LABORATORY ECONOMICS

Volume 2, No. 7, July 2024

Kimberly Scott, Editor, kscott@laboratoryeconomics.com

COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

ACLA Seeks Resolution of LDT Lawsuit by Year End

The American Clinical Laboratory Association (ACLA) is hoping that the lawsuit it has filed challenging the Food and Drug Administration's authority to regulate lab-developed tests will be fully briefed and ready for a court decision by the end of this year. ACLA President Susan Van Meter tells *LECPR* that its attorneys are discussing a proposed briefing schedule with the government and hope that the lawsuit can move quickly.

Continued on page 2.

Mandated Coverage of Biomarker Testing: Q&A with Epstein, Becker & Green's Robert Hearn

Since 2021, 17 states have enacted laws requiring insurance companies to cover biomarker testing and a handful of others have introduced such measures. An American Cancer Society survey of more than 300 oncology providers found that 66% reported the insurance coverage for biomarker testing is a moderate or significant barrier to appropriate testing for their patients.

Colorado in early June 2024 became the latest state to sign biomarker coverage legislation into law. Pennsylvania is close to passing a biomarker bill. *Laboratory Economics Compliance & Policy Report* recently spoke with Robert Hearn, an attorney with Epstein, Becker & Green, about what's behind the push to increase mandated coverage.

More on page 5.

Pathologists Accuse Former Employer of Anti-Competitive Practices

The saga of the Iowa Pathology Associates (IPA) legal fight continues, with a third lawsuit filed by the four pathologists named in IPA's original lawsuit. The four pathologists—Tiffani Milless, Caitlin Halverson, Renee Ellerbroek and Jared Abbott—are suing their previous employers, IPA and Regional Laboratory Consultants, alleging that the two companies have tried to suppress competition for pathology services in violation of state and federal law.

Details on page 8.

CONTENTS

ACLA Seeks Resolution of LDT Lawsuit by Year End

(*cont'd from page 1*)

Although ACLA did not seek immediate injunctive relief when filing the lawsuit, Van Meter says the group reserves the right to seek such relief if it is deemed necessary. Meantime, ACLA and other stakeholders are continuing to pursue legislation that would create a diagnostic-specific regulatory framework that recognizes the role of clinical diagnostics.

The lawsuit, filed by ACLA and HealthTrackRx Indiana Inc. on May 29, 2024, in the United States District Court for the Eastern District of Texas, argues that because the FDA's final rule on LDTs exceeds the agency's "lawful authority and is arbitrary and capricious and contrary to law, the rule should be set aside and vacated and defendants should be enjoined from enforcing or implementing the rule."

Susan Van Meter

According to the complaint, for decades laboratory-developed testing services have been regulated under the Clinical Laboratory Improvement Amendments Act of 1988 (CLIA), which imposes numerous laboratory-specific standards to ensure the validity and reliability of laboratory diagnostic testing services, including the training and qualifications of the skilled professionals who perform, supervise and interpret those tests.

"These laboratory professionals have not generally been required to comply also with the costly and burdensome pre-approval and clearance requirements that the Federal Food, Drug and Cosmetic Act (FDCA) authorizes FDA to apply to manufactured medical devices sold in interstate commerce," says the complaint. "Nor has congress ever granted FDA authority to regulate professional laboratory-developed testing services."

The complaint argues that the FDA's final rule threatens to upend the nation's entire laboratory profession by seeking to regulate all LDTs as if they are medical devices under the FDCA. In asserting authority to transform the regulatory framework that has applied for decades, FDA cannot point to any new statutory authority granted by Congress, it says. Nor can FDA contend that Congress has ever provided it with the resources that would be necessary to retain the personnel and build the expertise necessary to exercise sweeping authority over thousands of testing services provided by the nation's laboratories. To the contrary, Congress has recently entertained legislative proposals that would have granted FDA new authority to regulatory LDTs, and it declined to provide FDA that power.

"FDA's final rule relies on the extraordinary position that in 1976, when Congress expanded FDA's authority to regulate medical devices, it also quietly intended to outlaw—and subject to substantial civil and criminal monetary penalties—any professional laboratory-developed testing services that were not first approved or cleared by FDA," states the complaint. "The logic of FDA's position is that tens of thousands of professionals across the country performing millions of diagnostic testing services every year, working with thousands of doctors and patients, have for decades done so in open and direct violation of the law.

"According to the FDA, the only reason laboratories have not been civilly and criminally punished is because FDA has chosen to exercise unreviewable 'enforcement discretion.' In short, FDA is taking the position that a 'long-extant statute' grants it vast, 'transformative' regulatory powers that it has not previously exercised—a position that courts have rightly approached with deep skepticism."

If it is not vacated, FDA's unprecedented final rule will have devastating and far-reaching consequences not only for the nation's clinical laboratories, but also for the nation's healthcare system,

including the millions of vulnerable patients who depend on the essential clinical testing services that laboratories provided, says the complaint. FDA's final rule means that, in order to be legally marketed, virtually all diagnostic laboratory tests will have to undergo costly and time-consuming administrative review through a regulatory process that was designed for evaluating manufactured medical devices, not professional testing services.

The final rule states that FDA intends to apply this onerous regulatory regime to new and modified LDTs, which will dramatically increase research and development costs, hinder vital medical innovation and hamper adaption of existing tests to meet evolving patient needs, according to the lawsuit. The FDA itself has recognized "significant regulatory changes" to the treatment of laboratory testing services "could have negative effects on the public health."

According to the FDA, the only reason laboratories have not been civilly and criminally punished is because FDA has chosen to exercise unreviewable 'enforcement discretion.' In short, FDA is taking the position that a 'long-extant statute' grants it vast, 'transformative' regulatory powers that it has not previously exercised—a position that courts have rightly approached with deep skepticism.

"With respect to unmodified existing tests, FDA states that as a matter of enforcement discretion it generally does not intend—at least not at this time—to enforce certain especially burdensome medical-device requirements, such as premarket review," says the complaint. "But FDA's final rule means that in the agency's view all of those tests, including tests that physicians have relied on for decades, are being marketed illegally and are subject to FDA enforcement action at any time."

FDA Lacks Authority

The complaint states that FDA does not have authority to regulate professional laboratory-developed testing services as medical devices. The text and structure of the FDCA make plain that FDA's authority to regulate "devices," which dates to 1938 and was expanded through the Medical Device Amendments of 1976, extends only to physical products that are sold and distributed by manufacturers in interstate commerce, it says.

"The FDCA has never applied medical device regulation to laboratory testing services," says the complaint. "And for good reason: Those tests are not physical products sold and distributed by manufacturers. Instead, they are professional healthcare services offered by highly skilled and trained laboratory professionals that are outside FDA's regulatory expertise and are subject to different regulatory requirements. A laboratory-developed test is a process by which laboratory professionals use various tools—some of which may be individually regulated as devices—to derive diagnostic information that a patient and the patient's physician may use in making healthcare decisions."

LDTS Are Not Devices

FDA's assertion that laboratory testing services are devices just because the professionals performing those services use devices is as unreasonable as calling a surgical procedure a "device" because the surgeon uses a scalpel or calling a doctor's physical examination a "device" because the doctor uses a stethoscope, argue ACLA and HealthTrackRx.

"The fact that a skilled professional may use physical tools, in addition to his or her professional expertise, training and judgment, to perform a procedure does not mean the procedure itself is a device," says the complaint.

Equally untenable is FDA's contention that laboratory testing services are devices because they serve a similar function to in vitro diagnostic (IVD) test kits, which FDA regulates as devices. An IVD test kit is a "device" because it is a packaged set of components manufactured and sold in interstate commerce as a single physical product, like an at-home Covid test, the lawsuit asserts. Such commercial tests are fundamentally different from LDTs, which are professional services performed by professional clinicians in a laboratory.

Regulatory Uncertainty

In its proposed rule, FDA initially contended that nearly all existing LDTs would have to go through a burdensome approval or clearance process before they could continue to be used to help patients and physicians. In the final rule, recognizing that its sweeping interpretation would be unworkable and have devastating consequences, FDA tried to rewrite the FDCA in the guise of dozens of pages of vague, non-binding "enforcement discretion policies" that are designed to mitigate (but not eliminate) those consequences, says the complaint. The "need to rewrite" the statute "should have alerted [FDA] that it had taken a wrong interpretive turn, argues ACLA and HealthTrackRx.

FDA's assertion that laboratory testing services are devices just because the professionals performing those services use devices is as unreasonable as calling a surgical procedure a "device" because the surgeon uses a scalpel or calling a doctor's physical examination a "device" because the doctor uses a stethoscope, argue ACLA and HealthTrackRx.

"The final rule repeatedly warns that FDA may change its enforcement discretion policy at any time and bring the hammer down on laboratories for unlawfully marketing existing tests," says the lawsuit. "Even if FDA never takes that step, the rule creates enormous regulatory uncertainty for laboratories and places them in an impossible position: They must either 1) withdraw all their existing tests from the market (which FDA recognized would be devastating for patients and the public health); 2) incur massive costs to obtain FDA approval or clearance for their existing tests, which would divert resources from innovating and developing new tests and overwhelm FDA; or 3) continue serving patients by providing existing tests without FDA approval or clearance, even though FDA says that by doing so they are breaking the law and are subject to enforcement action at any time in the agency's sole discretion."

Undermines Innovation

In addition to casting a shadow over all existing tests, the final rule undermines innovation and threatens patient access to critical new diagnostic tests, argue ACLA and HealthTrackRx in the complaint. FDA lacks the expertise or resources to timely and efficiently review and approve new and modified laboratory-developed testing services, they say.

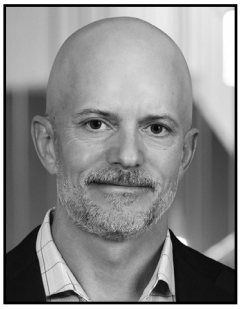
Moreover, given the need for FDA approval or clearance, the rule will discourage laboratories from devoting scarce resources to research and development, which will impede the creation of new and improved tests for cancer, infectious disease, cardiovascular disease and countless other diseases and conditions, says the lawsuit. Because many tests do not generate sufficient revenue to support the expense of seeking FDA approval or clearance, many important tests will never be developed – especially tests for rare diseases or that serve small patient populations, such as children or ethnic minorities, the groups argue.

"FDA has identified no genuine public-health justification for imposing these costs on laboratories and the physicians and patients who rely on them," says the complaint. "The agency's exercise of enforcement discretion for existing tests only underscores the lack of a valid public-health rationale for treating any laboratory-developed tests as medical devices.

MANDATED COVERAGE OF BIOMARKER TESTING: Q&A WITH EPSTEIN, BECKER & GREEN'S ROBERT HEARN (*cont'd from page 1*)

What was the impetus behind seeking legislative action on the issue of payer coverage of biomarker testing?
The impetus is that there is good scientific evidence that these types of tests really help identify certain types of cancers in ways that are significant to their clinical management. You've also got the pharmaceutical industry behind the new laws because many of their recent cancer drugs require that certain types of tests be performed either before or during their administration.

Many new cancer drugs have true companion diagnostic tests associated with them or there is a strong recommendation that certain types of NGS or hybrid biomarker testing be performed before the drugs are administered to determine propriety or expected efficacy or to monitor side effects during treatment. [In fact, more than 60% of oncology drugs launched in the past five years require or recommend biomarker testing before use].


Robert Hearn

These drugs are also incredibly expensive. And, while biomarker testing isn't cheap, the cost is less than giving someone the wrong chemotherapy or autoimmune drug for months before the physician realizes it's not working and has hurt the patient.

On top of that, a lot of the tests are for diseases that touch a lot of people, such as cancer, and there are emotional elements associated with them. There are a number of strong, well-established advocacy groups, such as the American Cancer Society, that are behind these legislative efforts. It's an interesting combination of stakeholders.

Are the measures that have passed similar or are there key differences?
The main difference is the scope of the various state laws. Some laws are Medicaid-oriented only, some are Medicaid and commercial pay and some are commercial pay only. For example, the Colorado law that just passed only mandates coverage for specified tests by commercial plans. It doesn't apply to the state Medicaid plan. A lot of that is driven by what the state Medicaid plans can afford.

Almost all the laws have some kind of medical necessity criteria that have to be met for mandatory coverage, but they can vary on specifics. The laws can also vary in the ranges of target diseases that are covered and how those target diseases are defined. Generally, there are biomarker tests that are associated with lots of conditions. Oncology is a primary one, but there are also tests for things like autoimmune disorders.

How are these measures similar to what Medicare requires in terms of coverage?
Medicare has a broad national coverage determination on genetic testing in relation to cancer. There's a series of local coverage determinations that sit under that NCD that are issued by individual Medicare administrative contractors.

Do you anticipate that this type of introduction of biomarker legislation will continue to spread across the country?
I think so. The question is whether the states that have resisted it so far will continue to be able to resist. The pace has slowed, but the bills are still out there. Pennsylvania is close to passing a law. I believe it's a Medicaid and commercial pay bill.

Who is arguing against laws mandating coverage?
At a certain level, it's the payer lobby who doesn't want to be pressed into making decisions they

have no or limited control over. There is political pressure over the expansion of Medicaid, too. You have this sort of weird intersection of stakeholders coming together. The opposition is less ideological and truly more fiscal. It comes down to dollars.

Is there a need for a national policy on this? In other words, is there a possibility that Congress could take this up or will this continue to be decided on a state level?
I think it's possible, but it's difficult in an election year. There are a lot of healthcare related issues that are getting kicked down the road. It's more likely that for some period of time, on the federal level, biomarker testing coverage will continue to be dealt with administratively by the Centers for Medicare and Medicaid Services and its MACs. States will address it relative to state-regulated commercial plans and Medicaid.

What is the significance of this movement for clinical laboratories?
It certainly won't hurt them. Theoretically, it will open up higher volumes of testing that they might not otherwise have been able to bill and collect from health plans. But you have to wonder if the reimbursement rates might get choked off a little bit. If the payers have to start paying for a certain number of tests for a particular patient, then something's got to give, and I think what ends up giving is how much labs get paid per test. It might be a little bit of a double-edged sword over time.

What is the significance for patient care?
I think the patients turn out to be the winners. Many of the cancer drugs that are coming out now really are dependent on the patients being identified as a good target for the drug. These tests really do help the oncology community determine whether a patient is a good candidate for a particular drug or whether a drug with potentially difficult side effects and high cost is working. All the data show that patients benefit from these tests.

States With Laws Requiring Coverage of Biomarker Testing

State and Bill Number	Commerical or State-Regulated Plans	Date Signed into Law
Louisiana	State Private Plans	June 2021
Illinois	State and Private	July 2021
Arizona	State and Private	May 2022
Rhode Island	State and Private	June 2022
Ohio	State and Private	December 2022
Kentucky	State and Private	March 2023
New Mexico	State	April 2023
Arkansas	State and Private	April 2023
Georgia	State and Private	May 2023
Maryland	State and Private	May 2023
Minnesota	State and Private	June 2023
Oklahoma	State and Private	July 2023
Texas	State and Private	August 2023
New York	State and Private	February 2024
Connecticut	Medicaid	June 2024
Florida	State Plans and Medicaid	June 2024
Colorado	Private	June 2024

Source: American Cancer Society

To what extent have insurance companies pushed back on this type of legislation?
They get involved and they don't love some of the laws, especially the ones with broad, fuzzy definitions of biomarker testing, but they are between a rock and hard place to a certain degree. It's a very emotional issue, and they have to be careful about not looking like they are impeding cancer care. They are trying to be mindful of their responsibility and their image while dealing with some of the legitimate issues created by the laws for them.

States with Biomarker Legislation Pending

State
Hawaii
Maine
Massachusetts
Nevada
New Jersey
Pennsylvania
Vermont
Washington
West Virginia

Source: American Cancer Society

Do you see this movement expanding to coverage of other types of testing?
I think so. I don't think it will happen quickly, but I do think it will eventually expand. I don't know that there is impetus for laws. I think coverage, especially for non-cancer-related drugs, will happen more as a matter of policy. There are a lot of new biomarker tests coming to market every year, and there's a pathway to commercial and government plan coverage for those tests absent new law.

It's not like insurers are refusing to cover biomarker testing without legislation. They are doing it – it might just not be as fast or as fulsomely as some people would like.

Pre-Authorization Bill Reintroduced in Congress

Lawmakers on June 14 reintroduced a bill that would streamline the prior authorization process under Medicare Advantage to better serve patients and reduce unnecessary administrative burdens for clinicians.

The Improving Seniors' Timely Access to Care Act (S. 4532/HR 8702), which has bipartisan support, is endorsed by the College of American Pathologists, the American Clinical Laboratory Association, the American Medical Association and more than 380 national and state healthcare organizations.

The measure establishes several requirements related to prior authorization under Medicare Advantage (MA) plans:

- The plans must establish an electronic prior authorization program that meets the specified standards, including the ability to provide real-time decisions in response to requests for items and services that are routinely approved;
- The plans must annually publish specified prior authorization information, including the percentage of requests approved and the average response time; and
- The plans must meet other standards, as set by CMS, relating the quality of prior authorization determinations.

The bill was originally introduced in 2021 and passed the House in 2022. Since then, the House and Senate have been working with the Centers for Medicare and Medicaid Services (CMS) to get the bill reintroduced.

In a statement, the American Hospital Association says that by removing unnecessary barriers that create delays in treatment, this bill will improve access to care for seniors and allow clinicians to focus more on care and less on burdensome paperwork.

Pathologists Accuse Former Employer of Anti-Competitive Practices

The lawsuit, *Goldfinch Laboratory, P.C. v. Iowa Pathology Associates*, P.C., et al, was filed May 13, 2024, in the U.S. District Court for the Southern District of Iowa. It follows two earlier lawsuits—one filed by Milless and Halverson in late 2023 alleging IPA discriminated against them on the basis of sex, age and pregnancy, and the original lawsuit filed by IPA in late 2022 accusing the four pathologists of breach of contract (for details, see the December 2023 issue of *Laboratory Economics Compliance & Policy Report*).

Milless, Halverson, Ellerbroek and Abbott left IPA in to form their own pathology practice in early 2023. Prior to the formation of Goldfinch, IPA was the only independent pathology practice in central Iowa that was not exclusively tied to one source of referrals. It also was the only independent pathology practice in central Iowa that offered dermatopathology services.

The lawsuit alleges that the non-competition clause of the agreement was not limited to prohibiting use of confidential IPA or RLC information—or any other legitimate business interest.

On Oct. 26, 2022, the four pathologists who formed Goldfinch advised IPA and RLC of their intention to leave IPA and form their own practice. According to the lawsuit, IPA and RLC had been trying to get each of the pathologists to sign an employment agreement since 2021, but the pathologists had refused. The agreement, in part, included a non-compete clause. The administrator of those corporations told the pathologists that the agreement was in effect even though they had not signed it.

The lawsuit alleges that the non-competition clause of the agreement was not limited to prohibiting use of confidential IPA or RLC information—or any other legitimate business interest. "Rather, its sole purpose was to attempt to prevent the formation of a pathology practice that would compete with IPA and RLC for referrals of pathology specimens from sources that were not bound by contract or otherwise to refer specimens only to one specified provider of pathology services," the complaint states.

Attempt to Suppress Competition

The lawsuit notes that the Federal Trade Commission (FTC) on May 7, 2024, issued a final rule banning non-compete agreements, saying that such agreements prevent new businesses from forming, stifle entrepreneurship and prevent novel innovation. The complaint notes that FTC Chair Lina Khan specifically noted that "the freedom to change jobs is core to economic liberty and to a competitive, thriving economy."

"Indeed, noncompete agreements are particularly contrary to public policy where, as here, they deprive patients of access to highly qualified physicians," says the lawsuit, which charges that the ongoing campaign by IPA and RLC to get the four pathologists to sign the noncompete agreement was only the beginning of their efforts to suppress competition in the market for pathology services and the submarket for dermatopathology services in central Iowa.

For example, the complaint alleges, IPA and RLC barred the pathologists from coming to the office after they announced their intention to form a competing practice and also refused to share slides with Goldfinch pathologists when those slides were required for continuity of care of the patient. In addition, IPA and RLC made false and deceptive statements designed to dissuade referral sources from making referrals to Goldfinch, according to the complaint. IPA also told refer-

ral sources that they cannot send outpatient clinical biopsies to Goldfinch because IPA held the exclusive contract for such biopsies—when in fact that was not true. At least one partner of IPA, or that partner's spouse, posted negative Google review falsely stating that Goldfinch pathologists are immoral and poorly trained.

Goldfinch estimates that, as a direct result of the anticompetitive, unfair and deceptive practices, it has lost several contracts with referral sources, resulting in the loss of more than $3.3 million. The Goldfinch pathologists are requesting a jury trial, along with an award of damages to be determined at trial, an injunction enjoining defendants from engaging in the wrongful and unlawful acts described in the lawsuit, an order for declaratory relief and court and attorney fees.

Medicare Spending on Lab Tests Decreased From 2021 to 2022

Medicare spending on clinical diagnostic laboratory tests decreased by 10% between 2021 and 2022, primarily due to changes in volume of testing, according to the Department of Health and Human Services Office of Inspector General (HHS OIG)'s semi-annual report to Congress, issued June 1.

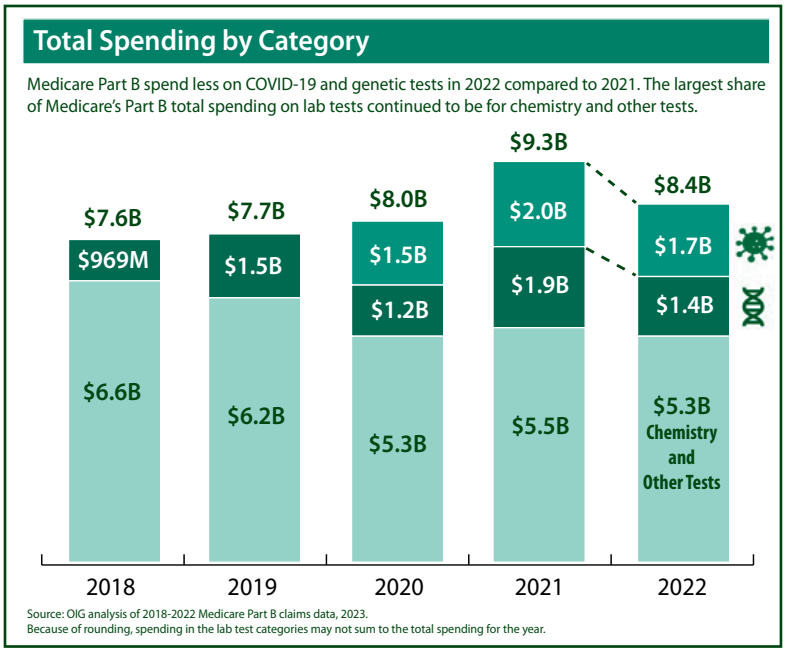
Total Medicare Part B spending grew between 2014 and 2022, with a sharp increase to $9.3 billion in 2021 and a drop to $8.4 billion in 2022, says the OIG, referencing a report first published in December 2023 (OEI-09-23-00350). The 10% decrease in spending on lab tests in 2022 marks the largest decrease in annual spending since 2014.

The decline is largely due to both a decrease in Covid-19 testing, which dropped 14%, and a drop in genetic testing, which decreased 26% from 2021 to 2022. In terms of volume, Covid-19 testing decreased from 25.8 million tests in 2021 to 23.3 million tests in 2022. Genetic testing decreased from 2.8 million tests in 2021 to 1.7 million tests in 2022.

Lessons Learned from PHE

The semi-annual report describes the OIG's work identifying significant risks, problems, abuses, deficiencies, remedies and investigative outcomes from October 1, 2023, through March 31, 2024. For example, in its ongoing oversight of HHS's response to the Covid-19 pandemic, the OIG identified lessons learned that can be applied to future public health emergencies (PHEs).

In report A-04-20-02027, the OIG determined that without effective controls, CDC may: 1) experience delays in the development of tests kits when responding to future PHEs; 2) not identify problems in a timely manner when developing test kits; and 3) risk damaging public trust, which could undermine its ability to accomplish its mission.



Department of Justice Continues Crackdown on Fraudulent Covid-19 Billing

In the latest case involving alleged Covid-19 fraud, the Department of Justice (DOJ) on June 13 filed a lawsuit against LabQ Clinical Diagnostics, Community Mobile Testing, Dart Medical Laboratory and their chief executive officer, Moshe Landau, alleging they fraudulently billed the federal program that reimbursed healthcare providers for Covid-19 testing provided to uninsured persons.

Prior to seeking reimbursement for Covid-19 testing services from the federa government's Uninsured Program, testing providers were required to attestt to the Health Resources and Services Administration that they had confirmed their patients were uninsured and that no one else would pay for the cost of the Covid-19 testing. The lawsuit alleges that the defendants frequently knowingly submitted claims to the Uninsured Program for Covid-19 testing that had been provided to people with health insurance coverage.

During the pandemic, LabQ provided Covid-19 testing for school districts and nursing homes, as well as to walk-up patients at numerous LabQ-branded vans and tents located on public streets in New York City. LabQ and Dart Medical received approximately $130 million from the Uninsured Program for Covid-19 Testing. In direct contravention of their promises and attestations to HRSA, however, the defendants frequently submitted ineligible and fraudulent claims to the program when the cost of the Covid-19 testing had been (or would be) reimbursed by another source and/or the Covid-19 testing had been provided to persons who had health coverage on the relevant date of the service, according to the lawsuit.

More specifically, the lawsuit alleges, the defendants engaged in the following schemes:

- They double-billed the Uninsured Program and other healthcare programs and private institutions for the same Covid-19 testing;
- LabQ and CMT employees frequently told patients and customers that LabQ did not need insurance information and, in instances when LabQ had patient insurance information, it often submitted claims to the Uninsured Program for those patients;
- They sought reimbursement from the Uninsured Program for Covid-19 tests provided to people with healthcare coverage in instances when they thought the patient's insurer might deny the claim for reimbursement.

As a result of the Defendants' fraudulent conduct, the Uninsured Program paid tens of millions of dollars to LabQ and Dart Medical to which they were not entitled, DOJ alleges. Further, at Landau's direction, LabQ, CMT and Dart Medical disbursed a significant portion of these funds to Landau's personal bank accounts. The lawsuit seeks damages and civil penalties under the False Claims Act as well as a recovery of government funds.

The government intervened, in part, in two whistleblower lawsuits before U.S. District Judge Lewis Liman that had been previously filed under seal pursuant to the False Claims Act.

COMPLIANCE 101:

Providing Medicare Beneficiaries an Advance Beneficiary Notice

All healthcare providers, including clinical and anatomic pathology laboratories, are required to provide a Medicare patient an Advance Beneficiary Notice of Noncoverage (ABN) in situations where Medicare payment is expected to be denied. For example, advance notice is required if the service may be denied as not reasonable and necessary. The ABN is a way for healthcare providers or suppliers to establish beneficiary knowledge of noncoverage and therefore, shift financial liability for these items or services if Medicare denied the claim. ABN Form CMS-R-131 is available here. There is an alternate format ABN for laboratory services here. Further instructions are found here.

The ABN is given to beneficiaries enrolled in the Medicare fee-for-service program. It is not used for items or services provided under the Medicare Advantage program or for prescription drugs provided under the Medicare Prescription Drug Program (Part D).

According to the waiver of liability section of the Medicare Claims Processing Manual, a signed ABN should be obtained from a patient prior to laboratory testing when there is a reason to believe payment of the claim may be denied for any of the following reasons: screening, medical necessity (unpayable or no diagnosis provided), frequency, experimental testing, research-only testing or non-FDA approved procedures. An explanation of the ABN and notification of potential personal financial liability must be given to the patient, and the patient should have the option to refuse the services.

Determining Necessity of ABN

First, determine the patient's diagnosis and write the diagnosis code on the front of the requisition, Second, verify if the lab test ordered for the patient is subject to a Local Coverage Determination or a National Coverage Determination. This is a useful tool for determining whether a test is subject to a coverage policy.

If the diagnosis code for the patient does not meet the medical necessity requirements set forth by Medicare or the test is being performed more frequently than Medicare allows, an ABN should be completed.

Refusal to Sign

If the beneficiary refuses to choose an option and/or refused to sign the ABN, the notifier should annotate the original copy of the ABN indicating the refusal to sign. Also, the notifier should consider not providing the item or service unless the consequences (health and safety of the patient or civil liability in the case of harm) are such that this is not an option. In any case, the notifier should provide a copy of the annotated ABN to the beneficiary and keep the original version of the annotated notice in the patient's file. In general, the notifier should retain the document for five years; electronic retention of the signed paper document is acceptable.

How to Deliver Notice

ABNs may be delivered electronically although the patient has the option of requesting paper issuance over electronic if he or she prefers. Regardless of whether a paper or electronic version is issued, the beneficiary should be given a paper copy of the signed ABN for his or her own records.

The healthcare provider will likely have financial liability of items or services if he or she knew or should have known that Medicare would not pay and fails to issue an ABN when required or issues a defective ABN. In these cases, the notifier is precluded from collecting funds from the beneficiary and is required to make prompt refunds if funds were previously collected. Failure to issue a timely refund to the beneficiary may result in sanctions.

In Brief

Averhealth to Pay $1.34 Million to Resolve FCA Charges Over Drug Tests

Avertest, LLC, a forensic drug testing company that does business nationwide under the name Averhealth, has agreed to pay $1.34 million to settle allegations that it knowingly violated the False Claims Act (FCA) by submitting to the Michigan Department of Health and Human Services (MDHHS) improper claims for payments for drug tests. In 2019, Averhealth, based in Richmond, VA, began performing drug screening and confirmation testing for the State of Michigan's Children's Protective Services and Foster Care programs under a contract with MDHHS. The settlement resolves allegations that from May 15, 2019, through Nov. 30, 2020, Averhealth violated the FCA when it submitted claims for positive drug test results for oral fluid samples that were not confirmed using a mass spectrometric method analytically different from the screening method and did not conform to the terms of the contract between Averhealth and MDHHS.

Owner of Path Lab Indicted Over Fraudulent Covid-19 Testing

A grand jury in Peoria, IL, on June 18 indicted Aaron Rossi of Morton, IL, on six counts of healthcare fraud, one count of mail fraud and four counts of wire fraud over alleged fraudulent Covid-19 testing. Reditus Laboratories LLC, located in Pekin, IL, a full-service pathology laboratory run by Rossi, provided Covid-19 PCR tests that were paid for with both public and private health insurance programs. From October 2020 until at least November 2021, Rossi established policies and procedures at Reditus that directly benefited himself financially and defrauded healthcare providers. Services provided were mischaracterized to receive payment for services not actually rendered. Rossi and Reditus also had a flat-rate contract with the State of Illinois, but Rossi developed a scheme to bill both the healthcare providers and the state, resulting in Reditus receiving double payments for the same Covid-19 PCR tests. Rossi faces maximum statutory penalties of up to 10 years in prison for each of the healthcare fraud charges and up to 20 years in prison for each of the mail fraud and wire fraud charges. Each of the 11 charges could also incur a $250,000 fine.

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

New from Laboratory Economics

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

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

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

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

Condensed Table of Contents

LABORATORY ℓ ECONOMICS

The Laboratory Economics Difference

100+ Pages of Charts, Tables and Graphs!

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

Our Research Methodology

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

About the Author

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

Personalized Client Support

Every purchaser of the ***The U.S. Clinical Laboratory Industry: Forecast & Trends 2023-2025*** report will get unrivaled client support. You'll get post-sale question and answer support by phone or online. Our goal is to develop long-term relationships that meet the ongoing needs of our clients. ***And if you're not 100% satisfied, we'll promptly send you a full refund no questions asked.***

ORDER FORM *(print this form then mail or fax to 845-463-0470)*

❑ **YES!** Please send me ***The U.S. Clinical Laboratory Industry: Forecast & Trends 2023-2025!***

_____ $995 (for subscribers to Laboratory Economics)

_____ $1,195 (non-subscriber price)

Name _____

Title _____

Company _____

Mailing Address _____

_____

Phone _____

e-mail address _____

❑ Please invoice us P.O. # _____

❑ Check enclosed (Payable to *Laboratory Economics*)

❑ Charge my: Amex MC Visa (circle one)

Card # _____

Expiration Date _____ Security Code _____

Cardholder's Name _____

Signature _____

Billing Address _____

_____

_____

Mail to: Laboratory Economics, 195 Kingwood Park, Poughkeepsie, NY 12601 • Fax order to 845-463-0470; or call 845-463-0080 to order via credit card

www.LaboratoryEconomics.com