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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

FDA To Move Forward on LDT Rulemaking

The Food and Drug Administration (FDA) will move forward with rulemaking on lab-developed tests (LDTs) now that Congress has failed to pass the VALID Act, a senior agency official announced recently at the annual meeting of the American Clinical Laboratory Association (ACLA), held in Washington, D.C., on March 1.

Elizabeth Hillenbrenner, associate director for scientific and regulatory programs at the FDA's Center for Devices and Radiological Health, said that the FDA would not wait on a legislative solution to oversight of LDTs. The FDA has long been seeking explicit authority to regulate LDTs while at the same time maintaining that it already has enforcement discretion to regulate these tests. Efforts to pass elements of the VALID (Verifying Accurate Leading-Edge IVCT Development) Act have failed to be approved by Congress several times in recent years. *Continued on page 2.*

OIG Targets Drug Testing Overpayments for G0483

A new report from the Office of Inspector General says that CMS could have saved up to $216 million over five years if it had better safeguards for monitoring payments to "at-risk providers" for the definitive drug testing procedure code G0483. The OIG report focused on G0483 (definitive drug testing, 22 or more drug classes) because it has the highest Medicare reimbursement rate (currently $247). There were a total of 1,062 at-risk providers, which routinely billed for G0483 (for 75% or more of their definitive drug testing services) during the audit period, according to the OIG. *Full details on page 10.*

EKRA Rulings Cause Confusion, Clarification Needed

Conflicting court rulings under the Eliminating Kickbacks in Recovery Act (EKRA) highlight the confusion that still surrounds this statute, says Charles Dunham IV, a corporate healthcare attorney with Greenberg Traurig, LLP (Houston), who believes the U.S. Department of Justice (DOJ) should issue clarification on the law. Despite requests by industry stakeholders for clarification, the DOJ still has not issued any regulations or guidance on EKRA, leaving clinical laboratories struggling to determine what is allowed under the law and the interplay with other healthcare fraud and abuse laws. *Continued on page 3.*

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FDA To Move Forward on LDT Rulemaking (*cont'd from page 1*)

"We paused our administrative efforts for many years while we worked with stakeholders and Congress to support efforts to pass the VALID Act," said Hillenbrenner. "At this point, we feel like we can't just stand by. All options are on the table, including rulemaking, and we are moving forward."

Hillenbrenner added that the FDA would prefer a legislative solution and is open to the possibility that VALID might be attached to the reauthorization of the Pandemic All Hazards Preparedness Act (PAHPA), which must be reauthorized by Sept. 30, 2023. Hillenbrenner said she believes VALID would provide a common framework for laboratory test developers, which would put the industry in a better position for the next outbreak.

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Besides creating a risk-based framework for in-vitro clinical tests (IVCTs), VALID also would implement a new technology certification pathway that would allow for the development of tests within the same scope of an FDA-approved test without going back through FDA review each time.

"If we had something like that in place, if we had developers who were certified to make PCR tests, for example, and we found ourself in a situation in the future where we needed to consider a notification policy, such as we had with Covid or monkeypox, we could leverage the technology certification assurances and know that if a test goes to market without FDA reviewing it first, such as in an outbreak, we have assurances that the developer knows what they are doing," she said.

VALID Likely to Be Reintroduced

The VALID Act is likely to be re-introduced in the current Congress, says ACLA President Susan Van Meter, who notes that if it is, ACLA intends to continue to work constructively with lawmakers and the FDA to find a legislative solution to oversight of LDTs that is acceptable both to the agency and to the lab community.

Susan Van Meter

"It is our view that there needs to be a legislative approach that would establish a diagnostic-specific and risk-based framework that recognizes the essential role of all clinical laboratories for there to be any role for the FDA in regulating tests developed by laboratories," she tells *LECPR*. "We are really in need of a modern, diagnostic-specific, regulatory framework for all diagnostic test developers. It would provide laboratories with predictability in regulation and bring LDTs out from under the medical device framework. The reason that legislation is really needed is that diagnostics are not medical devices. Under current law, ACLA does not view the FDA as having the authority to regulate LDTs."

Van Meter noted that in 2022 ACLA worked constructively with the congressional committees with jurisdiction over VALID, and she believes a number of improvements were made to the legislation. That said, ACLA does not support the VALID Act in its current form.

"There are still changes that need to be made," she said. "We'd like to see additional improvements, such as to the transition period and to technology certification to ensure that it allows for the latest innovation to benefit from that pathway."

EKRA RULINGS (*cont'd from page 1*)

"To date, even with requests from the lab industry and associations highlighting conflicts and concerns, nothing has been provided in terms of guidance," said Dunham during a March 22 webinar hosted by Lighthouse Lab Services (Charlotte, NC). "In December 2019, the Department of Justice responded to industry stakeholders seeking clarification that 'the statute is the statute' and has since started to enforce it."

Charles Dunham IV

EKRA, which became law in October 2018, prohibits knowingly and willfully soliciting, receiving, paying or offering any remuneration (including any kick-back, bribe or rebate) directly or indirectly, to induce a referral of an individual to a recovery home, treatment facility or laboratory, in exchange for an individual using the services of that home, facility or lab. The law applies to items and services covered under federal health programs and commercial insurance. A violation of EKRA may result in a fine of up to $200,000, imprisonment for up to 10 years, or both, for each violation.

A common issue related to the interpretation of EKRA is how it applies to employee compensation in contrast to the Anti-Kickback Statute (AKS), which has both a statutory exception for payments made to employees and a separate regulatory safe harbor governing employee agreements.

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

Conflict Between Two Rulings

On May 28, 2022, in *USA v. Schena*, the Northern District of California held that EKRA prohibits a laboratory from paying commissions to its sales personnel to secure referrals of patients indirectly from physicians. This ruling directly contradicts an earlier decision by the District of Hawaii in *S&G Labs Hawaii, LLC v. Graves*, which held that payments to a sales employee in compensation for marketing efforts directed at physicians and other lab clients did not violate EKRA.

In *Schena*, the court ruled that the interpretation in *S&G* was incorrect. The differences in the two cases are important to note, said Dunham. In *S&G*, which was a civil case, the court said that since there was no definition of "remuneration" or "individual," under the EKRA statute, the terms under EKRA should have the same meaning as under the federal AKS. The court noted that the person in question, Darren Graves, was not in a position to refer individual patients since client accounts that Graves interacted with are physicians, not individuals, and the remuneration was not paid in exchange for Graves' individual use of *S&G* lab services. Ultimately, the court ruled that Graves did not have direct contact with individual patients, and EKRA was not implicated.

The DOJ itself appears conflicted on what exactly it means "to induce" and who is actually in a position to make a referral.

In *Schena*, which was a criminal case, the court disagreed with the application of the AKS in *S&G* as "misplaced" and concluded that the "plain meaning of 'to induce a referral of an individual' includes situations where a marketer causes an individual to obtain a referral from a physician." Then, the court concluded, without explanation, that such inducement under EKRA

included marketers promoting test services to physicians rather than patients directly, therefore implicating EKRA.

The DOJ itself appears conflicted on what exactly it means "to induce" and who is actually in a position to make a referral, said Dunham. The DOJ argued in *Schena* that the term "to induce" under the AKS and EKRA would include mere promotion of test services to physicians who can make patient referrals to the laboratory ["physicians referred the patients, and they were caused to do so by the kickbacks received by the marketers"].

"The DOJ is taking the position that EKRA applies even though the payment went to the marketer, and even though the language in EKRA states the remuneration is to induce a person to make a referral (most marketers can't make referrals) or to induce an individual to receive a service (again, the marketer is not receiving the service)," said Dunham.

So, the DOJ is taking the position that laboratories can be held liable under EKRA even though all the AKS case law cited by the DOJ hinges on the "relevant decisionmaker standard"—in other words, who has the authority to make decisions regarding referrals. Under this AKS standard, to demonstrate the marketer is in a position "to refer" a patient [42 U.S.C. 1320a–7b(b)(2)(A)], the DOJ should have to demonstrate that a marketer is in the position of a relevant decisionmaker and is able to direct or control where those referrals are going, he added. Note that this is distinct from the "arrange for or recommend" prohibition under the AKS [42 U.S.C. 1320a–7b(b)(2)(B)] that marketers are typically charged under the AKS (and such language does not appear under EKRA).

EKRA Exceptions

The law provides that the following types of offers and payments are excepted from the prohibitions in Section 220(a):

1. **Disclosed Price Discounts:** A discount or other reduction in price obtained by a provider if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider.
2. **Bona Fide Employee Compensation:** A payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by volume of referrals, tests, procedures or billing.
3. **Medicare Part D Discounts:** A discount in the price of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under the Medicare coverage gap discount program.
4. **Personal Services:** A payment made by a principal to an agent as compensation for the services of an agent under a personal services and management contract that meet federal requirements (i.e., the Anti-Kickback personal services safe harbor).
5. **Copay Waivers:** A waiver or discount of any coinsurance or copayment by a healthcare benefit program if provided in good faith and not as a matter of routine.
6. **Federally Qualified Health Centers:** A remuneration described in section 1128B(b)(3)(I) of the Social Security Act.
7. **Alternative Payment Models:** A remuneration made pursuant to an alternative payment model or pursuant to a payment arrangement used by a state, health insurance issuer or group health plan is approved by the Secretary of Health and Human Services.

The two different rulings in *Schena* and *S&G* reflect a split in the 9th Circuit, which ultimately needs to be resolved by the 9th Circuit Court of Appeals, said Dunham. "These are concepts that can be argued on appeal to the 9th Circuit," he noted. "For now, it remains unclear how federal agencies will interpret these provisions and apply the two federal offenses when there is overlap."

Pre-Emption Provision Clear as Mud

The appeals court could also clarify EKRA's pre-emption provision, which was not addressed by the courts in either *Schena* or *S&G*, said Dunham. EKRA contains two pre-emption clauses. One says that EKRA does not apply to conduct prohibited under the AKS. The other states that EKRA does not pre-empt state law.

The two different rulings in Schena and S&G reflect a split in the 9th Circuit, which ultimately needs to be resolved by the 9th Circuit Court of Appeals.

The first pre-emption provision itself has created significant confusion, with many attorneys wondering why Congress used the term "prohibited" instead of "not prohibited" or "permitted" or "expressly authorized," explained Dunham. In fact, EKRA was likely modeled after the Florida Patient Brokering Act, which itself was recently amended a couple of times, first changing "not prohibited by" to "expressly authorized by" and later amended to change the "expressly authorized" language back to its original iteration of "not prohibited by."

"If there was this much confusion about the state law which we believe EKRA was structured after, then there is still confusion on the federal level about the pre-emption provision, and this is something the Department of Justice needs to address," he said.

Compensation of Sales Personnel

Clinical laboratories must look at both the AKS and EKRA in determining whether employees fit under an AKS safe harbor or EKRA employment exception, advised Dunham. EKRA essentially says that a lab can pay their sales personnel for engaging in any activity, it just can't be based on the number of individuals referred, the number of tests performed or the amount billed.

Therefore, to ensure compliance with EKRA, labs should establish "activities-based compensation," with clear tasks and criteria that is not prohibited under EKRA, and a payment formula that is not tied to revenue generated, said Dunham. He suggests using key performance indicators, such as number of potential account visits or calls, new account setup and onboarding, quality of account management services (surveys) and number of active and sustained client accounts, which may be considered compliant under the EKRA exception.

"If you establish a base salary, specify what base activities are included in that, and if you are going to pay a bonus, you need to determine what that is based on, as long as it not number of tests, number of individuals or revenue," he said, acknowledging that this can be challenging. "But with activities-based compensation, you can be creative in the sense that you can really identify the services and goals you want your sales personnel to meet."

At the end of the day, under the EKRA employment exception, Dunham believes it is reasonable and achievable for clinical laboratories to establish base targets or metrics to generate business, assess overall performance (and continued employment or promotion) by referencing such targets, and provide conditional bonus compensation to cover budget or costs.

What Goes Into Determining Coverage for Lab Tests?

Lon Castle, MD

While a number of factors go into determining coverage of clinical laboratory testing, clinical utility is perhaps the most important, say two lab benefit managers, speaking March 1 at the annual meeting of the American Clinical Laboratory Association (ACLA).

Lon Castle, MD, associate chief medical officer, precision medicine for eviCore healthcare, and Geoffrey Crawford, MD, MS, staff vice president of medical policy, Elevance Health, shared insight into what they consider when making coverage determinations.

Geoffrey Crawford, MD, MS

For a lab test to be covered, it must have three things: clinical utility, analytical validity and clinical validity, say both Castle and Crawford. Tests that do not demonstrate those three things are considered "experimental/investigational/unproven" and would not be covered.

"The most important consideration is clinical utility," said Crawford, who noted that tests approved by the Food and Drug Administration (FDA) are generally assumed to do what they are supposed to do, that is measure the analyte it is intended to detect or measure. "Clinical utility has to do with the net health benefit—evidence that the test ultimately does improve the health of the patient."

FDA Approval Not Enough

Approval by the FDA is not sufficient in and of itself for a positive coverage determination, said Castle, noting that the FDA only evaluates analytic and clinical validity, but not clinical utility, except in the case of companion diagnostics. The Centers for Medicare and Medicaid Services determines clinical utility.

"The FDA has a different threshold," noted Crawford. "It looks at safety and efficacy. We also look at clinical benefit."

According to Crawford, once Elevance Health determines that a particular lab test needs a coverage document, there is a team of researchers who examine available evidence, including, most importantly, peer-reviewed literature assessing outcomes. The draft policy is then presented to a committee of mostly external physicians for a final determination.

Lab-developed tests (LDTs) go through the same process as other tests, said Crawford, noting that if there is no peer-reviewed literature to allow Elevance Health to assess the safety or impact of a test on health outcomes, it probably would have a hard time meeting the definition of medical necessity.

Pre-Authorization

eviCore requires pre-authorization for lab tests that have high potential of being misused, especially if they are expensive tests, according to Castle. For example, pre-authorization is required for BRCA testing—misuse would be if it were ordered on a 30-year-old with no family history of cancer. Pre-authorization also is required for tests that use non-specific codes.

Inappropriately ordered lab tests can have a negative impact on patients, explained Castle. "There are a couple of different ways this can hurt," he said. "The test can either give an inaccurate result if the test doesn't actually work in that population, or you could be testing the wrong patient,

leading to incorrect assumptions about the presence of the genetic disorder in the family. That is why we want to be sure the appropriate tests are ordered."

Ideally, ordering physicians will submit pre-authorization requests for a lab test they order, but they don't always do it, acknowledged Castle, who noted that this puts labs in a precarious position.

"Labs are on the hook for the money if they perform the test and don't get paid," he said. "Some labs are able to contract with third-party companies to gather the pre-authorizations for them, but many labs don't have that ability."

Denials and Appeals

The main reason a test might not be covered during prior authorization is because of insufficient clinical information submitted by the laboratory or physician upon the initial request, said Castle. However, the laboratory or physician will often provide additional information after getting a denial, and the denial will be overturned.

"The best way for labs to improve the likelihood that the testing they provide will be covered is to provide the evidence up front," said Castle. "This is all about the evidence. If you have the evidence, and the test is good for patients, we want to cover it. Test developers really need to do the appropriate clinical studies."

eviCore healthcare, a division of Evernorth Health Services, provides medical benefit services for all types of payers, including fully insured, self-insured, Medicare Advantage and Medicaid. For lab benefits, eviCore has about 175 policies, which are available at www.evicore.com.

Elevance Health (formerly Anthem Inc.) operates an array of government and commercial health insurance plans, including Blue Cross and Blue Shield plans in 14 states. Elevance Health coverage policies for laboratory testing are available at https://www.anthem.com/ca/provider/policies/clinical-guidelines/

SALSA Reintroduced in Congress

To the delight of many in the lab industry, lawmakers on March 28 reintroduced the Saving Access to Laboratory Services Act (SALSA), which would attempt to halt additional Medicare cuts to clinical laboratory services under the Protecting Access to Medicare Act (PAMA).

The bill was introduced by Sens. Sherrod Brown (D-OH) and Thom Tillis (R-NC), along with Reps. Richard Hudson (R-NC), Bill Pascrell Jr. (D-NJ), Gus Bilirakis (R-FL), Scott Peters (D-CA) and Brian Fitzpatrick (R-PA). The measure would make permanent modifications related to determining the Medicare clinical lab fee schedule testing rates, in part by mandating statistical sampling of private payer rates, requiring reporting on widely available laboratory tests, increasing the length of time between data collection, changing the definition of "applicable information" required for reporting and setting annual limits on payment rate reductions and increases.

At the time PAMA was enacted, the Congressional Budget Office projected $2.5 billion in cuts to lab reimbursement rates over 10 years. However, PAMA has already led to nearly $4 billion in payment cuts to laboratories after three years of reductions.

Efforts to pass SALSA in 2022 failed, although Congress did delay the next round of cuts under PAMA by one year. Absent congressional intervention this year, payment for about 800 lab tests will be cut up to 15% on Jan. 1, 2024.

FTC, States Investigating Lab Test Claims in New Enforcement Trend

In what appears to be a new enforcement trend, the Federal Trade Commission and state regulators are increasingly conducting investigations into specific claims being made by clinical laboratories regarding test capabilities, according to sources in the lab industry.

Governments, both state and federal, are looking at whether or not patients are being adequately protected with regard to how laboratory testing is characterized, according to the sources. The investigations are being initiated under state and federal consumer protection laws and are looking into how tests are being marketed and whether the claims that are being made about the tests are true.

It's unclear why there is increased interest in test claims. However, it's worth noting that the Federal Trade Commission (FTC) recently issued new guidance on health products that specifically addresses claims made about what products can do.

The "Health Products Compliance Guidance," released Dec. 20, 2022, updates and replaces the FTC's 1998 guidance, "Dietary Supplements: An Advertising Guide for Industry." The scope of the new guidance is expanded to cover essentially all health-related product advertising and discusses in greater detail the amount and type of evidence required to substantiate health-related product claims. The FTC, as a general rule, expects claims to be backed by high-quality, randomized, controlled human clinical trials.

It's unclear why there is increased interest in test claims. However, it's worth noting that the Federal Trade Commission (FTC) recently issued new guidance on health products that specifically addresses claims made about what products can do.

According to the FTC guidance, "advertising" refers to a wide variety of marketing techniques and anyone participating in deceptive marketing is potentially liable under FTC law. Advertising refers not only to traditional TV, radio, print and internet ads, but also to statements or depictions on packaging and labeling, in promotional materials, on social media and influencer marketing and indirectly through healthcare practitioners or other intermediaries.

Relationship Between FTC and FDA

The FTC guidance also clarifies the interrelationship between the FTC and the Food and Drug Administration (FDA) as it applies to health-related product promotion. The FTC and the FDA share jurisdiction over the marketing of dietary supplements, foods, drugs, devices and other health-related products. The FDA has primary responsibility for claims that appear in labeling, including the package, product inserts and other promotional materials available at point of sale. The FTC has primary responsibility for claims in all forms of advertising.

"Because of this shared jurisdiction, the two agencies work closely together to ensure that their enforcement efforts are consistent to the fullest extent feasible," says the FTC in the updated guidance. "Marketers should be aware that the FDA/FTC Liaison Agreement doesn't limit the FTC's jurisdiction or prohibit the agency from taking action against deceptive labeling claims or obtaining orders that address all forms of marketing, including claims that appear in labeling."

Our sources say the current investigations do not appear to be related to quality of laboratory testing, only to the claims being made. They advise all clinical laboratories to ensure any claims they make about lab tests are true and accurate.

The FTC's updated guidance is available at https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf

End of Covid PHE Brings Changes for Labs

The end of the Covid-19 public health emergency (PHE) means clinical laboratories will face several changes related to coverage and reimbursement of Covid testing. The Biden administration has said the PHE will officially end May 11.


Joyce Greskco

Joyce Gresko, a partner with Alston & Bird (Washington, D.C.), tells *LECPR* that for the duration of the PHE, commercial insurers have been required to cover Covid testing and pay for it at the lab's list price or their negotiated rate, without any medical management or cost sharing. As of May 11, commercial insurers don't have to cover Covid testing, but if they do, they can impose conditions under which testing will be covered (medical management). Payment rates are also likely to decline.

Medicare and Medicaid
In addition, Medicare reimbursement for Covid-19 testing will drop once the PHE ends. During the PHE, Medicare has paid labs $75 for high-throughput Covid testing (U0003 and U0004), plus $25 for two-day turnaround of results (U0005), for a total of $100. After May 11, Medicare reimbursement for high-throughput Covid-19 testing will drop to $51, with no $25 add-on payment.

Medicare beneficiaries who are enrolled in Part B will continue to have coverage without cost sharing for laboratory-conducted Covid-19 tests when ordered by a provider, but their current access to free over-the-counter Covid-19 tests will end.

State Medicaid programs must provide coverage without cost sharing for Covid-19 testing until the last day of the first calendar quarter that begins one year after the last day of the PHE, which means mandatory coverage will end Sept. 30, 2024.

Flexibility Under CLIA
Prior to the PHE, pathologists who read slides or digital images from home were required to obtain a separate CLIA certificate. That requirement was waived during the PHE. This flexibility will continue as a matter of CMS policy, says Gresko, who notes that it is possible that this flexibility may be included in CLIA regulations in the future.

"Even before the pandemic, there were efforts to educate CMS [the Centers for Medicare and Medicaid Services] about what digital pathology looks like – it doesn't matter if the pathologist is working in a hospital, lab or at home, because the pathologist logs into the same system and does the same work in each of those locations," she says.

Specimen Collection from Homebound Patients
To facilitate Covid-19 testing of quarantined homebound patients, Medicare paid independent labs $23.46 for Covid -19 specimen collection (G2023). Likewise, Medicare paid independent labs $25.46 for specimen collection from nursing home patients (G2024). These payment amounts will end with the termination of the PHE.

EUAs for Covid-19 Products Not Affected
Since the FDA's emergency use authorization is separate from the HHS PHE declaration, the ending of the PHE will not affect the FDA's ability to authorize various products, including tests, treatments or vaccines for emergency use. Existing emergency use authorizations (EUAs) will remain in effect, and the agency may continue to issue new EUAs going forward when criteria for issuance are met.

OIG Targets Drug Testing Overpayments for G0483 (*cont'd from page 1*)

The OIG report said that although the at-risk providers billed a significantly higher percentage of definitive drug testing services using G0483 than the other providers, the at-risk and other providers had similar characteristics (such as the types of patients they tested and the frequency of testing). "This suggests that the at-risk providers may have been able to bill for definitive drug testing services using primarily procedure codes with lower reimbursement amounts," according to OIG.

What OIG Recommends

OIG has recommended that CMS: (1) expand program safeguards to prevent and detect at-risk payments to at-risk providers for procedure code G0483; (2) review at-risk payments made to at-risk providers during and after our audit period and recover any overpayments; (3) notify appropriate providers to exercise reasonable diligence to identify, report, and return any overpayments; and (4) educate providers that received payments that did not comply with Medicare requirements.

Top 20 Labs Billing a High Percentage of G0483

The table below lists the top 20 labs with the highest volume of allowed Medicare Part B services for G0483 that used this procedure code for 75% or more of its definitive drug testing in 2020. Beach Tox LLC (Torrance, CA) is at the top of the list with 28,987 allowed Part B services for G0483 representing 100% of its definitive drug test volume.

Beach Tox's owner, Billy Joe Taylor, 44, pleaded guilty in federal court last year to one count each of conspiracy to commit healthcare fraud and money laundering. Taylor faces a maximum penalty of 20 years in prison. A sentencing hearing is scheduled in the Western District of Arkansas federal court in Fort Smith on July 19.

Top 20 Labs Billing Medicare for 75%+ for G0483 in 2020

Laboratory	Location	G0480 (1-7 drugs)	G0481 (8-14 drugs)	G0482 (15-21 drugs)	G0483 (22+ drugs)	Grand Total Medicare Services	% G0483
Beach Tox LLC	Torrance, CA	0	0	0	28,987	28,987	100%
MD Spine Solutions (dba MD Labs Inc.)	Reno, NV	617	973	3,933	18,220	34,033	77%
Radeas LLC	Wake Forest, NC	461	252	1,940	17,734	29,599	87%
Medscan Laboratory Inc.	Williston, ND	212	830	2,204	16,256	29,411	83%
Ark Laboratory LLC	Waterford, MI	855	54	3,189	14,142	31,864	78%
South Georgia Toxicology	Valdosta, GA	419	976	2,150	13,113	27,334	79%
Lifebrite Laboratories	Brookhaven, GA	64	834	500	12,822	23,544	90%
Corona Pathology	Burbank, CA	0	0	0	11,644	12,657	100%
Nations Laboratory Services	Tecumseh, OK	0	0	0	10,973	11,158	100%
Ocean Marketing Corp.	San Pedro, CA	0	0	0	10,065	20,192	100%
RDx BioScience	Kenilworth, NJ	85	123	264	7,856	13,760	94%
Chabado Genomics Inc.	Torrance, CA	0	42	0	7,678	8,114	99%
Certus Laboratories	Ocean Springs, MS	0	21	908	6,943	8,820	88%
US Lab Inc	Costa Mesa, CA	37	694	484	6,725	9,589	85%
Pathlab Services Inc	Garden Grove, CA	0	0	0	5,738	10,067	100%
American Clinical Solutions	Ruskin, FL	141	455	264	5,551	7,482	87%
Center for Pain Management	Indianapolis, IN	36	0	0	4,941	5,174	99%
Physicians Toxicology Lab	Tampa, FL	35	143	858	4,918	9,822	83%
Apollo Path	Dallas, TX	440	0	134	4,764	6,802	89%
Pharmacyrxtox	Hattiesburg, MS	0	189	0	4,663	9,601	96%
Grand Total for all 5,180 labs		700,837	505,826	637,369	902,543	5,204,892	33%

Source: CMS and OIG (The full OIG report can be found at https://oig.hhs.gov/oas/reports/region9/92103006.asp.)

COMPLIANCE 101:
Program Basics for Clinical Laboratories

According to the Health and Human Services Office of Inspector General, clinical laboratories should require the development and distribution of written compliance policies that cover a number of areas, including standards of conduct, medical necessity, billing, reliance on standing orders, compliance with applicable HHS OIG fraud alerts, marketing, prices charged physicians for profiles, retention of records and compliance as an element of a performance plan.

Standards of Conduct

Laboratories should develop standards of conduct for all employees which clearly delineate the policies of the laboratory with regard to fraud, waste and abuse and adherence to all guidelines and regulations governing federally funded healthcare programs.

These standards should be made available to and understandable by all employees (e.g., translated into other languages, if necessary) and regularly updated as the policies and regulations of these programs are modified. The purpose of the standards is to ensure that employees know what to do, ensure that the laboratory has recourse in the event a violation occurs, and provide a basis for education and training and auditing and monitoring.

Written standards of conduct might include a mission and values statement, a code of ethics, workplace conduct and employment practices. This could include the following: non-discrimination; offering or receiving items of value to induce referrals; financial relationships with physicians and other referral sources; professional courtesies; improper billing activities; unfair competition; deceptive trade practices; privacy and confidentiality.

Employee Code of Conduct

The code of conduct could be simple or detailed. In either case, it should state that all employees are expected to comply with the letter, as well as the spirit of all laws and regulations affecting the employee's position and duties. CodeMap, a laboratory consulting company based in Chicago, suggests the following language:

"Each employee is responsible for her/her best efforts to act in a legal and ethical manner concerning all federal and state regulations relative to providing laboratory services to government funded healthcare programs."

The policy might then state that each employee is responsible for certain things, which would be listed. These might be general statements, such as "Understanding the rules and regulations regarding the marketing, sales, performance and billing of laboratory and pathology procedures as they apply to his/her job" and "Acting in a legal and ethical manner regarding all rules and regulations, as well as all laboratory compliance policies as outlined in the Laboratory Compliance Policy Manual." These statements might also be more descriptive and explicit.

The policy should also include a provision that employees report all suspect operations or practices either directly to his/her supervisor or by using the anonymous disclosure hotline.

All employees should be required each year to sign a certification that states they have received, read, understand and will abide by the organization's Employee Code of Conduct. All new employees should sign the certification within 60 days of date of hire.

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

In Brief

New PLA Codes Take Effect April 1

New Proprietary Laboratory Analyses (PLA) codes take effect April 1, 2023. These new codes (available at https://www.cms.gov/files/document/r11829CP.pdf#page=8) are priced by Medicare administrative contractors (MACs) unless they are nationally priced. MACs will only price PLA codes for laboratories in their jurisdiction. The following HCPCS codes are discontinued on April 1, 2023, and will be removed from the Clinical Laboratory Fee Schedule: 0324U and 0325U (Oncology (ovarian)).

UnitedHealthcare Expands Coverage of Precision Oncology Diagnostics

UnitedHealthcare has issued a new policy providing coverage for a variety of molecular tests used to personalize the care of cancer patients. The policy, effective April 1, addresses multiple cancer types and test technologies, as well as a spectrum of early-to-late-stage indications and clinical applications. The major changes from a prior policy focus on multi-gene sequencing tests for molecular profiling of solid tumors.

HHS OIG Asks for $82.3 Million Increase

The Health and Human Services Office of Inspector General (HHS OIG) has requested $514.8 million for FY 2024, an $82.3 million increase from FY2023. Approximately 21% of the funding supports HHS's broad oversight of Public Health Services programs, and 79% supports oversight of the Medicare and Medicaid programs.

The $29.8 million in additional resources for the Public Health Service programs will go toward a new emergency preparedness, response and recovery initiative, cybersecurity and digital technology expansion and pay and benefit increases. The additional $52.5 million for Medicare and Medicaid will go toward addressing the shortfall in current OIG investigative personnel to tackle healthcare fraud, as well as pay and benefit increases.

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