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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

HHS OIG Nixes AP Purchased Services Agreement

Anatomic pathology (AP) laboratories should be extremely cautious about entering into purchased services agreements with other laboratories. A new Advisory Opinion from the Health and Human Services (HHS) Office of Inspector General (OIG) advises that such agreements could generate prohibited remuneration under the federal Anti-Kickback Statute (AKS) and could be subject to sanctions. *More on page 2.*

FDA Tries Once Again to Regulate LDTs, Lab Groups Push Back

Clinical and anatomic pathology laboratory groups are decrying the Food and Drug Administration's (FDA) latest attempt to regulate lab-developed tests, arguing the agency continues to lack the authority for such oversight. As anticipated, the agency on September 29 issued a proposed rule that would allow the FDA to regulate LDTs as medical devices, much as they do in vitro diagnostic (IVD) tests manufactured by IVD companies. *Continued on page 4.*

Genomic Health Pays $32.5 Million to Settle FCA Allegations

Genomic Health Inc. (Redwood City, CA) has agreed to pay $32.5 million to resolve allegations that it violated the False Claims Act (FCA) by engaging in a nationwide scheme to improperly bill Medicare for certain laboratory tests used to diagnose and treat cancer patients. Genomic Health is a wholly-owned subsidiary of Exact Sciences Corporation (Madison, WI), which acquired it in November 2019. *Details on page 7.*

Navigating the CMS Audit Appeals Process: A Primer

The intricate world of healthcare constantly introduces an array of challenges for providers, including clinical laboratories. Mastery of the Centers for Medicare and Medicaid Services (CMS) audit appeals process is crucial to ensure full compliance with regulatory requirements but also to safeguard your lab's financial stability. *Laboratory Economics Compliance & Policy Report* recently spoke with Guillermo Beades, a partner with Frier Levitt (New Jersey) and cochair of the firm's insurance defense department about how to navigate CMS's audit appeals process. *See Q&A on page 9.*

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HHS OIG Nixes AP Purchased Services Agreements (*con't from page 1*)

In Advisory Opinion 23-06, issued Sept. 25, a requestor asked for the OIG's opinion on a proposed arrangement. Under this proposal, other laboratories had approached the requestor, an independent AP laboratory, about entering into written agreements that would require the requestor to purchase the TC from these other labs (some of which employed and/or were owned by physicians who might refer patients to the requestor). The requestor, in turn, would perform the PC and bill commercial insurers as an in-network provider for both the TC and PC and pay the other lab a fair market value per-specimen fee for performing the TC.

The other labs wanted to enter the proposed arrangement because of their out-of-network status with certain commercial insurers which prevents them from billing for certain AP services. Notably, the arrangements would not involve the purchase of AP services reimbursable by federal healthcare programs, the requestor explained.

This type of arrangement is known as a "purchased services" arrangement and is less common in the laboratory industry than client billing, according to Karen Lovitch, chair of the Health Law Practice with Mintz, a law firm in Washington, D.C.

Karen Lovitch

In a typical client billing arrangement between an AP laboratory and a physician practice, the treating physician orders an AP service, the laboratory performs one component of the AP service, the ordering physician's practice performs the other component, and the treating physician buys the component performed by the laboratory and bills the third-party payer for both components of the AP service.

"The parties enter into these arrangements for a variety of commercially reasonable reasons. For example, the physician practice may lack the infrastructure, personnel and equipment necessary to perform the TC, but it may prefer to interpret its own slides—that is, perform the professional component," explains Lovitch.

Purchased Services Agreement Implicates the AKS

In this opinion, the OIG concluded that the proposed purchased services arrangement implicated the Anti-Kickback Statute (AKS) and did not satisfy the safe harbor for personal services and management contracts, noting that the "Requestor was unable to certify that the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services."

In explaining this conclusion, the OIG highlighted several facts:

- The proposed arrangement would allow the requestor to give the other labs the opportunity to bill and receive payment for services they would otherwise not be able to bill due to their out-of-network status.
- In most instances, the requestor had the ability to perform the TC and PC itself and doing so was generally more efficient and cost-effective than paying a third party to perform the TC.
- Because the other labs did not have contracts that allowed them to bill commercial insurers for AP services, the physician owners/employees of the other labs would be more likely to refer AP services to laboratories that are in-network with commercial insurers.

- Entering into the proposed arrangement would likely result in referrals of federal healthcare program business to the requestor and, conversely, if the requestor did not enter into the proposed arrangement, it likely would not receive a significant volume of referrals, including federal healthcare program business, from the other labs.

Lovitch says that the OIG, not surprisingly, noted that the "carve out" of federal healthcare program business to minimize risk under the AKS did not save the proposed arrangement.

"For years, the OIG has viewed 'carve out' arrangements skeptically and has characterized them as potentially 'disguising remuneration for federal healthcare program business through the payment of amounts purportedly related to non-federal healthcare program business,'" she explains. "While the OIG commented that the carve out of federal healthcare business was 'not dispositive with respect to whether the proposed arrangement implicates' the AKS, the OIG usually view carve outs with suspicion."

"For years, the OIG has viewed 'carve out' arrangements skeptically and has characterized them as potentially 'disguising remuneration for federal healthcare program business through the payment of amounts purportedly related to non-federal healthcare program business.'"

Lovitch says the result here is not surprising for at least two reasons. First, she says the requestor presumably sought an unfavorable advisory opinion to prevent competitors from engaging in this business practice, which may have colored the OIG's views of the proposed arrangement.

Second, the OIG often views laboratory industry arrangements critically, she says, pointing to, for example, AO 15-04 in which the OIG said that exclusive arrangements between a lab and a physician practice could potentially generate prohibited remuneration under the AKS and AO 22-09, in which the OIG frowned upon a proposed arrangement under which a network of labs would compensate hospitals for certain specimen collection services.

Lovitch also points out that while the OIG issued an unfavorable opinion of a client billing arrangement in AO 99-13, laboratories across the country continue to enter into such arrangements, with appropriate safeguards in place. In that advisory opinion, the OIG concluded that the "proposed arrangement might constitute prohibited remuneration under the AKS if the requisite intent to induce referrals of federal healthcare program business were present."

Any lab contemplating a purchased services arrangement should consult with their compliance officer and legal counsel before entering into such an agreement, advises Lovitch.

"Going forward, laboratories should evaluate their purchased services arrangements and decide whether they present healthcare regulatory risks in light of this most recent advisory opinion," she says.

FDA Tries Once Again to Regulate LDTs, Lab Groups Push Back (*con't from page 1*)

In the proposed rule, the FDA seeks to amend its regulation defining "in vitro diagnostic products" to add the words, "including when the manufacturer of these products is a laboratory." While the proposed new regulatory text is only 10 words, the majority of the regulatory preamble is focused on FDA's justification for issuing the proposed rule and its claimed legal basis for doing so.

The American Clinical Laboratory Association (ACLA), the Association for Diagnostics and Laboratory Medicine (ADLM, formerly AACC), the College of American Pathologists (CAP) and others argue that the medical device framework used by the FDA to regulate IVDs does not work for LDTs, that the FDA has never had authority under the Food, Drug & Cosmetic Act (FDCA) to regulate LDTs and instead are urging the administration to work with the groups on other ways to ensure LDTs are safe and accurate. ACLA is specifically calling on the Administration to reengage with Congress on legislation tailored to diagnostics.

Historically, the FDA has exercised enforcement discretion over most LDTs because it has viewed them as lower risk due to the small volume and specialized needs of the single clinical laboratory's patient population, notes Jessa Boubker, an associate with Foley & Lardner LLP in Boston (See Boubker, Faget & Beaver, FDA Laboratory Developed Test Oversight: What Stakeholders Need to Know About Proposed Overhaul, *Health Care Law Today*, Oct. 10, 2023). The rule proposes to phase out this "enforcement discretion" over five years so that LDTs would fall under the same enforcement approach as other IVDs.

Jessa Boubker

Currently, LDTs are primarily regulated by CMS under the Clinical Laboratory Improvement Amendments (CLIA), which mostly focuses on laboratory processes and not the clinical validity of a test (i.e., how useful the test is in informing and supporting clinical decisions). Rather, CLIA requires labs to document analytical

Proposed Phaseout Timeline

STAGE	ACTION
Stage 1 (one year after final rule publication)	Ending the general enforcement discretion approach with respect to medical device reporting requirements and correction and removal reporting requirements (which will enable the FDA to systematically monitor adverse events)
Stage 2 (two years after final rule publication)	Implementation of all additional, but previously not regularly enforced, medical device requirements (e.g., registration and listing, labeling, investigational use requirements), except Quality System (QS) and premarket review requirements.
Stage 3 (three years after final rule publication)	Ending the general enforcement discretion approach with respect to QS requirements.
Stage 4 (three and one-half years after final rule publication, but not before October 2027)	Ending the general enforcement discretion approach with respect to premarket review requirements for high-risk IVDs (i.e., Class III medical devices), as well as Humanitarian Use Device LDTs.
Stage 5 (four years after final rule publication, but not before April 2028)	Ending the general enforcement discretion approach with respect to premarket review requirements for moderate-risk (i.e., Class II medical devices) and low-risk LDTs (i.e., Class I medical devices).

Source: Foley & Lardner LLP

validity (i.e., that the test can reliably detect a biomarker). All LDTs are classified as high-complexity tests and labs performing them must comply with rigorous quality control, proficiency testing and personnel requirements and must demonstrate the test's analytical validity. Although CLIA does not require labs to establish clinical validity, the major private sector accrediting organizations, such as CAP and the Joint Commission, do require that labs document clinical validation.

Previous attempts by the FDA to claim oversight of LDTs have failed. The FDA proposed a regulatory framework in 2014, but it was never finalized. Congress also attempted to establish a regulatory framework through the Verifying Accurate Leading-Edge IVCT Development (VALID) Act, which would have created a new risk-based framework for diagnostic tests. That effort failed to pass Congress in 2022 but was reintroduced in the House in 2023. The measure has not yet been reintroduced in the Senate.

Why Now?

The FDA has stated that the risk associated with LDTs are much greater than they were when the agency began exercising enforcement discretion in the 1970s, says Boubker. In the proposed rule, FDA notes that "today's LDTs are generally, among other things, used more widely, by a more diverse population, with an increasing reliance on high-tech instrumentation and software, and more frequently for the purpose of guiding critical healthcare decisions."

The agency also has become increasingly concerned that some LDTs might not provide accurate test results or perform as well as FDA-authorized tests and others complying with FDA requirements, according to the proposal. "Recent information, including evidence from a variety of sources, [such as] published studies in scientific literature, allegations of problematic tests reported to the FDA, the agency's own experience in reviewing IVDs offered as LDTs, news articles and class-action lawsuits suggest that this situation is getting worse," it says.


Octavia Peck Palmer

While the FDA has proposed a gradual phaseout of its discretionary enforcement approach, it does not intend to sweep in certain tests that were excluded from the general enforcement discretion approach initially. These include tests that are intended as blood donor screening or human cells, tissue and cellular and tissue-based products (HCT/Ps) donor screening tests required for infectious disease testing, tests intended for emergencies, potential emergencies or material threats; and direct-to-consumer tests.

In addition, the FDA proposes to continue applying enforcement discretion to "1976-type LDTs." These tests have the following characteristics common among LDTs offered in 1976: use of manual techniques (without automation) performed by laboratory personnel with specialized expertise; use of components legally marketed for clinical use, design and manufacture within a single CLIA-certified laboratory that meet the requirements under CLIA for high-complexity testing; Human Leukocyte Antigen (HLA) tests; and tests intended solely for forensic (law enforcement) purposes.

Duplicate Regulation

Lab groups continue to oppose FDA attempts to regulate LDTs. ADLM says it is disappointed to see the "FDA's attempt to circumvent Congress" with a proposal that would duplicate the regulation of LDTs, arguing that these tests are already regulated under CLIA.

"Simply, this would create a dual, expensive and potentially contradictory regulatory environment for clinical laboratories, eliminating most labs' ability to perform laboratory-developed tests and

drastically limiting patients' access to critical laboratory test results," says Octavia Peck Palmer, ADLM president. "We continue to advocate for a balanced, evidence-based approach to regulating laboratory-developed tests. We must identify what problems we are trying to fix and correct them without hindering scientific advancement or limiting patient access to these innovative, often life-saving tests. We urge the FDA to join us in working within the regulatory system to advance patient care and prioritize health equity."

ACLA President Susan Van Meter, who also maintains that the FDA currently lacks the authority to regulate LDTs, believes a legislative solution is the way forward. She thinks the VALID Act is a reasonable vehicle to establish a fair framework for regulating diagnostics.


Susan Van Meter

"There are attributes of VALID that are positive," she says. "It would establish a diagnostic-specific, risk-based framework, which is essential as diagnostics are not medical devices. We need a framework with robust grandfathering and a reasonable transition period, such as what is included in VALID. Any diagnostic-specific framework needs to recognize other reviewers, such as New York state, as well as allow for new review pathways that would embrace innovation, such as the technology certification policy in VALID, which would allow a test developer to secure approval on a suite of assays by bringing a representative assay through for assessment. Once that suite is cleared, there could be established clarity on what changes could be made post-market, thus allowing for rapid iteration to ensure that patients are getting the latest version of a test. VALID had all those things. It's not perfect, but we think there could be momentum that is built around that vehicle."

Van Meter also is concerned about not only the proposed rule's potential strain on laboratory resources, with an estimated $50 billion in cost to laboratories in the first five years of the plan, if implemented, but also the FDA's resources, noting that the FDA does not have the necessary staff to handle the level of new submissions that would result from the LDT proposal if finalized as written.

FDA Invites Input

The FDA is asking stakeholders to provide specific feedback on the following:

- Whether FDA should maintain its current enforcement discretion approach with respect to premarket review and some or all quality system requirements for LDTs already on the market.
- How the proposed phaseout policy may have unintended consequences for certain patient populations (e.g., Medicare beneficiaries, rural populations) and what steps could be taken to alleviate those consequences.
- Public health rationales for having a longer phaseout period for LDTs offered by laboratories with annual receipts below a certain threshold, such as $150,000.
- The definition of Academic Medical Center (AMC) and whether the FDA should implement a different phaseout approach for AMC laboratories.
- How FDA might leverage programs such as the New York State Department of Health Clinical Laboratory Evaluation Program or those within the Veterans Health Administration as part of the phaseout approach.
- Any implication of continued enforcement discretion for LDTs used for law-enforcement purposes and any factors that FDA should consider—particularly as it relates to civil rights and equity—regarding the scientific validity and accuracy of such tests.

Comments on the proposed rule are due Dec. 4, 2023.

GENOMIC HEALTH PAYS $32.5 MILLION TO SETTLE FCA ALLEGATIONS (*con't from page 1*)

Genomic Health's principal test, Oncotype DX, is used for patients diagnosed with breast, colon and prostate cancer. The Department of Justice alleged that Genomic Health perpetrated a scheme to evade Medicare's 14-day rule, which governs the billing of genomic laboratory tests such as Oncotype DX (CPT 81519). The 2023 Medicare reimbursement rate for this test is $3,873.

According to two whistleblower complaints, Genomic Health conspired with hospitals and doctors to cancel or delay orders so the company could charge Medicare for tests that should have been billed to the hospital or that were already covered by lump-sum payments that hospitals receive from the federal government.

"When medical test results are delayed, patient's health is at risk," says Erika Kelton, a partner at Phillips & Cohen (Washington, D.C.), which represented the whistleblowers. "This settlement recognizes the importance of whistleblowers in bringing wrongdoing to light."

Erika Kelton

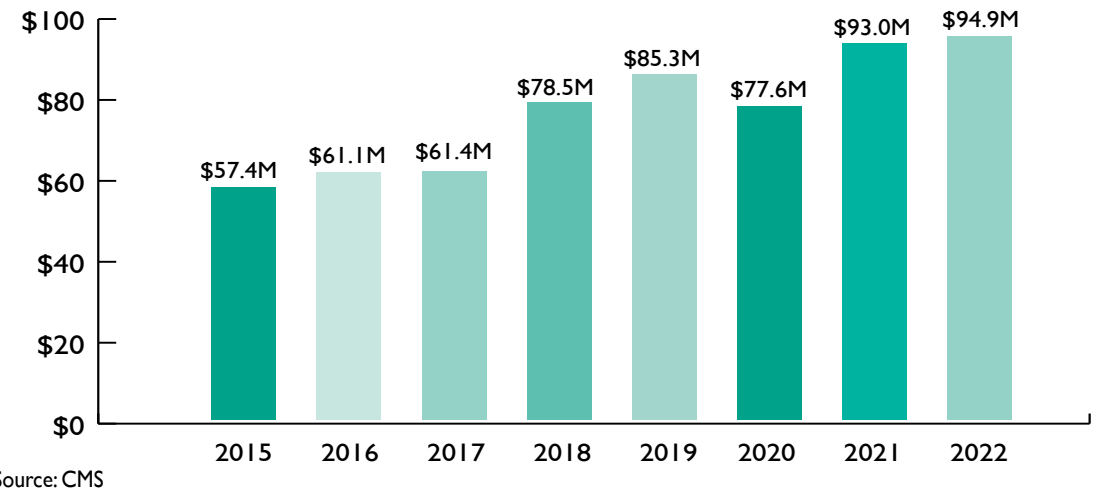
Allegations Span a Decade

The allegations spanned more than a decade, from January 2008 through February 2020, and allegedly involved Genomic Health using a series of workarounds to evade Medicare's "date of service" rule, which prohibits laboratories from separately billing the health insurance program for tests if a doctor ordered a test within 14 days of the patient's discharge or outpatient procedure.

During some or all of the time period covered by the settlement, Medicare's 14-day rule prohibited 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 in an inpatient or outpatient setting. For inpatient beneficiaries, such tests were covered under diagnosis-related group (DRG) payment.

For outpatient beneficiaries, Medicare's 14-day rule required (for most of the relevant time) tests ordered within 14 days of the patient's discharge to be billed to the hospital, but the hospital could then seek reimbursement from Medicare. However, if the test was performed more than 14 days after discharge from a hospital stay in either an inpatient or outpatient setting, then Medicare's 14-day rule permitted laboratories to bill Medicare directly for the test.

Annual Medicare Allowed Payments for CPT 81519



Source: CMS

The government alleged that Genomic Health improperly manipulated the 14-day rule in four ways:

- Genomic Health sought reimbursement from Medicare for claims on behalf of Medicare beneficiaries when Oncotype DX tests were ordered and submitted for testing within 14 days after an inpatient discharge. By submitting separate claims for these tests, Genomic Health received direct payment for tests that should have been covered as part of the DRG payment to the hospital.
- Genomic Health sought direct reimbursement from the Medicare program for Oncotype DX tests ordered within 14 days of a beneficiary's outpatient procedure. By submitting separate claims for these tests, Genomic Health received direct payment from Medicare for tests that should have been billed to the hospital.
- Genomic Health conspired with and encouraged hospitals and physicians to cancel and reorder Oncotype DX tests and failed to discourage providers who ordered tests within 14 days from canceling and reordering the tests after the 14-day time period had elapsed.
- Genomic Health failed to send timely invoices to hospitals for laboratory services that fell under the 14-day rule and instead wrote off the unpaid fees for laboratory services, thereby violating the Anti-Kickback Statute.

John Tremblay

"Medicare rules are intended to keep medical costs down," says John Tremblay, a partner with Phillips & Cohen. "This is a classic case of putting profits ahead of patients' health."

The civil settlement includes the resolution of allegations brought in two separate actions filed against Genomic Health under the qui tam provisions of the FCA. The relators' share from the proceeds of the settlement in this case will be $5,687,500.

Exagen to Pay $653,143 to Resolve Kickback Allegations

Exagen (Vista, CA), which makes diagnostic tests for the treatment of autoimmune conditions, has agreed to pay $653,143 to resolve allegations that it paid specimen processing fees to referring physicians to induce those physicians' use of Exagen's laboratory tests.

Exagen's flagship AVISE CTD assay is an advanced autoimmune rheumatic disease test specifically designed to aid physicians in the differential diagnosis of systemic lupus erythematosus (SLE). In 2022, Exagen delivered 135,210 of its AVISE CTD tests, according to a filing with the Securities and Exchange Commission. Total revenue for 2022 was $45.6 million.

According to the settlement agreement, Exagen agreed to factual admissions that it paid certain referring physicians to complete blood draws for patients pursuant to specimen processing agreements that Exagen entered into with those physicians. Exagen billed federal healthcare programs, including Medicare and other programs, for tests that it performed after receiving orders from the referring physicians to whom it paid the specimen processing fees. Exagen did so after becoming aware of a June 25, 2014, Special Fraud Alert from the Department of Health & Human Services' Office of Inspector General that warned laboratories that the practice of paying referring physicians specimen processing fees could present a substantial risk of fraud and abuse.

The settlement stems from allegations originally brought in a lawsuit filed by a whistleblower under the qui tam provisions of the False Claims Act (FCA). In connection with the settlement, the relator will receive 16% of the recovery.

NAVIGATING THE CMS AUDIT APPEALS PROCESS: A PRIMER (*con't from page 1*)

What triggers an audit typically?
What usually happens is that somebody is considered an outlier and they get targeted because of their large volume of claims. Also, claims that reimburse at a high rate are also more likely to be audited. They get compared to other providers in their region. But if you have a niche practice, you are more likely to bill codes that might stand out from your peers. The second way is if you are part of some target enforcement action where a particular code or procedure is being billed incorrectly in your region.

Are all claims automatically screened by CMS?
CMS has some of the best analytics. All claims are being tracked. It's very easy for an investigator to pull up a clinical laboratory to get a claim snapshot to see what they are billing and at what frequency. CMS has an open-source tracking system [https://data.cms.gov/tools/medicare-physician-other-practitioner-look-up-tool] where you can go on and click on a provider or procedure and see who is billing it the most.

How should a laboratory prepare for an audit?
You will receive a letter from CMS letting you know that claims are being audited. The first thing you want to do is make sure that you gather everything that is possibly going to support the test claim that you submitted. The more information you give that supports the claim the better. The audit is done remotely. You will get a findings letter from CMS where they will explain the deficiencies if they find them. You will then get an overpayment demand letter from your Medicare Administrative Contractor (MAC). The various deadlines are calculated five days from the date of on the letter from the MAC. You have 15 days from then to file a rebuttal. A rebuttal is not an appeal, but simply a mechanism for providers to present additional information or documentation that could clarify potential misunderstandings or rectify any errors identified in the initial audit. If you file within the first 30 days, you can stay recoupment of overpayments pending further appeal.


Guillermo Beades

At what point should a lab appeal?
If the rebuttal does not lead to a satisfactory resolution, you have 120 days to file a redetermination appeal. This stage presents another opportunity to provide additional supporting evidence to justify your claims.

How many levels of appeal are there?
There are five levels of appeal. The first level is redetermination – you are asking the MAC to reverse their decision. A reversal happens about 1% of the time.

The second level of appeal is with a Qualified Independent Contractor (QIC). You have 180 days from the unfavorable decision from the MAC to seek reconsideration with a QIC, who is hired by CMS. Although QICs frequently echo the MAC's findings, there are times when they reverse the unfavorable findings, in part or in whole.

If the QIC rubber stamps the MAC decision, you go to an administrative law judge, the third level of appeal. You have 60 days from receipt of an unfavorable QIC decision. That's a very important stage because it's the first time you have someone independent looking at this. It's like a mini-trial. The majority of time, CMS doesn't even show up. Having competent healthcare counsel with experience at these hearings is invaluable. You can get a fully favorable ruling, partially

favorable, fully unfavorable or partially unfavorable. You have a 60% shot of getting a partially favorable ruling, although each case is very fact-specific so the individual likelihood of success can vary significantly.

The fourth level of appeal is before the Medicare Appeals Council (MAC), which must be filed within 60 days of the ALJ's decision. This appeal is fully written. Once you get a decision from the MAC, your remedies are limited. This is harder to get overturned because you have to show that the ALJ made an actual error. The ALJ decisions get overturned maybe 30% of the time.

The final level of appeal is to file a lawsuit in district court. This is very rare. Most providers go through the ALJ phase and then call it quits.

At what point should a lab bring in legal counsel?
You don't always need legal counsel if you get an audit letter. But as soon as you get an overpayment demand, you should bring in legal counsel. The CMS audit process is littered with red tape. Be aware that if something is not filed in a timely manner, there is no recourse. That's why it's important to have legal counsel involved. Time flies and when you aren't paying attention to some deadline, it's very easy to miss a deadline based on a harmless error.

How should a lab navigate requests for recoupment?
There's one thing you have to keep in mind: CMS charges an interest rate of 11% on overpayments. The interest starts after 60 days of receipt of a demand letter. If you can pay it, you should. You are not waiving your right to appeal. If you win the appeal, you can get the money back. CMS will start recouping money from you from current claims. Pay first and then fight to get your money back. If you can't do that, stay recoupment as long as you can. You can only stay recoupment through the first two levels of appeal, and interest accrues during that entire time. If you win your appeal, you will get all that money back plus the interest.

You don't always need legal counsel if you get an audit letter. But as soon as you get an overpayment demand, you should bring in legal counsel.

What percentage of providers win their appeals?
That's hard to say because there might be some claims you lose on and some you win on. You have a good shot a little better than half to get CMS to reduce the recoupment in some way. But Medicare doesn't negotiate on recoupment. Private payers do and Medicaid will.

In cases where CMS gets it wrong, such as misinterpreting a local coverage determination, you have a high chance of being successful. When I think of appealable CMS cases, I feel like we always win, at least to an extent. We might get some of the money back. But in a case where a service or test is not properly documented, the adage is, if it wasn't not documented, it wasn't done. The only time we appeal those is to show CMS that even though it wasn't documented, it was done, so the provider doesn't face a potential fraud charge.

The most important takeaway is that when you are under any type of audit, if you keep making the same mistakes, it can lead to you getting kicked out of Medicare. CMS has many different types of audits, including targeted probe and education, unified program integrity contractor, supplemental medical review contract and recovery audit contractors. All audits carry some kind of risk. Strict compliance with auditors and guidance from competent healthcare counsel are invaluable when navigating these rough waters.

COMPLIANCE 101:

Medical Necessity and Requisition Design

Laboratory compliance plans should ensure that claims are only submitted to federally funded healthcare programs for services that the lab has reason to believe are medically necessary, according to the Health and Human Services Office of Inspector General (HHS OIG). Upon request, a laboratory should be able to provide documentation, such as requisition forms containing diagnosis codes, supporting the medical necessity of a service the laboratory has provided.

In its model compliance plan for clinical laboratories, the OIG says it recognizes that laboratories do not and cannot treat patients or make medical necessity determination. However, it also emphasizes that there are steps that labs can and should take to help maximize the likelihood that they only bill federally funded healthcare programs for tests that meet the reimbursement rules for those programs.

Physicians must be made aware that Medicare will only pay for tests that meet the Medicare definition of "medical necessity," and labs are in a unique position to deliver this information to their physician clients, the OIG states in the guidance.

"In our opinion, laboratories can and should advise physicians that when they instruct the laboratory to seek Medicare reimbursement for tests ordered, they should only order those tests that they believe are medically necessary to the diagnosis and treatment of their patients," says the OIG. It recommends that labs take specific steps to help ensure that the claims they submit to federal healthcare programs meet the appropriate program requirements. These include appropriate requisition design, notice to physicians, physician acknowledgements and test utilization monitoring.

Requisition Design

Each lab or lab company should standardize its non-customized test offerings and use common, uniform requisition forms that emphasize physician choice and encourage doctors to order, to the extent possible, only those tests they believe are appropriate for each patient.

In addition, the requisition forms should require physicians to document the need for each test ordered by inserting a diagnosis code for each test. With respect to chemistry tests, requisition forms should be designed to require physicians to order such tests individually unless 1) the test is specifically part of a CPT- or HCPCS-designed automated multichannel test series; 2) the test is part of a CPT-defined "clinically relevant test grouping," such as an organ or disease panel or profile; or 3) the test is part of a profile that has been customized at the request of the physician.

A printed statement should appear on every requisition form reiterating that when ordering tests for which Medicare reimbursement will be sought, physicians (or other individuals authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment of a patient, rather than for screening purposes.

CodeMap, a consulting company based in Chicago, suggests the following language: "Only tests that are medically reasonable for the diagnosis or treatment of a Medicare or Medicaid patient will be reimbursed. The Office of Inspector General takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act."

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

In Brief

Women Pleads Guilty to Submitting Claims for Unnecessary Respiratory Tests

A California woman pleaded guilty Oct. 5, 2023, to fraudulently submitting claims to government and private insurance programs during the Covid-19 pandemic for expensive and medically unnecessary respiratory pathogen panel (RPP) tests. From June 2020 to April 2022, Lourdes Navarro, of Glendale, CA, conspired with Imran Shams to obtain nasal swab specimens from residents and staff at nursing homes, assisted living facilities and schools for the purpose of testing for Covid. Matias Clinical Laboratory, dba Health Care Providers Laboratory (HCPL), then performed RPP testing on some of the specimens, even though only Covid testing had been ordered. Navarro and Shams submitted about $359 million in claims for the unnecessary RPP tests and were reimbursed about $54 million. Navarro will be sentenced Jan. 23, 2024, and faces a maximum penalty of 20 years in prison. Shams previously pleaded guilty and will be sentenced Jan. 9, 2024.

CLIAC to Meet Nov. 8-9, 2023, in Atlanta

The Clinical Laboratory Improvement Advisory Committee (CLIAC) will meet Nov. 8, 2023, from 8:30-5:30 p.m., EST, and Nov. 9, 2023, from 8:30 a.m. to 12 p.m. at the Centers for Disease Control and Prevention in Atlanta. A virtual Zoom option is available. Among the topics that will be addressed: efforts to address the CLIA top 10 laboratory deficiencies, the role of the laboratory in diagnostic and antimicrobial stewardship and standardization of test result communication.

Panel Issues Guidelines for Genetic Testing in ALS

An expert panel led by researchers at the Ohio State University Wexner Medical Center and College of Medicine has published a set of evidence-based guidelines for genetic testing and counseling for people with amyotrophic lateral sclerosis (ALS). The guidelines, published in the Annals of Clinical and Translational Neurology, consist of 35 statements to help improve and standardize genetic counseling and testing practice among neurologists, genetic counselors or any provider caring for people with ALS. Among the recommendations: All people with ALS should be offered testing with an ALS gene panel that includes the following: C9orf72, SOD1, FUS and TARDBP.

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