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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

Strategies for Getting In-Network With Payers

As many clinical and anatomic pathology laboratories know, getting in-network with a managed care provider is becoming increasingly more difficult. But there are some things that labs can do to make themselves more attractive to payers and thus more likely to be included in the preferred network. *Details on page 2.*

New Proficiency Testing Requirements Take Effect July 11, 2024

Clinical laboratories will need to comply with changes to proficiency testing requirements as of July 11, 2024. A final rule, published July 7, 2022, includes the addition and deletion of analytes that require PT and updates both the criteria for acceptable performance and PT program administrative processes. *Continued on page 5.*

Former Lab Owners, Compliance Officer Face Prison Time Over False Claims

In two recent cases, former owners of a Missouri clinical laboratory and a Kentucky toxicology lab face prison time over false claim convictions. In one case, the former owner could be sentenced to up to five years in prison for a scheme to dupe the federal government into paying for tests that it did not perform. In the second case, the owner and compliance officer of the toxicology lab have already started serving their prison sentences. *More on pages 7-9.*

Lab Groups Hail New Rule Streamlining Prior Authorization Requests

Laboratory groups are hailing a new federal rule requiring health insurers to streamline and disclose more information about their prior authorization (PA) processes. Under the final rule, issued Jan. 17, 2024, health insurers participating in federal programs must respond to expedited prior authorization requests within 72 hours and other requests within seven days. The new rule takes effect Jan. 1, 2026. *Continued on page 10.*

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STRATEGIES FOR GETTING IN-NETWORK WITH PAYERS (*cont'd from page 1*)

One of the reasons that labs may want to be in-network with a managed care provider is the No Surprises Act (NSA) of 2020, which prohibits labs and pathologists from balance-billing patients the difference between the in-network rate and the out-of-network rate, says Ann Lambrix, vice president, RCM Solutions, for Lighthouse Lab Services, a consulting company based in Charlotte, NC. Getting in-network with a payer ensures that the lab receives at least the agreed-upon contracted rate for a service it provides.

An open network basically means you can get in-network and you'll be offered the prevailing fee schedule once you are approved through the credentialing committee, which is usually less than what Medicare pays.

"This is the number one issue when a client comes to us," notes Lambrix. "They want to grow and expand, and reimbursement is very important. Understanding contracts and access to various markets are critical to their growth."

Lambrix and Brian Burns, vice president, managed care contracting, spoke about these issues during a Feb. 28, 2024, Lighthouse webinar, "How to Get In-Network & Improve Contract Negotiations.

Ann Lambrix

Brian Burns

Burns explains that the current payer landscape itself is confusing, with different types of PPOs and HMOs represented in Medicare Advantage, Medicaid and commercial payers. Despite changes to the healthcare environment, most Americans still receive health insurance through their employers, he says, and most are in PPOs.

"The payers try to get creative with prefixes and suffixes in describing and marketing their networks," notes Burns. "Something called HMO Select is going to be a smaller HMO than perhaps a larger HMO, which means fewer hospitals and fewer overall providers from which to choose. It's important to pay attention to what the name of a plan is, as it may indicate the size of the provider network." Another example may be a Blue Cross "Choice" health plan that may limit provider participation to a certain number of providers in a geographic area.

The decision by a payer to open or close a network is a business decision and does not require state approval as long as state access standards are still being met, says Burns, noting there are many reasons why a payer opens or closes a network.

"An open network basically means you can get in-network and you'll be offered the prevailing fee schedule once you are approved through the credentialing committee, which is usually less than what Medicare pays," he says. "A closed network always comes with an asterisk" as there may still be ways to get in such as if your lab offers a unique test or serves a special demographic.

While Quest and LabCorp continue to dominate provider lab networks, there are still opportunities for independent labs to make it into the network, especially if you know what payers are looking for. Among the ways to appeal to managed care payers:

- **Have an expansive test menu.** This adds value to a network.
- **Produce quality results with fast turnaround times.** Be able to share these results with

the payer. Lab values are very valuable for payers to receive as they help to fuel their internal population health management programs, particularly around chronic diseases.

- **Reach out to large physician practices that are in-network and get them to help you petition to get in-network.** Campaigns can work, says Burns, who suggests that postcards or letters be sent to the payer's marketing department or the executive suite. The notes should be professional and list the competitive advantages the lab offers to their network.
- **Partner with a local or regional organization to show a commitment to quality** (i.e., accountable care organizations, patient-centered medical homes and clinically integrated networks).
- **Offer unique, proprietary test services.**
- **Service a special demographic**.

Strategies for Pathologists

The NSA hit specialty groups, such as pathologists, particularly hard, says Lambrix, noting that being out of network actually gave them some leverage in their negotiations with payers as payers did not want members receiving surprise bills.

That said, pathology groups that are owned by hospitals or that have relationships with hospitals do have some leverage in their negotiations. Payers would prefer that their own pathology groups be in-network. But Lambrix acknowledges that independent pathology groups and labs may initially be more limited as to what the payer offers upfront but says that groups can improve their leverage over time.

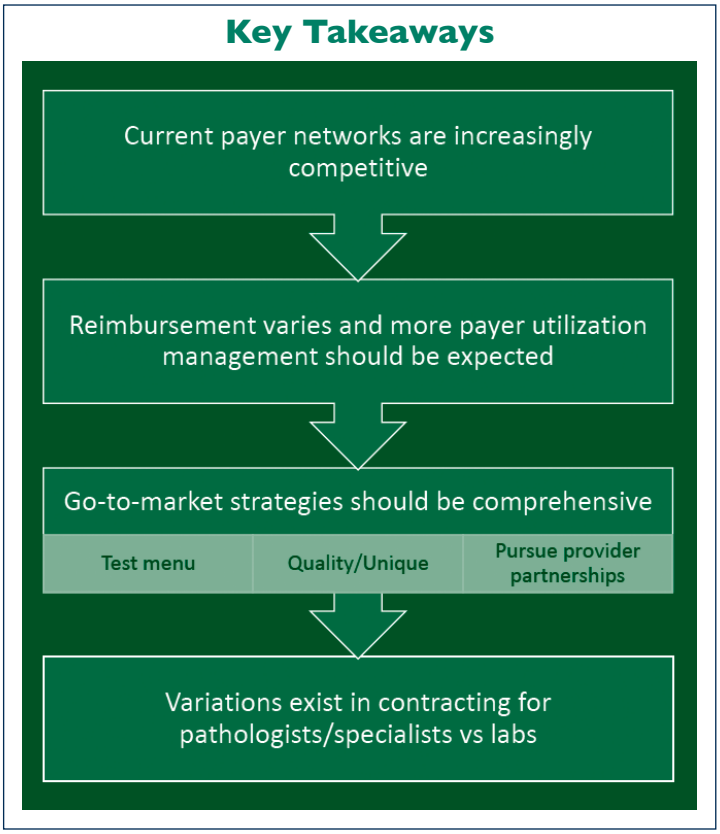
Burns adds that there are areas in the country where Quest and LabCorp don't want to be and notes that independent labs and path groups can fill a void in these areas.

"In year one, you're pretty much going to take the prevailing fee schedule the payer is offering. In some cases, that's 50% of Medicare although we have seen it as high as 110% of Medicare," he says. "Be the best provider you can, and once you have a track record, you have some leverage to try to negotiate an increase. Payers' margins are usually 2% or less, so a fair increase for a lab may be in the 3% to 5% range over a few years."

Create Added Appeal

Other ways that labs and groups can create added appeal for managed care providers:

- **Get credentialed** through a nationally recognized entity, such as the National Committee for Quality Assurance (NCQA). Report data in a way that pay-



ers can use in developing their HEDIS [Healthcare Effectiveness Data and Information Set] results. More than 227 million people are enrolled in plans that report HEDIS results. Additionally, many lab values cross-walk from HEDIS measures (which are for commercial plans) to Medicare Advantage Stars measures. Stars performance ratings, in part, rely on lab values, which may actually help to produce more revenue for the payer. Thus, supporting a payer's Stars initiatives is a great way to partner and be a valued network provider.

- **Participate in risk-based agreements and quality programs** (i.e., Blue Cross Blue Shield of Michigan's Physician Group Incentive Program).
- **Take care with appeal letters.** When a payer won't negotiate or says their network is closed, a good appeal letter that states your case in detail can make all the difference.

Negotiating Tips

Daniel Frier

Daniel Frier, a partner with the law firm of Frier Levitt (New York City) believes that one strategy clinical laboratories can use in their negotiating is to really sell how labs can help lower the total cost of care for a member.

"If labs are performing responsibly, they are helping to reduce the total cost of care," says Frier. "For example, genetic tests are expensive in the short term, but when used properly, they can reduce the total cost of care. Labs need to really sell these points when they are negotiating."

Frier also encourages labs to use their data as leverage in negotiations. "Payers want data," he says. "Labs can also develop data relationships with their referring doctors and provide that data to payers. Particularly in oncology, data is really sought after."

Labs should ask for auto renewal of their contracts and should attempt to get annual cost of living increases, advises Frier. He also suggests negotiating a two-year contract rather than one.

In terms of pitfalls when it comes to negotiating with payers, Frier says labs need to know what is and is not covered. "Make sure the tests you normally perform are included in the payer's coverage," he says. "You want to be sure you get paid for what you think you will be paid for."

Infinite Genomics Case Study

Infinite Genomics was formed as a molecular diagnostic laboratory in 2021. Although the lab is located in North Little Rock, Ark., it intended to offer PCR services to providers across the nation. To put that plan into action, the owners reached out to Lighthouse Lab Services.

"Their contract position was standard as they did not have many payer contracts prior to engaging us," notes Brennan Burns, VP of payer contracting for Lighthouse. "Since we specialize in working with lab startups, we knew there would be a handful of contracts we could obtain right away."

Getting a lab credentialed with insurance providers is essential to a smooth and consistent flow of reimbursements. Labs that remain out-of-network with particular payers often struggle to receive payments from those networks and will likely see payers try to steer patients in their region to in-network providers.

In this case, the lab's objective was to begin by obtaining national Medicaid and Blue Cross Blue Shield contracts, hoping to secure a partner to advance credentialing expeditiously.

Details on how Infinite Genomics was able to obtain its managed care contracts are available at https://www.lighthouselabservices.com/case-study-expanding-molecular-pcr-services-by-securing-nationwide-payer-contracts/.

NEW PROFICIENCY TESTING REQUIREMENTS TAKE EFFECT JULY 11, 2024 (*cont'd from page 1*)

Under current regulations, which have not been updated since 1988, PT is required for 86 analytes. The Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) have added 29 analytes to the list (see chart on page 6) and deleted five analytes: LDH isoenzymes, ethosuximide, quinidine, primidone and procainamide (and its metabolite, N acetyl procainamide).

The first time a lab fails, it has to conduct its own investigation. The second time, the accreditor or CMS will expect the lab to explain what happened. If a lab fails three times in a row, it has to stop testing that analyte for six months. That's called cease testing.

While the final rule takes effect in July 2024, the actual PT testing of the new analytes will begin Jan. 1, 2025, as PT testing operates on a calendar year, notes Brad S. Karon, MD, PhD, a professor of laboratory medicine and pathology at Mayo Clinic in Rochester, MN, and chair of the Council on Scientific Affairs for the College of American Pathologists.

"In the fall, labs will need to review what tests they have started and stopped doing," he explains. "They will need to re-enroll their analytes in a PT program for testing and enroll any new analytes."

Clinical laboratory testing has evolved significantly since 1992 when the Clinical Laboratory Improvement Amendments (CLIA) were implemented, and technology is now more accurate and precise than the methods in use at that time. In addition, many analytes not included in the CLIA PT regulations are now in routine clinical use. For example, tests for cardiac markers such as troponins and hemoglobin A1c were not routinely performed before 1992.

Brad Karon, MD, PhD

Participation in PT is required under CLIA for laboratories that perform moderate- or high-complexity testing. PT evaluates a laboratory's performance by testing of unknown samples just as it would test patient samples. An approved PT program sends unknown samples to a laboratory for analysis – five challenges three times per year. After testing, the lab reports its results to the PT program, which grades the results using the CLIA grading criteria and provides the lab with its scores. Labs may not refer PT testing to another laboratory. Laboratories must get four of the five challenges correct (80%) or the event will be considered unsatisfactory.

"The first time a lab fails, it has to conduct its own investigation," explains Karon. "The second time, the accreditor or CMS will expect the lab to explain what happened. If a lab fails three times in a row, it has to stop testing that analyte for six months. That's called cease testing."

There are seven CMS-approved proficiency testing programs: AAB – Medical Laboratory Evaluation, American Proficiency Institute, Accutest Inc., the College of American Pathologists, Commonwealth of Pennsylvania, Puerto Rico Proficiency Testing Service Program and WSLH Proficiency Testing.

Under the final rule, the grading criteria for PT testing is also more stringent than it had been previously, says Karon. Previously, CLIA prescribed a variety of acceptance limits (Als), including a multiple of the standard deviation around the mean of other participants in the peer group; fixed

limit as a percentage of assigned value; fixed limit in concentration units; and a mixture of percentage and concentration units, depending on the concentration of the analyte. For all new and currently required non-microbiology analytes, CMS will use fixed Als with or without percentages. Three analytes have only concentration-based Als: pH, potassium and sodium.

Microbiology

For microbiology specialties and subspecialties such as bacteriology and virology, the agencies also finalized requirements to specify broad categories of tests for which proficiency testing is required to allow flexibility for new technologies currently in use and those that may be developed in the future.

Under the final rule, laboratories that perform moderate and high complexity testing and also voluntarily participate in PT for waived tests are subject to compliance. This aligns the regulations with the CLIA statute, which does not exclude waived tests from the ban on improper PT referral.

The final rule also requires that the PT program have at least 10 laboratory participants for each specialty, subspecialty and analyte or test for which the PT program is seeking reapproval. CMS also clarified that certain contractors must be a private nonprofit organization or a federal or state agency, or an entity acting as a designated agent for the federal or state agency.

CLIA Regulation	New Analytes
General Immunology Section 493.927	Anti-HBs Anti-HCV C-reactive protein (high sensitivity)
Routine Chemistry Section 493.931	B-natriuretic peptide (BNP) ProBNP Cancer antigen (CA) 125 Carbon dioxide Carcinoembryonic antigen Cholesterol, low density lipoprotein, direct measurement Ferritin Gamma glutamyl transferase Hemoglobin A1c Phosphorus Prostate specific antigen, total Total iron binding capacity (TIBC), direct measurement Troponin I Troponin T
Endocrinology Section 493.933	Estradiol Folate, serum Follicle stimulating hormone Luteinizing hormone Progesterone Prolactic Parathyroid hormone Testosterone Vitamin B12
Toxicology Section 493.937	Acetaminophen, serum Salicylate Vancomycin

Former Lab Owner Faces Prison Time Over Fraudulent Billing

The former owner of a Missouri healthcare company and clinical laboratory has admitted submitting more than $3.8 million in fraudulent claims to Medicare, Medicaid and private healthcare benefit programs and faces up to five years in prison, a fine of up to $250,000, or both.

Carlos Himpler, 44, now of Baton Rouge, La., pleaded guilty Feb. 9, 2024, in U.S. District Court in St. Louis to a felony conspiracy charge. He is scheduled to be sentenced May 15.

Himpler, who at the time lived in St. Louis County, described himself as a "business development strategist" and owned or operated a series of healthcare-related businesses. Himpler's co-defendant, Franco Sicuro, MD, a psychiatrist, also owned businesses, including Advanced Geriatric Management LLC in Creve Coeur, Mo. In the fall of 2014, Himpler and Sicuro opened an in-house testing lab at AGM. They also opened Genotec DX, which they represented was a clinical testing laboratory, and agreed to split profits 50-50. Genotec was in the same building and used the same testing machine as AGM's lab.

According to the U.S. Attorney's Office for the Eastern District of Missouri, Himpler's and Sicuro's goal was to maximize their profits from the lab testing business. They sought accreditation for both labs under the Clinical Laboratory Testing Amendments of 1988 (CLIA). However, they did not disclose that both labs would employ the same part-time employee who would perform tests using the same machine, Himpler admitted in his plea.

To convince the state CLIA agency to grant Genotec a final certificate of compliance in November 2015, Himpler participated in causing Genotec to make misrepresentations to CLIA, including that Genotec's testing hours changed so that they no longer overlapped with AGM, that Genotec and AGM kept separate laboratory logs and that AGM stopped running lab samples and transferred its employee to Genotec in July 2015, when Genotec began running urine toxicology tests, the plea says.

They also concealed Sicuro's co-ownership of Genotec from Medicare, Medicaid and private healthcare insurers, while referring urine specimens from Sicuro's own practice, AGM, to Genotec.

Two Labs Billed for Same Testing

Himpler and Sicuro and other healthcare providers at AGM ordered urine toxicology tests for patients and referred those tests to AGM's lab and Genotec, which in turn sent the samples to outside reference laboratories. Both men knew that AGM and Genotec did not have the necessary testing equipment to confirm the amount of given toxin in the urine testing to a high degree of certainty, Himpler's plea says. They then billed health insurers for the testing.

Karen Lovitch

Under Medicare rules, the lab performing the testing must bill the Medicare program and cannot reassign the right to bill unless an exception applies, notes Karen Lovitch, chair of the Health Law Practice and co-chair of the Health Care Enforcement Defense Practice with Mintz (Washington, D.C.).

"If Genotec had complied with Medicare's 70/30 rule, it could have billed testing performed by another laboratory, but it presumably could not have done so given that it did not even have the necessary equipment," says Lovitch.

In March 2015, Himpler and Sicuro incorporated another laboratory company, Midwest Toxicology Group LLC, but never obtained CLIA certification or any lab equipment. Midwest was a lab in name only and was not authorized to perform tests on human specimens. When health insurers began scrutinizing claims submitted by Genotec and became resistant to paying them, Himpler and Sicuro created Midwest for the purpose of billing health insurers, the plea says. In many instances, each lab submitted a claim for the testing of the same specimen obtained from the same person on the same day of service, which Lovitch notes appears to be blatant fraud. The pair used Genotec's CLIA number.

If Genotec had complied with Medicare's 70/30 rule, it could have billed testing performed by another laboratory, but it presumably could not have done so given that it did not even have the necessary equipment.

Himpler admitted in his plea agreement that Medicare, Medicaid and private health insurers paid $3.8 million in fraudulent claims. Sicuro pleaded guilty in 2022 and was ordered to pay restitution. He also agreed to forfeit $3.1 million in assets.

Lovitch notes that a criminal prosecution related to misrepresentations to CLIA is a rare occurrence but adds that in this case it isn't surprising given the lengths to which these two individuals went to defraud third-party payers.

"It is also not surprising that the authorities detected this fraud given that urine toxicology testing continues to be under heavy government scrutiny," she says.

Lab Owner, Officer Sentence to Prison Over False Claims

A Lexington, Ky., toxicology lab, its owner and its compliance officer have agreed to more than $10 million in civil judgments to resolve False Claims Act (FCA) allegations. Both the owner and compliance officer have been sentenced to prison.

Ronald Coburn owned and operated LabTox LLC, a clinical laboratory that performed urine drug tests and billed them to Medicare and Kentucky Medicaid. Erika Baker was LabTox's director of operations and compliance officer. According to the U.S. Attorney's Office for the Eastern District of Kentucky, both Coburn and Baker knew that Medicare and Medicaid only pay for urine drug tests that are medically necessary. In his plea agreement, Coburn admitted knowing that urine drug tests ordered by courts for use in judicial proceedings are not medically necessary and thus not payable by Medicare or Medicaid.

With Coburn's knowledge and approval, however, Baker recruited a company called Blue Waters Assessment and Testing Services to refer court-ordered urine tests to LabTox. Coburn knew this was not medical testing but caused LabTox to bill the tests to Medicare and Kentucky Medicaid anyway, resulting in fraudulently-obtained payments of $1,864,429 between June 2019 and March 2021. Submission of these false claims for court-ordered urine drug tests constituted criminal healthcare fraud and also violated the FCA, triggering additional civil penalties. Coburn and LabTox's agreed civil judgment holds them liable for $5,592,287 because under the FCA, losses to the Medicare and Kentucky Medicaid programs are mandatorily trebled.

Baker's sentence and FCA judgment resulted from a similar fraud scheme. At Coburn's direction, Baker solicited urine drug tests from substance abuse recovery programs that did not provide

medical treatment—typically faith-based residential programs or homeless shelters. As part of the scheme, Baker misled sober home directors and induced the facilities to send LabTox more tests by putting facility staff on LabTox's payroll and compensating them based on the number of urine drug tests sent to the lab. Under Baker and Coburn's direction, LabTox billed Medicare and Kentucky Medicaid for urine drug tests, resulting in fraudulently obtained payment of $1,621,882. Baker and LabTox's agreed civil judgments hold them liable for $4,865,646, as mandatorily trebled damages.

The agreed civil judgments totaling $10,458,933 follow Coburn's and Baker's criminal convictions for healthcare fraud. In December 2023, Chief U.S. District Court Judge Danny C. Reeves sentenced Coburn to 46 months in prison and Baker to six months in prison, followed by six months of home confinement. Both were required to report to the Bureau of Prison's custody on Feb. 16, 2024.

The agreed civil judgments resolve a lawsuit brought by a private citizen under the *qui tam* provision of the FCA. As part of this resolution, the individual who filed the *qui tam* complaint will receive a portion of the settlement proceeds.

Labs Remain Under Heavy Scrutiny

While the facts in this case may seem egregious, it's a reminder that clinical laboratories remain under heavy scrutiny by the government, says Elizabeth Sullivan, chair of the healthcare practice group at McDonald Hopkins (Cleveland). This case involved a *qui tam* relator, which is a common way for laboratories to end up subject to government scrutiny, she notes.

Elizabeth Sullivan

"If the situation was not intentional fraud, at the very least there certainly appears to be a breakdown of compliance," she says, adding that there are actionable lessons labs can take away from this case related to compliance:

- Maintain an active compliance program, including policies and procedures and staff training that includes identifying, reporting and correcting fraud and abuse issues.
- Assess financial arrangements relating to business generation and sales and marketing to ensure that the arrangements do not run afoul of the federal fraud and abuse laws.
- The compliance officer role should be independent of any business development duties or incentives to avoid creating a conflict of interest.
- Not all medically unnecessary testing is as obvious as the situation described in this case. Ensure your laboratory has internal policies and procedures to monitor test orders in a way to identify medically unnecessary testing. If it appears that there are patterns of medically unnecessary testing being ordered, determine whether the situation can be addressed through education. Remember that overpayments are subject to the 60-day repayment rule, which requires investigation of suspected overpayments, calculation and repayment of any such overpayments.

Lab Groups Hail New Rule Streamlining Prior Authorization Requests

(*cont'd from page 1*)

The College of American Pathologists, the American Medical Association (AMA) and other physician organizations have been pressing CMS to revise the prior authorization system. On March 13, 2023, the CAP wrote a letter to CMS asking the agency to streamline the PA process, reduce physician practice burdens and prevent patient care delays in Medicare advantage and other public health plans.

Any prior authorization reforms must increase transparency and allow for swift approval decisions that recognize the value of timely patient access to laboratory testing for identifying, diagnosing and treating disease.

Survey data from the AMA show that 94% of physicians report care delays or disruptions associated with prior authorization. A 2022 report from the Health and Human Services Office of Inspector General (HHS OIG) highlighted concerns about prior authorization within Medicare Advantage, noting that inappropriate denials may prevent or delay beneficiaries from receiving medically necessary care and can burden providers.

The letter states that according to AMA's prior authorization survey, physicians and their staff spend an average of two business days per week completing the prior authorization workload for a single physician, and 88% of physicians describe their prior authorization burden as high or extremely high. CMS itself notes that "dissimilar payer policies, provider workflow challenges, inconsistent use of electronic standards and other technical barriers" associated with prior authorization are a "major source of burnout for providers."

Explanation and Transparency

Also beginning in 2026, impacted payers must provide a specific reason for denied prior authorization decisions, regardless of the method used to send the prior authorization request. Such decisions may be communicated via portal, fax, e-mail, mail or phone. According to the Centers for Medicare and Medicaid Services (CMS), this requirement is intended to both facilitate better communication and transparency between payers, provider and patients, as well as improve providers' ability to resubmit the prior authorization request, if necessary.

CMS is also requiring impacted payers to publicly report certain prior authorization metrics annually by posting them on their website. Among other improvements to the prior authorization process contained in the final rule:

- Requiring the PA process to be embedded within physicians' electronic health records, bring automation and efficiency to manual workflow.
- Mandating shortened PA processing timeframes.
- Requiring that payers provide physicians and patients more prior authorization-related information.

The American Clinical Laboratory Association (ACLA) believes the rule is a step in the right direction, but says it is encouraging CMS and bipartisan leaders in Congress to take additional measures to prioritize patient health and the critical role clinical laboratories play in informing patient care.

"Any prior authorization reforms must increase transparency and allow for swift approval decisions that recognize the value of timely patient access to laboratory testing for identifying, diagnosing and treating disease," says ACLA President Susan Van Meter. "These reforms would play a crucial role in enhancing effective use of screening and diagnostic tests so patients receive the right care at the right time."

COMPLIANCE 101:

Ensuring Compliance with Standing Orders under Medicare, Medicaid

Clinical laboratories must be very careful when relying on standing orders. The Department of Health and Human Services (HHS) carefully scrutinizes standing orders, especially when they have been in place for an extended period of time.

Although standing orders are not prohibited in connection with an extended course of treatment, too often in the past they have led to fraudulent and abusive practices, says the HHS Office of Inspector General (OIG) in its Model Compliance Plan for Clinical Laboratories. Labs must be vigilant about this and take appropriate steps to prevent abuse, the OIG stresses.

Thus, while laboratory compliance plans can permit the use of standing orders executed in connection with an extended course of treatment, the compliance plan should require the laboratory to monitor existing standing orders to ensure their continued validity.

"We suggest that, consistent with State law requirements, a laboratory should contact all nursing homes from which the laboratory has received such standing orders and request that they confirm in writing the validity of all current standing orders," the OIG writes. "In addition, in accordance with State law, laboratories should verify standing orders relied upon at draw stations with the physician, physician's office staff or such other persons authorized by law to order tests who have provided the standing orders to the laboratory."

With respect to End Stage Renal Disease (ESRD) patients, at least once annually, laboratories should contact each ESRD facility or unit to request confirmation in writing of the continued validity of all existing standing orders, says the OIG.

Meaning of Standing Orders

According to the Centers for Medicare and Medicaid Services (CMS), providers should be aware of the various meanings of the term "standing orders" (Complying with Documentation Requirements for Lab Services, MLN909221, September 2023). Some understand this to mean recurring orders specific to the care of an individual patient. Other interpret this as routine orders for services to a population of patients. Only medically necessary services ordered and provided, including those based on treatment protocols, are considered for payment when documentation supports the orders, and protocols are tailored to each patient.

"If you order diagnostic services for Medicare patients, you must also keep the documented order (including standing orders and protocols) or intent to order and medical necessity of the services in the patient's medical record," says CMS. "Keep this information available and submit it with the test results, upon request for a Medicare claim review."

CodeMap, a consulting company based in Chicago, advises that all standing orders be in writing and must be confirmed, at a minimum, every six months as to their continued validity. Laboratories should maintain on file all current, authorized standing orders and should maintain on file copies of all expired standing orders for a period of six years.

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

In Brief

Medicare Increases Specimen Collection Fees, Travel Allowance

For calendar year 2024, the Medicare Part B general specimen collection fee is increasing from $8.57 to $8.83. For specimens collected from a Medicare patient in a skilled nursing facility, the fee increases another $2, to $10.83 per specimen. To be eligible for the fee, the specimen must be used to perform a clinical diagnostic laboratory test, collected by a trained technician from a Medicare patient who is homebound or is a non-hospital inpatient and collected as a blood specimen through venipuncture or a urine sample collected by catheterization. The travel allowance mileage rate for specimen collection in CY2024 is $1.13. Medicare pays the per-mile travel allowance when the roundtrip travel to one location is greater than 20 eligible miles or when travel is to more than one location, regardless of the number of miles traveled. Medicare pays the travel allowance as a flat-rate allowance of $11.30 when the technician travels 20 eligible miles or less to and from one location for specimen collection from one or more Medicare patients.

Healthcare False Claims Judgments Exceed $1.8 Billion in FY23

Settlements and judgments under the False Claims Act (FCA) exceeded $2.68 billion in the fiscal year ending Sept. 30, 2023, according to the Department of Justice. The government and whistleblowers were party to 543 settlements and judgments, the highest number in a single year. Of the $2.68 billion, more than $1.8 billion related to matters involving the healthcare industry, including managed care providers, hospitals, pharmacies, laboratories, long-term acute care facilities and physicians. The FCA imposes treble damages and penalties on those who knowingly and falsely claim money from or fail to pay money to the United States.

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