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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

Seven Strategies for Ensuring Compliance in Hospital Outreach Laboratories

Because most hospital outreach laboratories don't have their own compliance officer or billing department, it's more important than ever for these labs to obtain adequate support from hospital administration so they can ensure they are in compliance with federal and state laws, as well as medical necessity and billing guidelines.

There are more than 3,000 hospitals and health systems that offer some form of lab outreach testing currently in the United States. Hospital outreach is defined as a hospital lab that provides testing for patients who are not receiving inpatient or outpatient services in the hospital. Hospitals with excess capacity in their labs often will contract with local physician groups to provide lab testing, offering an alternative to a national or regional independent laboratory. *Continued on page 2.*

Lab Compliance: Lessons Learned from 2023 Enforcement Activity

While there were many enforcement actions in 2023 involving Covid-19 testing, there are many other risk areas that labs should be aware of, including medical necessity, Medicare's 14-day rule, sham reference testing arrangements, waiver of patient copays, compensation of sales personnel and sham services arrangements, say David Gee and Caitlyn Forsyth, partners with Davis Wright Tremaine LLP.
Details on page 4.

Best Practices in Toxicology Billing and Coding

Getting paid for toxicology testing can be challenging if your lab does not have the proper billing and coding systems in place. During a recent webinar, Ann Lambrix, vice president of RCM Solutions, Lighthouse Lab Services, a consulting company based in Charlotte, NC, discussed best practices for toxicology billing and coding, including front-end processes, the importance of documentation, keys for requisitions, CPT/ICD-10 coding, internal and payer policies, denial management and key performance indicators and audits. *See page 8.*

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SEVEN STRATEGIES FOR ENSURING COMPLIANCE IN HOSPITAL OUTREACH LABORATORIES

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Ensuring compliance for outreach laboratories is more difficult because lab management has to convince typically conservative hospital administrators to think of outreach as a separate business generating income rather than just a cost center in the hospital, says Jane Hermansen, outreach and network manager at Mayo Clinic Laboratories in Rochester, MN. Too often, hospital labs are not fully recognized for their value and thus are not given the resources necessary to provide a service that is competitive with that of an independent lab.

Jane Hermansen

Hermansen and her team advise their hospital clients on how to set up and manage outreach laboratories. Their goal is to help hospitals keep lab testing local, with Mayo performing only specialized testing or testing the hospital lab can't provide (typically less than 5% of total testing). The outreach advisory service is a value-add for hospitals that use Mayo Clinic Laboratories as their primary reference lab. Currently, the Mayo outreach and network division is working with about 400 outreach labs.

"Laboratory outreach is not a department; rather, it is a service line that requires structure, support and a dedicated business focus," explains Hermansen. "Outreach is one of the top three most profitable service lines, but it's hard to make the case because lab is high volume, low dollar. A $30,000 surgery is going to get a lot more attention and support than a $65 lab test even though you may be doing 300 of those tests per day. Lab leaders need to demonstrate their value very specifically, and they need to be well-versed in the language of finance."

To be successful, Hermansen advises that managers of hospital outreach labs pay close attention to managing compliance in the following areas:

1. **Establishing a discounted fee schedule for outreach testing.** To be successful, an outreach lab must establish a separate, competitive outreach fee schedule and client-specific fee schedules so that testing is affordable. To do this, lab leaders should perform a cost-per-test analysis and set pricing in accordance with variable costs. Convincing administrators to leave behind the percent of charges mentality can be challenging, says Hermansen, but it's important to educate them that you are not reducing your charges, you are reducing your fee schedule. "The reality is you can get 0% of your market by charging $250 for a complete blood count (CBC) or you can get 80% of your market if your CBC is $50," she says. "You need to be careful not to price yourself out of the market."

2. **Getting paid.** Medical necessity and billing requirements are different for hospital lab outreach than they are for hospital inpatients. The most successful outreach programs have their own billing person or contract with an outside company that provides billing services, says Hermansen. Staff in the hospital's main billing department likely will not have the specific knowledge required to ensure compliance with Medicare's coverage policies or managed care providers' medical necessity requirements and are more likely to write off claims. For example, for inpatient Medicare patients, hospitals receive a predetermined, fixed amount under the Prospective Payment System – laboratory testing is included in this fixed amount. However, lab outreach testing is billed to the payer, whether federal or private.

   "Growing an effective outreach program requires a thorough understanding of how laboratory outreach testing is billed and identifying collection challenges," says Hermansen. "Successful outreach programs must be supported by billing processes that reduce write-offs and bad debt through prior authorizations and point-of-service collections."

3. **Meeting payer expectations.** Different payers have different requirements for the types of data they receive from labs. Some payers, for example, have HEDIS [Healthcare Effectiveness Data and Information Set] reporting built into the contract. The hospital outreach lab must ensure that it is providing payers with the correct data. Hermansen advises that leaders of outreach labs first understand what different payers require and then work with the hospital's information technology department to make sure it is able to capture and report that data.
4. **Ensuring connectivity of clients.** Ensuring the electronic health record (EHR) allows efficient access for providers to order laboratory tests and view results when located offsite is integral for maximizing efficiencies, as is using your hospital laboratory information system (LIS) to connect all market segments, such as the physician office, skilled nursing, other hospitals and home health. The Stark Law and Anti-Kickback Statute restrict how and what can be offered to lab clients (i.e., you cannot tie offers of connectivity to a certain volume or revenue). Hermansen advises consulting with legal counsel to ensure compliance.
5. **Setting up in-office phlebotomy.** There are strict rules governing a lab's use of phlebotomists in a provider's office. In some states it is allowed, in others it is not. One of the Health and Human Service Office of Inspector General's first fraud alerts, issued in 1994, dealt with a laboratory providing phlebotomists to a physician's office to collect samples for the lab. According to the OIG, the mere placement of a phlebotomist in a doctor's office would not necessarily indicate an unlawful referral arrangement, providing that the lab employee only performs services related to the collection of specimens. This is where things get tricky. To be in compliance with the law, the lab must ensure that the phlebotomist does not perform any other duties in the physician's office, such as taking vital signs, performing nursing functions or doing clerical work. Hermansen advises consulting with legal counsel to ensure there is a written contract specifying exactly what the phlebotomist is allowed to do. In addition, the phlebotomist should be closely monitored by the lab and the medical practice to ensure that the prohibitions in the contract are rigorously enforced. Hermansen says she has seen many different arrangements whereby labs provide phlebotomists to draw specimens in physicians' offices, including having an on-call phlebotomist who is available to draw from different offices as needed.
6. **Monitoring utilization of supplies.** The HHS OIG in 2005 issued advisory opinion 05-08 in which it said that a laboratory's provision of supplies to a physician's office for use in drawing specimens could potentially generate prohibited remuneration under the AKS if the supplies are not used specifically for the stated purpose. Hermansen advises that outreach labs have a process in place to monitor how supplies are used. "If you send 200 purple-top tubes a month to a provider, you had better be getting 200 purple-top tubes back," she says.
7. **Complying with the Eliminating Kickbacks in Recovery Act (EKRA)** and other laws. Whether the outreach program is new or expanding, a comprehensive sales and marketing strategy can amplify laboratory test offerings in the target area, enabling a competitive edge in the industry. However, hospital outreach labs must ensure they are in compliance with specific laws that govern sales practices in healthcare, such as EKRA and the Anti-Kickback Statute. "It's important to invest in a sales function, aligning compensation within legal guidelines," says Hermansen. "Mayo Clinic Laboratories even offers a training program for lab sales representatives."

Lab Compliance: Lessons Learned from 2023 Enforcement Activity

By David Gee, Partner, Seattle, Davis Wright Tremaine LLP, and Caitlin Forsyth, Partner, Portland, Davis Wright Tremaine LLP

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In the aftermath of the Covid-19 pandemic, 2023 was marked by many enforcement actions involving Covid-19 testing and Covid-19 test kits.[1] For example, in October 2023, a laboratory manager pleaded guilty to fraudulently submitting more than $359 million in claims for payment during the Covid-19 pandemic for expensive and medically unnecessary respiratory pathogen panel (RPP) tests. The government's allegations included that the manager obtained respiratory specimens purportedly for the purpose of performing Covid-19 tests but directed the laboratory to perform medically unnecessary RPP tests even though only Covid-19 testing had been ordered and even though there was no medical necessity supporting the performance of RPP tests.[2]

However, there are still many potential compliance missteps that laboratories not performing Covid-19 tests could take that would land them in hot water. This article highlights some of the risk areas for clinical laboratories to be mindful of, with a particular emphasis on lessons learned from recent enforcement actions including those related to Covid-19 testing.

Medical Necessity

In December 2023, pharmaceutical company Ultragenyx Pharmaceutical Inc. agreed to pay $6 million to resolve allegations that it caused the submission of false claims to Medicare and Medicaid by paying for free genetic tests to induce prescriptions of its drug. Ultragenyx entered into an arrangement with a genetic testing laboratory to provide genetic tests supporting medical necessity for Ultragenyx's drug at no cost to patients to induce the patients' treating physicians to prescribe the drug.[3] The laboratory was not part of the settlement, seemingly because none of the tests performed by the laboratory were billed to patients, payers, or government healthcare programs. Labs should nonetheless carefully consider any requests to participate in sponsored testing arrangements. There is potential risk of conspiracy allegations or False Claims Act (FCA) allegations linked to any tests referred by providers involved in the sponsored testing arrangements that are billed to federal healthcare programs.

In another case, the US Department of Justice (DOJ) announced in April 2023, that Genotox Laboratories Ltd. had agreed to pay $5.9 million to resolve FCA allegations that it submitted claims to federal healthcare programs for toxicology tests that were not covered and/or not reasonably and necessary, "including blanket orders and routine standing orders of drug testing for all patients in a provider's practice." According to the DOJ press release, "Genotox admitted and

[1] See, e.g., Justice Department Announces Nationwide Coordinated Law Enforcement Action to Combat COVID-19 Health Care Fraud, Press Release, United States Department of Justice, available at: https://www.justice.gov/opa/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat-covid-19

[2] Woman Pleads Guilty to $359M Fraud Involving Claims for Unnecessary Respiratory Tests Submitted with COVID-19 Tests, Press Release, United States Department of Justice, available at: https://www.justice.gov/opa/pr/woman-pleads-guilty-359m-fraud-involving-claims-unnecessary-respiratory-tests-submitted

[3] Pharmaceutical Company Ultragenyx Agrees to Pay $6 Million for Allegedly Paying Kickbacks to Induce Claims for Its Drug Crysvita, Press Release, United States Department of Justice, available at: https://www.justice.gov/opa/pr/pharmaceutical-company-ultragenyx-agrees-pay-6-million-allegedly-paying-kickbacks-induce

accepted responsibility for offering healthcare providers order forms known as 'custom profiles' for each provider to pre-select the tests to order, which Genotox then performed and billed, for all or nearly all of the provider's patients, generally at the highest reimbursement categories, such as definitive drug testing for 22 or more drug classes."[4]

Laboratories should carefully review the local coverage determinations issued by their Medicare contractors and coverage guidelines issued by their top payers and plan to follow up with providers with outlier ordering patterns to (re)educate such providers on the medical necessity guidelines.

Medicare's 14-Day Rule

In October 2023, Genomic Health, Inc. agreed to pay $32.5 million to resolve allegations that it submitted false claims to Medicare by submitting claims for testing in violation of Medicare's 14-day rule.[5]

Medicare's 14-day rule prohibits laboratories from separately billing Medicare for covered tests if a physician ordered the test within 14 days of the patient's discharge from a hospital stay. Laboratories providing tests for such patients are expected to bill the hospital directly as, for inpatients, the reimbursement the hospital receives from CMS for the hospital stay is intended to cover the costs of the tests and, for outpatients, the hospital is expected to seek reimbursement for the tests directly from Medicare.[6]

Hospital ("Sham") Reference Testing Arrangements

In December 2023, two men were sentenced to six and eight years in prison for their roles in a fraudulent scheme that used rural hospitals to bill for urine drug testing that was not reimbursable and not medically necessary. The government's allegations included that the men used rural hospitals "for billing in order to take advantage of private insurance contracts that provided higher reimbursement rates for these hospitals than for out-of-network laboratories," and that "the claims were submitted to falsely appear that the hospitals themselves did the laboratory testing when, in most cases, it was done by testing laboratories controlled by others."[7]

Claims for tests performed by a laboratory other than the laboratory or other provider submitting the claim should identify the fact that the test was referred out and the identity of the performing laboratory, in accordance with Medicare and payer guidelines on completion of the claim form and coding. Moreover, labs must also comply with the clear requirements of CLIA[8] and applicable state laws[9] requiring that the identity of the performing laboratory be properly disclosed on the test report.

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[4] Texas Laboratory Agrees to Pay $5.9 Million to Settle Allegations of Kickbacks to Third Party Marketers and Unnecessary Drug Tests, Press Release, United States Department of Justice, available at: https://www.justice.gov/opa/pr/texas-laboratory-agrees-pay-59-million-settle-allegations-kickbacks-third-party-marketers-and

[5] Genomic Health Inc. Agrees to Pay $32.5 Million to Resolve Allegations Relating to the Submission of False Claims for Genomic Diagnostic Tests, Press Release, United States Department of Justice, available at: https://www.justice.gov/opa/pr/genomic-health-inc-agrees-pay-325-million-resolve-allegations-relating-submission-false

[6] Frequently Asked Questions Revised Laboratory Date of Service Exception Policy, CMS, available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallabfeesched/downloads/clfs-dos-faqs.pdf

[7] Two Men Sentenced for Fraudulent Rural Hospital Billing Scheme, Press Release, United States Department of Justice, available at: https://www.justice.gov/opa/pr/two-men-sentenced-fraudulent-rural-hospital-billing-scheme

[8] See, 42 CFR §493.129.

[9] See, e.g., California Business & Professions Code § 1288.

Waiving Patient Copayments

In November 2023, a federal grand jury returned an indictment charging the owner and chief executive officer of a laboratory for his role in an alleged scheme to defraud federal healthcare programs of over $148 million in medically unnecessary definitive urine drug testing services. The government alleged that the defendant billed federal healthcare programs for definitive drug testing of not less than 15 substances in all urine specimens it received, regardless of the patient's treatment plan and history, or the request of the referring provider. Alleged actions contributing to the performance of medically unnecessary tests included "writing off patient co-pays, directing [laboratory] staff to fill out and submit order forms on providers' 'behalf,' concealing the true nature, permissibility and extent of testing from providers, orchestrating a pass-through billing scheme using hospitals, and paying kickbacks to physicians disguised as laboratory ownership interests."[10]

Although federal guidance and state laws recognize circumstances in which it may be appropriate for laboratories to waive patient responsibilities, the guidelines make clear that such circumstances are limited and not routine. Labs should also make sure such limited circumstances are delineated clearly in written internal and external billing policies on patient assistance and other appropriate discounts (e.g., cash or prompt payments).

Compensating Sales Personnel

Compensating sales personnel on a formula that takes into account the volume or revenue associated with the laboratory tests attributable to their sales efforts presents increasing risk under, potentially, the federal Anti-Kickback Statute (AKS) and the Eliminating Kickbacks in Recovery Act (EKRA).

For example, in January 2024, RDx Bioscience Inc. and its owner and CEO agreed to pay more than $13 million to resolve FCA allegations involving illegal kickbacks and medically unnecessary laboratory testing. The government alleged RDx paid five types of kickbacks to induce referrals of laboratory tests to RDx, one of which was RDx's payment of "commissions based on the volume and value of Medicare and Medicaid referrals to independent contract marketers."[11]

Although laboratories have long relied on the bona fide employee safe harbor under the federal AKS to compensate W-2 sales personnel on a variable basis (i.e., percentage of sales commissions), EKRA calls into question the propriety of that familiar approach. The sole EKRA exception protecting remuneration for marketing lab testing requires that the employee's or contractor's payment must not be determined or vary by "the number of individuals referred to a … laboratory; the number of tests or procedures performed; or the amount billed to or received from… the healthcare benefit program…."[12]

Likely due to competitive concerns, many laboratories apparently remain reluctant to depart from their long-standing practice of paying sales personnel a percentage of sales commissions.

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[10] Man Charged in $148M Medicare and Medicaid Fraud Scheme, Press Release, United States Department of Justice, available at: https://www.justice.gov/opa/pr/man-charged-148m-medicare-and-medicaid-fraud-scheme (emphasis added).

[11] New Jersey Laboratory and Its Owner and CEO Agree to Pay Over $13 Million to Settle Allegations of Kickbacks and Unnecessary Testing, Press Release, United States Department of Justice, available at: https://www.justice.gov/opa/pr/new-jersey-laboratory-and-its-owner-and-ceo-agree-pay-over-13-million-settle-allegations

[12] 18 U.S.C. § 220.

However, failure to come into compliance with EKRA may carry steep penalties, including a prison sentence.

For example, in October 2023, Mark Schena, the president of Arrayit Corporation, was sentenced to eight years in prison and ordered to pay $24 million for participating in, among other things, a scheme to pay kickbacks to marketers in the form of percentage of sales commissions to induce physicians' referrals of medically unnecessary allergy testing, in violation of EKRA.[13]

Sham Services Arrangements

Although AKS safe harbors and the EKRA exception described above may permit a laboratory to compensate physicians and others in a position to refer or influence referrals of testing to the laboratory for rendering legitimate (non-referral) services, so long as the agreement satisfies the requirements of the safe harbor and/or exception,[14] such compensation is protected only if the person receiving payment actually performs the legitimate services. Several recent enforcement actions involve allegations of "sham" management and consulting services that either were not performed or that were prohibited marketing practices.

For example, in December 2023, a former hospital executive and three physicians agreed to pay $880,000 to resolve FCA allegations also involving kickback allegations. The government alleged that the hospital executive and the physicians received thousands of dollars in payments from a purported management services organization (MSO) in return for ordering laboratory tests from a laboratory owned and operated by the MSO. The government alleged, effectively, that the MSO's "sham" payments to the physicians were in fact inducements to refer to the laboratory, and not payments for management services, as the physicians in fact provided no management services.[15]

Similarly, in August 2023, in a different type of sham arrangement, the owner of an Atlanta laboratory (LabSolutions) was sentenced to 27 years in prison due to his role in a scheme to defraud Medicare by billing Medicare for over $463 million in claims for genetic and other laboratory tests. The lab owner allegedly paid patient brokers to obtain signed doctors' orders from telemedicine companies. To conceal the alleged kickbacks, the lab owner allegedly "required patient brokers to sign sham contracts that falsely stated that the brokers were performing legitimate advertising services for LabSolutions, when … the brokers were [instead] deceptively marketing to Medicare beneficiaries and paying kickbacks and bribes to telemedicine companies for genetic testing prescriptions."[16]

Laboratories hoping to avoid government and payer scrutiny would be well served to learn from recent enforcement actions and incorporate proactive compliance monitoring aimed at the risk areas discussed in this article.

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[13] Silicon Valley Executive Sentenced For Defrauding Investors And Participating In Covid-19 And Allergy Testing Scheme, Press Release, United States Department of Justice, available at: https://www.justice.gov/usao-ndca/pr/silicon-valley-executive-sentenced-defrauding-investors-and-participating-covid-19-and

[14] See, 42 CFR § 1001.95218 U.S. Code § 220(b)(4).

[15] Hospital Executive and Three Texas Physicians to Pay Over $880,000 to Settle Kickback Allegations Involving Laboratory Testing, Press Release, United States Department of Justice, available at: https://www.justice.gov/opa/pr/hospital-executive-and-three-texas-physicians-pay-over-880000-settle-kickback-allegations

[16] Lab Owner Sentenced for $463M Genetic Testing Scheme, Press Release, United States Department of Justice, available at: https://www.justice.gov/opa/pr/lab-owner-sentenced-463m-genetic-testing-scheme (emphasis added)

BEST PRACTICES IN TOXICOLOGY BILLING AND CODING (*cont'd from page 1*)

Front-End Processes

Before a lab submits claims for toxicology services, it should make certain that its front-end processes are working efficiently. This means ensuring the flow of clean data for proper billing, building rules in the lab information and billing systems and reviewing CPT codes to make sure you are capturing all the charges and double-checking that test requisitions are properly coded and signed by the ordering physician.

"You want to make sure that the interfaces are running properly and the codes that you are putting on claims are correct and are being accepted by the payer and that your requisitions have the appropriate order and information needed to document the claims," says Lambrix. "This is all part of billing compliance, so we want to make sure we're checking all the boxes so that what you're submitting not only is correct for payment but will protect you in case of a payer audit."

Documentation

Payers are increasingly requesting medical records and clinical notes to make certain that the toxicology testing being performed is medically necessary, explains Lambrix. The lab must ensure that the test order has a valid signature, that it indicates all drugs and drug classes to be tested and that the documentation supports the medical necessity.

Ann Lambrix

When a definitive/quantitative test is performed, the record must also show that an inconsistent positive finding was noted on the presumptive testing or that there was no available, commercially or otherwise, presumptive test.

"You want to avoid ordering panels just because it's routine," she says. "There has to be a well-documented reason why you order a panel. When we do audits, that is sometimes where we see problems. Even though you may be submitting claims electronically and the documentation isn't included, you run the risk if a payer denies the claim and asks for records or if a payer does a post-payment review and wants their money back. It is imperative that there is an assessment and quality assurance process to review documentation and what might need to be improved."

While the frequency of payer audits declined during the height of the Covid-19 pandemic as payers' attention was diverted, Lambrix says that payers are once again ramping up pre-payment and post-payment reviews and audits. Just because a lab was paid for a claim, doesn't mean the claim was accurate, she notes. If documentation is poor, the lab risks not only takebacks by payers but also potentially loss of contract with the payer.

Requisition

A test requisition must include adequate patient identification information, patient sex, date of birth, name and address of the physician or of the laboratory referring the specimen, tests requested, date of specimen collection, source of specimen (when appropriate), clinical information (when appropriate) and the ordering physician's signature.

"When you're billing for toxicology tests, the requisition is very important," says Lambrix. "It's important to review the design and make sure that it's capturing the required information. It's also critical that you get the ordering physician's signature. What we see quite often in our reviews is that the ordering physician's signature is missing."

Data Flow

The laboratory information system and interfaces manage the flow of data within your lab. It is crucial that the lab review information on a regular basis to ensure that the data flowing through the system, such as fee schedule, patient demographics and charges, is accurate.

"We recommend that you have one fee schedule for all payers and not separate fee schedules for different payers because then you run the risk of pulling the wrong fee schedule for the wrong payer," says Lambrix. "We do recommend that you have a self-pay or cash fee schedule, and then, of course, you may have client bill fee schedules. You want to make sure that the interface and the feed that goes over to billing is pulling the correct fee schedule."

Having correct patient demographic information is also key to getting paid, she says, noting that incorrect patient information is responsible for a large number of denials. In addition, the lab must ensure that charges are mapped correctly for each payer. Lambrix advises that labs review these types of information at least yearly if not more often to ensure the interfaces are set up correctly.

CPT and ICD-10 Codes

While most payers prefer a bundled code, some actually want codes to be exploded, says Lambrix. If you are billing a bundled code and getting denied, check with your payer to see if they want individual codes listed.

Presumptive drug testing may be performed prior to definitive drug screen testing when a provider wants to rule out illicit drug use or to confirm the presence of a particular drug class without identifying individual drugs. Presumptive drug test codes include 80305, 80306 and 80307. Definitive drug testing codes range from 80320 to 80377 (G0480-G0483, with the exception of certain state payers).

ICD-10 codes are an important indicator of medical necessity, says Lambrix, who warns that labs should never change codes—any change should come from the ordering provider.

We recommend that you have one fee schedule for all payers and not separate fee schedules for different payers because then you run the risk of pulling the wrong fee schedule for the wrong payer.

"When you are submitting claims, payers don't get your documentation—they get a CPT code and they get a diagnosis code (ICD-10) and that has to tell why the patient is being tested for a particular drug," she says.

Billing Policies

Labs should have specific billing policies in place for patient billing, bad debt, adjustments and write-offs, advises Lambrix. If a patient has a copay, it's crucial that the lab attempt to collect that money. Not attempting to collect that money can raise compliance concerns or potential accusations that you are giving away services for free.

"A patient billing policy must be consistent across the board – what you're going to do with denials, what you're going to do with patient out of pocket, how many statements you're going to send, if there are discounts and, if so, what they look like," she says.

Bad debt and adjustment/write-off policies should also be spelled out, advises Lambrix. Anyone involved in billing should know when bills can be adjusted and when they should be written off. In some cases, it makes sense to have a third-party billing partner you can turn to for help.

"Toxicology billing isn't difficult, but there are some nuances that may be different from the other procedures you bill for," she says.

Payer Policies and Procedures

It's not just a question of whether you are contracted with a particular payer but whether the payer is willing to reimburse for the services performed, notes Lambrix. Just because Medicare pays for a particular test doesn't mean a managed care provider will pay for that test. Labs must understand payer policies, including prior authorization requirements and payer edits.

"All of these things, as you learn them, can be put on the front end of your billing systems so that you can prevent the mess that can occur on the back end," she says.

Denial Management

While no lab wants to have their claims denied, denials can actually be good opportunities to identify and fix problems on the front end, believes Lambrix. For example, if a payer indicates that a claim was not paid because it wasn't medically necessary or because it was not covered, this presents an opportunity for the lab to review and update its payer policies.

"Provider not eligible to perform service" is an indication that you are not in the payer's managed care plan. "Frequency limits exceeded" is a signal that you need to check the payer's policy or Medically Unlikely Edits. "Service is included in another service/procedure" means you should check National Correct Coding Initiative edits.

Billing Key Performance Indicators

Labs should establish key performance indicators (KPIs) in billing to help identify trends and potential billing problems, advises Lambrix, noting "what gets measured gets managed."

"We want to make sure when you bill a claim it is getting paid and the volume of tests you are performing is translating correctly to the volume that is billed," she says.

Top billing KPIs include clean claim/first-pass rate; bad debt/write-offs; gross collection rate; net collection rate; average price per accession; average payment per accession; denial rate (by test/CPT/client); days in accounts receivable; and pay ratio.

Prepare for Audits

Audits are to be expected and are not anything to be afraid of, says Lambrix. Payers expect you to understand the rules and are making payments in good faith.

"Just because you get paid for testing does not mean you get to keep the payment," she says. "You have to make sure you are prepared for audits and that you have sound processes on the front end."

Payers will be looking for "red flags" in toxicology billing, which include unbundling, overcoding and overutilization. Most payers prefer to have toxicology billing done using G codes, and if you bill codes in the 80000 series, that could be a problem, she says.

"Keep a close eye on overutilization," advises Lambrix. "If all you are billing is G0483, you likely will be flagged for an audit."

COMPLIANCE 101:

Ensuring Compliance with Medicare's Billing Policies

Laboratory compliance policies should ensure that all claims for testing and services submitted to Medicare or other federally funded healthcare programs are accurate and correctly identify the services ordered by the physician (or other individual authorized by law to order tests) and performed by the laboratory, according to the Health and Human Services Office of Inspector General (HHS OIG).

Laboratories should ensure that the CPT or HCPCS code that is used to bill Medicare or Medicaid accurately describes the service that was ordered and performed. To ensure code accuracy, laboratories may wish to include a requirement that the codes be reviewed by individuals with technical expertise in laboratory testing before such codes are approved for claims submissions.

The OIG views intentional upcoding (i.e., the selection of a code to maximize reimbursement when such code is not the most appropriate descriptor of the services) as raising false claims issues. If a lab continued to have questions about code selections, even after review by technical experts, the facility should direct its questions to its Medicare carrier or intermediary.

Medicare carriers and intermediaries have established lists of tests that must be accompanied by diagnostic information to establish medical necessity before Medicare coverage will be assumed. Laboratory compliance policies should direct that laboratories only submit diagnostic information obtained from the test ordering physician. Laboratories should not: 1) Use diagnostic information provided by the physician from earlier dates of service (other than standing orders); 2) use "cheat sheets" that provide diagnostic information that has triggered reimbursement in the past; 3) Use computer programs that automatically insert diagnosis codes without receipt of diagnostic information from the physician; or 4) make up diagnostic information for claims submission purposes.

Laboratories should: 1) contact the ordering physician to obtain diagnostic information in the event that the physician has failed to provide such information; 2) provide services and diagnostic information supplied pursuant to a standing order executed in connection with an extended course of treatment; and 3) accurately translate narrative diagnoses obtained from the physician to ICD-10 codes.

Tests Covered by Claims for Reimbursement

Laboratory compliance policies should ensure that the lab only submits claims for tests that were both ordered and performed. If a laboratory receives a specimen without a test order or with an ambiguous test order that is subject to multiple interpretations, the facility should check with the doctor to determine what tests he or she wanted performed before submitting a claim for reimbursement to Medicare.

Thus, if a lab performed a test that the doctor did not order, the lab will not erroneously bill for that test. Similarly, if a lab cannot perform an ordered test due to, for example, a laboratory accident or insufficient quantities of specimen, the lab should not submit a claim to Medicare. The OIG considers the submission of a claim for tests that were either not ordered or were not performed to be a potential false claim.

In Brief

New Jersey Lab, Owner Agree to Pay More Than $13 Million Over Fraud Allegations

RDx Bioscience (RDx) of Kenilworth, NJ, and its owner and chief executive officer Eric Leykin of Brooklyn, NY, have agreed to pay $10.3 million to the federal government to resolve False Claims Act allegations involving illegal kickbacks and medically unnecessary laboratory testing. RDx and Leykind will pay an additional $3 million to the State of New Jersey, which jointly funded claims paid by the New Jersey Medicaid program. RDx and Leykin have agreed to cooperate with investigations of and litigation against other participants in the alleged schemes. The settlement resolves five types of kickbacks paid to induce referrals to RDx for lab testing, including commissions paid based on the volume and value and referrals and kickbacks paid to one or more substance abuse recovery centers.

Elizabeth Holmes Excluded from Participation in Federal Health Programs for 90 Years

The Health and Human Services Inspector General Christi Grimm announced Jan. 19, 2024, that it has excluded Elizabeth Holmes for 90 years from participation in the federal healthcare programs due to her January 2022 conviction in the United States District Court, Northern District of California, for wire fraud and conspiracy to commit wire fraud against Theranos Inc. investors. The statutory minimum for exclusion based on convictions like Holmes's is five years, but when aggravating factors are present, a longer period of exclusion is justified. Holmes was sentenced in May 2023 to 11 years in federal prison and ordered to pay $452 million in restitution. Holmes founded Theranos Inc. in 2003 and served as its CEO and chairperson. Under her direction, Theranos claimed to have developed proprietary technology that was able to run several clinical diagnostic tests on small amounts of blood from a finger prick instead of through veinous draws. That was later proven to be false. Holmes' claims defrauded investors out of millions of dollars.

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