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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

What Does the LDT Final Rule Mean for Labs? Q&A With McDonald Hopkins' Jane Pine Wood

The final rule on laboratory-developed tests (LDTs), issued by the Food and Drug Administration (FDA) on April 29, has created quite a stir in the clinical laboratory community. The American Clinical Laboratory Association and its member company, HealthTrackRx, on May 29, 2024, filed a lawsuit against the Food and Drug Administration in the U.S. District Court for the Eastern District of Texas, challenging the rule. Subsequently, ARUP Laboratories (Salt Lake City) filed a declaration to support the lawsuit. *LE Compliance & Policy Report* recently spoke with Jane Pine Wood, counsel in McDonald Hopkins national Healthcare Practice Group, about the final rule and what it means for labs and LDTs.
Continued on page 2.

Fundamentals of Medicare Laboratory Billing: Avoiding the Pitfalls of Certain Test Ordering Policies

Clinical laboratories must comply with Medicare billing policies when submitting payment claims to Medicare. Specifically, Medicare will only pay for laboratory tests that are "reasonable and necessary" and are ordered by a treating physician. Attorneys with Baker and Donelson provide an overview of these fundamental billing requirements in light of a recent Department of Justice settlement over performance of certain urinary panel tests, specifically PCR urinalysis testing.
Details on page 6.

FTC Ban on Noncompete Agreements Presents Challenges for Labs

A Federal Trade Commission (FTC) ban on noncompete agreements could make it more difficult for clinical and anatomic pathology laboratories to protect their investments in lab personnel, as well as their proprietary information and assets.

On April 23, 2024, the FTC voted 3-2 to finalize a rule banning nearly all worker noncompete agreements nationwide. The rule was published in the *Federal Register* on May 7, 2024. All companies must comply with the final rule by Sep. 4, 2024. The FTC estimates that approximately 30 million American workers (about one in five) are subject to noncompete agreements. *Continued on page 9.*

CONTENTS

WHAT DOES THE LDT FINAL RULE MEAN FOR LABS? Q&A WITH MCDONALD HOPKINS' JANE PINE WOOD (*cont'd from page 1*)

What are the main differences between the proposed rule and the final rule?
In terms of the actual language of the rule, very little. The proposed rule basically said everything is an in vitro diagnostic (IVD) product, and the final rule basically says the same thing. The critical element is the 500 pages of preamble in which the FDA discusses its rationale for the rule and its exercise of enforcement discretion. The categories of enforcement discretion set forth in the preamble discussion are not exceptions or grandfathering that most people think of as exceptions or grandfathering. Most people think if there are exceptions or grandfathering, it's carved in stone. Instead, the FDA can modify, expand or remove any of these categories of enforcement discretion at any time. Some of the key language that the FDA used, "As with any enforcement discretion, FDA may update any of these policies as circumstances warrant or if the circumstances that informed the policies change." They added this caveat a number of times, while consistently taking the position that all LDTs are under their purview.


Jane Pine Wood

One of the things that is likely to be part of any expected legal challenge is whether the FDA has the authority to regulate LDTs—are LDTs really medical devices? There is still a fundamental issue that lawyers looking to challenge the FDA are not willing to concede. Even from the legal challenge perspective, if the FDA really felt it was so clear that LDTs are within their purview, they would not have to add those additional words to clarify. Obviously, it's still a sticking point.

Can you talk some more about these exceptions that the FDA is allowing, at least for now?
There is some misunderstanding that if your LDTs fall under enforcement discretion, it means your tests are grandfathered and you don't need to worry about this rule. A former FDA official posited that most LDTs would fall under one of the exemptions and that it's a low bar for compliance. However, it is not a low bar for most labs as the FDA regulatory world is entirely new for them, even if many will be able to avoid the need for premarket review. That is the key issue. Even if you have an LDT that falls within the three main categories of enforcement discretion—LDTs marketed prior to May 6 of this year; LDTs for which there is a critical patient need offered in integrated health systems; and LDTs with New York Clinical Laboratory Evaluation (CLEP) approval—there are still substantial requirements with which labs have to comply.

This time next year, all of the LDTs that are subject to these three main categories of enforcement discretion, as well as most other LDTs, will have to comply with the medical device reporting requirements. On the face of it, this makes sense. It's hard to challenge that a lab should have to report if there is a problem with a test and what you've done to correct it. It doesn't initially sound so bad, except that most labs don't have a formal mechanism for the intake of complaints, nor necessarily the familiarity with how they need to report them to the FDA because labs have not had to do it before.

In the past, a doctor might have mentioned something to a sales rep about results of a test seeming off, but it may not have been reported by the sales rep to the lab, or that lab might not have been diligent in terms of follow-up. We're in a different world here. Compliance with this first set of FDA requirements will require some work with the sales force and laboratory personnel. Sales reps have to be trained that if they hear someone express a concern about a test, there is a protocol that has to be followed. Within the laboratory, if something goes wrong, lab techs need to be trained to

escalate it and report it, not just fix the problem and rerun the tests. There is now a different set of regulations with respect to how that's documented and whether it is reportable or not. Labs need to develop these processes now because they go into effect May 6, 2025, even for LDTs that fall within the three main categories of enforcement discretion.

What about "1976-type tests" that are discussed in the rule?
"1976-type" LDTs will be under enforcement discretion, but they will not be subject to any phase-out of enforcement discretion, meaning that labs that only perform "1976-type" LDTs likely will not have any significant FDA obligations. The FDA stated in its webinar this month that these type of tests likely would capture a lot of IHCs and flow tests—manual tests that are not automated. The FDA explained that it will be posting a transcript of the webinar within the next couple of weeks. It will include a discussion of pre-1976 LDTs, which should provide some comfort to labs. [The presentation, slides and transcript are now available here].

What other requirements do labs that develop LDTs have to meet?
The good news is that LDTs that fall within one of the categories of enforcement discretion will not be required to submit applications for premarket review. But as of May 6, 2026, even for tests that fall within the exceptions for currently marketed LDTs, LDTs offered by integrated health systems and LDTs that have New York State CLEP approval, labs that develop LDTs have to comply with the FDA's registration and labeling requirements. Labs need to look at their LDTs and determine what class they fall into—Class I, Class II or Class III—and come up with labeling for each LDT and submit that to the FDA.

The FDA says it expects competitors of laboratories to look at fellow laboratories' labeling of their LDTs and alert the FDA if they believe the labeling is inaccurate. It means that there is even more pressure to make sure your labeling is accurate.

The FDA says it expects competitors of laboratories to look at fellow laboratories' labeling of their LDTs and alert the FDA if they believe the labeling is inaccurate. It means that there is even more pressure to make sure your labeling is accurate. Your sales reps have to stay on message; there can't be any off-label marketing. Labs really have to train sales reps that tests are now medical devices and they have to stay on message; there are additional rules that apply. Marketing teams also need to be trained.

The other thing, as well, if you have NY CLEP approval, be mindful that NY CLEP requires very specific descriptions of the test. The FDA has said that if the labeling that you submit to the FDA doesn't match your CLEP description, you're no longer eligible to fall within that CLEP exception.

My real concern, having represented labs for so long, is that sales reps tend to pivot their messaging depending on what they think their customers want to hear. There is going to be a lot of training and diligence to ensure everyone tows the line and don't promote off-label use.

What other concerns do you have about the final rule?
I have a concern about currently marketed LDTs. The FDA says if you are modifying your currently marketed LDT in a way that the FDA views as substantial, you no longer fall within that enforcement discretion exemption. So, if you add artificial intelligence (AI) to your test or if you have an LDT that changes from manual to automated or that changes from targeted sequencing to whole-genome sequencing, the FDA is taking the position that the LDT would be kicked out of the enforcement discretion exception for currently marketed LDTs.

The FDA did say that it recognizes that there may be reagent shortages or you might need to switch to a different piece of equipment because something broke down, but if the changes fall within the four categories that the FDA views as a substantial change, the LDT will be subject to full FDA regulations as a new LDT.

The other thing I am concerned about is that there is an enforcement discretion exception for integrated health systems, but it is a very narrow exception. It is for integrated health systems that are running LDTs ordered by a physician on staff within the health system, for a patient of the health system and performed by a laboratory of the health system. So, the exception won't have any applicability to hospital outreach programs where testing is performed for non-hospital patients. The FDA also says that this exception only applies where there is an unmet need; for example, when there is no currently FDA-approved test that is available for that disease or condition. Or there is one, but it's not indicated for use in that patient, such as it's approved for adults but not children.

There are a fair number of laboratories that have LDTs that are profitable, but there are also many that have LDTs that are breakeven at best, or in the red. If it's costing you even more to do those tests, you might rethink offering the tests.

Here's what's important—the FDA does not consider an LDT to be for an unmet need if there is an FDA-approved IVD, but it costs more. We all know that labs make decisions on tests all the time based on the costs involved, but such decisions must now consider the consequences of FDA regulation.

Many academic medical centers (AMCs) were concerned prior to the publication of the final rule because they assumed there would be more requests for them to provide more testing than they had the capacity to handle. But the exception for integrated health systems, such as AMCs, is only for LDTs that are used for their own patients.

It's also important to note that the FDA intends to reclassify a lot of Class III tests down to Class II. The FDA has indicated that the agency recognizes that many new LDTs that will have to go through premarket review are Class II devices, and it will be easier for laboratories to make minor modifications to Class II devices than to Class III devices. The FDA says it will continue to provide guidance, so it's important that labs continue to monitor the FDA's website.

What should labs be doing right now to prepare for compliance with this rule?
Labs should look at their LDTs and determine whether the tests fall within an enforcement discretion exception and determine what requirements are applicable. If they do fall within an exception, it probably makes sense to continue to offer the LDT, but labs will need to make an assessment based upon the costs that they will incur with the phase out of enforcement discretion for medical device reporting, labeling and registration, and certain QS standards.

If they don't fall within an exception, the lab will need to determine the cost effectiveness of continuing to offer the tests. Estimates range from about $500,000 to $2 million per test to go through the premarket review process. Labs will need to determine whether it might be cheaper to buy this test from someone else or is it cheaper to go through the premarket review process? They need to financially prioritize those LDTs they really need to keep and which ones they can let go.

Another factor in terms of cost is whether a lab's laboratory information system (LIS) will need to be upgraded. What I have been told anecdotally is that most laboratory information systems, un-

less they are currently being used for an FDA test, may not be adequate to meet the FDA's medical record keeping requirements and quality system requirements. There may need to be purchases of additional systems to add to the LIS or purchase of new standalone systems.

There are a fair number of laboratories that have LDTs that are profitable, but there are also many that have LDTs that are break even at best, or in the red. If it's costing you even more to do those tests, you might rethink offering the tests. Final decisions should not be made now, given that there is still substantial uncertainty regarding the FDA's enforcement discretion as well as possible legal challenges to the rule. However, labs should begin their analyses so that they are prepared to take action, if necessary, down the road.

Do you think a lot of labs will stop offering LDTs as a result of this rule?
I think a lot of labs will stop offering marginally profitable LDTs, especially if they can purchase them from someone else. The larger labs may not have a choice because they are expected to provide the test, but they also have more resources to go through this process. It also means they may have the opportunity to commercialize these tests if others aren't doing them in-house, so it's also a business opportunity.

Magellan Diagnostics Agrees to $42 Million Settlement Over Faulty Lead Tests

Magellan Diagnostics, a medical device company based in Billerica, MA, has agreed to plead guilty and pay $42 million to resolve criminal charges related to its concealment of a device malfunction that produced inaccurately low lead test results for potentially tens of thousands of children and other patients.

As part of the criminal resolution, Magellan will plead guilty to violations of the federal Food, Drug and Cosmetics Act and pay a $21.8 million fine, $10.9 million in forfeiture and a minimum of $9.3 million to compensate patient victims. The resolution reached May 21, 2024, also includes a deferred prosecution agreement to resolve felony conspiracy fraud charges against the company.

Magellan's devices – LeadCare Ultra, LeadCare II and LeadCare Plus – detected lead levels and lead poisoning in the blood of children and adults using either venous blood samples or fingerstick samples. LeadCare II, which was predominantly used to test fingerstick samples, accounted for more than half of all blood lead tests conducted in the United States from 2013 through 2017. LeadCare Plus and LeadCare Ultra were predominantly used to test venous samples.

According to the Department of Justice, Magellan has admitted that it misled its customers and the Food and Drug Administration (FDA) about a serious malfunction that affected Magellan's LeadCare devices when they were used to test venous blood samples. By hiding the malfunction and later deceiving customers and the FDA about when the company discovered the malfunction and the risks associated with the malfunction, Magellan cause an estimated tens of thousands of children and other patients to receive inaccurately low lead test results.

As part of the criminal resolution, Magellan has agreed to compensate all patients who were demonstrably harmed for the pecuniary damages they suffered as a result of the malfunction in Magellan's blood testing devices. Three former executives of the company in 2023 were indicted in U.S. district court and charged with conspiracy to commit wire fraud, wire fraud, conspiracy to defraud an agency of the United States and introduction of misbranded medical devices into interstate commerce with intent to defraud and mislead.

Fundamentals of Medicare Laboratory Billing: Avoiding the Pitfalls of Certain Test Ordering Policies

By Alissa D. Fleming, Mary Grace Griffin, and Katherine Denney, Shareholders with Baker Donelson

Clinical laboratories must comply with Medicare billing policies when submitting payment claims to Medicare. The Centers for Medicare & Medicaid Services (CMS) safeguards the federal funds allocated to the Medicare program and other federal health care programs by creating extensive frameworks of protective restrictions, including restrictions on what clinical laboratory tests may be ordered and who may order such tests.

Alissa D. Fleming

As set forth under the Social Security Act, the Medicare program can only be used to pay for those medical services that are "reasonable and necessary."[1] Any clinical laboratory test that is not ordered by a "physician who is treating the beneficiary," that is, "the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem" is not considered "reasonable and necessary."[2] These requirements form a foundation for laboratory billing compliance. While clinical laboratories have a vested interest and knowledge of testing approaches that lead to efficient and effective patient outcomes, attempts to implement policies that remove clinical decisions from the treating provider run afoul of fundamental Medicare program requirements for clinical laboratories and can subsequently subject the clinical laboratory to significant liability.

This article provides an overview of these fundamental billing requirements in light of the recent U.S. Department of Justice settlement in the *qui tam* case captioned *United States ex rel. Bibb v. Gamma Healthcare Inc. et al.*, No. 1:20-cv-00250-SNLJ (E.D. Mo). (Gamma), which demonstrates the risks of failing to adhere to these fundamental concepts. The Gamma settlement also reiterates recent issues related to the medical necessity of performance of certain urinary panel tests, specifically PCR urinalysis lab tests.

What Tests May Be Ordered?

To receive payment under either Part A or Part B of the Medicare program, an item or service must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[3] To determine whether a particular test is "reasonable and necessary," the provider or supplier must consider not only whether the test is recognized as being "reasonable and necessary" for any medical condition, but also whether the test is recognized as being "reasonable and necessary" for the particular patient for whom the test is being ordered. For any particular test, CMS generates specific guidance to establish whether a test is covered or non-covered in consideration of the use of the test (e.g., through the process of issuing National Coverage Determinations and Local Coverage Determinations). For example, CMS has specifically identified excessive or improper urine drug testing as an area of heightened fraud and abuse concerns due to its history of abuse.[4] These historic trends increase government scrutiny of medical necessity determinations connected to certain clinical laboratory tests.

Who May Order the Tests?

CMS requires that the laboratory test is ordered by the physician "who furnishes a consultation

1 42 U.S.C. § 1395y(a)(A).
2 42 C.F.R. § 410.32(a).
3 42 U.S.C. § 1395y(a)(A).
4 See Healthcare Fraud Prevention Partnership, *Examining Clinical Laboratory Services: A Review by the Healthcare Fraud Prevention Partnership* (May 2018), (cms.gov).

or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem."[5] This requirement is expanded to include orders by nonphysician practitioners, including nurse practitioners and physician assistants, who "furnish services that would be physician services if furnished by a physician" and "are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefits."[6] Notably, the list of appropriate nonphysician providers does not include entities like clinical laboratories.

Mary Grace Griffin

Potential FCA Liability

Under the False Claims Act, a provider or supplier is liable if the provider "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim."[7] When a provider or supplier enrolls in the Medicare program, the entity signs a "Certification Statement" that includes a certification that the entity will abide by all Medicare laws, regulations, and program instructions applicable to the provider. In combination with the False Claims Act, this certification creates provider liability for any violation of Medicare policies including the medical necessity and ordering requirements.

CMS, through the HHS-Office of the Inspector General (OIG), monitors for behavior that violates Medicare laws, regulations, and program instructions, but qui tam lawsuits brought under the False Claims Act also allow a private person to bring claims on behalf of the government and receive a portion of the damages if the case is successful.[8] Particularly given the broad oversight over clinical laboratories afforded by the qui tam lawsuits, clinical laboratories must carefully review their billing policies to ensure they do not create opportunities for medically unnecessary services or allow for the ordering of tests without an order by a licensed healthcare provider.

Recent Enforcement Action

The importance of compliance review of any clinical laboratory billing policies is exemplified by the recent ramifications of a billing policy established by Gamma, a Missouri corporation that provided clinical laboratory testing and digital radiology services in eight states before ceasing operations in November 2020.[9] In a letter from Gamma's Chairman and Chief Executive Officer, Gamma established a policy for its nursing home clients that dictated the tests that would be run for urinary tract infections in long-term-care residents.[10]

Specifically, Gamma stated that it would automatically perform additional testing when a urinalysis returned a positive result. When the test was positive, a "portion of the sample [would] be diverted for polymerase chain reaction (PCR) analysis." The stated reasoning for this automatic testing was to provide "faster and more precise diagnosis" and "fully support the infection control and antibiotic stewardship programs of individual clients."[11] However, under this policy, PCR analysis was performed despite not being ordered by an appropriate provider.

5 42 C.F.R. § 410.32(a).
6 42 C.F.R. § 410.32(a).
7 31 U.S.C. § 3729(a)(l).
8 31 U.S. Code § 3730.
9 Complaint Under the False Claims Act, *United States of America, ex rel. Bradley Bibb, M.D. v. Gamma Healthcare Inc., Jerry Murphy, and Jerrod Murphy*, No. 1:20-cv-00250-SNLJ (E.D. Mo. 2020).
10 Complaint Under the False Claims Act, *United States of America, ex rel. Bradley Bibb, M.D. v. Gamma Healthcare Inc., Jerry Murphy, and Jerrod Murphy*, No. 1:20-cv-00250-SNLJ (E.D. Mo. 2020).
11 Exhibit 1 to Complaint Under the False Claims Act, *United States of America, ex rel. Bradley Bibb, M.D. v. Gamma Healthcare Inc., Jerry Murphy, and Jerrod Murphy*, No. 1:20-cv-00250-SNLJ (E.D. Mo. 2020).

Critically, Gamma's requisition forms were structured such that physicians could not opt out of the urine PCR tests. The PCR analysis was also performed instead of urine cultures that were actually ordered by the provider.

When comparing the PCR analysis with a urine culture, it is the government's position that a urine culture is a "gold standard" testing mechanism and a more affordable form of testing for urinary tract infections.[12] In other words, there was no clinical validity establishing that urine PCR tests were more efficacious than less expensive urine culture or that urine PCR tests provided any information that improved clinical outcomes even though urine culture takes longer to result. The government heavily scrutinized Gamma's policies because licensed healthcare providers could not opt out of the PCR test and also were not provided any mechanism to specifically order the PCR test. Providers had no control over whether to order the urine PCR test.

Katherine Denney

Physician Complained about Gamma Policy

Despite the test's connection to the underlying urinalysis, the order for the PCR test did not independently meet medical necessity requirements and was not ordered by a licensed health care provider. At least one physician complained about Gamma's policy to the Medicare contractor that managed complaints for the Medicare Advantage and Part D programs.

Subsequently, as of Sept. 9, 2020, Gamma's Medicare payments were suspended, as permitted under 42 C.F.R. § 405.371.[13] Gamma, its Chief Executive Officer, its Chief Operating Officer, and its Chief Information Officer (each of whom had ownership interests in Gamma) entered into a settlement agreement with the DOJ on March 27, 2024, to resolve claims submitted from Jan. 1, 2020 to Oct. 31, 2020. The total settlement amount was $13,619,660.18, along with additional payment obligations for both Gamma and the individual defendants in certain sale circumstances. Each of the defendants will also be excluded from Medicare, Medicaid, and all other federal healthcare programs for a period of 15 years.

In this enforcement action, several factors weighed against the argument that the clinical laboratory was seeking solely to improve patient outcomes through the automatic performance of tests without a licensed healthcare provider ordering the test. The extensive penalties that Gamma received for a period of less than one year serve as a warning of the potential liability that noncompliant policies and practices can create, resulting in the potential ordering of medically unnecessary tests.

Conclusion

Outside the foundational requirements for clinical laboratory billing, clinical laboratories must also stay apprised of changing National Coverage Determinations, Local Coverage Determinations and other CMS guidance applicable to laboratories due to the certifications clinical laboratories make through their Medicare enrollment. Clinical laboratories must consider these additional sources of guidance and the complex ecosystem they create when developing and implementing billing policies and practices.

Importantly, clinical laboratories must not interfere with a licensed healthcare provider's process of ordering clinical laboratory tests for their patients or encourage the ordering of medically unnecessary tests. Taking any actions that interfere with the provider's ability to choose the appropriate clinical laboratory tests for their patients can result in significant liability as demonstrated by the recent Gamma settlement.

12 Complaint Under the False Claims Act, *United States of America, ex rel. Bradley Bibb, M.D. v. Gamma Healthcare Inc., Jerry Murphy, and Jerrod Murphy*, No. 1:20-cv-00250-SNLJ (E.D. Mo. 2020).

13 *Settlement Agreement among the United States of America, Gamma Healthcare, Inc., Jerry W. Murphy, Jerrod W. Murphy, Joel W. Murphy, and Bradley Bibb, M.D.*, March 25, 2024.

FTC Ban on Noncompete Agreements Presents Challenges for Labs

(*cont'd from page 1*)

The U.S. Chamber of Commerce and others business groups have filed challenges to the ban, along with a separate challenge by the tax firm Ryan LLC. A Texas federal judge on May 3 stayed the Chamber's lawsuit, saying that the Ryan lawsuit, which was filed a day earlier, should proceed and encouraged the Chamber to intervene due to the similarity of issues. The U.S. Chamber of Commerce filed a motion to intervene in the Ryan LLC, which was granted by the court. Ryan and the Chamber both claim that the FTC lacks the legal authority to adopt rules banning conduct that it deems to be an unfair method of competition. The FTC is also facing a challenge to its rule in Philadelphia federal court by a Pennsylvania-based tree trimming company.

Danielle Tangorre

Definition of Worker

The final rule defines the term "worker" broadly. The term includes current and former workers, paid and unpaid workers, employees, independent contractors, interns, externs, volunteers, apprentices and sole proprietors. The rule does not apply to existing noncompete agreements for "senior executives." However, employers are banned from entering into or attempting to enforce any new noncompete agreements, even if they involve senior executives, after the effective date of the rule. A "senior executive" is defined as a worker who in the preceding year was in a policy-making position and received total compensation of at least $151,164. The FTC estimates that fewer than 1% of workers are estimated to be senior executives under the final rule.

In a small or mid-sized lab, a senior executive would include the owner, other C-suite executives, director of operations and maybe the vice president of marketing, says Danielle Tangorre, a partner with Robinson+Cole (Albany). The FTC will look as to whether the individual has sufficient bargaining power and had a "bespoke agreement." The FTC views department heads or other highly paid non-C-suite to not have sufficient bargaining power to avoid exploitation and coercion, she adds.

The final rule defines the term "worker" broadly. The term includes current and former workers, paid and unpaid workers, employees, independent contractors, interns, externs, volunteers, apprentices and sole proprietors. The rule does not apply to existing noncompete agreements for "senior executives."

Definition of Noncompete Clause

The rule defines a "noncompete clause" as a term or condition of employment that either "prohibits" a worker from, "penalizes" a worker for or "functions to prevent" a worker from 1) seeking or accepting work in the United States with a different person where such work would begin after the conclusion of the employment that includes the term or condition; or 2) operating a business in the United States after the conclusion of the employment that includes the term or condition.

The noncompete ban applies to terms and conditions that:

- Expressly prohibit a worker from seeking or accepting other work or starting a business after their employment ends.
- Require a worker to pay a penalty (or extinguishes an employer's obligation to provide promised compensation or to provide benefits) for seeking or accepting other work or starting a business after their employment ends.

- Restrain such a large scope of activity that they function to prevent a worker from seeking or accepting other work or starting a new business after their employment ends, although they are not expressly triggered by these specific undertakings.

"Forfeiture-for-compensation" provisions, which are commonplace in deferred compensation agreements, are barred if they impose adverse financial consequences on a former employee as a result of the termination of an employment relationship, expressly conditioned on the employee seeking or accepting other work or starting a business.

Other types of restrictive employment agreements, such as confidentiality agreements, nondisclosure agreements (NDAs), training-repayment agreements (TRAPs), garden leave provisions and non-solicitation agreements, are not categorically prohibited. However, if these types of agreements have the same functional effect as a term or condition prohibiting or penalizing a worker from seeking or accepting other work or starting a business after their employment ends, then they will be barred under the final rule.

Laboratories should also re-examine their contracts. Non-disclosure agreements are still permissible as long as they are not so broad as to act like a noncompete agreement. If you don't have those agreements in place, you may want to consider implementing them.

The ban only applies to noncompetes between businesses and workers. It does not apply to noncompetes in franchisor/franchisee contracts although it does apply to noncompete agreements between employers and workers at franchises. The ban does not apply to noncompetes between a buyer and seller of a business in a bona fide sale. The seller can agree to a noncompete individually but not for any of the business's workers.

Steps Labs Should Take Now

Tangorre advises that clinical and AP laboratories monitor the legal challenges, as well as state and local developments in the noncompete arena. Meantime, labs should begin preparing now for the ban in case the legal challenges are unsuccessful. She says labs should start by identifying which employees are senior executives who have current noncompete agreements and thus not subject to the rule. For most laboratories, the noncompete ban will apply to members of the sales and marketing team, scientists and other highly trained individuals and pathologists.

Labs then need to individually notify all affected workers, both current and former, before the effective date that their noncompete provisions are no longer enforceable. The notices must be provided in writing and may be delivered by hand, mail, email or text message. The FTC has published a model notice with recommended language. An all-staff email with the model language would meet this requirement, even if you use noncompetes only for some workers.

Laboratories should also re-examine their contracts, says Tangorre, who notes that non-disclosure agreements are still permissible as long as they are not so broad as to act like a noncompete agreement. If you don't have those agreements in place, you may want to consider implementing them.

"Labs will still be able to protect their pricing, but the details will be in the nitty gritty," she explains. "It is yet to be seen if they will be able to protect all of their accounts. That will be the challenge here."

COMPLIANCE 101:

Compliance with Applicable HHS OIG Fraud Alerts, Advisory Opinions

The Health and Human Services (HHS) Office of Inspector General (OIG) periodically issues fraud alerts setting forth activities believed to raise legal and enforcement issues. Laboratory compliance plans should require that any and all fraud alerts issued by the OIG are carefully considered by the legal staff, chief compliance officer or other appropriate personnel.

Moreover, the compliance plans should require that a laboratory cease and correct any conduct criticized in such a fraud alert, if applicable to laboratories, and take reasonable action to prevent such conduct from recurring in the future. If appropriate, a laboratory should take the steps described in the model compliance program guidance concerning investigations, reporting and correction of identified problems (see *LECPR*, October 2023). HHS OIG fraud alerts are available at oig.hhs.gov/compliance/alerts/

Among notable fraud alerts relevant to clinical and anatomic pathology laboratories:

- Covid-19 scams (Feb. 28, 2023)
- Rental of office space in physician offices by persons or entities to which physicians refer (February 2000)
- Genetic testing scam (Sept. 27, 2019)
- Laboratory payments to referring physicians (June 25, 2014)
- Arrangements for the provision of clinical lab service (Dec. 19, 1994)

Advisory Opinions

In addition, the OIG issues advisory opinions, which are legal opinions issued to requesting parties about the application of the OIG's fraud and abuse authorities to the party's existing or proposed business arrangement. While an OIG advisory opinion is only binding on the requesting party, they are often relied upon by others as insight into the OIG's thinking.

Advisory opinions affecting clinical and AP laboratories include:

- Purchase of technical component of AP services from certain laboratories (No. 23-06, Sept. 25, 2023)
- Prepaid card as incentive to return colorectal cancer screening test (No. 23-03, March 24, 2023)
- Specimen collection services for laboratory testing (No. 22-09, April 25, 2022)
- Free genetic testing and genetic counseling services (No. 22-06, April 6, 2022)
- Free labeling of test tubes and specimen collection containers for dialysis facilities (No. 16-12, Nov. 28, 2016)
- Per-order fee to tests transmitted to lab by an electronic health record services vendor (No. 14-03, April 1, 2014)
- Discounted pathology services provided to physicians (No. 99-13, Nov. 30, 2013)
- Lab assistance to support physician groups in developing their own lab (No. 13-03, June 13, 2013)
- Provision of pathology laboratory management services to a third party (No. 11-15, Oct. 3, 2011)
- Financial assistance with cost-sharing obligations for genetic tests for financially needy individuals (No, 11-05, May 13, 2011)
- Lab proposal to provide free blood collection supplies to physicians and pay those physicians for the collection of blood samples (No. 05-08, June 6, 2005)

In Brief

FDA Approves Self-Collection for HPV Testing

The Food and Drug Administration (FDA) has approved self-collection of vaginal samples for HPV testing. Roche and Becton, Dickson and Company (BD) both said May 15 that the FDA had approved the use of samples self-collected in a clinical setting with their respective HPV tests. The BD Onclarity HPV Assay is approved for HPV testing on self-collected samples without the need for a traditional Pap test. HPV self-collection is also approved for use with Roche's cobas HPV test. The self-collection must occur in a healthcare setting, such as at a patient's doctor's office, an urgent care center or a mobile clinic. The U.S. Preventive Services Task Force recommends screening for cervical cancer with cervical cytology every three years for women ages 21 to 29 and every five years for women ages 30 to 65.

Balance Diagnostics Agrees to $2.5 Million FCA Settlement

Balance Diagnostics, a diagnostic testing facility based in Cedarhurst, NY, has agreed to pay $2.5 million to settle a False Claims Act lawsuit brought by the Department of Justice (DOJ). Balance provides on-site mobile diagnostic testing services, such as video steganography and ultrasound procedures. The settlement resolves claims that occurred from January 2009 through December 2019, Balance paid hundreds of thousands of dollars to more than 100 physicians and their practices in the New York City area to induce them to refer patients for diagnostic testing services at the Balance offices. DOJ alleged that the so-called rent payments for the office space were based entirely upon the number of patient referrals and, in many cases, were well above the fair market rental value of the leased office space. Balance will pay the United States $1,725,850 million and the State of New York $774,150.

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