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Kimberly Scott, Editor, kscott@laboratoryeconomics.com

# COMPLIANCE & POLICY REPORT

*Compliance and Regulatory Analysis for Lab Directors and Managers*

## How to Navigate the Challenge of Paying Lab Sales Reps Without Violating the Law: Part 2

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. We also spoke with Gee's partner in Los Angeles, Alex Porter, a former federal prosecutor with the Department of Justice's (DOJ) Healthcare Fraud Strike Force and Healthcare Fraud Coordinator for the Central District of California, who frequently works and advises with Gee on EKRA and sales compensation issues. *See page 2 for the second of our two-part interview.*

## Questions and Answers about the FDA's Final Rule on LDTs

The Food and Drug Administration (FDA) has been fielding many questions about its final rule on laboratory-developed tests since issuing it on May 6, 2024. In addition to posting frequently asked questions, the agency is also holding a series of webinars to address specific topics related to the rule. The next webinar, on Sept. 24, 2024, will cover labeling requirements for in vitro diagnostic products, including LDTs. *See page 5 for some of the most common questions asked and the FDA's response.*

## AMP Sues FDA Over Lab-Developed Test Rule

The Association for Molecular Pathology (AMP) and pathologist Michael Laposata, MD, PhD, on August 19 became the latest to file a lawsuit challenging the recent Food and Drug Administration (FDA) rule regulating laboratory developed tests (LDTs) as medical devices. The lawsuit was filed in the U.S. District Court for the Southern District of Texas. *More on page 8.*

## Proposed Medicare Physician Fee Schedule Contains a Mix of Good and Bad

Although the proposed Medicare Physician Fee Schedule (MPFS) for 2025 does include cuts to physicians, including pathologists, it also contains some positive changes. The proposed MPFS, released July 10, would provide coverage for four new CAR T-cell services and increase the clinical labor rates for key laboratory clinical labor types. The College of American Pathologists (CAP) advocated for these changes. *Details on page 9.*

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## How to Navigate the Challenge of Paying Lab Sales Reps Without Violating the Law: Part 2 (*cont'd from page 1*)

**Alex, do you have anything to add about the current legal landscape for laboratories regarding sales compensation under EKRA or the AKS?**

In addition to the *Graves* and *Schena* decisions David mentioned [in part one of the Q&A, August 2024], there is one more recent opinion from the U.S. District Court in Pennsylvania in April 2024. Like the U.S. District Court in Hawaii in *Graves*, this court upheld a contract that called for bonus payments by a lab (Lehigh Valley Genomics) to a third-party marketing group (GF Industries of Missouri) that were "based upon the number of samples produced, the type of test, and the type of insurance associated with the sample."

*Alex Porter*

On the third day of a five-day bench trial in June 2023, the lab asserted for the first time that the contract was not enforceable because it was illegal under EKRA. After extensive post-trial briefing, the Pennsylvania district court ruled that the lab had failed to demonstrate that the contract was illegal under EKRA. The court not only cited *Graves* and *Schena*, but also cited two AKS opinions from the Fifth Circuit Court of Appeals (in Texas), the *Marchetti* and *Miles* cases.

Although emphasizing that its holding was a "narrow one … based upon the limited—and somewhat unusual—record presented," the court found there was not enough evidence presented at trial to show that the contract marketer was "paid to influence healthcare decisionmakers—and thus, to 'induce a referral of an individual'—as opposed to being compensated for advertising and marketing services." Therefore, "neither the 'subject,' nor the 'performance' of the agreement—which include[d] providing marketing services and being compensated based on the success of those services—[was] specifically proscribed by EKRA."

The Pennsylvania district court opinion only serves to increase the confusion within the lab industry about the application of EKRA to the challenge of properly compensating sales representatives, whether employed sales representatives or contract marketers as in the Pennsylvania case. Significantly, the Pennsylvania district court was not even presented with the question of whether the marketing arrangement was enforceable or appropriate under the AKS, despite relatively extensive discussion of *Marchetti* and *Miles*, both cases that focused on the AKS and did not even involve EKRA.

It's also worth mentioning that the *Marchetti* opinion, also published in 2024, and also involving clinical laboratory sales and marketing, arguably signals a conflict between the Fifth Circuit Court of Appeals and the *Mallory* decision issued by the Fourth Circuit Court of Appeals [discussed by David in part one of the Q&A, August 2024].

*I should add a caution that in my experience the DOJ is much more likely to interpret the AKS broadly the way the Mallory court did than as narrowly as the Marchetti court did.*

The *Marchetti* opinion seems to carve back the broad holding of *Mallory* that paying contract marketers on a percentage of revenues basis violates the AKS, by ruling that commission-based payments to contract salespeople are not per se illegal, but that courts must look to the intent behind the payments and determine whether the defendant intended to induce referrals, which is illegal, or to compensate advertisers, which is permissible under the AKS. According to the Fifth Circuit Court of Appeals, the fact the contract provided for compensation based on the "value of each referral," does not alone prove intent to induce referrals. Instead, the government must prove the defendant intended to "improperly influence" those who make healthcare decisions on behalf of patients.

I should add a caution that in my experience the DOJ is much more likely to interpret the AKS broadly the way the *Mallory* court did than as narrowly as the *Marchetti* court.

As David mentioned [in part one of the Q&A, August 2024], of the three federal court opinions interpreting EKRA, including the most recent Pennsylvania district court opinion, the only judicial opinion that interprets EKRA in the context of a government enforcement action under EKRA is the federal court's order in *Schena*. For that reason, it is important for laboratories to pay close attention to *Schena* in setting compliance standards. The other two opinions also involved the question of the enforceability of a commercial contract in a civil lawsuit, and it is unclear how much weight a court would give to those decisions in a criminal enforcement matter involving EKRA.

*One of the "chicken-and-egg" complications is that labs fear they will face a competitive disadvantage if they change their sales employee compensation models from the historic lab industry and standard business model of percentage-of-revenues commissions before other labs do.*

Although EKRA gives the DOJ the authority to issue regulations, it doesn't require them to do so. As a former federal prosecutor, it's my experience that the DOJ favors having flexibility in the ways they can use the statute to prosecute bad actors, and they can be selective in cases they pursue. It remains to be seen whether DOJ will prosecute a case in which a lab pays percentage-based compensation to an employee sales rep; if it does, that could create an opportunity for a meaningful judicial challenge to reconcile the AKS and EKRA with respect to the question of percentage-based sales commissions to *bona fide* employees. Right now, those two simply don't line up.

**So, David, in light of the lack of clarity about EKRA, what should laboratories do with *bona fide* employees?**

*David Gee*

Alex is right about the confusion, and the confusion about what EKRA means has, not surprisingly in my view, led to "paralysis" within the industry as far as EKRA is concerned. EKRA is especially challenging. Unlike the AKS, EKRA does not have an exception or safe harbor for *bona fide* employees that would allow payments to sales representatives that vary with the volume or value of the laboratory business they generate that is reimbursed by any commercial or governmental healthcare benefit program. That makes it much harder when trying to advise clinical laboratories how to comply with EKRA, especially when they already have made the compliance choice and undertaken the expense to hire and manage sales representatives as *bona fide* employees.

There is resistance to move away from the standard percentage of sales commission for employed sales representatives that has been the longstanding practice in the lab industry and in most other industries. One of the "chicken-and-egg" complications is that labs fear they will face a competitive disadvantage if they change their sales employee compensation models from the historic lab industry and standard business model of percentage-of-revenues commissions before other labs do. Many labs have told me that the leading clinical laboratories have not yet changed their sales commission practices, although I have not been able to verify that.

I have helped several labs set up different sales compensation models that we believe meet EKRA, but those solutions are harder to implement. It's difficult to convince people to do things differently. It's more complicated to administer. It's harder for the sales representatives to understand. In some instances where we have put those EKRA-compliant compensation solutions in place, we have had to come back to tweak them to make them simpler or more manageable.

Because one of the EKRA exceptions simply incorporates the AKS personal services and management contracts safe harbor, the alternative models we have worked to develop for EKRA compliance are similar to those I mentioned previously [in part one of the Q&A, August 2024]. These are between labs and contract marketers, using metrics besides volume or value of business generated between the parties (e.g., the number of contracts signed with lab customers or types of physician specialties, the successful opening of new service territories, the introduction of new lines of testing). Another approach I have suggested to clients is to categorize their customers and prospects on a qualitative basis and then consider what is involved in servicing a particular account or type of account.

*In sum, there are ways of establishing compensation for sales reps where you are not tying the amount of compensation to the amount of testing or the number of patients. Of course, these are alternatives to approaches that are commonly used in most other industries and therefore require more thinking and more ingenuity, and more selling and education to the sales team, but it can be done.*

For example, you could have three tiers of compensation based on different levels of complexity – considering that for an account with two doctors, there are likely to be less facets to manage (lower complexity) and worry about than an account with 30 doctors (higher complexity). Another very appropriate metric is client education and the extent of necessary demographic and billing information the lab receives from the client – this can be measured in terms of "clean claims" against some meaningful performance and compliance standards, and the sales team can be very helpful in significantly improving client responsiveness in this area.

Alternatively, for employees, stock options that are linked to productivity and growth of the company may also be a permissible way to align incentives. Generally speaking, as long as it's not done in a way that bases sales compensation on the volume or value of referrals, there is nothing in the AKS or EKRA that prohibits it.

In sum, there are ways of establishing compensation for sales reps where you are not tying the amount of compensation to the amount of testing or the number of patients. Of course, these are alternatives to approaches that are commonly used in most other industries and therefore require more thinking and more ingenuity, and more selling and education to the sales team, but it can be done.

I advise that labs consult with experienced legal counsel when setting up compensation arrangements with their sales representatives. EKRA is a criminal statute that comes with a maximum 10-year sentence and substantial financial penalties.

**Is there anything wrong with just paying an employed sales rep a set salary?**
No, there's nothing wrong with that under either AKS or EKRA – that is likely the most conservative course. But even that "safe" choice prompts questions about how much is the right salary amount and how that should be decided. The recent Texas indictments [discussed in part one of the Q&A] are a good reminder that merely calling sales compensation a salary or flat rate is not enough. The labor and employment laws – the federal laws, Title VII, the Americans with Disabilities Act, the Age Discrimination in Employment Act and the Equal Pay Act, and state anti-discrimination laws – generally require that you should have some valid and appropriate performance standards that you use in setting compensation, especially for diverse employees you have hired to perform essentially the same job functions. It's important that there is some consistency and fairness in your sales compensation plan so you don't face a legal challenge under the employment laws even if you manage to get it right under EKRA and the AKS.

## QUESTIONS AND ANSWERS ABOUT THE FDA'S FINAL RULE ON LDTS (*cont'd from page 1*)

**Q: If another manufacturer's FDA-authorized IVD is modified by a laboratory manufacturer, including a modification for use on a new patient population, is that IVD an LDT? If a healthcare provider orders an IVD for a use that is outside the IVD's authorization for an individual patient, is that IVD an LDT?**

A: As discussed in the preamble to the LDT final rule, an LDT is an IVD that is intended for clinical use and that is designed, manufactured and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high-complexity testing. This definition does not exclude previously FDA-authorized IVDs that are modified by a laboratory for a use that is outside the IVD's original authorization. Please refer to the preamble to the final rule for a discussion of the phaseout policy, including targeted enforcement discretion policies such as those relating to modifications of an FDA-authorized IVD and to LDTs for unmet needs.

When a healthcare provider orders an IVD for a use that is outside the IVD's authorization, that does not dictate whether the IVD is an LDT or not – i.e., whether it is designed, manufactured and used within a single laboratory that is certified and meets the regulatory requirements under CLIA to perform high-complexity testing. We note that under the FD&C Act, a healthcare practitioner may prescribe or administer a legally marketed device to a patient for any condition or disease within a legitimate healthcare practitioner-patient relationship (see section 1006 of the FD&C Act (21 U.S.C. 396)). This could include situations where the healthcare practitioner specifically orders the use of an IVD outside of its original authorization for an individual patient.

**Q: If a single laboratory designs and manufactures an IVD but uses the IVD at different subsidiaries, is the IVD an LDT? If not, how would the FDA treat these IVDs?**

A: LDTs are IVDs that are intended for clinical use and that are designed, manufactured, and used within a single CLIA-certified laboratory that meets the regulatory requirements under CLIA to perform high-complexity testing. If an IVD is designed, manufactured, or used in more than one laboratory, it is not an LDT.

FDA's phaseout policy in the final rule applies to "IVDs offered as LDTs." These are IVDs that are manufactured and offered as LDTs by laboratories that are certified under CLIA and meet the regulatory requirements to perform high-complexity testing, even if those IVDs do not fall within FDA's traditional understanding of an LDT because they are not designed, manufactured and used within a single laboratory. FDA adopted this scope because it recognizes that not all laboratories have understood the limited nature of FDA's general enforcement discretion approach and have been offering IVDs based on the approach even when those IVDs do not fit what FDA generally considers to be an LDT.

The targeted enforcement discretion policies for certain new LDTs introduced after May 6, 2024, are all limited to LDTs as defined by FDA in the preamble to the final rule.

**Q: Are the stages of the phaseout policy measured from the publication date or effective date of the final rule?**

A: The specified timelines for the phaseout policy stages are set for one to four years after the publication date of May 6, 2024.

**Q; How will premarket review of LDTs under the phaseout policy affect review timelines for other IVDs?**

A: The FDA notes that its premarket review timelines are negotiated with industry in connection with MDUFA [Medical Device User Fee Amendments] reauthorization. FDA generally meets the timeframes for MDUFA decisions negotiated with industry, including for IVD submissions outside of the pandemic. As previously mentioned, reauthorization of MDUFA aligns with the timeline for industry to come into compliance with premarket review requirements under the phaseout policy. This will provide an opportunity for FDA and industry to negotiate regarding user fees and performance goals for premarket reviews.

**Q: Does the FDA classify LDTs as test systems, including instrumentation, sample preparation and pre-analytical processing, or does classification of LDTs only pertain to the parts that the laboratory develops or modifies on its own?**

A: FDA classifies IVDs manufactured by laboratories, including laboratory developed tests, in the same way it does other IVD test systems.

Test systems are a set of components – such as reagents, instruments, and other articles – that function together to produce a test result. Test systems include components and are accompanied by instructions for use for sample preparation and pre-analytical processing. Classification of the test system is based on the intended use and risk of the test system.

The most efficient method for an IVD manufacturer to determine the classification of a device type that has already been classified by FDA is by searching the product classification database, included on the resources and references page of the webinar slide deck. Searching FDA's 510(k), PMA, and De Novo databases may also be helpful in understanding what specific IVDs fall within a given device type and how such IVDs are regulated.

An IVD may be of a type that has not already been classified by the FDA and, therefore, would not be in the product classification database. As a reminder, device types that have not been classified by FDA previously, and that were not on the market prior to the enactment of the Medical Device Amendments on May 28, 1976, are automatically Class III unless they are reclassified by FDA. If an IVD has not been classified, manufacturers should assess the risk of their IVD and submit the appropriate premarket submission based on the assessed risk.

If the manufacturer believes their IVD is high risk, a PMA is likely required. If the manufacturer believes their IVD is low or moderate risk, the IVD may be eligible for de novo classification. The de novo process provides a pathway to class I or class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

**Q: How does a laboratory manufacturer determine which type of premarket submission is required, if any? What type of premarket submission is required for a test that is not classified?**

A: We recommend laboratories start by searching the product classification database to see if the device type has already been classified by FDA.

If the IVD is of a type that has already been classified by FDA, the database includes the device Class (I, II, or III), the type of submission required (if any), and if applicable, the classification regulation number.

If the IVD is not of a type listed in the classification database, you should assess the risk of your IVD to determine the premarket submission type that is most likely appropriate based on the assessed risk.

- If you believe the IVD is high risk, a PMA is likely required. As a reminder, only about 5% of IVDs currently listed with FDA require a PMA.
- A moderate or low risk device may be eligible for de novo classification.

If after searching FDA's medical device databases and assessing the risk of your IVD you have questions regarding the classification of your IVD, you can seek feedback from FDA via a pre-submission or 513(g) request.

**Q: Can manufacturers use unauthorized IVDs offered as LDTs that were marketed prior to May 6, 2024, as predicate devices to establish substantial equivalence in 510(k) submissions to the FDA?**

A: A predicate device for purposes of FDA clearance of a 510(k) submission is a "legally marketed device." A legally marketed device is a device that has been approved or cleared by FDA, or that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required. The final rule does not change this requirement.

**Q: FDA states that the agency intends to request submission of labeling for certain IVDs offered as LDTs. What does this mean, and what is the scope of the FDA's review of this labeling?**

A: For IVDs that fall within the NYS CLEP [New York State Department of Health Clinical Laboratory Evaluation Program], unmet needs or "currently marketed IVDs offered as LDTs" (i.e., those that were first marketed prior to May 6, 2024) enforcement discretion policy, FDA intends to request that manufacturers submit certain labeling information to the agency in connection with the listing of the IVD as provided in 21 CFR 807.26(e). Labeling includes IVD performance information and a summary of supporting validation, as applicable. This information will help FDA more closely monitor currently marketed IVDs offered as LDTs and identify those that may lack analytical validity, clinical validity, or safety.

As part of its review of labeling for currently marked IVDs offered as LDTs, FDA intends to look closely at claims of superior performance and whether those claims are adequately substantiated. FDA generally intends to take action where the labeling of a currently marketed IVD offered as an LDT is false or misleading, and/or the IVD offered as an LDT lacks the appropriate assurance of safety and effectiveness for its intended uses as a result of any such claims that are not adequately substantiated.

**Q: Are therapeutic drug monitoring (TDM) LDTs covered by the final rule?**

A: TDM tests, including mass spectrometry-based TDMs, are IVDs. TDM tests manufactured by laboratories are covered by the final rule and the phaseout policy described in the preamble to the final rule.

**Q: How does this impact screening tests, such as those performed in newborn screening laboratories? Babies flagged by newborn screening go on to receive diagnostic testing to confirm or deny the screening result.**

A: Newborn screening tests, including those offered as LDTs, are IVDs and generally fall within the scope of the phaseout policy. Certain newborn screening tests may fall within one of the targeted enforcement discretion policies in the preamble, such as the policy for "currently marketed IVDs offered as LDTs" (i.e., those that were first marketed prior to May 6, 2024) or the policy for LDTs approved by, conditionally approved by, or within an approved exemption from full technical documentation, under NYS CLEP.

## AMP Sues FDA Over Lab-Developed Test Rule Final Rule (*cont'd from page 1*)

An earlier lawsuit against the FDA was filed May 29, 2024, by the American Clinical Laboratory Association and HealthTrackRx Indiana Inc. in the United States District Court for the Eastern District of Texas (*LECPR*, July 2024).

"AMP remains very concerned about the wide-sweeping and long-lasting consequences the FDA rule will have for our members and patients across the country," says Maria Arcila, MD, president of AMP. "We filed this lawsuit to ask the court to vacate the FDA rule given the agency's lack of authority to regulate LDTs and to avert the significant and harmful disruption to laboratory medicine. AMP will continue working with key stakeholders to develop a more effective and efficient legislative framework that ensures high-quality patient care while continuing to foster rapid innovation and the promise of new diagnostic technologies."

*Many smaller laboratories aiming to survive the FDA's regulatory overreach—especially those serving isolated, rural or disadvantaged communities—will be forced to sell themselves to the few national laboratory conglomerates or private equity firms that can afford the extraordinary cost of FDA compliance.*

AMP has long maintained that the best approach to ensuring the continued development of accurate and reliable LDT procedures and for correct utilization, precise interpretation and proper application of molecular test results is through modernizing the current Clinical Laboratory Improvement Amendments (CLIA) regulations promulgated by CMS. AMP's legislative proposal to update CLIA builds on the existing oversight framework and provides enhancements where necessary to provide assurances of test quality."

**'Unprecedented Power Grab'**

According to the complaint, this case challenges "a historically unprecedented power grab that will jeopardize the health of hundreds of millions of Americans and, by Defendant FDA's own admission, impose tens of billions of dollars in new regulatory mandates on thousands of laboratories and laboratory professionals by subjecting their customized analytical processes (called "laboratory developed testing procedures" or "LDTs") to burdensome, duplicative and unnecessary FDA regulation for the first time in American history."

Unless the court acts, many laboratories and laboratory professionals will be forced to stop providing vulnerable patients with cutting-edge medical care and will abandon ongoing efforts to develop additional LDTs that could timely diagnose fast-moving diseases (e.g., cancers) and mitigate emerging public-health threats (e.g., the next pandemic), the complaint states.

"Others will risk, and many will have to declare, bankruptcy trying to comply with the FDA's new mandates—leading to significant job losses in the pathology profession, driving future doctors into other fields, reducing training opportunities and further exacerbating the ongoing shortage of pathologists in the United States," the complaint states. "Many smaller laboratories aiming to survive the FDA's regulatory overreach—especially those serving isolated, rural or disadvantaged communities—will be forced to sell themselves to the few national laboratory conglomerates or private equity firms that can afford the extraordinary cost of FDA compliance."

The lawsuit, filed by Hyman Phelps & McNamara, asks that the court vacate the final rule, set it aside and enjoin the defendants from "taking any action in furtherance of the enforcement of the final rule."

## PROPOSED MEDICARE PHYSICIAN FEE SCHEDULE CONTAINS A MIX OF GOOD AND BAD

(*cont'd from page 1*)

The following are the new CAR T-cell services for which coverage was approved:

- **HCPCS Code 3X018:** Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day (RUC work RVU of 1.94).
- **HCPCS Code 3X019:** Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage) (RUC work RVU of 0.79).
- **HCPCS Code 3X020:** Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration (RUC work RVU of 0.80).
- **HCPCS Code 3X021:** Chimeric antigen receptor T-cell (CAR-T) therapy, CAR-T cell administration, autologous.

To ensure that these services were appropriately valued, the CAP led a multispecialty effort to develop and present RVU recommendations at the September 2023 American Medical Association RUC meeting. The CAP supports the RVU recommendations proposed by CMS.

**Cuts to Pathologists**

Unfortunately, the proposed rule also would cut payments to physicians, including pathologists. The cuts stem largely from the expiration of two congressional Medicare pay relief packages that were intended to offset the previously finalized cuts in the 2023 and 2024 Medicare Physician Fee Schedules.

Under the proposed rule, pathology professional and technical payments would be cut by an average of 2.8% due to a reduction in the conversion factor, although reductions for some procedures could be cut by as much as 9%. The professional component of CPT 88305, tissue exam by pathologist, for example, would be cut by 3% to $34.94, while the technical component would be cut by 3% to $34.62.

The professional component of 88314, histochemical stains add-on, would be cut by 5% to $83.80, while the technical component would be cut by 6% to $65.04. The technical component of 88346, immunofluorescence, per specimen, initial antibody stain, would be cut by 7% to $107.42, while the professional component would be cut by 3% to $33.65. In only a few instances would payment increase. The technical component for CPT 88355, morphometric analysis, for example, would go up by 16% to $60.83, while the professional component would increase by 6% to $77.65. The CAP has published an impact table for the proposal, available here.

**Quality Payment Changes**

The proposed MPFS also includes six new Medicare Incentive Payment System (MIPS) Value Pathways (MVPs). The current MIPS performance threshold would be maintained, which would help prevent a MIPS penalty for CY 2024. The American Medical Association has urged Congress to make statutory changes to improve MIPS and address what it sees as fundamental problems with the program by reducing steep penalties that disproportionately hurt small and rural practices, prioritizing access to timely and actionable data, aligning MIPS with facility quality programs and incentivizing the development and reporting of new clinically relevant quality and cost measures.

Comments on the proposed MPFS are due Sept. 9, 2024.

## Lab Co-Owner Sentenced to Prison for Fraudulent Billing

The former owner of a St. Louis healthcare company and laboratory was sentenced August 13 to 20 months in prison and fined $100,000 for submitting more than $3.8 million in fraudulent claims to Medicare, Medicaid and private healthcare benefit programs.

Carolos Himpler, 44, owned and/or operated a series of healthcare-related businesses. Himpler's co-defendant, Franco Sicuro, MD, owned Advanced Geriatric Management LLC (AGM) in Creve Coeur, Mo. In the fall of 2014, Himpler and Sicuro decided to open an in-house testing lab at AGM. They also opened Genotex Dx, which they held out as a clinical testing laboratory and which was in the same building and used the same testing machine as AGM's lab.

Himpler and Sicuro sought accreditation for both labs under the Clinical Laboratory Improvement Amendments (CLIA). They did not disclose that both labs would employ the same part-time employees who would perform tests using the same machine. To convince CLIA to grant Genotec a final certificate of compliance in November 2015, Himpler participated in causing Genotec to make misrepresentation to CLIA, including that Genotec's testing hours "changed" so that they no longer overlapped with AGM.

The misrepresentations also included claims that AGM stopped running lab samples and transferred its employees to Genotec in July of 2015, and that Genotec did not begin running samples until July of 2015. In reality, the AGM lab continued operating after July 2015 and Genotec started testing months before then. The pair concealed Sicuro's ownership of Genotec from Medicare, Medicaid and private healthcare insurers, while referring urine specimens from Sicuro's own practice, AGM, to Genotec.

**Improper Pass-Through Billing**

Himpler and Sicuro and other healthcare providers at SGM ordered urine toxicology tests for patients and referred those tests to AGM and Genotec, which in turn sent the samples to outside "reference" laboratories. Both men knew AGM and Genotec did not have the necessary testing equipment to confirm the amount of given toxin in the urine testing to a high degree of certainty, Himpler's plea says. They then billed health insurers for the testing, despite knowing that Medicare, Medicaid and many private insurers bar "pass-through billing," or billing for tests performed by others.

When health insurers became resistant to paying Genotec claims, Himpler and Sicuro in March 2015 created another laboratory company, Midwest Toxicology Group LLC, for the purpose of billing health insurers. Midwest was a lab in name only and was not authorized to perform tests on human specimens. Himpler and Sicuro never obtained CLIA certification or any lab equipment for Midwest. In many instances, Himpler caused Genotec and Midwest to each submit claims for the testing of the same specimen obtained from the same person on the same day of service. The pair also falsely used Genotec's CLIA number on claims submitted under Midwest's name.

Himpler admitted in his plea agreements that Medicare, Medicaid and private health insurers paid $1.4 million in pass-through billing and $2.4 million in split billing. Himpler pleaded guilty in February in U.S. District Court in St. Louis to a felony conspiracy charge. Sicuro pleaded guilty in November 2022 and has satisfied the restitution owed. He also agreed to forfeit $3.1 million in assets.

# COMPLIANCE 101:

## The Importance of Inpatient Clinical Laboratory Test Utilization Management Programs

Clinical laboratory test utilization management programs for inpatients in hospitals and health systems are critical to ensuring that the right testing is being performed for the right patient at the right time. Jordan Laser, MD, notes that while advanced and molecular tests continue to expand in both scope and utility, often these tests are ordered outside the scope of clinical context or are over-ordered. Laser is senior director of clinical and medical affairs at Bio-Techne (Austin), as well as the CEO and founder of Laser Laboratory Consulting. Laser explains that there are a few techniques for establishing a utilization management system in a hospital:

*Jordan Laser, MD*

**The Gatekeeper Method**

Under the gatekeeper method, a hospital lab will alert the person in charge of utilization management if the lab gets an unusual request for an inpatient test. That person then contacts the provider to determine if the test was appropriately ordered. "This method can be very successful; however, the gatekeeper method relies on a few key individuals to make the decisions," says Laser. "Thus, providing round-the-clock coverage can be challenging."

Other challenges include test requests that bypass the hospital lab altogether. Gatekeeping only works for those requests that come through the lab. If they are sent out directly to reference laboratories from hospital departments, the utilization management team loses the opportunity to ensure appropriate utilization. Finally, the gatekeeper method requires reaching out to the provider which poses a challenge if the inpatient test request is both appropriate and urgently needed.

**Diagnostic Algorithms**

A second utilization management method is creating previously approved diagnostic algorithms, which is more of a proactive method for test approvals. All stakeholders need to come together to determine which tests are appropriate for specific patient presentation.

"Limitations to this method are that it requires stakeholders to consider all patient care scenarios, and the algorithms are ill equipped to deal with patient-to-patient variables," notes Laser. However, diagnostic algorithms do enable rapid decision-making, reducing the friction for these preapproved tests.

**Clinical Decision Support within Electronic Medical Records (EMRs)**

This method is an evolution of diagnostic algorithms, essentially combining algorithms with ordering and approval rules within the EMR. There are distinct advantages to this approach, including real-time data collection on the appropriateness of ordered tests (through ask-on-order entry questions) and adherence to the algorithms. This helps ensure that the right test is being ordered.

An example of this could be cardiomyopathy genetic testing. Stakeholders and clinical experts can determine under what clinical presentation it is appropriate to order certain tests, such as a young patient with heart failure with a specific ejection fraction. When these rules are embedded within the EMR, the EMR can proactively alert the provider that cardiomyopathy genetic testing is appropriate when these conditions are met. This not only prevents inappropriate test orders, but can actually encourage appropriate testing even when not initially considered by the ordering provider.

"Implementing clinical decision support such as this is obviously challenging both from a clinical and technical perspective, but when implemented correctly, it has the ability to maximize clinical value while preventing waste of resources," says Laser.

## In Brief

### Pair Accused of Kickback Scheme Involving Lab Testing

A St. Louis County man and an Alabama woman have been charged with engaging in an illegal kickback scheme involving genetic and Covid-19 tests given to seniors. Willie Ann Cleveland and Timothy C. Peoples were indicted August 7 in U.S. District Court in St. Louis on one count of conspiracy to receive and pay healthcare kickbacks. Peoples, 56, of Bridgeton, MO, and Cleveland, of Tuscaloosa, AL, have both pleaded not guilty. From 2017 through Aug. 7, 2024, Peoples collected biological specimens for genetic and Covid-19 testing, primarily from Medicare patients at senior citizen centers in eastern Missouri, according to the indictment. Peoples and Cleveland created sham contracts to conceal the kickbacks as a "monthly flat marketing fee." The indictment also says Cleveland and Peoples offered to pay a physician a $100 kickback in exchange for each lab test ordered. The conspiracy charge is punishable by up to five years in prison, a $250,000 fine, or both.

### WHO Declares Mpox a Public Health Emergency

In response to a growing outbreak in the Democratic Republic of Congo (DRC) and neighboring countries in Africa, the World Health Organization (WHO) on Aug. 14, 2024, declared mpox a public health emergency of international concern (PHEIC), WHO's highest level of alarm. This is the second time WHO has declared mpox a PHEIC in two years. The first was in response to a multi-country outbreak in 2022, which sickened nearly 100,000 people, including 32,000 in the United States. Caused by an Orthopoxvirus, mpox was first detected in humans in 1970 in the DRC. The disease is considered endemic to countries in central and west Africa.

In the United States, there have been fewer than 35,000 cases of mpox reported. The majority of U.S. cases are in people who are not vaccinated or who have only received one dose of the JYNNEOS vaccine. Two doses of JYNNEOS are recommended to provide maximum protection. The Centers for Disease Control and Prevention (CDC) recommends the vaccine for people 18 and older who are at risk for mpox. These include men who have sex with other men, transgender or nonbinary people, people who have had skin-to-skin contact with someone with mpox and people who have had sex at a commercial venue or in association with a large public event.



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