right, 9:00, 4 cm from nipple,", are 3 tan-yellow to pink-white cylindrical cores of fibrofatty breast tissue ranging from 1.2-1.5 cm in length and averaging 0.2 cm in diameter. The fragments are inked blue and submitted in their entirety in 1 cassette.

B. Received in formalin, labeled with the patient's barcode and "breast, right, 10:00, 11 cm from the nipple," are 2 tan-yellow to pink-white cylindrical cores of fibrofatty breast tissue measuring 1.2 and 1.5 cm in length and ranging from less than 0.1-0.3 cm in diameter. The fragments are inked green and submitted in their entirety in 1 cassette.

Code: A: CPT 88305 (breast, biopsy core, 2 sectors); B: CPT 88305 (breast, biopsy core, 2 sectors)

"While the CPT book doesn't provide a comprehensive list of all specimens, there are helpful resources available," says Mildenberger, adding that Lighthouse has compiled a comprehensive list of specimens that provide a crosswalk to the appropriate CPT code.

Comingled Tissue

When multiple specimens are combined in a single container, determining how to code each individual specimen can be complex, says Mildenberger. Specimens are often bundled or unbundled based on the types of specimens received.

Comingled Tissue Example

✗ Incorrect Code Selection:

Left fallopian tube and ovary, salpingo-oophorectomy. Acute salpingitis. Benign epithelial cysts of ovary. No malignancy identified.

Code: CPT 88305

Uterus, supracervical hysterectomy. Intramural leiomylomas. Benign endometrial polyp. Post-menopausal atrophic endometrium. Focal serosal acute inflammation extending into underlying myometrium. No malignancy identified.

Code: CPT 88307

☑ Correct Code Selection

Uterus, cervix and bilateral fallopian tubes and ovaries, hysterectomy and bilateral salpingo-oophorectomy (104 g):

- Inactive endometrium with benign endometrial polyp.
- Myometrium with adenomyosis.
- Cervix without significant pathological change.
- Serosa with fibrous adhesions.
- Left ovary with serous cystadenoma, 12.8 cm in greatest dimension.
- Right ovary with seromucious cystadenoma, 3.0 cm in greatest dimension.
- Bilateral fallopian tubes without significant pathological change.

Code: 88307x3

Documentation Requirements

Detailed documentation is the foundation for proper CPT coding, says Mildenberger. The documentation must clearly support the medical necessity for the services provided. Many CPT codes have medically unlike edits (MUEs) or Correct Coding Initiative (CCI) edits that result in upfront denials. The appeal process for these denials may require the inclusion of the final report to ensure a successful appeal. However, if the final report is not accurately documented, it can lead to unsuccessful appeals or payment recoupment.

Detailed documentation will become crucial in the upcoming months as two Medicare administrative contractors, Palmetto and WPS, have finalized new local coverage determinations (LCDs) regarding special and IHC stains (*see brief on page 12*). Providers in the Palmetto and WPS regions are encouraged to review the new LCDs to ensure their current documentation will meet the required conditions.

Molecular and Genetic Testing

Common mistakes when billing for molecular and genetic testing include using incorrect or outdated CPT codes, using unlisted codes when a specific code exists and failing to support the charge by not documenting the medical necessity or test results.

Mildenberger advises that labs know the NCDs: (National Coding Determinations), LCDs and commercial payer policy for each test you perform. "This will allow you to outline reimbursement policies and have a good understanding of how payment will be affected."

Labs should also know their payer mix, she says, recommending that labs research whether you participate with the plans that represent your target population and identify payers that require preauthorization.

PROVISTA HEALTH, OWNER ORDERED TO PAY $26 MILLION OVER UNNECESSARY RPP TESTS

(*cont'd from page 1*)

In its complaint, filed July 18, 2023, the United States alleged that Britton-Harr owned and operated Provista Health, LLC, as well as other corporate entities that sought to profit from the unfolding Covid-19 pandemic by offering Covid-19 tests to nursing homes as a way to bill Medicare for a wide array of medically unnecessary respiratory pathogen panel (RPP) tests. The complaint alleged that these RPP tests were not medically necessary because the beneficiaries had no symptoms of a respiratory illness and because the tests were for uncommon respiratory pathogens.

The complaint also alleged that Britton-Harr and Provista Health submitted claims for RPP tests that were never ordered by physicians and sometimes for RPP tests that were never performed, including more than 300 claims that stated that the nasal swab test sample was supposedly collected from the beneficiary on a date after the beneficiary had died.

Also on July 18, the United States filed an application for prejudgment remedies under the Federal Debt Collection Procedures Act seeking to attach and garnish certain financial assets of Britton-Harr and to obtain financial discovery from him to help ensure funds would be available to satisfy the judgment. Despite a court order prohibiting Britton-Harr from selling his house in Annapolis without approval from the court, he sold the house on Sept. 23, 2023, for $575,000 and dissipated the financial proceeds from the sale. On March 4, the court granted the United States' motion to hold Britton-Harr in civil contempt for violating this order and ordered him to deposit $575,000 with the court's registry.

THREE FLORIDA LABS TO PAY ALMOST $2.5 MILLION OVER MANIPULATED DIAGNOSIS CODES

(*cont'd from page 1*)

Vista Clinical Diagnostics, LLC; Access Dermpath, Inc.; and Advanced Clinical Laboratories, Inc., will pay $2.45 million to the United States, the State of Florida, the State of North Carolina and the Commonwealth of Virginia. According to the settlement, the labs billed for clinical laboratory services using diagnosis codes that were generated by a macro and inserted into beneficiaries' reimbursement submissions. This allegedly occurred from Jan. 1, 2017 through Dec. 31, 2021. According to allegations, these diagnosis codes were generated by the defendants and not provided by the beneficiaries' physicians.

The settlement concludes a lawsuit originally filed in the United States District Court for the Middle District of Florida by relator Balbina Castillo, a former employee of Vista Clinical Diagnostics. Castillo sued under the qui tam, or whistleblower, provisions of the False Claims Act permitting private citizens to sue on behalf of the United States for false claims and to share in the recovery. Castillo will receive more than $440,000 of the proceeds from the settlement.

Contemporaneous with the settlement, Vista Clinical Diagnostics, Access Dermpath and Advanced Clinical Laboratories have entered into a five-year Corporate Integrity Agreement with the Health and Human Services Office of Inspector General. The agreement requires the labs, among other obligations, to establish and maintain a compliance program meeting certain requirements and to submit to an Independent Review Organization's review of the labs' Medicare claims to determine whether such claims were medically necessary, appropriately documented and correctly coded.

Admera Health to Pay More Than $5 Million to Settle Allegations of Kickbacks to Third-Party Marketers

Admera Health LLC has agreed to pay the United States $5.4 million to resolve allegations that it violated the False Claims Act by paying commissions to third-party independent contractor marketers in violation of the Anti-Kickback Statute (AKS). Admera will pay an additional $147,851 to individual states for claims paid to Admera by state Medicaid programs.

Admera is a New Jersey-based company that provides biopharmaceutical research services for healthcare institutions and provided clinical laboratory testing services to healthcare providers relating to pharmacogenetics until 2021. The settlement announced July 24, 2024, resolves allegations that from Sept. 1, 2014 through May 21, 2021, Admera made commission-based payments to independent contractor marketers in return for recommending or arranging for the ordering of genetic testing services in violation of the AKS.

As part of the settlement, Admera admitted that it made millions of dollars of commission payments to independent-contractor marketers to induce them to arrange for or recommend that healthcare providers order and refer clinical laboratory services to Admera, including genetic tests, that were reimbursable by Medicare and/or Medicaid. These arrangements took into account the volume and value of genetic testing referrals, and Admera was informed that the payment of commissions to independent contractors did not comply with the AKS but continued to enter into such contracts.

The settlement includes the resolution of claims brought under the qui tam provision of the False Claims Act by relators, Sunil Wadhwa and Ken Newton, co-founders of Financial Halo LLC/ MedXPrime, a former third-party marketer for Admera. The relators will receive $862,343 of the proceeds from the settlement.

Guardant Health to Pay More Than $900,000 in FCA Settlement Over Improper Ordering Relationship

Guardant Health Inc., a precision oncology company based in Palo Alto, CA, has agreed to settle allegations that it knowingly violated the False Claims Act (FCA) and regulations of the Defense Health Agency (DHA). Guardant voluntarily disclosed the conduct to the Health and Human Services Office of Inspector General.

It will pay $913,933 to settle FCA allegations and $31,082 in an administrative settlement with the DHA. As alleged by the government, in February 2022, Guardant hired the stepdaughter of a local physician who had asked the company to hire her. In this role, the stepdaughter was responsible for the account of her stepfather. Employees involved in the hiring knew of the relationship between the stepdaughter and the physician, and that the stepdaughter was not qualified for the role. The physician ordered significantly more Guardant tests per quarter after the hiring. As a result of the increase in business from the physician, Guardant's South Texas sales team was recognized as one of the best performing regions in 2022. Guardant cooperated with the government's investigation of the issues and took prompt and substantial remedial measures.

Shortly after receiving information regarding the physician's referrals, Guardant stopped billing federal healthcare programs for Guardant tests ordered by the physician. Guardant also terminated the physician's family member's employment.

COMPLIANCE 101:

Waivers of Federal Healthcare Enrollees' Cost-Sharing Amounts

While the Health and Human Services Office of Inspector General (HHS OIG) has had longstanding concerns about the routine waiver of cost-sharing amounts for federal healthcare program enrollees (i.e., Medicare and Medicaid patients), new guidance from the OIG offers further clarification on its views.

In updated FAQs published July 8, 2024, the OIG reiterates its prior guidance that "[H]ospitals have the ability to provide relief to uninsured and underinsured patients who cannot afford their hospital bill and to Medicare beneficiaries who cannot afford their Medicare cost-sharing amounts. [OIG] fully supports hospitals' efforts in this area." As a general matter, the federal Anti-Kickback Statute and the Beneficiary Inducements civil monetary penalties (CMP) do not apply to cost-sharing waivers provided to uninsured persons or to persons insured solely by commercial health plans, including qualified health plans.

Routine Waivers Can Be Suspect

The OIG does stress, however, that routine waivers of federal healthcare program enrollees' cost-sharing amounts could be problematic. "In particular, hospitals that routinely waive cost-sharing amounts—as part of a financial assistance policy or otherwise—for reasons unrelated to individualized, good-faith assessments of financial hardship may be held liable under the federal Anti-Kickback Statute, the Beneficiary Inducements CMP, or both," the OIG writes in the July 8, 2024, update.

"However, cost-sharing waivers to federal healthcare program enrollees could be structured—and hospitals' financial assistance policies could be drafted—so that the waivers would be protected by a safe harbor to the federal Anti-Kickback Statute or an exception to the Beneficiary Inducements CMP or otherwise would present sufficiently low risk to avoid sanctions under these statutes," says the OIG. "For example, hospitals can structure certain cost-sharing waivers to enrollees to satisfy an available safe harbor for hospitals' waivers of cost-sharing amounts for inpatient services. In addition, OIG has repeatedly stated that waivers of federal healthcare program enrollees' cost-sharing amounts on the basis of an enrollees' financial need—provided the waiver is not routine, not advertised and is made pursuant to a good-faith, individualized assessment of the enrollees' financial need—likely are low risk under the federal Anti-Kickback statute."

Don't Advertise Waivers

Rachel Yount, an attorney with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., (Washington, D.C.), says that while the government has expressed a long-standing concern about the routine waiver of Medicare and Medicaid patients' copayments, which can implicate the Anti-Kickback Statute and the Beneficiary Inducement CMP, individualized, good-faith assessments that patients have a financial hardship typically present sufficiently low risk under these laws.

"Providers and suppliers should avoid advertising the availability of copayment waivers, but the government indicates that including information about the availability of a financial assistance policy on a provider's or supplier's website is permissible," she advises.

In Brief

Lawmakers Ask FDA to Suspend LDT Final Rule

The House Appropriations Committee has requested that the Food and Drug Administration (FDA) suspend implementation of the laboratory-developed tests final rule that went into effect May 6. The request was included in the FY25 appropriations bill for the Department of Agriculture, Rural Development, Food and Drug Administration and related agencies, which passed out of committee July 10. Lawmakers have asked that the FDA continue working with Congress to modernize the regulatory approach for LDTs. Several groups representing clinical and anatomic pathology laboratories have advocated for a delay that would allow Congress time to enact legislation that would focus oversight on tests that are highest risk to patients. During a Capitol Hill briefing on July 9, the College of American Pathologists (CAP) discussed how Congress can promote patient safety without overburdening laboratories through enacting a diagnostic reform package that provides oversight of LDTs and allows for innovation of new technologies.

New LCDs on Special and IHC Stains Less Restrictive Than Proposals

Two new local coverage determinations (LCDs) on medical necessity guidelines for special stains and immunohistochemistry (IHC) stains, which took effect July 14, 2024, incorporate multiple comments from the pathology and laboratory community and are less restrictive than the proposed LCDs. The LCDs, L36805 and L35922, apply to pathology or laboratory providers covered by Palmetto (Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia and West Virginia) or WPS (Indiana, Iowa, Kansas, Michigan, Missouri and Nebraska). Both LCDs state that Medicare will only cover special stains and IHC stains ordered by pathologists when all of the following conditions are met: the stains are medically necessary so that a complete and accurate diagnosis can be reported to the treating physician, results of the stain are communicated to and are used by the treating physician in the treatment of the patient, and the pathologist documents in the pathology report why the additional stains were performed. The LCDs state that reflex templates or pre-orders for special stains and/or IHC stains prior to the review of the routine H&E stain by the pathologist are not reasonable and necessary, with limited exceptions.

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

New from Laboratory Economics

The U.S. Clinical Laboratory Industry
Forecast & Trends 2023-2025

"This is an ideal resource for preparing business plans and market strategies, creating dynamic data-driven presentations and deepening your understanding of the U.S. laboratory testing market."

The publisher of *Laboratory Economics* has just released The U.S. Clinical Laboratory Industry: Forecast & Trends 2023-2025. With this special report, you can tap into 100+ pages of proprietary market research that reveals critical data and information about key business trends affecting the clinical laboratory market.

- More than 100 charts and graphs
- Industry size and growth rates for 2012-2025
- Medicare claims data for key laboratory codes
- Hospital laboratory cost report data for more than 100 hospitals
- Top 50 hospitals by outreach lab CLFS and PFS payments
- Detailed data on the fast-growing PCR-based testing market
- CLIA test volume figures for the top hospitals, independent labs and POLs
- Top 30 U.S. laboratory companies by total revenue
- Key mergers, acquisitions and joint ventures
- Private-Payer Reimbursement Survey Results

Condensed Table of Contents

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The Laboratory Economics Difference

100+ Pages of Charts, Tables and Graphs!

The U.S. laboratory testing market has been fundamentally altered by Medicare's new market-based payment system, which will directly impact virtually every payer category with profound consequences for all laboratories. The pace of consolidation will accelerate, new investment will be centered on proprietary molecular diagnostics, and successful managed care contracting will be paramount to the survival of most laboratories. Big change accentuates the need for informed decision-making. Choosing the best path to the future depends on two critical factors: quality of information and insightful analysis. ***The U.S. Clinical Laboratory Industry: Forecast & Trends 2023-2025*** can help you make educated decisions. You'll get an insider's market expertise combined with the objectivity of an outsider for the best possible insight into the laboratory market's competitive dynamics.

Our Research Methodology

The U.S. Clinical Laboratory Industry: Forecast & Trends 2023-2025 includes data gathered the old-fashioned way—through primary research. The estimates and market analysis in this report have been built from the ground up, not by regurgitating stale numbers from old reports. Proprietary surveys and extensive interviews with commercial lab executives, hospital lab directors, and respected consultants form the basis of this report. And no stone has been left unturned in our examination of the CLIA database, Medicare test volume and expenditure data, hospital cost reports, Securities & Exchange Commission filings and company annual reports.

About the Author

Jondavid Klipp is president and publisher of ***Laboratory Economics LLC***, an independent market research firm focused on the business of laboratory medicine. Prior to founding ***Laboratory Economics*** in April 2006, Mr. Klipp was managing editor at Washington G-2 Reports. During his seven-year employment with G-2, he was editor of Laboratory Industry Report and Diagnostic Testing & Technology Report. Mr. Klipp also authored several landmark research reports, including ***G-2's Lab Industry Strategic Outlook 2005, U.S. Laboratory Reference Testing: Profile and Pricing Trends*** and ***The Laboratory Market Leaders Report***. Prior to joining G-2, Mr. Klipp was an HMO analyst at Corporate Research Group in New Rochelle, New York, and a senior writer in the equity research department at Dean Witter in New York City.

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