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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

How to Ace Your Lab's Competency Assessments

Given that failure to perform competency assessments is one of the top citations issued by CLIA inspectors, it's crucial that laboratory managers have a regular schedule for conducting assessments. Repeat citations during inspections can shut down your clinical laboratory and result in suspension of the lab director's license. *For details on how your lab can ace its competency assessments, see page 2.*

Top Five Lab Billing and Coding Challenges

As most clinical laboratories know, getting claims reimbursed by payers can present multiple challenges, particularly when the claims are for molecular diagnostic testing. Clarisa Blattner, Senior Director, MDx Support Services for XiFin, a revenue cycle management firm based in San Diego, shares with *LECPR* five of the top billing challenges clinical laboratories face and offers tips on how to address them.
Details on page 5.

National Diagnostics Action Plan Proposes Solution for Future Pandemics

The Covid-19 pandemic revealed myriad weaknesses in the nation's ability to meet emerging health threats. To address these gaps, the American Clinical Laboratory Association (ACLA) and Johns Hopkins Center for Health Security are proposing a National Diagnostics Action Plan for the United States (NDx Action Plan).
More on page 8.

Kentucky Labs to Pay $1.7M to Settle FCA Allegations

Two Kentucky drug testing labs have agreed to pay $1.74 million to settle allegations that they billed Medicare and Medicaid for medically unnecessary urine drug tests. The settlement follows an earlier agreement reached by the same laboratories.
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How to Ace Your Lab's Competency Assessments (*cont'd from page 1*)

CLIA regulations require that all laboratories receive an initial inspection and then be surveyed every two years. Unannounced inspections might also be conducted if there is a complaint about a lab.

One of the most common citations during inspections is failure of a lab's technical supervisor or technical consultant to follow written policies and procedures to periodically evaluate personnel performance and competency of all staff involved in pre-analytic, analytic and post-analytic phases of testing, says Lori Millner, PhD, Laboratory Director and Technical Consultant, Lighthouse Lab Services, a consulting company based in Charlotte, NC. Millner spoke during an April 27 webinar sponsored by Lighthouse Lab Services.

Lori Millner, PhD

According to CLIA statistics, almost 19% of all labs (726) received a citation for failing to follow the "Personnel Competency Standard" (D5209) in 2021. While many labs have a plan for assessing competency, too often directors or managers do not keep a regular schedule for performing the assessments.

"It's not enough to just have a plan," said Millner. "You must also have the tools to execute the plan properly."

Millner recommends that labs use a template to ensure that all six elements of personnel performance and competency are covered (*see p. 7*), dedicate an individual to perform the task and use automated software to keep track of important dates.

Why Is Competency Cited So Often?

One reason why clinical laboratories struggle with personnel competency assessment is confusion about the requirement and its interpretation, says Leah Westover, MPH, MLS(ASCP), Director of Sales for MediaLab, a QMS software company based in Lawrenceville, GA. This can lead to mistakes by competency assessors, such as competencies being too consolidated or incorrect timing of intervals for assessments.

Leah Westover, MPH, MLS

"Interpretations can vary between labs and inspection teams," explains Westover. "Don't forgo contacting your accrediting body if you are confused or need guidance. It's not shameful to ask questions about your scenarios to ensure you're on the right track with the regulatory interpretation."

Who Is Qualified to Assess Competency?

Moderate-complexity testing. In laboratories performing moderate complexity testing, the team member performing the competency assessment must be qualified as a technical consultant. This person must possess, at a minimum, a bachelor's degree and two years of laboratory training or experience with non-waived testing in the designated specialty.

High-complexity testing. In laboratories performing high-complexity testing, the team member must qualify as a technical supervisor. This person must possess, at a minimum, a bachelor's degree and four years of laboratory experience with high-complexity testing. However, a technical supervisor may delegate the responsibility to a general supervisor, who must have either a bachelor's degree and one-year of high-complexity testing experience or an associate's degree and two years of high-complexity testing experience. The lab must ensure that it has on-hand documentation needed for team member qualifications.

Not only do technical personal need to be assessed, but assessors themselves must be assessed, notes Westover. Documented competency assessment is required for individuals fulfilling the following personnel responsibilities: clinical consultant, technical consultant, technical supervisor, general supervisor and testing personnel.

"If assessors also perform patient testing, they must also have formal competency assessments on the appropriate test systems with all six CLIA elements included," she added. "Software systems can provide structure and automated scheduling for these assessments."

Competency Assessment Procedures

CLIA requires that six elements must be assessed for each test system and all phases (pre-analytical, analytical and post-analytical). (See the six elements below). These requirements apply to team members for each CLIA lab they work in (even in the same lab system). States may require additional competency elements to be assessed.

CLIA elements one through four can be handled in written checklists, says Westover, who suggests adding subtasks. For example, under "Task 1," you might add "Evaluates specimens for acceptability," "Performs testing steps according to procedure," and "Evaluates results appropriately."

"What we don't want to see is just the six CLIA elements listed," said Westover. "That's not enough. You need to be a little bit more granular."

Westover suggests having backup documentation saved to the electronic record, such as intermediate test results, as well as results of quality control and proficiency testing. Finally, the completed checklists should be signed by the assessor, along with date and time.

Six CLIA Assessment Elements

1. Direct observations of routine patient test performance.
2. Monitor the recording and reporting of test results.
3. Review intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records.
4. Direct observation of the performance of instrument maintenance and function checks.
5. Assessment of test performance through testing of previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
6. Assessment of problem-solving skills.

CLIA 5 – PT Documentation

The assessor should ensure that each team member has documented evidence of a proficiency testing (PT) kit or repeat sample/blind duplicate activity for each phase of assessment, says Westover.

"You really want to plan out your PT delivery schedule and assignments," she advises. "Be sure to save PT records and results with your competency forms or in electronic systems."

CLIA 6 – Problem Solving Skills

Many labs use a quiz or quiz bank, but you can also document trouble-shooting activities or other problem-solving examples in your observation checklists, says Westover. For example, if there is an instrument-problem log, it would be useful to save and upload this documentation. "A quiz or some kind of problem-solving activity must be included at each phase of assessment," she explains.

Incorporate Assessments into Daily Activities

The College of American Pathologists (CAP) suggests trying to incorporate your competency assessment activities in your routine practices and procedures, says Westover, noting that it's better to capture competency detail as it's happening rather than waiting until someone is due for assessment. Among CAP's suggestions:

- Assessment of the recording of quality control test results and instrument maintenance data in element three can be performed during the monthly supervisory review process of these results.
- Assessment of test performance in element five can be performed during reviews of proficiency testing or alternative performance assessment records.
- Assessment of problem-solving skills in element six can come from monthly reviews of corrective action logs where problems with quality control or instrument function were investigated.

"Try to get into the mindset that competency is an ongoing process, not, 'I need to stop what I am doing because Sally Smith is due today,'" says Westover. "You should be thinking about competency throughout the year."

Competency Consolidation Problems

According to CMS, clinical laboratories can structure their competencies based on the unique procedures for the test. Specifically, CMS states that as long as there are no unique aspects, problems or procedures associated with any test on the testing platform, all tests performed simultaneously on the same testing platform may be combined. However, any test with unique aspects, problems or procedures within the same testing platform should be assessed separately and proficiently.

"With this guidance in mind, combining separate analytes on the same testing platform for competency assessments is acceptable," says Westover. "Think about your analyzers and test systems – create an assessment for each, covering the analytes that run on that platform, assuming there are no unique aspects."

In the same sense, it may be helpful to avoid combining assessments into large categories such as "chemistry" or "microbiology" if you're not clearly differentiating how each testing platform is being assessed separately, she says.

Ultimately, it is up to the lab director to ensure that competency assessments are performed and documented, says Westover. "Don't place your license at risk by failing to perform this CLIA requirement," she urges.

Top CLIA Deficiencies, 2021

Regulatory Subpart	*Deficiency*	*# All Labs with Deficiency*	*% All Labs with Deficiency*
Personnel Competency Assessment (D5209)	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.	726	18.96%
Analytic Systems (D5413)	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided, These conditions must be monitored and documented.	670	17.50%
General Lab Systems (D5217)	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I or this part.	623	16.27%
Verification of Performance Specifications (D5421)	Each laboratory that introduced an unmodified, FDA-cleared or approved test system must demonstrate that it can obtain performance specifications comparable to those established by the manufacturer.	610	15.93%
Analytic Systems (D5403)	The procedure manual must include the requirements for specimen acceptability, microscopic examination, step-by-step performance of the procedure, preparation of materials for testing, etc.	560	14.63%
Procedure Manual (D5401)	Written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel.	558	14.57%
Analytic Systems (D5417)	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.	494	12.90%
Post-Analytic Systems (D5805)	The test report must indicate the following: for positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number, the name and address of the laboratory location where the test was performed, and other requirements specified in 493.1291(c).	447	11.67%
Laboratory Director's Responsibility (D6016)	Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that the proficiency testing samples are tested as required under subpart H of this part.	392	10.24%

Source: *Division of Clinical Laboratory Improvement and Quality, CMS*

Top Five Lab Billing and Coding Challenges (*con't from page 1*)

1 Patient Ineligible or Benefits Not Covered

More than 50% of claims can be rejected because the patient is not eligible for the services, says Blattner. Insurance eligibility and benefit verification can be complex due to the increasing number of high deductible plans, more frequent changes to a patient's insurance plan, as well as a larger population of uninsured patients.

Laboratories need an eligibility and benefits verification process that is easy and efficient and can provide current and accurate patient demographics and insurance information. Blattner suggests that labs have eligibility transactions that are connected directly to the payor and an automated process that runs in real-time. The information returned should provide accurate eligibility and benefits information, coverage and coverage limitations, and patient out-of-pocket responsibility at the plan level to provide granular information based on in-network and out-of-network status.

"Having an automated eligibility and benefits verification process aids in keeping the clinical workflow moving, while ensuring a timely clean claim submission, expedited adjudication, leading to fewer claim denials and expedited cash collections," says Blattner.

2 Constant Changes with Payor Requirements and Payor Policies

Payors are constantly adding to or changing requirements for laboratory claims, notes Blattner. Most recently, UnitedHealthcare published a Reimbursement Policy Update Bulletin in May 2023 for its commercial plans. The policy indicated that UnitedHealthcare no longer requires the submission of a unique test ID obtained through the Genetic Test Registry (GTR); however, effective with dates of services on or after Aug. 1, 2023, the policy requires the submission of a DEX Z-code, which would be obtained through the Palmetto DEX Registry. The Palmetto Z-code should be reported in Loop 2400 or SV-101-7 for professional electronic claims and in Box 19 for paper claims. Claims for molecular pathology services will be denied if the Z-code information is missing, invalid, or does not match the service represented by the CPT code reported on the claim.

Clarisa Blattner

Another recent change is explained in a Novitas Solutions Billing and Coding Article for Molecular Pathology and Genetic Testing (A58917). Effective June 11, 2023, when reporting CPT code 81479, the specific gene tested must be entered in Box 19 for a paper claim or electronic equivalent for the claim. Failure to include this information on the claim will result in Part B claims being rejected. Medical records may also be requested when CPT code 81479 is billed. The medical records must clearly identify the unique molecular pathology procedure performed, its analytical validity and clinical utility, and why CPT code 81479 was billed.

Payors do not always publish changes, says Blattner, therefore, it's imperative that your billing partner has the appropriate expertise and resources to monitor payor front-end rejections, identify, investigate, and resolve changing payor edits, and provide payor education and coordination on standards.

"Laboratory billing partners should have a robust system that is agile and flexible, so any changes in payor requirements can be accommodated quickly and efficiently," she says.

3 Missing Billing Information

Laboratories continue to be challenged with obtaining pertinent billing information because they don't have direct patient interaction. Many laboratories still rely on their staff to manage bill-

ing functions manually; however, this creates risks for errors and inconsistencies which may result in false claims.

Blattner suggests that laboratories use an exceptions-based approach that highlights billing errors in which patient billing information is invalid or missing. If a patient's insurance subscriber ID number is invalid or missing, the revenue cycle management system should be able to automatically send correspondence to the patient and/or ordering physician directing them to a client and/or patient portal to add/update the information for billing in real-time, without intervention from the staff. This will result in accurate information, a quick resolution to the error, and expedited claim submission.

4 Increase in Request for Additional Information and Denials

Laboratories have seen an increase in requests for additional information and in denials due to the lack of medical necessity, notes Blattner. Many payors now require medical records or additional clinical information prior to adjudicating a molecular pathology claim. Many payors have also provided documentation requirements in their clinical medical policies providing guidance on what is required to justify medical necessity for specific tests, which should be documented by the ordering physician in the patient's medical record.

Whether it's a request for additional information or a medical necessity denial, laboratories should have a revenue cycle management system that automates the denial and appeals process. Blattner recommends using configurable automation to map claim adjustment reason codes and remark codes to automate next actions, as well as categorizing reason codes and remark codes and conducting a root cause analysis to determine if they can proactively be prevented.

Blattner cites as an example a CO50 denial when the payor has determined the test to be a non-covered service because it is not deemed a "medical necessity." The revenue cycle management system should be able to automatically populate relevant data into a payor proprietary appeal letter and access the test requisition form, test report, and supporting clinical documentation/medical records, creating an appeals package, and submitting the documents to the payor, with no staff intervention.

Using an RCM system with an automated appeals process capability, coupled with document storage technology, can improve efficiency of appeals management, reducing cost and increasing reimbursement, says Blattner.

"Automating the appeals management process and incorporating payor-specific requirements improves appeal success rates and the speed of reimbursement," she says. "With molecular diagnostics laboratories seeing a continual increase in appeals, an automated appeals process is a necessity."

5 Patient Engagement and Patient Financial Responsibility

Effective patient communication touchpoints and technology enables laboratories to support patients in preparing for out-of-pocket expenses and increase test completion rates. Laboratories need to be able to easily engage with patients throughout their journey—from the order through specimen collection and return, delivery of results and reimbursement. Having a patient communication platform that makes it simple to push timely, relevant, personalized messages to patients about such things as how to complete their at-home specimen collection and how to pay a bill is exceedingly important, says Blattner.

"Patient engagement is vital in facilitating reimbursement and maximizing cash collection," she notes. "Patients expect transparency and ease of access to information from their healthcare encounters. Because many laboratory, pathology and molecular diagnostic encounters are not directly patient-facing, patient engagement tools are essential, particularly when it comes to communicating claim denials and patient financial responsibility."

An accurate patient responsibility estimator is a vital tool in improving patient engagement and ensuring patients are not blindsided with unexpected costs. Providing price transparency early in the diagnostic ordering process is an excellent way to enhance both the patient and ordering physician experience, as well as to support evolving surprise billing rules and regulations. XiFin has developed a patient responsibility estimator, a sophisticated application that allows providers to share cost estimates with the patient prior to care. By uniquely leveraging important data from the billing system, the XiFin patient estimator tool can provide access to the expected reimbursement at the CPT level by payor plan. Using this in conjunction with real-time eligibility information, providers can determine the amount that should be collected from a patient at the time of the order.

"To succeed operationally and financially, labs must implement a revenue cycle management process that maximizes timely reimbursement," says Blattner. "That requires interoperability with other systems throughout the patient journey, integrating payor policies and regulatory compliance in real-time, automating processes to reduce errors, and ensuring financial integrity with an accounting package that is GAAP [generally accepted accounting principles] and SOX [Sarbanes-Oxley Act] compliant."

CDC Cautions That Mpox Outbreak Is Not Over

The Centers for Disease Control (CDC) in a May 15 Health Alert cautions that while cases of mpox (formerly known as monkeypox) have declined since the peak in August 2022, the outbreak is not over.

The CDC says that it continues to receive reports of cases that reflect ongoing community transmission in the United States and internationally. The agency is currently investigating a cluster of cases in the Chicago area.

From April 17 to May 5, 2023, a total of 12 confirmed and one probable case of mpox were reported to the Chicago Department of Public Health. All cases were among symptomatic men, and none of the patients were hospitalized. Nine (69%) of the 13 cases were among men who have received two JYNNEOS vaccine doses. The median age was 34 years old, and several of the men had recently traveled to New York City, New Orleans and Mexico.

The CDC notes that although vaccine-induced immunity is not complete, vaccination continues to be one of the most important prevention measures. Although approximately 1.2 million JYNNEOS mpox vaccine doses have been administered in the United States since the beginning of the outbreak, only 23% of the estimated population at risk for mpox has been fully vaccinated. The CDC is urging clinicians to be on alert for new cases of mpox and to encourage vaccination for people at risk.

The CDC is also urging clinicians to refamiliarize themselves with mpox symptoms, specimen collection, laboratory testing procedures and treatment options. When collecting specimens, healthcare workers and laboratory personnel should follow the "Biosafety Laboratory Guidance for Handling and Processing Mpox Specimens."

Clinical laboratories should take measures to minimize the risk of laboratory transmission when testing routine clinical specimens from confirmed or suspected mpox patients, says the CDC. These may include limiting the number of staff testing specimens, avoiding any procedures that could generate infectious aerosols and wearing appropriate personal protective equipment. More information is available at the CDC's "Information for Laboratory Personnel."

National Diagnostics Action Plan Proposes Solution for Future Pandemics

(*con't from page 1*)

The NDx Action Plan describes steps that are urgently needed to prepare for future infectious disease emergencies, as well as the actions that must be taken at the first signs of such events. ACLA has submitted the plan to federal lawmakers in response to a request for information related to the upcoming reauthorization of the Pandemics and All Hazards Preparedness Act (PAHPA). PAHPA was first signed into law in 2006 and reauthorized in 2013 and 2019. The measure must be reauthorized again by Sept. 30, 2023.

Susan Van Meter

Since the NDx Action Plan was drafted, the PREVENT Pandemics Act was passed in the Consolidated Appropriate Act of 2023. While this is an important first step toward improving the nation's preparedness infrastructure, there is still more work to be done, believes ACLA President Susan Van Meter.

"It's important to get clarity in data reporting from labs during a public health emergency," she tells *LECPR*. "At the same time we are prioritizing getting test results to patients, providers and public health authorities, we are asked for information we simply don't have access to, such as demographic info. As part of this plan, we recommend streamlining data collection."

Supply Chain, Strategic Reserves

The NDx Action Plan recommends that Congress clarify that laboratory infrastructure is part of our nation's critical infrastructure and pre-event contracts should be put in place to ensure a state of readiness with testing capacity in place.

"While the PREVENT Pandemics Act authorizes HHS to contract directly with domestic manufacturers to ensure reserve manufacturing capacity for important medical products, we believe it would be useful to clarify that this authority expressly allows HHS to contract directly with clinical laboratories to ensure reserve testing capacity," says Van Meter in a letter to lawmakers overseeing the PAPHA reauthorization. "Even if test supplies are available, patients may have trouble accessing testing services if laboratories do not have capacity to conduct additional testing. Thus, reserve capacity of clinical laboratories is critical to preventing testing shortages in the face of surging demands."

ACLA also believes that more should be done to establish a uniform and standardized system for data sharing with public agencies and that Congress should ensure that burdens on data providers are manageable and streamlined, given the critical role that such providers play during a public health emergency.

Similarly, while new Strategic National Stockpile (SNS) authorities permit vendor-managed inventory practices for domestic manufacturers, the NDx plan recommends that Congress should expressly indicate that clinical laboratories can be a site to maintain reserves of SNS testing supplies using Vendor Managed Inventory processes.

Standardize Data Sharing

ACLA also believes that more should be done to establish a uniform and standardized system for data sharing with public agencies and that Congress should ensure that burdens on data providers are manageable and streamlined, given the critical role that such providers play during a public health emergency. In particular, the association urges the following: 1) clini-

cal laboratories be required to report only the information they receive from ordering providers; 2) state, local and tribal public health agencies cannot impose additional or different reporting requirements from federal requirements; and 3) reporting elements be required by regulation, rather than pronouncement by the Secretary of Health and Human Services.

"Robust data collection and analysis are essential to health emergency management and advancing equity, including understanding test results and patient data that illuminate health disparities in infection and mortality rates," says the NDx plan. The U.S. government "should work to standardize data to improve national visibility and understanding about capacity distribution, trends and gaps (whether regional or demographically based)."

Expedite Access to LDT Testing

Currently, the Food and Drug Administration (FDA) has in place a process for third-party review of Emergency Use Authorization (EUA) applications, but ACLA believes the agency should establish a Pre-EUA program and leverage EUA processes to provide swift access to validated testing in future emergencies.

"Ideally, at the beginning of a potential emergency, when a pathogen of concern is identified, the pre-emergency bilateral response contracts with test developers would be triggered," says Van Meter. "These agreements would allow test developers covered by them to access patient samples and swiftly develop and launch tests for patient care in a Pre-EUA environment. That is, laboratory-developed tests (LDTs) should be leveraged in clinical settings during this period of time."

Congressional committees have begun hearings on the PAHPA reauthorization. The Senate Health, Education, Labor and Pensions Committee held its first hearing May 4, 2023. The House Emergency and Commerce Subcommittee on Health held its first hearing May 11, 2023.

Billing, Coding & Payment

Noting that rapid establishment of medical billing codes, coverage and national payment rates is essential to ensure robust access to tests, the NDx Action Plan recommends that CMS develop a mechanism to set and communicate broad, national coverage and payment for testing of new pathogens of concern.

Policymakers should also take legislative action to provide for long-term and predictable reimbursement to clinical laboratories, says ACLA. "Although the Consolidated Appropriations Act included a one-year delay in the pending 15% cuts in Medicare payment for about 800 laboratory tests, additional legislation is needed to ensure a sustainable pathway for Medicare payment for clinical laboratory services," writes Van Meter, noting she anticipates reintroduction in this Congress of the bipartisan Saving Access to Laboratory Services Act (SALSA). In fact, since the ACLA comments were sent to Capitol Hill, SALSA was introduced in the House and Senate by a group of bipartisan legislators. The legislation is gaining cosponsors.

Congressional committees have begun hearings on the PAHPA reauthorization. The Senate Health, Education, Labor and Pensions Committee held its first hearing May 4, 2023. The House Emergency and Commerce Subcommittee on Health held its first hearing May 11, 2023.

KENTUCKY LABS TO PAY $1.7M TO SETTLE FCA ALLEGATIONS (*cont'd from p. 1*)

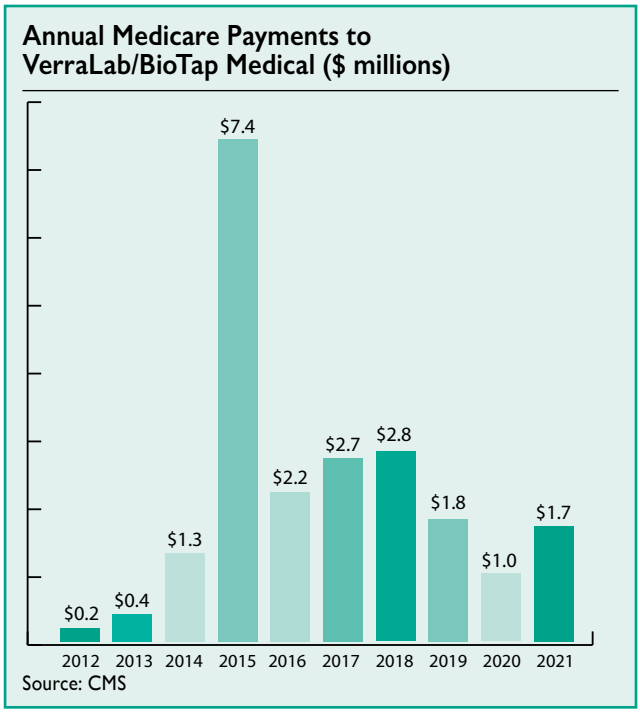
According to a May 9 news release from the U.S. Justice Department, Blue Waters Assessment and Testing Services (Lexington, KY) collected urine specimens for drug testing ordered by Fayette County family courts.

Blue Waters sent these specimens to VerraLab JA (Louisville, KY), which does business as BioTap Medical. BioTap performed the urine drug tests and billed them to Kentucky Medicaid and Medicare.

Federal law prohibits Medicare and Medicaid from paying for medically unnecessary drug tests, including those ordered by courts. The Justice Department alleged that BioTap knew the tests were court-ordered, and not used for medical diagnosis or treatment, but submitted them to Kentucky's Medicare and Medicaid programs anyway.

BioTap has agreed to pay about $1.49 million to resolve the allegations against it, while Blue Waters and its owner, David Waters, have agreed to pay $250,000.

BioTap collected more than $20 million in Medicare payments for lab testing (drug and other tests) over the 10-year period from 2012 to 2021, according to data from CMS. In calendar-year 2021, Medicare paid BioTap a total of $1.7 million for 20,827 test services for 3,377 beneficiaries. Most of BioTap's volume is for PCR-based microbiology tests and toxicology.



The settlements resolve a lawsuit brought by two private individuals, Nam Nguyen and Misty Nall, under the qui tam provisions of the False Claims Act. Qui tam whistleblowers are eligible to receive between 15% and 30% of the government's recovery. In this case, the whistleblowers will receive approximately $295,000 from the settlements.

The case is titled *United States ex rel. Nam Nguyen & Misty Nall v. Blue Waters Assessment & Testing Services, LLC; Crossroads Counseling Services, Inc.; David Waters; and VerraLab, Case No. 5:21-CV-00297-DCR.*

BioTap's $126K Settlement for Specimen Validity Testing

The latest settlement follows a separate $125,983 agreement that VerraLab/BioTap reached with the Office of Inspector General in early 2019. That agreement resolved allegations that VerraLab/BioTap submitted claims to Medicare for specimen validity testing (SVT). SVT is a quality control process that evaluates a urine drug screen sample to determine if it is consistent with normal human urine and to ensure that the sample has not been substituted, adulterated, or diluted. Medicare considers SVT not to be medically necessary (i.e., a non-covered service) when it is used to ensure specimen hasn't been tampered with, rather than to treat or diagnose a patient.

COMPLIANCE 101:

Education and Training Requirements

According to the Health and Human Services Office of Inspector General (HHS OIG), laboratory compliance programs should require compliance and ethics training for all employees, especially personnel involved in billing, sales, marketing and specimen collection and/or test ordering. Such training should emphasize the company's commitment to compliance with all laws, regulations and guidelines of federal and state programs.

Under the HHS OIG's Compliance Program Guidance for Clinical Laboratories, labs are to maintain records of each year's basic compliance training, including lists of which employees complete the compliance training; when they completed it; records of test scores or assessments, if applicable; and the content of the basic compliance training.

Compliance training should be a condition of employment and all employees should be required to participate in basic training within 90 days of hire and then annually thereafter, according to CodeMap's Compliance Policy Manual for Clinical Laboratories, 2023 Edition. Basic compliance training includes, at a minimum, information concerning the Laboratory Code of Conduct; basic functions and activities of the Laboratory Compliance Program; the employees' obligation to the program, as well as to obey all laws, rules and regulations concerning the employee's duties and responsibilities; employee's obligation to report any suspected wrongdoing via the Laboratory Disclosure Program; and how to recognize potential compliance issues.

The laboratory may use either internal or external resources to deliver basic compliance training, including online courses; participation in seminars, lectures, webinars and teleconferences; classroom instruction; and review of written materials.

Advanced Training

In addition to basic compliance training, labs should require targeted employees to also complete advanced compliance training on an annual basis. Targeted employees are individuals holding positions as corporate officers, managers and any other employees that work in sensitive areas, such as coding, billing, compliance, sales and marketing.

Advanced compliance training may cover such topics as: CPT/HCPCS coding rules; medical necessity compliance and documentation; federal fraud and abuse legislation such as federal anti-kickback provisions, Stark self-referral prohibitions and the False Claims Act; the Eliminating Kickbacks in Recovery Act; claims development and submission rules and procedures; reimbursement principles; and other rules and regulations that govern participation in federally funded healthcare programs.

Leave No Doubt About Commitment

Laboratory compliance programs should leave no doubt in the mind of employees and others associated with the provider about the company's commitment to compliance, says the HHS OIG.

"Compliance should be one of the company's most important priorities," says the OIG in its program guidance. "In addition to the compliance and ethics training and continuing education programs, a simple way to re-emphasize this message is to post in common work areas and other prominent places accessible to all employees a notice clearly reminding employees of the laboratory's commitment to compliance with all laws and regulations."

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

In Brief

CMS to Allow Remote Reads of Digital Pathology

The Centers for Medicare and Medicaid Services on May 11, 2023, issued additional guidance regarding CLIA regulations now that the Covid 19 public health emergency has ended. Of note, the guidance allows pathologists the ability to continue reviewing digital data and digital images remotely if specific criteria are met. The guidance also allows non-pathologists clinical laboratory personnel to review digital images and data remotely.

UnitedHealthcare to Cover Exome, Genome Sequencing for Certain Non-Cancer Indications

A new UnitedHealthcare policy, effective April 1, provides coverage of whole-exome and whole-genome sequencing for a variety of non-cancer indications. The policy applies to all UHC commercial benefit plans, as well as the company's individual exchange benefit plans in all states except for Colorado, Massachusetts, Nevada and New York. UHC states that the policy is limited to genetic testing in an outpatient setting or upon discharge from an inpatient setting.

CMS Releases Laboratory Registry

CMS on May 11 posted the 2022 laboratory registry that makes available information that is useful in evaluating the performance of laboratories. The registry includes a list of labs that have been convicted of fraud, false billing or kickbacks and those that have had their CLIA certificates suspended, limited or revoked. The registry also includes: persons who have been convicted of violating CLIA requirements; labs on which alternative sanctions have been imposed; labs whose accreditation has been withdrawn; labs that have been excluded from participation in Medicare or Medicaid; civil settlements; and all appeals and hearing decisions.

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