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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

Key Compliance and Regulatory Issues in Digital Pathology

Since the Food and Drug Administration (FDA) approved the first digital pathology system in 2017, more and more pathology groups have turned to whole-slide imaging for secondary or even primary reads of specimens. One of the main drivers for the move to digital pathology is the promise of increased efficiency and productivity. However, those who use digital pathology in their practices must comply with various laws and regulations to ensure that patient data is protected. *LECPR* recently spoke with Emily Johnson, an attorney with McDonald Hopkins, about key compliance and regulatory issues in digital pathology. *See page 2 for the Q&A.*

Exploring Standards That Support LDT Developers

As clinical laboratories try to navigate new Food and Drug Administration (FDA) requirements for lab-developed tests, it's important that they understand the standards they must meet to develop and implement new tests, say experts who spoke recently during an August 15 Clinical Laboratory Standards Institute (CLSI) webinar, part of the organization's LDT Foundations webinar series. *More on page 5.*

FTC Noncompete Ban Blocked from Taking Effect; Agency May Appeal

The Federal Trade Commission (FTC) may appeal a federal court's ruling that blocked the agency's noncompete rule from taking effect. On Aug. 20, 2024, the federal court in the Northern District of Texas said that the FTC had exceeded its authority and that the rule was unreasonably broad and did not sufficiently consider alternatives (*Ryan LLC v. Federal Trade Commission*). *Details on page 8.*

United Healthcare to Launch Gold Card Program

Effective Oct. 1, 2024, United Healthcare will launch a national Gold Card program, which will reward contracted provider groups who consistently adhere to evidence-based care guidelines. The Gold Card program will apply to all UnitedHealthcare commercial, Individual Exchange, UnitedHealthcare Medicare Advantage and UnitedHealthcare Community Plans. *Continued on page 9.*

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KEY COMPLIANCE AND REGULATORY ISSUES IN DIGITAL PATHOLOGY (*cont'd from page 1*)

What are some of the main issues under the Health Insurance Portability and Accountability Act (HIPAA)?

Pathology groups are subject to HIPAA. When utilizing digital technologies, labs and pathology groups typically contract with vendors for the software solutions necessary to operate digitally. These vendors are considered business associates of the disclosing pathology group when they receive protected health information (PHI) in connection with the services they provide to the pathology group. Under the HIPAA Final Rule, business associates also have direct liability for compliance with HIPAA. Therefore, both parties are obligated to comply with HIPAA.

Emily Johnson

Any time PHI is used and disclosed digitally, the risk of unauthorized disclosure increases. The most common HIPAA issues that arise for digital pathology involve use of unsecure software solutions that expose data and disclosure of PHI to an unauthorized individual.

Are there other privacy and data concerns?

In addition to security, an issue that comes up frequently is how PHI can be used and disclosed by digital pathology vendors for purposes unrelated to the services provided by such vendor. Specifically, oftentimes, the contract between the pathology group and the vendor permits the vendor to use, de-identify, and aggregate data from the pathology group and use that data to sell pathology insights to pharma or other interested industries. Pathology groups may not realize that the vendor has these rights and is profiting off the group's data.

Historically, vendor contracts with software providers or other IT vendors have been signed with minimal review by providers, who presumed that these contracts were non-negotiable. However, as the practice of medicine has evolved and patient data has not only become more and more available but also has become more valuable, providers should review their contracts to understand what data rights their vendors have and who might be profiting off their data.

Any time PHI is used and disclosed digitally, the risk of unauthorized disclosure increases.

A few questions pathology groups should ask themselves when contracting with a vendor include: 1) how is my data being used and disclosed?; 2) what is the recipient entity's role with respect to such data?; 3) does the recipient entity intend to use my data or aggregate it with other data for a purpose unrelated to the purpose for which I disclosed my data to such entity?; 4) is the recipient entity selling or otherwise monetizing my data? It is critical to understand the defined terms (e.g., data, PHI, de-identify, aggregate, use, and disclose) in the agreement to determine who might have rights to your data.

Most usages of data involve de-identified data. However, if the use involves identifiable patient information (PHI), then patient consent would be required.

In terms of state licensure, what regulations should pathologists be aware of when it comes to digital pathology?

Digital pathology is not a workaround for licensure, and pathologists are required to be licensed in the state in which the specimen originates (i.e., where the patient is). There are exceptions in some states for limited consultations. However, those rarely come into play in the scenario and pathology

groups should make sure they have the appropriate licenses before engaging in professional services in states in which they are not licensed.

What about telemedicine? What's important to know about that from a digital pathology perspective?
Digital pathology is what enables pathologists to provide remote consultations effectively and quickly. However, although digital pathology is permitted under the CLIA regulations, telemedicine/telepathology arrangements must be set up compliantly under the Stark Law and Anti-Kickback Statute in order for the telemedicine services to be reimbursable.

How does the Stark Law and Anti-Kickback Statute affect digital pathology?
The federal physician self-referral law (commonly referred to as the Stark Law) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (e.g., ownership, investment, or compensation), unless an exception applies. It also prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third-party payor) for those referred services.

With respect to AKS, any remuneration that passes between a party to a digital arrangement should be evaluated to confirm that it will not be perceived as a kickback.

There are a number of exceptions to the Stark Law that permit certain DHS services to be provided under certain circumstances, regardless of the type of financial relationship between the referring physician and the entity furnishing the service. Under the in-office ancillary services (IOAS) exception to the Stark Law, the general prohibition on ownership, investment and compensation arrangements does not apply to services furnished on a referral basis, if those services satisfy each element of the exception. Each element of the IOAS exception must be satisfied in order for the arrangement to be permissible under the Stark Law, which includes certain location requirements.

Specifically, the services must satisfy one of three location tests: the same building test, a centralized building used by the group practice for the provision of some or all of the group practice's clinical laboratory services, or a centralized building that is used by the group practice for the provision of some or all of the group practice's DHS.

There is a minority thought that because a digital grossing camera is located in the billing group's office and the digital interpretative services rendered by the pathology group are performed on systems cross-validated to the billing group's lab equipment, the location test is satisfied. However, there has been nothing from the government to support the argument that digital presence may be sufficient to satisfy the physical location requirement. Until such guidance is issued, that argument should not be relied upon given the fact that Stark is a strict liability statute.

With respect to AKS, any remuneration that passes between a party to a digital arrangement should be evaluated to confirm that it will not be perceived as a kickback.

What other laws and regulations come into play related to digital pathology?
The Medicare anti-markup limitations apply to digital pathology because it applies to the technical or professional component of a diagnostic test. It applies when the test (1) was ordered by the bill-

ing physician or other supplier, and (2) is performed by a physician who does not "share a practice" with the billing physician or other supplier.

When that's the case, the billing provider is prohibited from marking up the cost of the test beyond what such provider paid for it unless the performing physician is considered to "share a practice" with the billing physician or other supplier. To be considered to "share a practice," one of the following tests must be satisfied: (1) the performing physician must furnish "substantially all" (i.e., at least 75 percent) of his or professional services through the billing physician or other supplier; or (2) the performing physician must be an owner, employee, or independent contractor of the billing physician or other supplier and the technical component or professional component must be performed in the "office of the billing physician or other supplier."

Satisfying the 75% Test

To satisfy the 75% test, the pathology group must essentially dedicate a pathologist nearly full time to perform the services. To satisfy the "office of the billing physician or other supplier" standard, (1) the performing physician must be an owner, employee or independent contractor of the billing supplier, and (2) the technical component or professional component must be performed in the "office of the billing physician or other supplier." This is essentially another location requirement that requires the performing physician to perform the services in the offices of the billing provider. Again, without clarity from CMS on the use of digital presence to satisfy in-office presence, relying on that argument presents risk.

Can you discuss some common digital pathology arrangements and the risks they present?

Digital pathology arrangements where the pathology group performs all aspects of the service and bills for the services present the least risk because the services are performed and billed for by the same provider. Arrangements where the pathology group performs digital services on behalf of a referring specialty, and the referring group bills for the services present risk if the location requirements mentioned above are not satisfied. Arrangements with digital slide processing companies must be structured to not run afoul of AKS.

CDC Issues Health Alert on Mpox Testing

The U.S. Centers for Disease Control and Prevention (CDC) has issued a health alert about the ongoing mpox outbreak in the Democratic Republic of the Congo (DRC) and its spread to neighboring countries.

For all laboratories performing mpox testing using an orthopoxvirus or monekypox virus (MPXV) genetic test without any additional clade-specific testing occurring, CDC recommends that laboratories send clinical specimens collected from patients who traveled from DRC, its neighboring countries or any country with clade I mpox cases, or had close or intimate contact with symptomatic people from these countries, to a lab that can perform clade-specific testing as quickly as possible.

If clade-specific testing is warranted but not available in a jurisdiction, specimen submission to a capable public health laboratory or to CDC is encouraged. Specimen submission to CDC can be coordinated through your state or local health department. Due to mutations that may impact clade-specific PCR tests, laboratories should use a test that targets a viral essential gene (e.g., the CDC NVO test) as part of a testing strategy to ensure mpox cases are not missed.

EXPLORING STANDARDS THAT SUPPORT LDT DEVELOPERS (*cont'd from page 1*)

The new requirements begin taking effect in May 2025 and will be phased in over a period of four years, explains Shannon Bennett, MS, MBA, CMQOE(ASQ), Mayo Clinic. CLSI offers a number of tools and guidance documents to help clinical laboratories navigate the changes.

Shannon Bennett

For example, CLSI offers a tool called Method Navigator that helps laboratories in developing and implementing lab tests, says Tabitha Kern, MS, MLS(ASCP)^{CM}, CLSI. The tool presents different requirements and regulations important to the life of an assay. The EP19 test life phase model breaks down the eight phases in the development of a test, divided into two categories: establishment and implementation. There are more than 20 best practice CLSI documents in the evaluation protocols library that support the required method of evaluations, such as EP05 (Precision), EP18 (Risk Assessment) and EP25 (Reagent Stability).

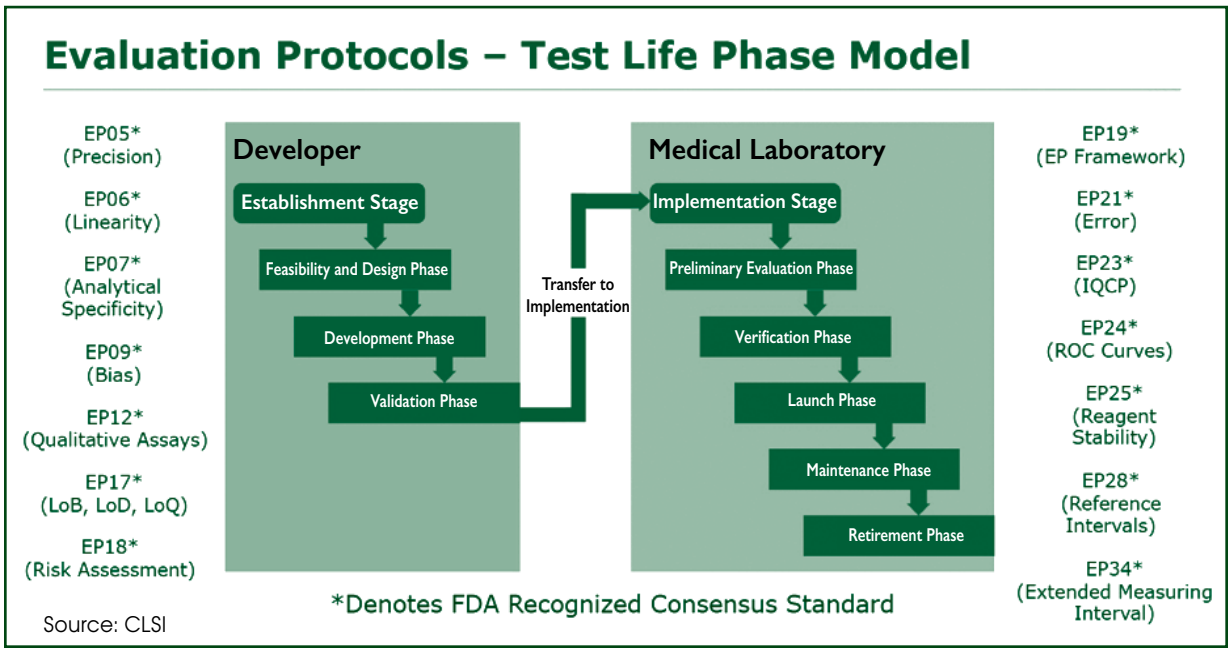
Tabitha Kern

In addition, CLSI's quality management systems support laboratories' technical operations with 12 quality system essentials (QSEs), ranging from QMS01 (QMS Framework) to QMS26 (Lab Records).

"These are the fundamental building blocks of quality and support any organization's workflow," says Kern. "These QSEs are universally applicable."

Each phase of the test life phase model has an outline of links to various requirements and regulations that should be considered, she adds. For example, there are links to requirements under the verification phase and under the validation phase. In each phase, the requirements are outlined in a simplified manner and are accompanied by the necessary evidence needed to meet them.

Method Navigator also has numerous checklists that are available to track and document work that was completed during the different phases of the life of a test, notes Kern. Checklists can be filled in on Method Navigator or can be downloaded to a Microsoft Word file.



Questions and Answers

What should a laboratory do to prepare for Stage 1 and Stage 2 requirements?
Jonathan Genzen, MD, PhD, MBA, ARUP Laboratories: Familiarize yourself with the Stage 1 requirements for medical device reporting, corrections and removals, and complaint files. The FDA is requiring that the laboratory have established procedures that it will follow by May 6, 2025. A big part of the requirements for this is record keeping, so you need to think about how you will store all information you may receive about a complaint, document it and evaluate it to determine whether that ultimately is a reportable event.


Jonathan Genzen

It's not too early to start to familiarize yourself with Stage 2. Labeling is going to be complicated. It's essentially the information that comes in a package insert as well as advertising. Maybe even try to create a label and then think about how you would manage that when you scale up to all your LDTs. This is also a good time to put together a list of all your LDTs.

Bennett: We would all love concrete instructions from the FDA on how to do all of this, but it's not there yet. We are going to have to get comfortable with ambiguity and do the best we can.

Michelle Campbell, MS, MLS(ASCP), assistant professor of laboratory medicine and pathology, Mayo Clinic College of Medicine and Science: When you're identifying your LDTs, be sure to identify those with modifications to FDA-authorized assays. Collaborate with other members of the healthcare team to identify what modifications were really necessary to determine what compromises you are willing to make. Also, start educating your healthcare team about the final rule. Start with bite-size pieces to help people get comfortable with the new requirements.


Michelle Campbell

Is it possible to estimate what the FDA's expectations are for validation and verification on automated systems used for LDTs?
Genzen: I'm getting a lot of questions about the impact of automation with the final rule. There are many types of automation, and it's going to be hard to generalize. When I read the final rule, I think about them talking about automation in basically two ways—one in which relates to the pre-1976 exemption category. They basically said if an assay is using automation or software, it doesn't qualify for the exemption. The other way they describe automation is a significant modification to either a currently marketed assay or a modification to another manufacturer's diagnostic. Taking something from manual to automated is a significant modification, according to the FDA. I think that's one of the biggest burdens of the final rule because many of us use automation for relatively straightforward purposes to prevent repetitive motion injuries. I am hoping there is additional clarification and guidance on this. Also, there really isn't clarification of automation in the pre-analytical phase – we will need more guidance on this.

Where do you recommend that labs that have not used CLSI documents start with this whole process?
Campbell: I would start with the CLSI document EP19, which is foundational for LDTs. It's an overview of the test life phase model. I would also look at the EP LDT Quick Guide, which categorizes EP documents and resources into different buckets, so you have a starting point.

Bennett: CLSI also has some very good crosswalks for CAP requirements, Joint Commission, ISO. For example, I looked at the ISO one this morning and searched for "non-conformance," and there's a whole list of CLSI documents that could be helpful.

Are there any short guidance documents for performing these study protocols?
Campbell: That's probably the most intimidating part about diving into CLSI resources because they are so comprehensive, but it's important to have that level of detail when you are talking about developing and implementing laboratory tests. But there is need for guidance that are more bite-size. There are three that I want to touch on—implementation guides (IGs), establishment guides (EGs) and quick guides (QGs).

The FDA is clear that cost is not an unmet need, so if Lab A offers that test for a million dollars, and you offer that test for five dollars, and the other lab's test is FDA approved, you don't have an unmet need for your test.

Establishment guides are essentially summaries of study design protocols for validation studies that are included in EP documents. Quick guides are similar, but they are for non-protocol-driven EP documents. Lastly, the implementation guides are for the end-users. What I really like about them is that many have embedded workbooks that allow you to document the factors that were included in your study design and also some data analysis tools.

How small or how large of a modification to a test has to occur to classify it as an LDT?
Bennett: That is a great and extremely complicated question because it depends on a number of factors. Some of the significant types of modifications include changing a major component, such as a reagent change, adding a technology—such as AI—or making a change to intended use. Some of those may be obvious, and some are not. For example, say my reagent manufacturer has a production issue and now I need to find a backup reagent – it's the same thing, just a different manufacturer. Does that warrant it being a modification? The FDA does have a guidance document called "Deciding When to Submit a 510(k) for a Change to an Existing Device," and it goes through a thought process for understanding whether a modification rises to the standard of needing a submission or can I just validate the change, document it internally and not need to make a submission. It's really on a test-by-test basis that you will need to make that decision.

Genzen: I think the FDA did acknowledge in the final rule that there are certain activities that occur in a laboratory that relate to things like specimen stability where they may release future guidance. I think they are aware of the ambiguity here.

I am confused about what is considered an unmet need. Can you provide any clarification?
Bennett: We will need some FDA guidance on this. The FDA in the final rule defines a test for an unmet need as that test is not available to patients in any other way. What I am guessing the FDA will expect is for the lab to document why it feels the test meets an unmet need. An important caveat here: The FDA is clear that cost is not an unmet need, so if Lab A offers that test for a million dollars, and you offer that test for five dollars, and the other lab's test is FDA approved, you don't have an unmet need for your test.

Genzen: The other thing that doesn't factor into unmet need is superior performance of your assay. If you have an assay with 5% imprecision, and the FDA-approved test has 50% imprecision, your test doesn't count as meeting an unmet need. I think the goal of the unmet need provision was to address testing for rare diseases and conditions, but the limitations essentially eliminate the ability to use the unmet need provision for things like outreach testing and for most reference or referral lab settings.

FTC Noncompete Ban Blocked from Taking Effect; Agency May Appeal

(*cont'd from page 1*)

At the core of the court's decision was whether the FTC had the legal authority to enact a sweeping ban on noncompete agreements. The FTC had based its authority on Section 6(g) of the FTC Act, which allows the agency to create rules to prevent "unfair methods of competition." The court, however, found that this section of the FTC Act does not explicitly grant the agency the power to implement substantive rules, such as the proposed noncompete ban.

"The FTC would likely have to significantly tailor any prohibition on noncompetes if it tried to reinstate a similar rule to avoid the rule being found arbitrary and capricious."

The court emphasized that the FTC's authority under the law was limited to procedural rules, and issuing a broad substantive rule like a blanket ban on noncompetes required explicit authorization from Congress.

The FTC had finalized the ban on April 23, 2024, and the final rule was published in the Federal Register on May 7, 2024. The ban was set to take effect Sept. 4, 2024. Ryan LLC, a Texas tax services firm, filed a lawsuit against the FTC. The U.S. Chamber of Commerce and other industry groups later joined the lawsuit as plaintiffs-intervenors in support of Ryan's challenge to the rule. Ryan and the industry groups claimed that the FTC lacks the legal authority to adopt rules banning conduct that it deems to be an unfair method of competition.

FTC Has Options

Danielle Tangorre, a partner with Robinson+Cole (Albany), tells *LECPR* that the FTC has stated it is considering an appeal of the rule. Alternatively, the FTC may choose to individually bring case-by-case enforcement action for violations of Section 5 and unfair methods of competition in lieu of any formal attempt to codify a ruling, she says.

Danielle Tangorre

"Overall, it may be more challenging to reinstate this rule after the Loper Bright decision particularly since the court found that the rule was 'unreasonably overbroad without a reasonable explanation,' says Tangorre. "The FTC would likely have to significantly tailor any prohibition on noncompetes if it tried to reinstate a similar rule to avoid the rule being found arbitrary and capricious."

The *Loper Bright* decision overturned long-standing doctrine known as "Chevron deference," essentially expanding the judiciary's power to review and reject interpretations of statutes adopted by federal administrative agencies.

According to the law firm of Holland & Knight, the FTC could seek a stay of the Ryan court's decision and order, pending the outcome of an appeal. Litigation also continues in federal courts in Florida and Pennsylvania. Though the decision in Ryan is not the final word in the litigation challenging the rule, employers are now relieved of the obligation to comply with the rule by the initial effective date of Sept. 4, 2024. Employers nationwide should continue to monitor the course of the various cases challenging the rule, the firm says.

Tangorre suggests that clinical laboratories and other businesses will want to still review compliance with any state law requirements, monitor updates for any appeals and may wish to consider tailoring their noncompetes and nonsolicitations in consultation with legal counsel to avoid any potential enforcement actions, she says.

UNITED HEALTHCARE TO LAUNCH GOLD CARD PROGRAM (*cont'd from page 1*)

Qualifying care provider groups will follow a simple notification process for eligible procedure codes rather than the prior authorization process. This advance notification will confirm eligibility and network status, but it will not require clinical information, according to the College of American Pathologists (CAP).

To be eligible for Gold Card status, practices must have had a minimum annual volume of at least 10 eligible prior authorizations across participating lines of business for two consecutive calendar years across all Gold Card eligible codes and show a prior authorization approval rate of 92% or higher for two consecutive years. Provider groups can view their UnitedHealthcare Gold Care program status via the UnitedHealthcare Provider Portal.

Practices do not need to apply for Gold Card status. UnitedHealthcare will make each practice's Gold Card status determination available to them as well as reporting of the practice's performance as compared to program eligibility criteria.

The CAP has advocated for gold card programs to reduce physician practice burdens and prevent patient care delays for many years. In a March 2023 letter, the CAP asked the Centers for Medicare and Medicaid Services to streamline prior authorization processes in Medicare Advantage (MA) and other public health plans through gold card programs. The CAP has also successfully advocated in Arkansas for a gold card payment safeguard that ensures health plans do not deny or reduce reimbursement for pathologists who complete a service requested by an exempt gold-card provider. Wyoming recently became the second state to codify CAP's gold care payment safeguard.

CMS, MACs Will Not Finalize Proposed LCD on Testing for Allograft Rejection

The Centers for Medicare and Medicaid Services (CMS) and Medicare Administrative Contractors (MACs) have decided not to finalize a proposed local coverage determination (LCD) on molecular testing for solid organ allograft rejection.

The proposed LCD was issued on Aug. 10, 2023, but in response to comments and upon further review of evidence, CMS says it will not finalize the proposal as written. Instead, the MACs intend to issue a new LCD in the coming months.

At this time, neither CMS nor the MACs have changed coverage for these blood tests that monitor for organ transplantation rejection when ordered by their physicians in medically appropriate circumstances. Patients with transplanted hearts, lungs or kidneys who meet Medicare's existing local coverage criteria can continue to access these blood tests, including under the following circumstances:

- When there are signs or symptoms of rejection;
- After a physician-assessed pretest, including for surveillance testing;
- After an indeterminate biopsy;
- As a replacement for a biopsy when deemed clinically appropriate by the patient's qualified physician; and
- For evaluation of the adequacy of immunosuppression.

When the new LCD is posted, it will be available for review in the Medicare coverage database.

ICD-10 Updates Take Effect Oct. 1, 2024

Effective Oct. 1, 2024, the Centers for Medicare and Medicaid Services is updating the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM).

For 2020, there are 252 additions, 35 deletions and 13 revisions. As is typical, the majority of the deleted codes are expanded into additional codes. Deleted codes will no longer be accepted by Medicare Administrative Contractors beginning Oct. 1, 2024. Among the new codes are 63 for neoplasms, 27 for digestive and eating disorders, 33 for musculoskeletal and 30 in injury, poisoning and other external causes.

In addition, deleted and expanded codes often affect the covered code lists of Local Coverage Article (LCAs) and National Coverage Determinations (NCDs). CMS has issued Transmittal R12691CP, which updates the covered diagnosis codes of the following NCDs:

- **190.12** Urine Culture, Bacterial
- **190.13** Human Immunodeficiency Virus (HVI) Testing (Prognosis Including Monitoring)
- **190.14** HIV Testing
- **190.15** CBC
- **190.16** Partial Thromboplastin Time (PTT)
- **190.17** Prothombin Time (PT)
- **190.18** Serum Iron Studies
- **190.19** Collagen Crosslinks, Any Method
- **190.20** Blood Glucose Testing
- **190.21** Glycated Hemoglobin/Glycated Protein
- **190.22** Thyroid Testing
- **190.23** Lipids Testing
- **190.24** Digoxin
- **190.25** Alpha-fetoprotein
- **190.26** Carcinoembryonic Antigen
- **190.27** Human Chorionic Gonadotropin
- **190.28** Tumor Antigen by Immunoassay CA 125
- **190.29** CA 15-3/CA 27.29
- **190.30** CA 19-9
- **190.31** Prostate Specific Antigen
- **190.32** Gamma Glutamyl Transferase
- **190.33** Hepatitis Panel/Acute Hepatitis Panel
- **190.34** Fecal Occult Blood Test

More information on the 2025 ICD-10-CM changes can be found here.

Advocacy Groups Call on Congress to Block Physician Medicare Cuts

More than 120 medical organizations, including the College of American Pathologists, have called on Congress to pass legislation to stop the 2.8% Medicare physician payment cuts that are set to take effect on Jan. 1, 2025.

In a September 10 letter sent to Senate and House leaders, the groups called on lawmakers to intervene to prevent the cuts, noting that the proposed 1.8% payment reduction will coincide with an expected 3.6% increase in medical practice cost inflation, as measured by the Medicare Economic Index (MEI). "When adjusted for inflation, Medicare physician payments have declined by 29% from 2001 to 2024," the groups write. "This is clearly not a sustainable trajectory."

Since 2020, Congress has mitigated but not eliminated reductions caused by the application of Medicare's budget-neutrality adjustment, which statutorily prohibits any net increase in cost to the federal government when adjustments to the MPFS exceed $20 million. Most recently, in the Consolidated Appropriations Act of 2024, Congress provided 2.93% of relief to help offset 2024's payment cut, once again mitigating but not eliminating the reduction and failing to keep up with medical inflation for 2024. However, the additional 2.93% expires at the end of 2024.

The groups are calling for Congress to pass bipartisan legislation that has been introduced in the House to add a permanent MEI-based inflationary update to the MPFS.

COMPLIANCE 101:

Proficiency Testing Basics

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), all clinical laboratories must participate in a proficiency testing (PT) program, either through the Centers for Medicare and Medicaid Services or through an accreditation organization, such as the College of American Pathologists or The Joint Commission. The PT program must be approved by CMS. A list of approved programs is available here.

Proficiency testing (PT) is the testing of unknown samples sent to a laboratory by an approved PT program. Most sets of PT samples are sent to participating laboratories three times per year. After testing the PT samples in the same manner as its patient specimens, the laboratory reports its sample back to their PT program. The program grades the results using CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed the testing.

PT testing is important because it is a tool the laboratory can use to verify the accuracy and reliability of its testing. Routine reviews of PT reports by the laboratory staff and director will alert them to areas of testing that are not performing as expected and also indicate subtle shifts and trends that, over time, would affect their patient results.

PT is not required for any test that is waived. However, enrolling in a PT program and performing PT on your waived tests will provide you with an excellent indication of the accuracy of the waived tests and thus improve the quality of testing you provide to your patients. It also serves to demonstrate the accuracy of your testing if it is ever questioned.

PT is only required for a limited number of tests found in Subpart I, Proficiency Testing Programs for Nonwaived Testing, of the CLIA regulations. If your laboratory performs any of the tests found in subpart I, you must perform PT on each of the tests.

Multiple Laboratory Locations
PT enrollment and participation is required for each CLIA certificate. If you offer non-waived testing at more than one site, but the testing is all included under one certificate, you must enroll in an approved PT program for all the "regulated" analytes covered under that certificate, not for each site. If you have a separate certificate for each site, you must enroll in PT for the tests to be performed at each site.

Changing PT Programs
You may not randomly change from one approved PT program to another. Laboratories must enroll and participate in one approved program for one year before designating a different program. Laboratories should enroll in the fall for the next calendar year. However, if you apply for a new CLIA certificate mid-year or add a "regulated" specialty, subspecialty or analyte in the middle of the year, you may change PT programs at the next PT enrollment period.

Documentation
You must keep a copy of all your records, such as the step-by-step PT sample preparation and handling, all the steps taken in the testing of the sample, a copy of the PT program results form used to record and submit your PT results (includes the attestation statement), a print screen if results are entered electronically, and the PT program's evaluation of your laboratory's performance. These copies must be maintained for a minimum of two years from the date of the PT event. If any corrective actions are taken as a result of an unsatisfactory or unacceptable score, maintain records of these actions for two years also.

In Brief

CDC Selects Lab Partners to Help Develop Test for Bird Flu

The Centers for Disease Control and Prevention (CDC) has selected five clinical laboratory partners to help develop a test for avian influenza (H5N1), or bird flu: ARUP Laboratories, Quest Diagnostics, Labcorp, Aegis Sciences and Ginko Bioworks. The partnership marks a shift for the CDC in that it enables commercial labs to work on testing solutions alongside the agency, rather than once a public health emergency arises, to make a test for bird flu available quickly if it is needed. The announcement came shortly after an individual in Missouri, who had no known contact with animals or poultry, became infected with an H5 virus. This is the first time a human has tested positive for H5 without a known source of the virus. Both the CDC and the Missouri Health Department of Health and Senior Services continue to investigate. The individual, who has since recovered, had underlying health conditions, according to the CDC. A total of 15 human cases of bird flu have been identified in the United States since 2022.

Lawsuits Over LDT Final Rule Consolidated

The College of American Pathologists (CAP) reports that two lawsuits challenging the Food and Drug Administration's (FDA) plans to regulate lab-developed tests will be consolidated into one, according to a motion filed in the U.S. District Court Eastern District of Texas. The lawsuits were filed by the American Clinical Laboratory Association and the Association for Molecular Pathology. Both groups argue that the FDA's final rule on LDTs exceeded the agency's authority and violated the Administrative Procedures Act. Under a timeline set in the September 9 motion, amicus briefs in support of the plaintiffs are due October 7. ACLA's and AMP's closing briefs are due by November 25, and the FDA's closing brief will be due by December 23. The CAP has also opposed FDA regulation and is drafting an amicus brief that urges the court to also vacate the regulation.

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

New from Laboratory Economics

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- How national reference labs are rated by service, turnaround time, price and overall best value
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The U.S. Laboratory Reference Testing: Market Profile & Trends 2024-2027 has been written to help laboratories make more informed decisions regarding the tests they refer out, the prices they pay and how changes in referral and contracting processes might cut costs.

Our Research Methodology

The U.S. Laboratory Reference Testing: Market Profile & Trends 2024-2027 includes data gathered the old-fashioned way—through primary research. The estimates and market analysis in this report have been built from the ground up. Our proprietary reference testing survey combined with extensive interviews with commercial lab executives, hospital lab directors, and respected consultants form the basis of this report. And no stone has been left unturned in our examination of Medicare test volume and expenditure data, hospital cost reports, Securities & Exchange Commission filings and non-profit company tax reports.

About the Author

Jondavid Klipp is president and publisher of ***Laboratory Economics LLC***, an independent market research firm focused on the business of laboratory medicine. Prior to founding ***Laboratory Economics*** in April 2006, Mr. Klipp was managing editor at Washington G-2 Reports. During his seven-year employment with G-2, he was editor of Laboratory Industry Report and Diagnostic Testing & Technology Report. Prior to joining G-2, Mr. Klipp was an HMO analyst at Corporate Research Group in New Rochelle, New York, and a senior writer in the equity research department at Dean Witter in New York City.

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