LABORATORY ECONOMICS Volume 2, No. 4, April 2024

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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

Final LDT Rule Expected Soon

A final rule on Food and Drug Administration (FDA) regulation of laboratory-developed tests (LDTs) has been sent to the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) for review and is expected to be published as early as April. If the final rule is finalized as proposed, it is likely to be met with litigation challenging FDA's authority to regulate such tests. *Details on page 2.*

CLIA Personnel Changes a Win for Patient Care, Lab Staff

Groups representing clinical laboratory personnel are praising final changes to the Clinical Laboratory Improvement Amendments (CLIA) program, especially personnel requirements, saying the changes will have a positive impact on patient care. *More on page 3.*

Resolving Managed Care Disputes Between Labs and Payers

Clinical and anatomic pathology laboratories often run into difficulty getting their claims paid, especially if they are out-of-network with a payer. Bridget Gordon, co-chair of the Clinical Laboratory Practice Group at Hooper, Lundy and Bookman (Los Angeles), recently spoke with *Laboratory Economics Compliance & Policy Report* about how to handle disputes with managed care companies. *See page 5.*

Capstone Diagnostics to Pay $14.3 Million in Kickback Case

Capstone Diagnostics (Atlanta) and its owner, Andrew Maloney, 57, have agreed to pay $14.3 million to resolve allegations that they violated the Anti-Kickback Statute by paying volume-base commissions to independent contractor sales representatives to arrange for or recommend medically unnecessary urine drug tests and respiratory pathogen panels (RPPs). Maloney and Capstone have agreed to cooperate with the Justice Department's investigations of other participants in the alleged schemes. *Continued on page 9.*

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FINAL LDT RULE EXPECTED SOON (*cont'd from page 1*)

The proposed rule on LDTs was published Sept. 29, 2023, and the FDA declined to extend the 60-day comment period, which closed on Dec. 4, 2023. The FDA received more than 6,000 comments on the proposal, with many of them expressing opposition to FDA oversight of LDTs. The fact that the agency has moved so swiftly indicates that the proposal is a top priority for the FDA, write Steven Tjoe and Matt Wetzel, attorneys with the law firm of Goodwin Proctor LLP, in a life sciences blog.

Susan Van Meter

The OMB held meetings with interested stakeholders the week of March 18, and the House Energy and Commerce Committee Subcommittee on Health held a hearing on the proposal March 21. All this signals that the final rule remains on track for potential issuance in April 2024, the target date for final action, write Tjoe and Wetzel.

Among those submitting comments and testifying at the hearing was Susan Van Meter, president of the American Clinical Laboratory Association (ACLA). In her comments, Van Meter says the rule, if finalized as proposed, would require laboratories to divert resources currently dedicated to research and development to focus on backward-looking activities in support of FDA approval of tests that have long been offered by laboratories and relied upon by physicians.

> *Everyone testifying and many in the committee on both sides of the aisle said the medical device authorities are not well suited for diagnostics. Even the test manufacturers have said that diagnostics are different from medical devices. Authorities need to be changed through legislation so there is a diagnostic-specific framework.*

"Laboratories would be forced to examine test menus and make difficult decisions about which tests could support FDA submissions, likely resulting in the removal of low-volume tests, including for rare diseases, from test menus," she says. "That would also mean diverting resources away from the development of the next generation of diagnostics for cancer, infectious disease, cardiovascular disease, neurology and numerous other disease and conditions."

Does FDA Have Authority?

Van Meter tells *LE Compliance & Policy Report* that there is consensus by Republicans and Democrats on the House Energy and Commerce Committee Subcommittee on Health, which held the March 21 hearing, that the rule is not the best way to regulate LDTs. In addition, there remain questions about FDA's fundamental authority to regulate these tests. ACLA has long held the position that the agency lacks the authority to regulate LDTs.

"All of this came out at the hearing, and we are pleased with that discussion overall," she says. "Everyone testifying and many in the committee on both sides of the aisle said the medical device authorities are not well suited for diagnostics. Even the test manufacturers have said that diagnostics are different from medical devices. Authorities need to be changed through legislation so there is a diagnostic-specific framework."

ACLA will continue to push for Congress to pass legislation to establish such a framework, says Van Meter. The VALID (Verifying Accurate Leading-Edge IVCT Development) Act has been reintroduced in the House but not yet in the Senate. The measure would implement a risk-based review system for all diagnostic tests, including LDTs, under the FDA.

"We think there are some positive attributes to VALID," she says. "We would still like to make some tweaks to it, but we are hopeful momentum will pick up and it will be reintroduced in the Senate."

Van Meter is hopeful that publication of the final rule will spur lawmakers to act. Even if there are exceptions in the final rule for certain LDTs, such as those for rare diseases or pediatric patients, exceptions are not the solution.

"The issue at heart of this is the application of medical devices authorities to diagnostics," she says. "The rule is absolutely the wrong direction. I think when the final rule comes out, we will see heightened interest in Congress in taking some action."

CLIA Personnel Changes a Win for Patient Care, Lab Staff (*cont'd from page 1*)

In particular, the groups are pleased that the Centers for Medicare and Medicaid Services (CMS) did not finalize its proposal to allow those with a bachelor of science degree in nursing (BSN) to perform high-complexity tests. In its proposed rule, issued in July 2022, CMS had acknowledged that a BSN is not equivalent to a degree in biological or chemical science, but had nevertheless proposed to create a separate route by which BSNs could perform high-complexity testing, without any additional documented training.

Jim Flanigan

In fact, under a 2016 memorandum to state survey agency directors (16-18-CLIA), CMS had already given authorization for those with bachelors or associates degrees in nursing to perform such testing (*LECPR*, May 2023, p. 1). However, CMS received more than 19,750 comments from laboratory personnel groups on the proposed rule opposing the creation of a separate route for BSNs.

In its final rule issued Dec. 28, 2023, CMS agreed with commenters that the breadth and depth of science courses in a nursing curriculum is considerably less than those required for a B.S. in biology or chemistry. The agency also agreed that nurses' education also lacks training in fundamental areas of laboratory sciences, such as pre-analytic, analytic and post-analytic phases of testing, calibration, quality control and proficiency testing.

Under the final rule, nurses can perform high-complexity testing only if they have completed the requisite additional science coursework and clinical training to meet the equivalent of an associate degree in laboratory sciences or medical technology. Individuals with a nursing degree may still qualify as moderate complexity testing personnel, which covers most point-of-care testing, but cannot serve as lab directors or technical consultants in those settings. The personnel requirements of the final rule take effect Dec. 28, 2024.

"The American Society for Clinical Laboratory Sciences was very pleased with the outcome of the formal rulemaking process on a number of levels," says Jim Flanigan, Executive Vice President of ASCLS. "ASCLS, and most every other professional society in the clinical laboratory community, had been working to overturn how CMS has used nursing degrees as a qualification to perform diagnostics. This was a significant area of risk for patients that is now closed."

DCLS a Qualifying Degree for High-Complexity Labs

Flanigan also said he was pleased to see ASCLS's long-term advocacy of the clinical doctorate in clinical laboratory science (DCLS) come to fruition when CMS officially accepted the DCLS as a

qualifying degree for high-complexity laboratory director.

A DCLS is an advanced professional doctorate designed for practicing clinical laboratory scientists or medical technologists who have at least a bachelor's degree and wish to further their level of clinical expertise and develop leadership and management skills.

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Associate Route Added to TC Qualifications

Since the CLIA rules were first adopted in 1992, an anomaly has existed as to who is qualified to perform competency assessments (CA) on high-complexity testing personnel (TP) and moderate-complexity TP, according to the American Medical Technologists (AMT). The previous rules allowed a general supervisor (GS) with an associate degree in medical technology (or equivalent), plus two years' clinical training or experience, to perform CA on high-complexity TP.

However, for moderate-complexity TP, the rules require that CA be performed by a technical consultant (TC) who has a minimum of a bachelor's degree in a biological or chemical science or laboratory science. Accordingly, under previous rules, most MLTs can assess competency of high-complexity TP, but cannot perform CA on moderate-complexity TP.

The final rule adds a route by which individuals with an associate degree in laboratory science or medical technology, plus four years' clinical training and/or experience, can qualify as TC in a moderate-complexity setting. Thus, after the final rule takes effect in December 2024, most MLTs will be qualified to perform CA for both moderate- and high-complexity TP.

Other Personnel Changes

CMS also finalized its proposal to eliminate a degree in a "physical science" as a route to qualifying for various personnel classifications in nonwaived labs. CMS will now recognize bachelor's degrees in a biological or chemical science, or in medical/clinical laboratory technology or science. Individuals who hold a bachelor's degree (or equivalent of 120 semester hours) in physical sciences or other non-traditional major must meet an "educational algorithm" to qualify for positions that require a minimum of a bachelor's degree.

Individuals who qualified for any position by virtue of a degree in a physical science or other henceforth non-qualifying degree (e.g., nursing) on the effective date of the final rule will be grandfathered (i.e., they won't have to satisfy the educational algorithm course requirements—so long as they are employed continuously from the effective date of the revised rules.

RESOLVING MANAGED CARE DISPUTES BETWEEN LABS AND PAYERS (*cont'd from page 1*)

What are the most common types of disputes your lab clients have with managed care payers?

Bridget Gordon

We are frequently dealing with underpayments and improper denials for a number of reasons, including, but not limited to, lack of prior authorization, medical necessity denials and problems with timely filing of claims submissions and appeals. We work with payers to educate them about coverage determinations (both local and national), especially in the molecular diagnostics lab space, ADLT status, and to educate them about clinical support for some of the testing that our clients are providing, as well as the purpose of the testing and benefits for the payer's beneficiaries. Some payers are unfamiliar with the testing that's being provided, and seemingly use that as a basis for denial.

A lot of our lab clients are non-contracted with the majority of payers. We work heavily in the Medicare Advantage and commercial space. Often, we are dealing with improper denials and improper underpayments, both on the non-contracted/out-of-network side and the contracted/in-network side. In those cases, we generally initially make outreach to specific payer contacts we have through a demand letter to provide notice to the payer of the issues and seek their involvement through more informal meet and confer.

To achieve the best results, it's usually a combination of improving internal claims submissions and appeals process but also holding payers accountable to their obligations of processing and paying claims at the appropriate rates.

Are there there things labs could be doing better in terms of claims submissions?

We do sometimes see issues on the lab side of things when it comes to claims submission and appeals. For example, the lab may not be submitting timely claims, may be failing to timely appeal claims, or may not be providing requested supplemental documentation, such as requisitions forms and test results. I push firmly on the payers, but it's also a learning exercise for labs on how to better hone their internal claims processes and procedures. That might involve having their billing team and claims team review online payer policies on the payer's electronic provider portal, setting internal alerts for timely claims submission and appeals, setting up an internal system to follow when the lab receives a request for supplemental documentation from a payer (including for outreach to ordering clinicians) or in certain instances creating a better prior authorization process and reaching out to the ordering clinicians to educate them about the prior authorization requirements for various payers.

To achieve the best results, it's usually a combination of improving internal claims submissions and appeals process but also holding payers accountable to their obligations of processing and paying claims at the appropriate rates.

What are payers getting wrong?

On the payer side, what we see that the payers doing wrong most frequently in the lab space is improperly denying or underpaying claims based on alleged lack of medical necessity because the payer is misinterpreting the local or national coverage determination (LCD or NCD) because they don't understand the testing being provided to their beneficiaries, or they are using outdated clinical coverage policies to deny claims on medical necessity grounds. Especially in states where

biomarker legislation is in effect, that can be particularly challenging with some of these payers because they are relying on coverage policies that are arguably in violation of these biomarker laws. [In recent years, a number of states have passed laws mandating coverage of comprehensive biomarker testing. Biomarker legislation is also pending in additional states]. We have sent letters on behalf of lab clients informing payers about biomarker legislation in a number of states and about their obligation to comply with such legislation. I think it's going to be an ongoing battle with payers. There may ultimately be litigation on that front.

It's critical that labs read their managed care contracts with the payers carefully. A lot of providers see the contracts as take it or leave it and they don't push back on any of the language in the contracts. But managed care contracts, just like other contracts, often can be negotiated.

We also find that payers sometimes are not paying at the appropriate rate for the lab testing services provided, particularly on the Medicare Advantage side. We have a couple of clients who are using unlisted molecular diagnostic codes and the payers get confused by them, even when there are specific Z codes that tell them the exact test that is being provided. We often work with the payers to educate them about unlisted codes and Z codes, such that the payers can update their internal payment mechanisms to recognize the Z codes and pay the appropriate associated rates.

The commercial side can get more complicated rate-wise because payers often have complicated payment algorithms that are not always clear. But we will certainly push back on super-low payments on both molecular diagnostic tests and more standard lab tests, for our out-of-network lab clients, and ensure the contract rate is being paid for our in-network lab clients.

How do you work with payers to determine the appropriate payment?
On the commercial side, we take the stance that what the lab charges is the appropriate reasonable and customary rate. The payers typically are willing to engage in a meet and confer process from there. There are some payers who will take a more hardline approach and say the only method for claims resolution is to go through their typical appeal process. I always advise clients to exhaust all levels of appeal with the payers and ensure they are keeping thorough documentation of their appeal attempts. Litigation remains a path to challenge claims as well, though is considered amongst a variety of options in negotiating with the payers, rather than as the first channel by which to proceed. On the whole, many of our clients are reluctant to immediately engage in litigation, given the ongoing business relationship with the payors for most clients, but it is a viable and powerful option, when it becomes needed to make forward momentum.

It's critical that labs read their managed care contracts with the payers carefully. A lot of providers see the contracts as take it or leave it and they don't push back on any of the language in the contracts. But managed care contracts, just like other contracts, often can be negotiated. Payers may not bend on everything, but with ongoing negotiations a provider can usually get at least two or three main provisions modified so they are more favorable to the provider going forward.

At what point should labs appeal their claims?
Generally, to protect their rights later, I will tell clients that they should be appealing every denied claim at all levels. If there are claims that were denied where the client didn't appeal, it can be much more difficult to get payer engagement, as the payer will say the appeals must be exhausted before they are willing to meet and confer. Clients need to have everything documented when it

comes to claim submission and appeals, including proof of when any appeal was sent. I encourage clients to try to get access to payers' online portals if they can. It's tricky because a lot of payers don't allow non-contracted providers to have access to their online portals, but if you reach out to the payer, sometimes they will make exceptions and allow you to have access to it. Paper claims submissions and appeal submissions should be sent in a trackable format or return receipt requested. Labs should ensure they have thorough written documentation of all actions taken on any claim and of all communications with the payer for the claim.

When do labs usually come to you?
Usually in the middle of the process, where the lab has accumulated a large volume of outstanding claims or denied claims. After providing the payer with a spreadsheet of disputed claims, sometimes the payer will say these 100 claims haven't even been appealed yet, so we won't even talk to you about those but we will talk to you about the ones that have been appealed. We always talk about claims as a moving target because there will always be some payments that come in, claims that get further appealed, claims that get denied, and so both the lab and payer need to be open to the universe of disputed claims changing over the course of their discussions. We always include language when we submit disputed claims to payers that the claims are subject to change and that we will provide a revised spreadsheet of disputed claims as time passes to ensure all disputed claims are accounted for.

How often are you successful in recouping payment? We are pretty successful in getting the payers to release at least partial payment on some of the disputed claims, particularly for clients with robust documentation and appeals.

Do labs seek additional help mainly with large numbers of outstanding claims or high dollar amounts?
Yes, labs typically come to us when there is a larger volume or a larger dollar amount at issue, or they are having issues with a large swatch of payers. We also have clients come to us when they are being audited by a payer or have received correspondence from the Special Investigations Unit (SIU) from a payer, which can be a precursor to the request for an overpayment. For smaller amounts, we serve more in an advisory role, providing guidance and advice regarding some things the lab might consider doing better on claims submissions and appeals and alerting the lab to some things to look out for from the payer. With smaller dollar value claims disputes, we also often prepare a demand letter that the lab can send to the payer and then they can handle the back and forth with the payer themselves.

How often are you successful in recouping payment?
We are pretty successful in getting the payers to release at least partial payment on some of the disputed claims, particularly for clients with robust documentation and appeals. It depends on whether we get engagement from the payer on the front end at our initial outreach step, though we are relentless with continued follow-ups. We have one lab client in the molecular diagnostic space who works with more than 40 payers and we have gotten them over $20 million without the need for litigation, but through ongoing meet and confer and education of the payers. I tell all my clients that if you are not going after the payers with timely appeals and demand letters, and litigation, you are leaving money on the table. The squeaky wheel gets the money. We challenge all different payers, from Medicare fee-for-service to Medicaid, Medicare Advantage, managed Medicaid, to commercial payers. The level of success is partially dependent on whose desk it lands on and whether they are willing to engage, as well as how well the lab has documented its claims and followed all appeals processes.

We are pretty relentless. I would estimate that we get at least a portion of payments more than 50% of the time, but it's very dependent on the payer. Sometimes payers choose to reprocess disputed claims, and sometimes there's a more formal settlement agreement on the disputed claims. Even in contracted situations, payers might improperly deny claims in violation of their contractual obligations, but out-of-network claims are the trickiest, because often the provider does not have a set point of contact at the payer to resolve any dispute. Having outside counsel and a formal demand letter, as well as the potential for litigation, definitely gets payers' attention.

We can tweak the language in the contracts to try to impose additional obligations on the payer, often acting as the third-party administrator for the Other Payer, such as including language that the payer has to help coordinate discussions between the lab and the ERISA plan and must ensure that the Other Payer is following the plan's pricing of claims.

Do you also help labs negotiate in-network contracts?

Yes, I work on those negotiations and the firm as a whole does that kind of work. Many of our clients will engage a consultant, and we rely on the client to tell us what rates they are looking for. We provide redline feedback on the payer-proposed contracts and advise clients on legal language or specific provisions and language to seek to include. We often push back on dispute resolution language, appeals language, payment requirements, and overpayment/recoupment language to make it more favorable for labs. There's often also what is referred to as "Other Payer" language in managed care contracts – such as with Anthem that involves BlueCard claims, out-of-state claims, and can also involve ERISA claims, that is really important for purposes of getting paid by plans that may have access to a provider's contract but not be the actual contracting entity. We can tweak the language in the contracts to try to impose additional obligations on the payer, often acting as the third-party administrator for the Other Payer, such as including language that the payer has to help coordinate discussions between the lab and the ERISA plan and must ensure that the Other Payer is following the plan's pricing of claims.

Lab Owner Pleads Guilty to $30M Medicare Fraud Scheme

A Florida man pleaded guilty March 26 to his role in a scheme to defraud Medicare by billing for over-the-counter Covid-19 test kits and genetic tests that were ineligible for reimbursement and procured by paying illegal kickbacks and bribes.

According to court documents, Robert M. Clark, 29, of Pompano Beach, was the figurehead owner of Clear Choice Diagnostics Inc. Clark and his co-conspirators, including the true owner of Clear Choice, purchased Medicare beneficiary identification numbers without lawful authority and then used those numbers to bill Medicare for over-the-counter Covid -19 test kits. Clark and his co-conspirators also paid illegal kickbacks and bribes to marketers in exchange for referrals of Medicare beneficiaries for genetic tests.

In total, they submitted approximately $30 million in fraudulent claims, of which Medicare paid about $15 million. Clark faces up to five years in prison. He is scheduled to be sentenced on June 20.

CAPSTONE DIAGNOSTICS TO PAY $14.3 MILLION IN KICKBACK CASE (*cont'd from page 1*)

As alleged in the criminal complaint filed in the Northern District of Georgia, between August 2017 and December 2018, Capstone entered into an arrangement with a program operating as Do It 4 the Hood (D4H), which held itself out as providing after-school mentoring services to at-risk teenagers in Georgia. Once enrolled, participants were required to submit frequent urine specimen collections for drug testing without regard to medical need or the history of the participant. Maloney was aware that the participants needed the tests to participate in the program and that many of these participants were covered by Medicaid.

Capstone engaged in both a fraudulent drug-testing program and a scheme to profit off the Covid-19 pandemic by paying independent contractor sales representatives to recommend respiratory pathogen panels to senior communities interested only in Covid-19 tests.

Capstone, with Maloney's knowledge and approval, paid the operators of D4H a percentage of Medicaid reimbursements for samples submitted by the program, in violation of federal law. While the scheme was ongoing, Capstone submitted more than $1 million in claims, causing Georgia Medicaid to pay out at least $400,000 in claims related to the fraudulent drug testing. In addition to Maloney's guilty plea, four other individuals have pleaded guilty in connection with this fraudulent drug testing scheme:

- Duriel Gray, 45, of Cartersville, Ga., pleaded guilty to conspiracy to receive healthcare kickbacks in the Northern District of Georgia. Gray is licensed to practice medicine in Georgia and was recruited to be the "medical director" for D4H in Georgia. D4H used Gray to provide a "standing order" under which Capstone could submit the fraudulent drug testing claims to Medicaid. Gray did not have a physician-patient relationship with the students, never examined any of them and did not review or discuss the drug tests with any of the participating students. For this role in the scheme, Gray received approximately $30,000. On April 13, 2023, Gray was sentenced to two years of probation and ordered to pay $417,200 in restitution.

- Bree-Anna Harris, 32, of Phoenix, pleaded guilty to conspiracy to commit healthcare fraud and money laundering to charges filed in the Northern District of Georgia and Western District of North Carolina. Among other things, Harris incorporated an entity, BPolloni Consulting LLC, which entered into a purported marketing agreement with Capstone. The arrangement between BPolloni and Capstone was used to receive and conceal the fraudulent kickback payments and distribute them to her coconspirators. On Dec. 4, 2023, Harris was sentenced to 36 months in prison for her role in the D4H scheme and related schemes in North Carolina and elsewhere.

- Glenn Pair, 36, of Stonecrest, Ga., pleaded guilty to conspiracy to commit healthcare fraud and money laundering in the Western District of North Carolina. On July 27, 2022, Pair was sentenced to 70 months in prison for his role in the D4H scheme and related schemes in North Carolina, South Carolina and elsewhere.

- Rachel Sheats, 48, of Woodstock, Ga., pleaded guilty to conspiracy to pay healthcare kickbacks in the Northern District of Georgia in January. Sheats was Capstone's chief

operations officer during the relevant time and served as a key point person for D4H at Capstone. Sheats has yet to be sentenced.

Civil Settlement in RPP Scheme

Maloney and Capstone also entered into a civil agreement under which they agreed to pay $14.3 million to the federal government and several states to resolve claims arising from the submission of false claims to government healthcare programs. In addition to the allegations described above, the civil settlement resolves allegations that, between April 2020 and December 2021, Maloney and Capstone sought to profit off the Covid-19 pandemic by paying independent contractor sales representatives to recommend RPPs to senior communities interested only in Covid-19 tests.

I don't take a broad brush approach and say you can never use independent contractor sales reps. There is a framework in which you can create payment arrangements with sales reps who are technically 1099 contractors, but it has to be service-based.

To generate orders, Capstone's independent sales representatives completed test requisition forms for RPPs using forged signatures of physicians who had only ordered Covid tests and sham diagnosis codes that did not reflect the medical conditions of the senior community residents receiving the tests. Capstone subsequently billed federal healthcare programs for these medically unnecessary tests and paid its sales representatives a commission for each test. The federal share of the settlement is approximately $13.9 million and approximately $400,000 constitutes a recovery for state Medicaid programs.

Be Careful of Commission-Based Sales

Charles Dunham, a corporate healthcare attorney with Greenberg Traurig LLP (Houston), says that while there are two safe harbors under the AKS for sales and marketing activities—one for bona fide employees and one for independent contractors—the government has always closely scrutinized payment arrangements with 1099 contractors.

Charles Dunham

"The government believes independent contractors present a higher risk because the provider has less control over their activities," he says. While no charges were brought under the Eliminating Kickbacks in Recovery Act [EKRA] in this case, Dunham notes that EKRA also does not permit volume-based commission payments to independent contractors.

"I don't take a broad brush approach and say you can never use independent contractor sales reps," says Dunham. "There is a framework in which you can create payment arrangements with sales reps who are technically 1099 contractors, but it has to be service-based. Compliance requires a bit of complexity. It's easy to pay somebody based on commission. It's harder to implement a program where the formula is activities based and not on the volume or value of the business generated. I tell clients they should evaluate what types of programs would work best for them."

Dunham also says that one thing that stands out in this case is the individual owners and officers are being held accountable. "The DOJ continues to seek individual accountability more and more in healthcare fraud cases," he says. "I advise clients to be aware of the responsibility the governing body and the managers have and the potential risks they face. You have to have compliance from the top down."

COMPLIANCE 101:

Clinical Laboratory Sales and Marketing

Sales and marketing by clinical laboratories present numerous compliance challenges, particularly since some practices that may be common in other industries are prohibited in healthcare. Not only do labs need to ensure their marketing is truthful, they must also be sure that any practices designed to bring in new clients do not run afoul of federal laws, including the Stark Law, the Anti-Kickback Statute (AKS) and the Eliminating Kickbacks in Recovery Act (EKRA).

According to the Health and Human Services Office of Inspector General (HHS OIG), clinical laboratory compliance plans should require honest, straightforward, fully informative and non-deceptive marketing.

"It is in the best interests of patients, physicians, laboratories and Medicare alike that physicians fully understand the services offered by the laboratory, the services that will be provided when tests are ordered and the financial consequences for Medicare, as well as other payers, for the tests ordered," says the OIG in its model compliance plan for clinical laboratories. "Accordingly, laboratories that market their services should ensure that their marketing information is clear, correct, non-deceptive and fully informative."

CodeMap, a consulting company based in Chicago, recommends that before any marketing materials are distributed to existing or prospective customers, the chief compliance officer review and approve their distribution.

Compliance with EKRA

Clinical laboratories must also ensure compliance with EKRA, which makes it a criminal offense to offer or receive remuneration in exchange for inducing a referral to a recovery home, clinical treatment facility or clinical laboratory. In the years since EKRA's enactment, the Department of Justice's enforcement actions have broadened EKRA's scope beyond reducing fraud in the addiction treatment industry to include all clinical laboratory activities.

Legal experts doubt that DOJ will adopt regulations implementing EKRA. In an alert from Holland & Knight, attorneys Dan Silverboard and Tom Stephenson say it is imperative for stakeholders in the clinical laboratory industry to monitor enforcement activities and case opinions to determine the scope of EKRA's prohibitions.

Two conflicting court rulings indicate that the statute prohibits clinical laboratories from structuring compensation paid to sales representatives (whether employees or 1099s) based on revenue generated from their marketing activities. A 2022 court ruling in *USA v. Schena* strongly suggests that EKRA most likely prohibits clinical laboratories from paying their marketers percentage-based compensation, regardless of whether the marketer targets doctors or prospective patients, say Silverboard and Stephenson.

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 employers and a separate regulatory safe harbor governing employee agreements. EKRA contains an exception that applies to compensation agreements for both employees and independent contractors. But unlike the bona fide employee safe harbor to the AKS, the exception under EKRA prohibits compensation determined by or varying with 1) referrals to the laboratory, 2) the number of tests or procedures performed, 3) the amount billed or received from payers. As such, on its face, EKRA would prohibit payments that are otherwise permitted under the AKS.

In Brief

Gamma Healthcare, Owners, to Pay $13.6 Million Over Medically Unnecessary Lab Tests

Gamma Healthcare (Poplar Bluff, Mo.), and three of its owners—Jerry W. Murphy, Jerrod W. Murphy and Joel W. Murphy—have agreed to pay the United States $13.6 million to resolve allegations they violated the False Claims Act (FCA) by submitting claims to Medicare for lab tests that were not ordered by healthcare providers and were not medically necessary. Gamma, Jerry Murphy and Jerrod Murphy also agreed to a 15-year exclusion from participating in federal healthcare programs. The settlement resolves allegations that, from Jan. 1, 2020, to Oct. 31, 2020, Gamma and the Murphys submitted claims for medically unnecessary PCR urinalysis laboratory tests that were not ordered by treating physicians. When a physician ordered a urinalysis (UA) with culture and sensitivity (C&S) or just a C&S, Gamma automatically performed and submitted claims to Medicare for a urinary tract infection panel of tests by PCR. Medicare reimbursement for UA with C&S is typically $11 but a panel of UTI PCR tests is reimbursed an additional $573. Physicians expressed concerns to Gamma about the UTI PCR tests as early as March 2020.

Florida Man Faces Prison Time Over AKS Violations

Jeffrey Tamulski, 50, of Tampa, Fla., pleaded guilty in federal court on March 26, 2024, to conspiracy to commit an offense against the United States in connection with a scheme to violate the Anti-Kickback Statute. Tamulski and five co-defendants were previously charged by indictment in September 2019 in connection with the conspiracy and a related healthcare fraud scheme. On behalf of certain laboratories, Tamulski recruited outside marketing groups, including Ark Laboratory Network LLC, a company owned by Tamulski's conspirators, to refer patients' DNA samples to the laboratories for genetic tests. Tamulski and certain conspirators entered into kickback agreements with labs under which they paid Ark bribes in exchange for delivering DNA samples and orders for genetic tests. From January 2018 through January 2019, Medicare paid these laboratories approximately $4.6 million. The charge to which Tamulski pleaded guilty carries a maximum penalty of five years in prison and a fine of $250,000. Tamulski's sentencing is scheduled for Aug. 6, 2024.

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.

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- Medicare claims data for key laboratory codes
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- 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

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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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