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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

FDA Final Rule on LDTs Will Stifle Innovation, Have Negative Effect on Patient Care, Say Lab Groups

The Food and Drug Administration (FDA) final rule on laboratory-developed tests, announced April 29, grandfathers in LDTs offered prior to the rule taking effect and allows for enforcement discretion for certain categories of tests. However, groups representing clinical laboratories believe the FDA still has failed to address serious concerns and maintain that the rule will have a negative effect on patient care. The rule is scheduled to be published in the *Federal Register* on May 6, 2024.

The College of American Pathologists says it remains concerned that the FDA is moving forward with its regulatory oversight plan for LDTs without making the additional changes needed to ensure both patient safety and access to accurate and innovative testing.
Continued on page 2.

What Are Labs Required to Disclose Regarding Patient Financial Responsibility?

A recent ruling by a federal appeals court in North Carolina highlights the thorny issue of a clinical laboratory's duty to let a patient know exactly what their financial responsibility might be for a diagnostic laboratory test. *Continued on page 5.*

No Surprises Act Dispute Resolution Presents Challenges, But Narrow Networks Are Real Problem

More than two years after its enactment, the No Surprises Act has become mired in an independent dispute resolution quagmire, say experts with XiFin, a revenue cycle management firm based in San Diego. *Details on page 7.*

HHS OIG Recommends that CMS Improve Its Lab Test Rate Setting in PHEs

The Centers for Medicare and Medicaid Services (CMS) procedures for clinical diagnostic laboratory test (CDLT) rate setting could be improved for future public health emergencies (PHEs), concludes the Health and Human Services Office of Inspector General (HHS OIG) in a new report. *More on page 9.*

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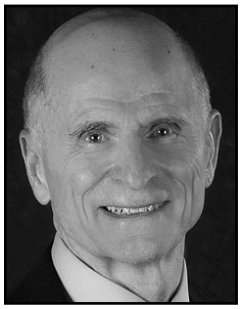
FDA Final Rule on LDTs Will Stifle Innovation, Have Negative Effect on Patient Care, Say Lab Groups (*Cont'd from page 1*)

"LDTs have been crucial for the advancement of medicine and contributed to the evolution of modern scientifically based healthcare services," says CAP President Donald Karcher, MD, FCAP, in a statement. "Today, LDTs continue to have a critical role in scientifically based diagnostics and clinical care for patients. While full FDA oversight of a small number of LDTs posing the highest risk to patients (tests using unconventional methods and/or non-transparent algorithms, with no opportunity to external verification of accuracy) may be warranted, many pathologists and laboratories will be forced to soon decide whether they will continue to offer lower-risk, well-validated and high-quality LDTs given the great cost and regulatory burden of the FDA's new rules."



Donald Karcher, MD

Targeted Enforcement Approach

In the final rule, the FDA is amending the definition of "in vitro diagnostic products" to state that IVDs are devices under the Food, Drug and Cosmetic Act "including when the manufacturer of these products is a laboratory."

In conjunction with this amendment, the FDA is phasing out the general enforcement discretion approach for LDTs and is adopting targeted enforcement approach discretion policies for several categories of IVDs manufactured by a laboratory in certain circumstances. The agency says the final phaseout policy "fulfills the core goal of greater oversight of laboratory-manufactured IVDs while also accounting for other key public health interests, such as helping to maintain access to those beneficial IVDs on which patients currently rely and access to certain IVDs for which there is little financial incentive to development."

Following a four-year phaseout period, the FDA will no longer have a general enforcement discretion approach for LDTs. The phaseout will take place in five stages:

Stage 1	Beginning one year after publication date of the final rule, the FDA will expect compliance with Medical Device Regulation (MDR) requirements, correction and removal requirements and Quality System (QS) requirements under Section 820.198.
Stage 2	Beginning two years after publication date of the final rule, the FDA will expect compliance with requirements not covered during other stages of the phaseout policy, including registration and listing requirements, labeling requirements and investigational use requirements.
Stage 3	Beginning three years after publication date of the final rule, the FDA will expect compliance with QS requirements under section 820, other than requirements under section 820.198 (complaint files), which are already addressed in Stage 1.
Stage 4	Beginning three and a half years after publication date of the final rule, the FDA will expect compliance with premarket review requirements for high-risk IVDs offered as LDTs (IVDs that may be classified into class III or that are subject to licensure under section 351 of the Public Health Service Act), unless a premarket submission has been received by the beginning of this stage, in which case the FDA intends to continue to exercise enforcement discretion for the pendency of its review.
Stage 5	Beginning four years after publication date of the final rule, the FDA will expect compliance with premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs (that require premarket submissions), unless a premarket submission has been received by the beginning of this stage in which case the FDA intends to continue to exercise enforcement discretion for the pendency of its review.

The FDA will continue to use enforcement discretion for "1976-Type LDTs"; Human Leukocyte Antigen (HLA) tests that are designed, manufactured and used within a single laboratory certified under CLIA that meets the requirements to perform high-complexity histocompatibility testing (the testing must be used in connection with organ, stem cell and tissue transplantation to perform HLA allele typing, for HLA antibody screening and monitoring, or for conducting real and virtual HLA crossmatch tests); and tests intended solely for forensic (law enforcement) purposes.

It is strange to have all those details not specified in the rule or in guidance, he says. It leaves it entirely up to FDA discretion, which is concerning because that is subject to change, and it may be challenging for laboratories to predict with certainty exact requirements for LDTs with that degree of ambiguity. Enforcement discretion is a type of grandfathering, in a way, but without the protections to better allow a test to be supported long term. It's not ideal.

Additional Enforcement Discretion

In response to comments on the proposed rule, issued Sept. 29, 2023, the FDA has added additional enforcement discretion policies for the following:

- LDTs manufactured and performed within the Veterans Health Administration or the Department of Defense.
- LDTs approved by the New York State Clinical Laboratory Evaluation Program.
- LDTs manufactured and performed by a lab integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system.
- LDTs that were first marketed prior to the issuance of this rule and that are not modified, or that are modified in certain limited ways.
- LDTs for non-molecular antisera LDTs for rare red-blood cell (RBC) antigens where such tests are manufactured and performed in blood establishments, including transfusion services and immunohematology laboratories and where there is no alternative available to meet the patient's need for a compatible blood transfusion.

Jonathan Genzen, MD, PhD, Chief Medical Officer for ARUP Laboratories (Salt Lake City), notes that while the FDA says in its explanation of the rule that it will use enforcement discretion for certain tests, those exceptions are not part of the rule itself, which is actually very short.

Jonathan Genzen, MD, PhD

"It is strange to have all those details not specified in the rule or in guidance," he says. "It leaves it entirely up to FDA discretion, which is concerning because that is subject to change, and it may be challenging for laboratories to predict with certainty exact requirements for LDTs with that degree of ambiguity. Enforcement discretion is a type of grandfathering, in a way, but without the protections to better allow a test to be supported long term. It's not ideal."

Genzen adds that in the short term, many clinical laboratories' LDTs may not be immediately impacted, but says he is very worried about the future impact on these types of tests. The FDA's strictness of requirements regarding test modifications may mean that routine modification for things like platform changes or reagent shortages would actually force many LDTs in clinical lab

settings to be subject to FDA oversight in greater frequency than what the FDA is conveying. He says that he is also worried about the longer-term impact of submission fees on development of new tests. Premarket authorization fees can be as high as $483,000 per submission.

Genzen believes that the rule will stifle innovation and is likely to lead to market consolidation, which will drive testing away from the patient.

"Let's say a facility develops an LDT that meets an unmet need and is used mostly for their own patients, but they also have an outreach program that supports clinically beneficial testing for the community and associated clinics and outside hospitals," he explains. "Those hospitals are not owned by the same corporate entity, that lab could not perform the LDT on those patients and would have to send the specimens out to a reference laboratory. This also decreases the lab's test volume, which decreases their financial resources to support ongoing testing and test development."

"I think it's likely that we'll see many labs decide that it is just not financially viable to support LDTs, and testing will consolidate more to reference labs or regional hubs," Genzen continues. "Given decreased competition, consolidation is often accompanied by an increase in the price of tests across the market, which is exactly what we want to avoid in the U.S."

Chilling Effect on New LDTs

Jeffrey Gibbs, an attorney and director with Hyman, Phelps & McNamara and a contributor to the FDA Law Blog, agrees that the final rule will have a chilling effect on development of LDTs.

"The rule will have a profound effect on the availability of LDTs," Gibbs tells LECPR. "The new enforcement discretion provisions will have only a small overall impact. Grandfathering will mean tests need to stay largely static if a lab wants to avoid a submission, even as technology and clinical knowledge evolves."

Jeffrey Gibbs

Gibbs adds that the FDA continues to overstate the risks and give little weight to the benefits of LDTs. The agency begrudgingly acknowledges that some LDTs offer some benefits but that does not factor meaningfully into its analysis. What's more, the requirement for labs to assess whether modifications of FDA-cleared tests trigger the need for a new submission introduced yet another layer of complexity, he believes.

"The rule is going to result in a great deal of ambiguity and uncertainty," says Gibbs. "The FDA and industry will need to spend significant resources getting clarity. The rule will materially and adversely affect the healthcare system in ways the FDA never considered."

Agency Shares Thinking About LDTs in Public Health Emergencies

The FDA also issued two draft guidances April 29. One provides the agency's thinking about an enforcement discretion policy for certain laboratories offering certain unauthorized IVDs for immediate response to an emergent situation, such as an outbreak of an infectious disease, in the absence of a declaration applicable to IVDs under section 564 of the Food, Drug and Cosmetic Act (FD&C Act). The other provides insights into the FDA's thinking about the factors the agency intends to consider when developing a policy regarding enforcement discretion for certain IVDs during a public health emergency declared under section 564 of the FD&C Act.

Genzen notes the guidance appears to be restricted to a subset of government laboratories, state or local labs, or labs that have some type of agreements with the government, so it may actually be too restrictive to be fully useful in an emergent public health crisis.

What Are Labs Required to Disclose Regarding Patient Financial Responsibility?

(*Cont'd from page 1*)

When a commercial insurance company denies coverage for a test performed by a clinical laboratory, the lab may be permitted to bill the patient for the service, notes Robert Mazer, senior counsel with Baker Donelson (Baltimore). The amount charged is frequently more than the insurer would have paid for a covered test and more than the patient's related cost-sharing responsibility for such a test.

Robert Mazer

"Laboratory billing personnel are generally familiar with principles that determine amounts that a commercial insurer will pay for a test and related patient financial responsibility," says Mazer. "Many patients are not. Patients who receive a bill from a laboratory for an uninsured test for an amount that is in excess of the anticipated out-of-pocket cost for the test provided by the lab may believe that they have been subject to an unfair, deceptive or fraudulent practice in violation of state consumer protection laws."

Patients Sue Labcorp

In *Nolan v. Lab. Corp. of Am.* (No. 23-01282, 2024 WL 1554760, 4th Circuit, April 10, 2024), two patients sued Labcorp in a North Carolina federal court claiming that the lab's patient acknowledgement form omitted material information and was otherwise false and misleading in violation of the Nevada and Florida consumer protection laws [Labcorp is headquartered in Burlington, NC].

In 2018, Nathaniel Nolan visited one of Labcorp's Nevada locations and Helena Wittenberg visited a Florida location to have tests performed that were ordered by their healthcare providers. Prior to the testing, Nolan and Wittenberg presented their insurance information to Labcorp, and Labcorp provided them with estimates of their financial responsibility via the patient acknowledgement form.

At the time Labcorp conducts testing, it has not yet determined whether a patient's health insurance will cover the requested testing. But the patient acknowledgement assumes that all services will be covered by the patients' respective insurers. If the service is covered by insurance, Labcorp bills the patient's insurance the negotiated health plan allowed rate. If the service is not covered by insurance, Labcorp bills the patient directly at the patient list price.

Although the patient acknowledgement informs the patient of the estimated health plan allowed rate, it does not inform the patient of the list price that will be applicable if the testing is not covered by insurance. The appellants in this case alleged that the list price for a lab test was substantially higher than the health plan allowed rate and "grossly exceed[s]" Labcorp's cost for providing the test. They also alleged that Labcorp knows this list price prior to conducting any lab testing and yet fails to provide it to insured patients even though the patients could receive a bill that is nearly 15 times higher than the negotiated rate.

The patient acknowledgement states in bold caps that it is only an estimate of charges and, in smaller font, that it "assumes all services will be covered" by the patient's insurance. The acknowledgement lists each of the tests prescribed, the health plan allowed rate for each of those tests, the estimated amount paid by health plan and the patient's out-of-pocket expenses after taking into consideration the deductible, coinsurance and copay amounts in the patient's plan. The second page of the patient acknowledgement contains additional language that states, in part, "Your health plan may not pay for these services, and you will be personally responsible for payment of these services." Nowhere does the patient acknowledgement indicate the list price that patients will

be charged should the patient's insurer deny coverage.

The appellants' health plans ultimately denied coverage for some or all of the lab tests provided by Labcorp. Nolan received an invoice for $316.98, which included a $292 charge for the Vitamin D test, nearly 16 times higher than the $18.93 listed on his patient acknowledgement. Wittenberg's insurer also denied coverage for her testing. In 2018, Wittenberg visited Labcorp on two different occasions before learning that it was outside of her insurance network. Originally, she received the health plan allowed rate of $44.60 for her first visit and $65.27 for her second. But after her insurer denied coverage for the tests, Wittenberg received two list price invoices for $335 and $650 respectively.

Labs should review the documentation that it provides to individuals seeking lab tests to make sure that it adequately informs them regarding the amounts that they may be required to pay and that the disclosures otherwise satisfy state law requirements.

On Dec. 29, 2021, the appellants filed their complaint, asserting that Labcorp violated Nevada and Florida laws on deceptive trade practices. The district court dismissed the case, concluding that the patient acknowledgement did not contain any false or misleading statements. The patients appealed that decision to the United States Court of Appeals for the Fourth Circuit, which concluded that the patients' complaint included one legally valid claim.

List Price is a Material Fact

The appellate court rejected the Nevada patient's argument that the patient acknowledgement included false and misleading statement of fact concerning the price of the laboratory services in violation of the Nevada statute. However, the court determined that in not providing the patient with the list price for the test, the lab violated Nevada law by failing to disclose a material fact. The court also ruled that the lab had not violated Florida law as it did not include any false or misleading statements.

The appellate court decision did not resolve the patients' lawsuit. The court remanded the case to the district court to determine if the facts proven at trial demonstrated that the laboratory did not provide the patient with the test's list price and therefore willingly failed to disclose a material fact in violation of Nevada law.

Mazer notes that while the court reached different results under Nevada and Florida law in this case and laws in other states or related interpretations may be different than those in effect in either of those states, the appellate court's decision may nevertheless lead to increased attention generally to the application of state consumer protection laws to clinical laboratories' disclosure and billing practices.

"As a result, labs should review the documentation that it provides to individuals seeking lab tests to make sure that it adequately informs them regarding the amounts that they may be required to pay and that the disclosures otherwise satisfy state law requirements," says Mazer. "Given the lack of established principles in this area, labs should monitor related legal developments closely."

No Surprises Act Dispute Resolution Presents Challenges, But Narrow Networks Are Real Problem (*cont'd from page 1*)

The No Surprises Act (NSA), passed in January 2022, is designed to protect patients from unexpected out-of-network medical expenses incurred during emergency room visits; non-emergency care received at, or provided in conjunction with, a visit to an in-network hospital, hospital outpatient department or ambulatory surgical center; or air ambulance services.

Diana Richard

While the NSA has created some benefits for patients, it also has placed a heavy burden on providers, says Diana Richard, AVP, national accounts, pathology/radiology/health systems, XiFin.

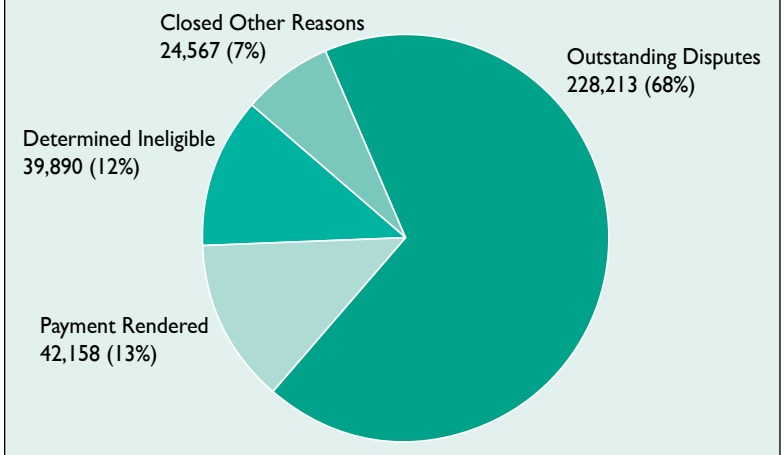
"I think in some circumstances the law is having the intended effect," she says. "But going through the independent resolution process to establish out-of-network payments is an issue for providers because the process is complex. Complicating the issue is that clinical laboratories and pathology practices don't have the benefit of confirming a patient's insurance status prior to receiving the specimen. Discovery of the fiscal impact of an out-of-network patient, at the earliest, would be discovered at the time the specimen is recorded in the LIS, but only if that LIS documents in-network versus out-of-network status. Most do not, and therefore the specimen is processed, and the issue is discovered at time of billing, after the cost to perform the test has been absorbed."

Leigh Polk

According to Leigh Polk, senior account-based marketing manager for XiFin, most of the controversy surrounding the law has been related to the independent dispute-resolution (IDR) process, which allows disputing parties to resolve disagreements regarding out-of-network payments or denials. A number of lawsuits have been filed challenging the IDR process. In addition, the Centers for Medicare and Medicaid Services (CMS) has received substantially more disputes than anticipated, leading to confusion and delays.

More than 300,000 surprise billing disputes were initiated through the federal IDR process from April 2022 through March 2023, which far exceeds the agency's original estimated caseload, according to Polk.

Out-of-Network Surprise Billing Disputes Initiated Through the Federal IDR Process



Source: XiFin from CMS Federal IDR Process Update

CMS indicates that a frequent cause of dispute processing delays is the difficulty in determining if the dispute is eligible for the IDR process. As a result, in October 2023, CMS released proposed changes to the IDR process to improve operations and timely payment determinations.

Key changes to the process include:

- Standardizing code usage for federal IDR eligibility.
- Utilizing IDR portal for open negotiation notices.

- Timeline for open negotiation response notice.
- Specifics of batched qualified IDR items and services.
- Limitation on batched determinations.
- Timely eligibility determinations by certified IDR entities.
- Direct fee collection for streamlined process.

In addition to the proposed changes, CMS also released the 2024 IDR fees, which are increasing as a result of the significant backlog of cases. The administrative fee increase was mitigated by the Texas Medical Association lawsuit victory in 2023, challenging how the IDR process is administered and how fees are assigned. As a result, it was determined that a fee of $115 per party per dispute was appropriate. This decision was reached after recognizing that a fee of $50 was insufficient to cover the operational expenses of the IDR process and portal, while a fee of $350 posed financial challenges for providers.

IDR Fees

IDR Fees Effective Dates	*2022 January 1*	*2023 January 1*	*2023 August 3*	*2024 January*
Administrative	$50	$350	$50	$115
Single Determination	$200 to $500	$200 to $700	$200 to $700	$200 to $840
Batch Determination	$268 to $670	$268 to $938	$268 to $939	$268 to $1173

Source: XiFin

Narrow Networks at the Heart of the Problem

Both Polk and Richard believe that the IDR process needs revision but an underlying issue is that payers are keeping providers out of their networks, thus forcing the problem of out-of-network payment versus in-network payment.

"CMS's proposal might help fix the IDR process, but it's not helping fix the root cause of the issue, which is narrow networks," says Polk.

"Historically, laboratories may have had strategic or logistical reasons for staying out of network with specific payors. With the complications of the IDR process, we would hope payers would offer an opportunity to ease these burdens for providers and patients but that has not been the case," says Richard. "The marketplace is so saturated, particularly with the larger labs, that even if provided the opportunity to go in-network, payers are offering very low reimbursement rates, to the point it may not be financially viable for the pathologist or the laboratory to participate. This is giving the payer all of the control over the out-of-network adjudication process while also controlling a provider's ability to get in-network at a financially economical level. That scenario typically does not end well for patients who may find increasing numbers of providers unwilling to take their insurance. Neither the patient nor the provider wins in either of those scenarios."

Both Polk and Richard suggest that labs and pathologists work with their billing companies to determine which payers they are in-network and out-of-network with so they can analyze the impact these factors are having on their revenue.

"We try to give our clients the data they need to make an informed decision and develop a strategy," notes Richard. "We categorize payers into contracted and non-contracted payor groups for ease of reporting and management. In addition, we also track trends against the expected reimbursement by test by payer. This allows us to work with customers to not only track payers impacting the largest amount of revenue, but we can also monitor patient out-of-pocket levels along with denial and adjudication patterns that may initiate macro-level discussions at a local or industry-wide level."

HHS OIG Recommends that CMS Improve Its Lab Test Rate Setting in PHEs

(*cont'd from page 1*)

Specifically, CMS could improve its communication with laboratory associations and the Medicare Administrative Contractors (MACs) pricing coordinators and its procedures to provide the MACs with additional flexibility when they set interim CDLT rates to respond to a PHE.

Neither the Clinical Laboratory Fee Schedule (CLFS) statute nor its implementing regulations specifically address how pricing coordinators could quickly set rates for new CDLTs before the lengthy public consultation rate setting process, notes the OIG. Normally, CMS fills that delay by using its longstanding MAC interim rate setting policy. Accordingly, in March 2020, MACs set rates for new Covid-19 viral tests through CMS's interim MAC rate setting policy. However, CMS had to take additional action beyond its standard rate setting procedures to set and adjust rates for CDLTs.

"As a result, CMS's standard rate setting procedures did not allow the MACs to set rates that were adequate to cover the cost of conducting Covid-19 viral tests for all laboratories at a time when CMS was working to increase testing capacity," write the OIG in its report. "CMS may have missed opportunities to obtain important information that could have improved its response to the Covid-19 pandemic from laboratory association and the MACs pricing coordinators when it made decisions about the new CDLT rates."

OIG Recommendations and CMS Comments

The OIG recommends that CMS: 1) establish procedures to improve communication among stakeholders involved in setting new CDLT rates during a PHE, and 2) improve its procedures, which may require seeking legislative authority, for setting and adjusting rates for new CDLTs during a PHE.

In written comments on the draft report, CMS did not explicitly state its concurrence or nonconcurrence with the OIG's recommendations but stated that it would take the findings and recommendations into consideration for future PHEs. CMS said that it engaged with stakeholders to identify and address barriers and needs to ensure the availability and timeliness or testing throughout the Covid-19 PHE.

In addition, CMS maintains that by following typical and established procedures, MACs had the ability to set payment amounts for new test codes in their respective jurisdictions until Medicare established the CLFS payment rates.

1 Interim payment rates set by MACs	Interim payment rates are set by MACs for new CDLTs prior to the public consultation payment rate setting process, using the crosswalking or gapfilling basis.
2 Public consultation payment rate setting process	After receiving public comments, CDLT payment rates are set using the crosswalking or gapfilling basis. These payment rates are set until applicable information is available to establish a payment amount using the weighted median of private payer rates.
3 Weighted median of private payer rates	Once applicable information is available, payment rates for CDLTs are calculated using the weighted median of private payer rates. These payment rates are updated every three years by CMS using information reported by entities from their component labs.*

*Component labs are those that may have their own National Provider Identifier number but belong to a larger lab that has a single Tax Identification Number.

Source: HHS OIG

UnitedHealthcare Delays Z Codes Once Again

United Healthcare (UHC) is once again delaying implementation of its new molecular pathology policy requiring use of DEX Z-Codes until June 1, 2024. UHC says the delay is to allow providers additional time to integrate the Z-Codes into their claims processes.

This marks the third time that UHC has delayed the effective date of its Z-Code requirement for commercial claims. Initially, the requirement was scheduled to start Aug. 1, 2023. It was then delayed to Oct. 1, 2023, and delayed again to April 1, 2024.

The latest delay was announced in a UHC bulletin issued April 1. Effective June 1, UHC will deny payment for 133 CPT codes and 104 proprietary lab analysis codes unless the test has received a Z-Code and successfully passed a technical assessment from Palmetto's GBA's MolDx program. High volume codes that will be affected by the requirement include CPT 81479 (unlisted molecular pathology procedure), CPT 81279 (JAK2 gene targeted sequence analysis) and CPT 81455 (targeted genomic sequence analysis panel).

Laboratories not currently registered with the DEX Diagnostic Exchange Registry that plan to submit molecular diagnostic claims are urged to sign up by visiting the DEX Registry. Z-Codes will be phased in, with Phase I to include all molecular diagnostic tests relevant to the Medicare age population (65+); prenatal carrier screening tests and specific services billed under 81479 (genetic disease carrier status for procreative management and pharmacogenomics testing, including single gene and multi-gene panel).

Two Doctors Sentenced in Urine Drug Testing Scheme

The owner and medical director of a Kentucky pain clinic were sentenced April 12 for their respective roles in a scheme that defrauded Medicare, Medicaid and commercial insurance companies of more than $4 million for medically unnecessary urine drug testing.

William Lawrence Siefert, 70, of Dayton, Ohio, medical director of the Northern Kentucky Center for Pain Relief, was sentenced to one year and six months in prison and ordered to pay $1,968,763.10 in restitution. Timothy Ehn, 51, of Union, Ky., the clinic owner and a licensed chiropractor, was sentenced to two years and six months in prison and ordered to pay $3,773,569.30 in restitution.

Medically Unnecessary Tests

According to evidence presented at trial, Ehn and Siefert orchestrated a scheme in which clinic staff billed for urine drug tests that were not medically necessary but were reimbursed by taxpayer-funded insurance providers like Medicare and Medicaid. Ehn and Siefert continued their scheme even as their expensive drug-testing machine malfunctioned because it was not properly maintained, which caused it to produce results that falsely suggested patients were testing positive for street drugs like ecstasy or heroin. Insurance proceeds from urine drug testing ended up comprising three-quarters of the clinic's revenue.

"The defendants enriched themselves through a fraudulent urine drug testing scheme that cost Medicare, Medicaid and commercial insurance companies over $4 million," said Principal Deputy Assistant Attorney General Nicole M. Argentieri, head of the Justice Department's Criminal Division. "The Criminal Division is committed to protecting American taxpayers from doctors who abuse their positions to steal public money by billing for unnecessary medical procedures."

The Department of Justice (DOJ) worked with the Drug Enforcement Administration and the FBI on this case. DOJ's Fraud Section leads the Criminal Division's efforts to combat healthcare fraud through the Healthcare Fraud Strike Force Program. Since March 2007, the program has charged more than 5,400 defendants who collectively have billed federal healthcare programs and private insurers more than $27 billion. The program consists of nine strike forces operating in 27 federal districts.

COMPLIANCE 101:

Test Pricing, Direct Billing

Laboratories are paid for their services by a variety of payers in addition to Medicare and other federally funded healthcare programs. Such payers often include health insurers, other healthcare providers and physicians. The prices that laboratories charge, particularly to physicians and especially for panels and profiles, raise compliance issues that should be addressed in a laboratory's written compliance policies, according to the Health and Human Services Office of Inspector General's (HHS OIG) Model Compliance Plan for Clinical Laboratories.

Such compliance policies should ensure that as tests are included in or added to profiles, the price for the enhanced profile increases and the overall price for the profile is never below cost. Laboratories that do not increase the price to a doctor for an enhanced profile or that charge below costs for an enhanced profile and then bill Medicare or another federally funded healthcare program the full third-party price for the profile components will be risking false claims and kickback enforcement actions.

According to CodeMap, a consulting company based in Chicago, a laboratory may offer discounts to customers ordering higher volumes of tests, but the resulting price after all discounts may never be below fair market value and may not be dependent on the volume or value of Medicare or Medicaid tests referred to the laboratory by the physician client. No tests may be provided to customers or potential customers free of charge or below market value either as a professional courtesy or in order to secure additional business.

Direct Billing

Direct billing is required for Medicare-reimbursed laboratory tests. Tests must be billed directly to Medicare by the laboratory or the physician performing the test. If an outside laboratory performs a tests on a referral from a physician, only the reference laboratory may legally bill Medicare for the procedure. According to CodeMap, hospitals and reference labs, which send specimens to other laboratories, may bill for tests performed by other laboratories if the referring laboratory meets any one of the following exceptions:

- The referring lab is located in or is part of a rural hospital;
- The referring lab is wholly-owned by the reference lab;
- The referring lab wholly owns the reference lab;
- Both the referring lab and the reference lab are wholly-owned by a third entity; or
- No more than 30% of the tests for which the referring laboratory receives requests annually are performed by another laboratory.

Hospital laboratories also must comply with the requirement that all tests performed for Medicare outpatients must be billed by the hospital and no other lab.

CodeMap's Compliance Policy Manual for Clinical Laboratories, 2023 Edition, is available for purchase at www.codemap.com.

In Brief

Laboratory Owners Charged in $36 Million Covid-19 Testing Fraud Scheme

An indictment was unsealed April 24 in the Southern District of Florida charging three men for their alleged roles in a $36 million healthcare fraud, wire fraud and money laundering scheme that involved submitting false and fraudulent claims for Covid-19 testing to healthcare benefit programs, including Medicare and the Health Resources and Services Administration (HRSA) Covid-19 Uninsured Program. Enrique Perez-Paris, 47, of Aventura, Fla., and Diego Sanudo Sanchez Chocron, 47, of Venice, Calif., and Gregory Charles "Milo" Caskey, 57, of San Antonio, Texas, co-owners of Innovative Genomics, conspired to submit claims for medically unnecessary and non-reimbursable Covid-19 testing between November 2019 and June 2023. They also allegedly paid illegal kickbacks and bribes to patient recruiters who arranged for healthcare providers to refer the tests to Innovative Genomics. If convicted, they each face a maximum penalty of 20 years in prison on each of the conspiracy counts and a maximum penalty of 10 years on each healthcare fraud count.

Owner of Genex Lab Indicted on Failure to Pay Almost $5.8 Million in Taxes

A federal jury on April 23 indicted a Los Angeles man who allegedly evaded the payment of nearly $5.8 million in federal taxes over several years by using a shill to illegally collect Medicare reimbursement payments made to his blood-testing company. Armen Muradyan, 58, is charged with one count of tax evasion. Muradyan owned and operated a Burbank-based blood testing laboratory called Genex Laboratories Inc. Medicare and bank records show that Medicare paid millions of dollars in reimbursements to Genex for blood testing. The reimbursements were wired to bank accounts in the name of an individual identified in court documents as "L.S." – Muradyan's long-time friend to whom Muradyan had offered to pay $2,000 per month to pretend to be Genex's owner. Between 2015 and 2020, Muradyan's unreported income was approximately $16.2 million, resulting in unpaid taxes of $5.8 million.