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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

Medicare's MolDX Working to Streamline Policies, Speed Assessments

Medicare's Molecular Diagnostics (MolDX) program was developed in 2011 to identify and establish coverage and reimbursement for molecular tests. The program has agreements with four Medicare administrative contractors (Palmetto GBA, Noridian Healthcare Solutions, WPS Government Health Administrators and CGS Administrators) that cover 28 states. Palmetto administers the program. *LE Compliance & Policy Report* recently spoke to Gabriel Bien-Willner, MD, PhD, chief medical officer at MolDX, about developments in the program. *See the full interview on pages 2-4.*

Top Compliance Challenges for Clinical Laboratories

LE Compliance & Policy Report recently spoke with David Gee and Caitlin Forsyth, attorneys with Davis Wright Tremaine, about compliance challenges clinical laboratories are facing. Gee is a partner in the firm's Seattle office. Forsyth is counsel in the firm's Portland office.

Medical necessity, especially in regard to urine drug testing and Covid testing, continues to present serious challenges for labs. Marketing in the toxicology space also is a focus of government agencies. *Details on page 7.*

Payment, Coverage Key Policy Concerns for MAWD Pathology

Payment and coverage for molecular diagnostic tests top the list of worries that keep Natasha Villanueva, MHA, MLS(ASCP)CM, Vice President of Clinical Laboratory for MAWD Pathology Group (Lenexa, KS), up at night.

"I am concerned about all of the evolving policies surrounding molecular diagnostics," Villanueva tells *LECPR*. "It is difficult to keep up with all of the different payer policies. Some of the policies are too vague, and many keep evolving. It feels like the goal posts are always moving." *Continued on page 5.*

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***Welcome to the first issue of* Laboratory Economics Compliance & Policy Report.** *Each month we will bring you in-depth interviews with policymakers, attorneys, lab compliance officers and others, along with insight into the latest compliance, regulatory and policy developments affecting clinical and anatomic pathology laboratories. Interested in subscribing? Details on page 12. Kimberly Scott, Editor*

MEDICARE'S MOLDX WORKING TO STREAMLINE POLICIES (*cont'd from page 1*)

MolDX applies to labs in 28 states. How does Medicare reimburse molecular diagnostic tests in the other states?
There's nothing magical about the MolDX program in terms of policy or instruction from CMS [The Centers for Medicare and Medicaid Services]. The program was put in place to have specific controls and expertise in the area of molecular diagnostics. It's a joint operations agreement between four MACs. In terms of making policy and ensuring that services are reasonable or necessary, there are really no differences. Non-MolDX MACs have all the same processes and procedures, but they don't necessarily have the same policies or edit logic that we have.

Why don't the others use the MolDX program?
I cannot answer this with any certainty. Participation in the program comes without any cost to the partners, and to understand why they do not join you will need to ask them. My suspicion is that it is a political question more than anything. Any MAC can join, but at the end of the day, these are Medicare contractors bidding for contracts from CMS, and they have to weigh the value of participating in the program with the politics of potentially helping a competitor.

Do you have any sense whether the policies under MolDX are more or less restrictive than those of the other MACs?
It's my opinion that we have the most progressive policies for molecular diagnostics. We often set groundbreaking policies that other MACs copy or that other private payers copy.

Are there any new initiatives aimed at lowering growth in Medicare spending on genetic tests?
No, because we don't believe in the core tenet of that question, which is that there is some objective to reduce spending for services that may be necessary. However, we want to ensure that the Medicare funds are spent wisely and that molecular lab tests that demonstrate clinical value get reimbursed. A lot of our processes and procedures are to differentiate and delineate where the money is appropriately being spent. We only want to decrease spending where it's not appropriate, but not decrease spending where it is appropriate.

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Have there been any major changes to the MolDX program in the past year?
There have been changes to the scalability of the program and continuous improvement in how we operate. Policy is one small segment of what we do. We create procedures for every new service that is reviewed. We create processes for pricing services appropriately. There are growing pains. In the past year, as we have more resources and have added more staff, we've been able to really catch up and ensure that when we tell providers their technical assessments will be done within two months, we meet those deadlines.

How many employees does MolDX have?
We have roughly 15 FTEs, including five medical directors, clinical lab scientists, administrative staff, nurse coordinators and project management staff. When I started in 2018, we had three. We also have external medical reviewers.

How many policies does MolDX currently have in place?
It is fewer now than four years ago. We used to write separate policies for different providers for similar tests. In 2019, we started writing foundational policies, meaning the policies are based on analytes, not specific tests, and many tests can fall under the scope of a single policy. That has allowed us to retire a lot of old policies that were now duplicative. Writing policy is a highly regulated process that takes a lot of time. Since the 21st Century Cures Act became law [Dec. 2016], it's become even more difficult.

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There was a time when we were writing what felt like 30 to 40 policies a year. It was completely unsustainable. Now we are writing around four to eight a year, and we take a lot more care when we write them. The policy defines if services are reasonable and necessary. The policy doesn't speak to individual providers, it speaks to analytes measured, and services provided for specified intended uses. There are coverage criteria and technical assessments. You either meet that or don't meet that.

What is the normal turnaround on a technical assessment?
To get coverage under an existing policy, a technical assessment will take between two weeks and two months.

Do you anticipate any major changes in the coming year?
We will continue to have process improvements. We will continue to expand and improve how we review data. With the four MACs under MolDX, it doesn't mean everything is always done the same because there are a lot of moving parts, and the process can be difficult to control. We want to tighten up the deployment and edit logic. We want to ensure that claims are adjudicated the same from jurisdiction to jurisdiction.


Gabriel Bien-Willner, MD, PhD

What is something you wish clinical laboratories understood about the MolDX program that you don't think is widely known?
The goal of the MolDx program is not to "not pay for things." It is to identify services that are reasonable and necessary. However, we are bound by the constraints of the Medicare program. For example, we get complaints about why we don't cover screening tests. But we can only cover things that are a Medicare benefit. You may have a great screening test, but we are never going to be able to cover that under Medicare unless it is a covered benefit.

When do labs performing molecular diagnostic tests have to get a DEX Z-Code?
Assuming there is already a coverage policy/standard of care (existing LCD) that you fall under, you should register for a Z code once your test is ready for deployment. Your test needs to demonstrate analytical validity, clinical validity and clinical utility. Once you submit documentation, it will take up to two months to review to determine if conditions under policy are met. Registration for a Z code is required. The Z code is permanent, but if you make modifications to the test, you keep the Z code but you have to update your registration. Material changes to the test may need additional TA review.

What are the latest LCDs that MolDX has approved?
The last major policy we put out was our infectious disease panel testing policy. There were limitations to the prior respiratory panel policy that this supersedes. The previous policy only applied to viral respiratory pathogens, but it did not include bacterial pathogens. It was designed for generally healthy beneficiaries, but immunocompromised patients were not being served well by that policy. There was a request to reconsider the policy in light of that.

The policies we have are living, breathing documents that must reflect the current evidence. Upon review, we determined that the MolDX process for panel formulation and evidentiary review could have the same logic apply to any large panel of pathogens across the board. There was no coverage for any other pathogen panels. We realized that there could be other valuable pathogen panels that could be covered if we expanded the policy.

We explicitly called out certain conditions wherein it was already demonstrated that there was value. Under this policy, any molecular infectious disease panel could potentially meet coverage criteria, but it also requires all such panels to undergo registration under the MolDX program.

How many additional tests have been approved under this policy?
There have been tests that have demonstrated that they were reasonable and necessary under this policy that were not previously covered—they may have been reimbursed, but they weren't covered. I'm talking about GYN-related panels such as for sexually transmitted disease. It is important to note that there is a difference between coverage and reimbursement. There were a lot of panels that were registered for completely different intended uses that did not have clinical validity behind them and were not covered. There was a fair amount of abuse where people were improperly billing for services that were not medically necessary, but there were no controls in place, so the payer didn't know what they were paying for.

I would say another problem is when you have codes that aren't well-constructed so it makes it difficult to develop policy. Coding causes all kinds of problems when it's not well thought out.

Will there always be a need for coverage policies for molecular?
Under 21st Century Cures Act, anything that could expand coverage requires a policy.

Are there specific tests that present particular problems in terms of determining coverage?
The ones that are more difficult are the ones that get the most attention and have the most sophisticated assessment process. I would say another problem is when you have codes that aren't well-constructed so it makes it difficult to develop policy. For example, 81599—what is that? That could be anything, as long as it's a multianalyte test with an algorithm. Does that come under MolDX or not? Coding causes all kinds of problems when it's not well thought out.

To add to that, what is an algorithm? We wrote an article defining what an algorithm is. It's on the Medicare coverage site. If you are a lab and you want coverage for a test, the first thing you should do is go to that site and look to see if there is already a policy that covers your test. [That site is available at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56853].

PAYMENT, COVERAGE KEY POLICY CONCERNS (*cont'd from page 1*)

Medicare's Molecular Diagnostics (MolDX) program, which has been adopted by four of the seven Medicare administrative contractors (MACs), is especially vexing, says Villanueva, who believes it's not always clear what validation data the MolDX program wants for its technical and clinical assessments. United Healthcare Medicare Advantage has also adopted MolDX policies in the Medicare jurisdictions that have implemented the MolDX program (Sept. 2021 Reimbursement Policy Update Bulletin, available at https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-reimbursement/rpub/UHC-MEDADV-RPUB-SEP-2021.pdf).

Natasha Villanueva

"It's exceptionally difficult when you are talking about next-generation sequencing panels," says Villanueva, who believes payer policies sometimes lag behind current science. "I hate to see payers making decisions that may not be based on best practices and advancing technology. Sometimes it feels like reimbursement is driving coverage." [For more on how MolDX determines its test coverage policies, see the Q&A with MolDX Chief Medical Officer Gabriel Bien-Willner, MD, PhD, on pp. 1-4].

Use of Preferred Labs Narrows Options

Use of preferred labs by payers also presents challenges to many clinical and AP laboratories, believes Villanueva. Some payers, such as UnitedHealthcare, guide testing to specific preferred laboratories [United has 50 Labs-of-Choice through its Beacon Lab Benefits Solutions].

"It's a bit of a monopoly," she says. "It's hard to become a preferred lab. A lot of physicians feel they have to send testing to the major national labs, as they are preferred. We have had several clients tell us they have received letters from payers when they send a test to a lab that's not on the preferred list. It really limits options for our clients."

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Pre-Authorization Challenges

MAWD Pathology also has experienced challenges with payer pre-authorization requirements, says Villanueva. In most cases, the pre-authorization has to be initiated by the ordering physician, but many will send tests to MAWD without receiving pre-authorization first.

"We don't reject the test. We work with the clinician to try to get pre-authorization, but it does add to our workload. In some cases, we will run the test and not get paid. That is not something we can continue doing."

FDA Oversight of LDTs

Villanueva also tells *LECPR* that she has concerns with the prospect of changes to regulations surrounding lab-developed tests (LDTs). While the Verifying Accurate Leading-edge IVCT Development (VALID) Act was excluded from the year-end 2022 funding package approved by Congress, the VALID Act or similar legislation could be reproposed in the future. Though Villanueva views the intentions of the policy as positive, she has concerns that proposed legislation may limit access to LDTs due to Food and Drug Administration (FDA) and third-party review bandwidth and associated costs.

Regarding FDA review, MAWD has experienced frustration with the review process for lab-developed tests firsthand. MAWD developed a SARS-CoV-2 Dual Target By RT-PCR Covid assay early in the Covid-19 pandemic. Initially, MAWD was allowed to run the test under an umbrella emergency use authorization (EUA). However, the FDA on Nov. 15, 2021, ended that policy, essentially requiring developers of all Covid-19 LDTs to seek FDA marketing authorization. The reversal of the policy decision was based on a legal memorandum by the Health and Human Services Office of General Counsel (https://www.politico.com/f/?id=00000174-e9b2-d951-a77f-f9fe04fa0000). LDTs for non-Covid-19 uses remain subject to the FDA's historical posture of enforcement discretion.

The intention of the policy is good in that it can weed out bad actors, but the review process is not timely. We submitted for approval for our assay, and it took 14 months before it was even reviewed.

"The intention of the policy is good in that it can weed out bad actors, but the review process is not timely," says Villanueva. "We submitted for approval for our assay, and it took 14 months before it was even reviewed. We did finally get a response from the FDA this month, but we still don't have final approval."

MAWD is able to continue performing Covid-19 testing using its own LDT, but if the FDA does not approve the test, it will have to stop using it, says Villanueva. Although the volume of testing has declined considerably since its peak early in the pandemic (about 50,000 per week), the lab still performs about 1,000 Covid-19 tests per week using its LDT.

SALSA Preferred Alternative to PAMA

Amid concerns about Medicare cuts for laboratory tests mandated by the Protecting Access to Medicare Act of 2014 (PAMA), Villanueva says she would like to see Congress pass the Savings Access to Laboratory Services Act (SALSA). That measure would also enact permanent reform to the way Medicare pays for clinical laboratory services. It would require payment rates for certain widely available clinical diagnostic laboratory tests to be based on a statistical sampling of private sector rates. The measure would expand the sampling on which Medicare pricing is set, establish a ceiling and a floor for rate increases and decreases and improve the types of private payer data used to set Medicare payment for lab tests.

Many in the lab community believe SALSA would repair the flawed data reporting and payment methodology enacted under PAMA. Since PAMA was passed in 2014, total Medicare payment for clinical laboratory testing has been cut by almost 30%.

[Although Congress did not pass SALSA in 2022, it did include in its 2023 Omnibus Appropriations Bill a one-year reprieve—till January 2024—from Medicare cuts of up to 15% for more than 800 laboratory tests, along with provisions to mitigate Medicare payment cuts to physicians over the next two years, lift the 4% statutory Pay-As-You-Go payment cuts to Medicare in 2023 and delay mandatory reporting under PAMA by one year.]

"We are pleased with the delays Congress passed at the end of 2022, but it would be nice to have a more permanent solution," says Villanueva. "Continued Medicare payment cuts just are not sustainable."

TOP COMPLIANCE CHALLENGES FOR CLINICAL LABORATORIES (*cont'd from page 1*)

What are the biggest compliance challenges clinical labs are facing right now?

Forsyth: We are seeing continued compliance issues around medical necessity, especially with respect to urine drug testing. We're also seeing medical necessity challenges around Covid testing and respiratory panels. With respect to Covid testing, a lot of commercial health plans are fighting coverage mandates under the CARES (The Coronavirus Aid, Relief and Economic Security) Act. [The law generally requires insurance companies and group health plans to cover the cost of testing for Covid-19].

Caitlin Forsyth

The federal mandate is still in effect under the CARES Act. From the lab's perspective, there is a broad coverage mandate. But the agencies charged with administering it – the Centers for Medicare and Medicaid Services and the Departments of Treasury and Labor – have come out with some guidance in the form of frequently asked questions (FAQs) that health plans are relying upon to support their efforts to limit their coverage obligations.

Labs are sometimes able to informally resolve coverage disputes with payers, but we're starting to see more and more of these coverage disputes play out in the courtroom. It could be the lab arguing that they are entitled to payment for testing or it could be the payer saying that they have paid for testing that was not medically necessary and that it is entitled to repayment.

We are also seeing audits related to the Covid-19 Uninsured Program. The program, which is administered by the Health Resources and Services Administration (HRSA), ran out of funds and stopped accepting claims in March of 2022. HRSA and the Department of Justice (DOJ) are now investigating whether claims were properly submitted to the program.

Gee: The FAQs issued by the Departments charged with implementing the CARES Act Covid-19 testing coverage make some issues clearer and some issues murkier. In payer disputes, the issue has been about getting on the same page with payers about what is covered and what is not.

How are payers determining that claims are not medically necessary?

Forsyth: A lot of labs doing Covid testing relied on telemedicine networks that look a lot different to payers than the traditional lab referrals. Many people were not going to their primary care doc for a referral for testing. It seems that there is some distrust by payers of remote authorization for tests. Another medical necessity hot spot concerns "surveillance" and "return to work" testing.

Don't most employers pay for return-to-work testing?

Gee: In some cases, the employer has a self-funded insurance plan and will attempt to impose their coverage. There also is some mixed messaging. It has been a challenge for people trying to operate in good faith.

David Gee

The biggest issue is that there is a presumption created by the federal law and interpreted by the three agencies that the testing would be appropriate if ordered by a physician. Virtually everyone was doing walk-up testing early on. There was an urgency to get people tested. Lab owners and operators were investing their capital to set up testing kiosks. It was kind of a brave new world. The difficulty is that there was messaging coming from the White House that all this testing was going to be available and that you wouldn't be charged for it.

The consequence of that is that labs have been subjected to inordinate scrutiny even though the White House pushed to have that testing available to the public. The government fanned the flames and commercial payers are doing what they do best, which is not to pay.

The government paid a substantial amount of money to ensure that testing was being done. Now there is a push to look back and determine whether that testing was proper. Some payers are trying to claw back money from labs. There is some litigation going on in regard to that.

I think we will start to see enforcement actions under EKRA involving variable compensation to W-2/bona fide employees.

What other areas are hot regarding fraud investigation re labs?
Gee: We're seeing a lot in the toxicology space, especially third-party involvement in marketing or delivery of the testing. This is consistent with the government's focus on independent contractor marketing and compensation in the EKRA [Eliminating Kickbacks in Recovery Act] era.

There is a perception by the DOJ that there are improprieties and a lack of oversight by the sales and marketing forces in the lab industry. Almost invariably, even if the investigation begins with a medical necessity question, it will turn to sales and marketing practices of the laboratory.

What advice do you have for labs and pathologists to stay in compliance with state and federal laws and regulations?
Gee: There is a need for good resources and publications related to lab compliance. There have been a lot of new entrants in the lab space in the last two to three years, and they have no context for compliance. Some of them are surprised to learn that there are laws regarding laboratory testing and billing and a legacy of enforcement and that there are ways to manage risk.

The 1998 OIG Compliance Guidance for Laboratories outlines key considerations and policies. It starts with assigning the compliance responsibility to someone. There are off-the-shelf compliance programs, but they won't do a lot of good if there is not an understanding of how they should be implemented.

Looking into your crystal ball, what compliance issue do you anticipate could be coming down the road—something that isn't a big concern now but could become a larger challenge?
Forsyth: I think we will start to see enforcement actions under EKRA involving variable compensation to W-2/bona fide employees. While many labs have brought their sales teams entirely in-house (i.e., all sales representatives are W-2 employees), they are still paying those sales representatives on a variable (commissions) basis, notwithstanding the fact that EKRA exempts payments made to employees only if the employee's payment is not determined by or does not vary by referrals or amount received from payers.

COMPLIANCE 101:
Program Basics for Clinical Laboratories

Originally issued in 1997 and updated in 1998, the Health and Human Services Office of Inspector General's Model Compliance Plan for Laboratories remains an essential roadmap for clinical laboratories in development of their compliance programs. **All** clinical laboratories, regardless of how much testing they perform or what kind of testing they do, should have a written compliance program and should have a program to ensure the plan is implemented and enforced. The OIG suggests that the comprehensive compliance program should include, at a minimum, the following elements:

1. Written standards of conduct for employees.
2. The development and distribution of written policies that promote the laboratory's commitment to compliance and that address specific areas of potential fraud, such as billing, marketing and claims processing.
3. The designation of a chief compliance officer or other appropriate high-level corporate structure or official who is charged with the responsibility of operating the compliance program.
4. The development and offering of education and training programs to all employees.
5. The use of audits and/or other evaluation techniques to monitor compliance and ensure a reduction in identified problem areas.
6. The development of a code of improper/illegal activities and the use of disciplinary action against employees who have violated internal compliance policies or applicable laws or who have engaged in wrongdoing.
7. The investigation and remediation of identified systemic and personnel problems.
8. The promotion of and adherence to compliance as an element in evaluating supervisors and managers.
9. The development of policies addressing the non-employment or retention of sanctioned individuals.
10. The maintenance of a hotline to receive complaints and the adoption of procedures to protect the anonymity of complainants.
11. The adoption of requirements applicable to record creation and retention.

Written Policies and Procedures

Laboratory compliance plans should require the development and distribution of written compliance policies. These policies should be developed under the supervision and direction of the chief compliance officer or the equivalent and should, at a minimum, be provided to all individuals who are affected by the specific policy at issue. Policies should, at a minimum, address the following areas: standards of conduct, medical necessity, billing, reliance on standing orders, compliance with applicable fraud alerts, marketing, prices charged, record retention, and compliance as an element of performance.

Each month, *Laboratory Economics Compliance & Policy Report* will delve into various elements of a compliance plan as recommended by the HHS OIG. Next month we will look at the OIG's guidance on standards of conduct.

CMS Considers Proposed Changes to CLIA Requirements

A proposed rule that would allow nurses to perform high-complexity laboratory tests and individuals with "professional doctorates" or a "master's equivalency" to serve as directors of high-complexity laboratories is currently undergoing review by the Centers for Medicare and Medicaid Services (CMS).

More than 20,000 comments have been submitted on the changes, proposed July 26, 2022 (CMS-2022-0119-0001). CMS has two years to issue a final rule, but representatives from industry groups say they expect a final rule to be issued this calendar year. Observers are awaiting input from the Clinical Laboratory Improvement Advisory Committee, which will meet again April 12-13.

The proposal would also increase CLIA fees by 20% and implement an annual inflation adjustment. A number of groups, including the American Association for Clinical Chemistry (AACC) and the College of American Pathologists (CAP), support some of the proposed changes while opposing others.

Concern About Classifying Nurses as High-Complexity Personnel

The CAP, for example, supports the CLIA proposals that address practice and technology changes, such as the updates to the histocompatibility regulations, but believes the current CLIA requirements for the laboratory director and technical supervisor of the immunohematology laboratories should be maintained. The CAP also is concerned about the proposal allowing nurses to be classified as high-complexity laboratory testing personnel.

While the CAP supports having the nursing degree as a separate qualifying degree, it recommends that CMS create testing personnel criteria that leverage point-of-care testing in a hospital or health care facility. "This category would allow nurses to fulfill their roles within the health care delivery team while ensuring the reliability and accuracy of laboratory testing," says the CAP in comments, noting that nurses lack the specialized scientific and technical knowledge essential for understanding the pre-analytic, analytic or post-analytic phases of the testing, which are critical to overseeing moderate- and high-complexity testing.

The American Society for Clinical Laboratory Science (ASCLS) also opposes the proposal to allow nurses to perform high-complexity tests, saying that the proposed rule omits any requirement for training and demonstrated competency to perform high-complexity testing relative to those who have four-year degrees in clinical laboratory science, chemistry or biology.

The AHA also opposes this proposal, writing that "the types of laboratory tests classified by CMS as high complexity require a level of knowledge, training and result interpretation that we believe exceeds the typical nurses training – even at the doctoral and masters' levels."

High-Complexity Laboratory Director

CMS is also proposing to expand qualifications for a high-complexity laboratory director (HCLD) to include "professional doctorates" and individuals with "master's equivalency" who meet certain training, experience and certification requirements. Currently, this position is limited to certain MDs and board-certified PhDs. ASCLS is in favor of this proposal, says Jim Flanagan, Executive Vice President, noting in comments that "these professionals exceed the requisite scientific skills necessary to increase efficiency, facilitate patient management outcomes, and improve timely access to accurate and appropriate laboratory information by participating directly in patient care decisions, monitoring laboratory utilization, and conducting research on the diagnostic process to improve test selection, interpretation, and the diagnostic process."

However, AACC strongly objects to this proposal, saying that the Doctorate in Clinical Laboratory Sciences (DCLS), which CMS calls a "professional doctorate," falls short of meeting the requirements necessary for a person to serve as HCLD (as does master's equivalency).

The CAP also opposes the inclusion of the DCLS degree as a qualifying degree under CLIA. "While the CAP supports the advancement of clinical laboratory professionals in the field of laboratory science, we are concerned that the DCLS degree may cause confusion among the public about the distinctions between a clinical pathologist and a DCLS," the CAP writes in comments.

In Brief

Medicare Price Cuts, PAMA Reporting Delayed Another Year

As part of the Continuing Appropriation Act of 2023, signed into law Dec. 29, 2022, lawmakers delayed implementation of the next round of price cuts to the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) called for under the Protecting Access to Medicare Act (PAMA). Without Congressional intervention, laboratories would have faced up to a 15% cut in Medicare payment for tests paid under the CLFS.

The law also suspends PAMA-related reporting requirements for labs for an additional year. The next PAMA reporting period is now Jan. 1, 2024, through March 31, 2024, for data collection period of Jan. 1, 2019, through June 30, 2019. After the next data reporting period, there is a three-year data reporting cycle for clinical diagnostic laboratory tests (that is 2027, 2030, etc.).

CLIAC To Meet April 12-13, 2023

The Clinical Laboratory Improvement Advisory Committee (CLIAC), managed by the Centers for Disease Control and Prevention (CDC), will meet next April 12-13, 2023. The committee provides scientific and technical guidance to the Department of Health and Human Services (HHS). A full list of CLIAC recommendations is available at https://www.cdc.gov/cliac/docs/CLIAC_RecommendationsTable_Oct2022.pdf.

DOJ Continues to Investigate COVID-19 Fraud, False Claims Allegations

The Department of Justice (DOJ) is continuing to investigate alleged fraud by recipients of Covid-19 pandemic relief funds, accoring to Michael Granston, deputy assistant attorney general in DOJ's Civil Division. Attorneys with Mintz Levin who attended the American Conference Institute's 10th Annual Advanced Forum on False Claims and Qui Tam Enforcement report that the DOJ's cyber-fraud initiative is very active and that the agency is currently investigating a number of cyber-fraud and FCA allegations out of the public view.

Granston also provided some interesting statistics during his discussion of DOJ's statutory authority to dismiss qui tam cases, according to Mintz attorneys. He reported that over the last five years, relators have filed more than 3,000 FCA cases, and during that time period, DOJ has sought to dismiss only 58 cases.

"While a closely watched case regarding the standards that govern DOJ's exercise of its dismissal authority is currently before the Supreme Court, in practice, the statistics offered by Granston show that DOJ rarely uses its dismissal authority," writes Mintz's health care enforcement defense practice group in EnforceMintz, available at https://www.mintz.com/insights-center/viewpoints/2406/2023-02-09-enforcemintz-newsletter-health-care-enforcement-year. That approach seems likely to persist, as Granston noted that [the] DOJ will continue to exercise its dismissal authority "sparingly and transparently."

CDC Offers Free Online CLIA Training

The Centers for Disease Control and Prevention (CDC), through its Division of Laboratory Systems, offers a free on-demand course designed to equip learners with foundational information about CLIA, including the history, its importance and the implications for clinical laboratories that are subject to the regulations. The online eLearning course is designed for anyone who has a role associated with clinical laboratory testing. The course provides continuing education and PACE credit hours. Details are available at https://www.cdc.gov/labtraining/training-courses/Introduction-Clinical-Laboratory-Improvement-Amendments-1988.html.

Covid-19 Public Health Emergency Ends May 11

The Biden administration says it will end the Covid-19 national emergency and public health emergency (PHE) on May 11. They are currently set to expire on March 1 and April 11, respectively. The administration plans to extend the emergency declarations to May 11 and end both emergencies on that date. The wind-down aligns with the administration's previous commitments to give at least 60 days prior notice to termination of the PHE.

CMS Halts Independent Dispute Resolution Temporarily

The Centers for Medicare and Medicaid Services (CMS) on Feb. 10, 2023, instructed Independent Dispute Resolution (IDR) entities to hold all payment determinations in out-of-network disputes until CMS can issue additional guidance. According to XIFIN, the CMS announcement comes after a February 6 Texas District Court ruling backing the Texas Medical Association's claim the IDR process, as described in the final rule, contradicted language in the No Surprises Act. CMS says IDR entities should not issue new payment determinations until receiving further guidance. In addition, certified IDR entities also should recall any payment determinations issue on or after Feb. 6, 2023.

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