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# COMPLIANCE & POLICY REPORT

*Compliance and Regulatory Analysis for Lab Directors and Managers*

## Warren Investigating Google Efforts to Monetize Military Tissue Samples

Sen. Elizabeth Warren (D-Mass.) has launched an investigation into reports that Google has been trying to secure exclusive access to millions of tissue samples held at the Department of Defense's (DoD) Joint Pathology Center (JPC). The JPC has more than 31 million blocks of human tissue and 55 million slides, including many rare samples, making it the federal government's premier pathology reference center supporting the Military Health System (MHS). *Continued on page 2.*

## Navigating New CMS Billing Edits for Drug Testing

A new National Correct Coding Initiative (NCCI) edit under Medicare is resulting in increased denials in toxicology testing. The new edit, which took effect July 1, 2023, affects CPT codes 80305, 80306 and 80307 for presumptive drug tests and G0480-G0483 and G0659 for definitive drug tests. *Details on page 4.*

## Pathologists Call for Changes to Palmetto Special Stains Policy

State pathology societies and the College of American Pathologists (CAP) are calling on Medicare Administrative Contractor (MAC) Palmetto GBA to remove certain coverage limitations to its revised draft special stains Local Coverage Determination (LCD).
*Continued on page 6.*

## Billing & Coding Is Top Compliance Concern

Sixty-nine percent of laboratory directors say that "billing and coding" is one of their top compliance concerns, according to a recent survey conducted by *Laboratory Economics Compliance & Policy Report*. "Keeping up with payer policies" was cited by 57% and "understanding coverage policies (especially for molecular diagnostics)" was cited by 41%.
*More survey result details on page 8.*

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## Warren Investigating Google Efforts to Monetize Military Tissue Samples

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This repository represents a valuable resource for clinicians, pathologists and healthcare data analysts to better understand and diagnose diseases, from infectious diseases to cancers. JPC has been pursuing repository modernization efforts, to include digitizing the glass slides, a massive undertaking.

According to a December 2022 investigation by ProPublica, a nonprofit news agency, Google approached JPC in 2015 to pursue digitizing the valuable—and potentially profitable—pathology slides. The investigation alleged that Google tried to privately broker a deal with the JPC, bypassing the typical government contracting process that would include soliciting competitive bids to make sure any agreement maximizes the benefit to the public interest. The ProPublica report alleged that Google had a confidential plan to turn the collection of slides into an immense archive that—with the help of the company's burgeoning and potentially profitable AI business—could help create tools to aid the diagnosis and treatment of cancer and other diseases.

According to ProPublica, at least a dozen DoD staff members have raised ethical or legal concerns about Google's quest for servicemember's medical data. Underlying their complaints are concerns about privacy, favoritism and the private use of a sensitive government resource in a time when AI in healthcare shows both great promise and risk.

"Google launched its years-long campaign by submitting an 'unsolicited proposal,' which would have provided the company with 'exclusive access' to the data for at least four years," said Warren in announcing the investigation. "The proposal included 'a requirement that it be able to charge the government to store and access the digitized information,' effectively excluding the government from tapping into its own data unless it paid a fee to Google. In an effort to cover its tracks, Google also inserted a non-disclosure agreement into the proposal, and disturbingly, may have attempted to improperly influence the process by making an employment offer to a DoD employee."

**'Clear Favoritism'**

Warren, chair of the Senate Armed Services Subcommittee on Personnel, sent a letter July 26 to Google CEO Sunar Pichai and Secretary of Defense Lloyd J. Austin III, asking for answers about these secretive dealings. In her letter, Warren alleged that DoD showed clear favoritism toward Google getting the JPC contract. She cited three specific instances, which she says raise ethical and legal concerns about DoD's relationship with Google.

> *"We need to be very cautious. The data taken from people who gave not only their specimens, but also in some cases, their lives for their country, should not be disrespected."*

"Despite Google's best efforts to obtain exclusive access, JPC issued a request for information in 2020 for a pilot project to modernize its archives," says Warren. "Google doubled down on its brazen tactics after the company lost the pilot project to Johns Hopkins. In a letter to DoD, Google wrote that the company had been unfairly excluded from 'full and open competition,' a bold claim considering the frequent interactions between Google and JPC over the better part of the last decade."

Frustrated by its lack of success at DoD, Google launched a lobbying campaign in Congress, where the company secured favorable report language in the National Defense Authorization Act for fiscal year 2023 stating that the process by which the JPC has chosen to digitize its archives

may not fully incorporate advances in technology to scale this effort in a timely manner, according to Warren. She says the public deserves a full accounting of Google and DoD's "secretive interactions regarding private health data contained at the JPC, complete transparency of Google's efforts to skirt the public contracting process . . . and information about DoD's blatant favoritism toward Google." Warren has asked Google and DoD to answer a detailed set of questions about their dealings.

**Raises Ethical Concerns**

The efforts by Google to gain exclusive access to the JPC's slides raises myriad ethical and privacy concerns, believes M.E. "Doc" de Baca, MD, Chair of the College of American Pathologists' (CAP) Council on Informatics and Pathology Innovation, and vice president of Medical Affairs for Sysmex, America. She notes that servicemembers and veterans signed consent agreements allowing DoD to retain their tissue samples so they could be used for the public good, but to her knowledge there was no consent given to sharing their samples with third parties, such as Google.

*M.E. "Doc" de Baca, MD*

"I would love to have access to that data, but don't believe that Google's interests are the same as those of the DoD and the country," she says. "I have not seen any examples of for-profit companies undertaking a project of this magnitude for the public good or out of altruism. I think it's dangerous for companies having this much power."

That said, de Baca does believe there should be a national pathology data center created and funded by the federal government that could be accessed by researchers. Pathology departments across the country could upload data files, which would continue the original goal of the Armed Forced Institute of Pathology (AFIP).

"This would allow the government to have a data set that it could share and perhaps even charge for," she says. "It could be a goldmine for pharmaceutical companies and researchers."

De Baca stresses that she supports innovation in informatics but warns that those making the decisions consider all of the ethical implications of allowing a for-profit company to have exclusive access to tissue samples and personal information of servicemembers. Even if the slides were de-identified, ethical concerns remain.

"We need to be very cautious," she says. "The data taken from people who gave not only their specimens, but also in some cases, their lives for their country, should not be disrespected."

### AFIP Evolution

The Armed Forces Institute of Pathology (AFIP) was founded in 1862 as the Army Medical Museum in Washington, D.C., on the grounds of Walter Reed Army Medical Center. It primarily provided second opinion diagnostic consultations on pathologic specimens, such as biopsies from military, veterans and civilians medical, dental and veterinary sources. The repository has served as the basis for major pathological studies. The AFIP played a critical role in the standardization of pathologic diagnosis of tumors.

The 2005 Base Realignment and Closure proposal included a realignment of Walter Reed that would have relocated the AFIP to the National Naval Medical Center in Maryland, Dover Air Force Base in Delaware and Fort Sam Houston in Texas. Ultimately, Congress passed legislation in 2008 establishing the Joint Pathology Center to assume many of the responsibilities of the AFIP.

## NAVIGATING NEW CMS BILLING EDITS FOR DRUG TESTING (*cont'd from page 1*)

When laboratories submit claims for both the presumptive drug test and the definitive drug test, the definitive drug test will be denied, according to Ann Lambrix, vice president of revenue cycle management solutions for Lighthouse Lab Services, who spoke about the new edit during a webinar August 16. Currently, these edits cannot be bypassed using an NCCI modifier, says Lambrix. A modifier fix is forthcoming, but it won't be available to labs until October 1.

"Essentially, Medicare said these two services are mutually exclusive and that it is not reasonable to perform both types of testing in the same session," she explains. "However, we know it is reasonable. Fortunately, because of all the pushback, Medicare has walked this back."

Effective Oct. 1, 2023, with the next quarterly NCCI update, the Centers for Medicare and Medicaid Services (CMS) will allow for the use of a modifier to bypass the edits in cases when billing these presumptive and definitive test codes is necessary and allowable. The change will be retroactive to July 1, 2023.

Lambrix suggests that clinical laboratories may wish to wait to submit their drug testing claims (with the appropriate modifier as applicable) until after CMS implements the modifier change on October 1. Another option is to bill now and appeal the denial to the Medicare Administrative Contractor (MAC). This will be largely dependent on whether your lab has the billing personnel required to submit and follow through on appeals.


*Ann Lambrix*

"For this particular edit, the modifier indicates that these services were medically necessary," says Lambrix. "Labs must ensure documentation in the medical record satisfies the criteria required when using the modifier to override the NCCI edit. The testing should support the patient's clinical need and aid in provider's decision-making. We highly advise that you review this with your internal billing compliance department."

Lambrix cautions that labs avoid the appearance of reflex testing. Routinely blanket ordering large panel drug screens is a practice that may put you in a payer's sights for audits or pre-payment reviews, she warns. Labs can use local coverage determinations as a guide for education and training.

Because most other payers follow the same edit rules as Medicare, Lambrix expects Medicaid and commercial payers to adopt the new edit and modifier. It is unclear whether other payers will also make the new modifier rules retroactive to July 1.

**A Sign of Things to Come?**

As payers increasingly use technology for data mining and to identify trends and outliers, it's likely there will be more efforts such as these made to reduce overutilization and spending on drug testing, says Lambrix.

"The good news with this particular issue is that most likely this will be walked back and there is a path forward for payment," she says. "But this is not unique to toxicology, it is across the board in healthcare. It is important that you understand appropriate utilization, you understand medical necessity and you understand what the payer is looking for."

Lambrix expects to see an increase in outsourced and third-party auditing vendors and suggests that labs consider using a revenue cycle management denial management platform to help identify and alleviate billing concerns before they impact your revenue cycle.

**Advocacy and Visibility**

Given that opioid overdoses are increasing and, in fact, are the number one killer in America of adults between ages 18 and 45, toxicology testing remains crucial for helping combat this epidemic, says Jon Harol, president of Lighthouse Lab Services. He believes it is incumbent on the lab industry to better advocate for the importance of toxicology testing.

In fact, the National Independent Laboratory Association (NILA) has drafted a letter to CMS regarding payment for presumptive and definitive drug testing. While NILA commends the agency for amending the edit and allowing the use of a modifier to bypass the edit, NILA Executive Director Mark Birenbaum, PhD, says this does not go far enough and requests that the edit be removed completely.

There are many instances when it is clinically appropriate to perform both a presumptive and definitive drug test on the same day, particularly for a patient suspected of illicit drug use or when a presumptive test inadequately detects a medication, write Birenbaum.

"Not only is presumptive and definitive drug testing important for suspected illicit drug use, but many types of conditions, such as chronic pain and behavioral health issues often seen in the Medicare population, require drug testing to monitor the appropriate use of therapeutic drugs and to ensure appropriate care," he says. "It is simply not feasible for a patient, particular frail, elderly patients with an already heavy burden of traveling to a physician's office, to return a day later to provide another sample for the definitive test."

Anyone interested in signing the letter should contact NILA at www.nila@nila-usa.org.

## Tips on Getting Paid for Drug Testing

- When providing medical necessity documentation for presumptive and definitive drug testing code (on appeal), it is useful to include the patient's medical record, says Lambrix. The requisition itself is not enough, nor are the results. The documentation should include the patient's chart or notes from the doctor to indicate why both tests were to be performed on the same patient on the same day.
- In cases where there are two different labs performing the presumptive and definitive drug testing (i.e., the second test goes to a reference lab), whichever test is submitted to the payer first will get paid. Thus, timeliness is a factor in getting paid, at least until October 1, when MACs begin reprocessing claims.
- Labs will need to make a business decision whether to submit the claim initially or wait until October 1 to submit the claim, notes Harol. "Do you go through the administrative hurdles to submit an appeal to maybe get dollars in the door a little bit quicker or do we wait until October 1 to get the same dollars but a little easier? That's the decision you have to make."
- Another strategy is to bill for the higher paying claim now (definitive) and bill for the presumptive after October 1, but some payers may refuse to pay for definitive testing submitted first. "Each path that might be recommended will also bring in a unique set of challenges you need to be prepared for," says Lambrix. "That's why we recommend working this out with your internal billing compliance teams and partnering with your billing vendor."

## Pathologists Call for Changes to Palmetto Special Stains Policy

(*cont'd from page 1*)

The LCD (L35922), which took effect in 2015 and was subsequently revised in 2020, would deny Medicare coverage of some special histochemical stains and immunohistochemical stains used in the diagnosis or evaluation of surgical pathology specimens, including certain cancers, such as breast, gastrointestinal and prostate.

According to Jonathan Myles, MD, chair of the CAP Council on Government and Professional Affairs, technological advances in IHC and medical practice necessitates the coverage policies be modified. In December 2021, the CAP sent a formal appeal to Palmetto and other MACS who had adopted Palmetto's policies with proposed revisions to the LCD.

Cigna Government Services was the first MAC to propose revisions to the LCD in February 2023, followed by First Coast's recission of its special stains LCD. Palmetto subsequently followed Cigna with proposed revisions, and on July 17, 2023, Palmetto hosted a virtual public meeting to receive input on the proposed changes. At the same time, the CAP submitted a letter to Palmetto detailing specific recommendations to the policy.

*Jonathan Myles, MD*

"Palmetto did not respond to the comments during the meeting, but we are hopeful that our letter and comments will result in expanded coverage for special stains and immunohistochemistry," says Myles.

While the CAP commends Palmetto for proposed updates to the LCD, including removing the age limit for Lynch Syndrome tumor screening for microsatellite instability (MSI)/DNA mismatch repair by qualitative IHC for individuals with newly diagnosed colorectal or endometrial cancer, the CAP continues to have concerns regarding the coverage guidance and the summary of evidence areas. In particular, the CAP is calling for changes to the following areas:

**IHC for Breast Pathology**

The LCD limits coverage of companion diagnostic test Ki-67 to only PharmDx Ki-67 (MIB-1) by Agilent Technologies (in the population of patients with ER+, HER2-lymph node positive high-risk breast cancer). The CAP agrees with Palmetto that Ki-67 has prognostic value in the population of patients with ER+, HER2-lymph node positive high risk breast cancer. It also agrees that Ki-67 testing is reasonable and necessary for both prognosis and therapy.

"There is no evidence that the specific clone (Dako) used in the PharmDx test is superior to other Ki-67 clones," says the CAP in its comments. "Further, there is no evidence that the methodology of interpretation of the results is superior with this clone. Limiting coverage of Ki-67 testing to this single test would likely limit access to care for patients as many institutions may not carry this particular clone and use other equally efficient Ki-67 clones."

**Special Stains for GI Pathology**

According to the Palmetto LCD, scientific data demonstrates that the combined number of gastric biopsies requiring special stains or IHC is roughly 20% of biopsies received and examined in a pathology practice. Some specialty practices might sometimes exceed this number of special stains, but "one would not expect to see routine high utilization of special stains or IHC." Palmetto says that providers who exceed the 20% criteria may be subject to additional action.

The CAP argues that the predetermined 20% threshold is arbitrary and is not supported by evidence or consensus of the pathology community. The LCD appears to derive this standard from a single 2006 study whose results have never been demonstrated to be generalizable and do not suggest or support an across-the-board application to every provider regardless of circumstances, says

the CAP, which recommends that Palmetto strike this entire paragraph from the final LCD. Alternatively, a more general statement emphasizing compliance with the LCD coverage parameters may be expressed, such as: "Compliance with the limitations provisions of this policy may be monitored and addressed through post-payment data analysis and subsequent medical review audits."

The CAP also recommends that Palmetto expand coverage for MMR/MSI testing beyond colorectal and endometrial cancers to include patients with gastroesophageal junction cancer, small bowel cancer and other solid tumors that are being considered for immune checkpoint inhibitor therapy.

**Special Stains for Prostate Pathology**

The CAP believes that Palmetto's understanding of special stains and IHC for prostate is incomplete, noting that there are discordant statements about how the number of core biopsies inform risk stratification. The CAP agrees that the number of positive biopsy sites and percentage of core involvement of the sites *CAN* affect therapeutic choices. However, one statement contradicts another by stating it is not reasonable and necessary to perform IHC testing on cases with morphologically suspicious cores when prostate cancer is present in other cores because it provides no additional actionable information to the treating physician.

The CAP recommends that the LCD language be amended to allow coverage for IHC staining of *SUSPICIOUS* core biopsies. The college also takes issue with some of Palmetto's comments regarding risk stratification and is asking they be amended to allow additional workup to provide necessary risk stratification.

**IHC for Skin/Soft Tissue/Nervous System Lesions**

The Palmetto LCD states that it is well recognized that most skin lesions, including melanomas and other pigmented skin lesions, are diagnosed with routine H&E slides. Soft tissue masses may require stains, but most do not, according to Palmetto. The primary role of IHC for central nervous systems and peripheral nervous system lesions is to differentiate primary from metastatic lesions, it states. The CAP is requesting that Palmetto remove the statement about most soft tissue masses not requiring stains from the final LCD, arguing that it is not based on any available scientific evidence. The CAP also requests that Palmetto amend the statement about the primary role of IHC to include other uses of IHC, including classifying CNS tumors and for prognosis and therapy.

**Special Stains for Lung Cancer**

The LCD states that the diagnostic challenge of a lung biopsy can often prompt the need for additional stains to define the neoplasm. Two important considerations can result in the need for additional stains that need to be considered, says Palmetto: 1) The diagnosis of squamous cell cancer can often be made without the use of any special stains, and 2) The diagnosis of non-small cell carcinoma often requires additional stains, but it is essential that tumor tissue be carefully triaged to allow the patient's sample to be tested for molecular markers when clinically indicated.

The CAP recommends that Palmetto delete the first point, arguing that it lacks any scientific validation and seems at odds with the statement that a lung biopsy often prompts the need for additional stains.

**IHC for Cervical/Bladder/Kidney Tumors**

Palmetto states that a variety of IHC stains have found limited use in cervical, gynecological and urological tumor settings. "In unusual cases of cervical dysplasia, markers or surrogate markers for HPV may be useful where the diagnosis on conventional H&E stain cannot be made with certainty. These markers are clearly not reasonable and necessary on all biopsies," the LCD states.

"Similarly, it is rare to need stains to prove that an endometrial or ovarian cancer is a serous cancer or that a kidney neoplasm is an oncocytoma, an eosinophilic or chromophobic renal cell cancer," it says.

The CAP requests that Palmetto delete both statements, arguing they are anecdotal and not based on scientific evidence.

## Billing & Coding Is Top Compliance Concern (*cont'd from page 1*)

The survey was conducted in August 2023 and received 51 responses from lab directors at hospitals and independent labs. The top compliance challenges cited were focused on billing and coding, and payer policies.

Less worried about compliance concerns included "ensuring compliance with the False Claims Act" cited by only 6% of respondents and "understanding requirements governing custom test panels" cited by 10%.

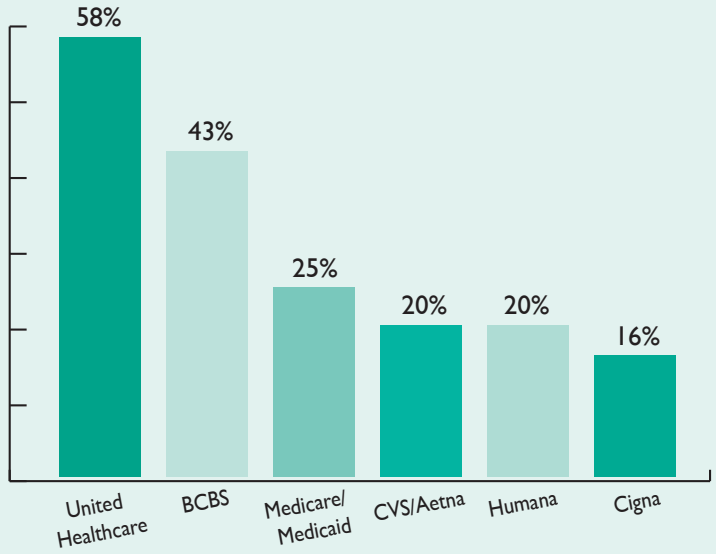
### What Are Your Lab's Top Compliance Challenges?*

| | |
|---|---|
| Billing and coding | 69% |
| Keeping up with payer policies | 57% |
| Understanding coverage policies (especially for molecular diagnostics) | 41% |
| Pre-authorizations | 35% |
| Proficiency testing and other CLIA requirements (including competency assessments) | 22% |
| FDA regulation of diagnostic tests (including lab-developed tests) | 14% |
| Protecting sensitive data/cybersecurity | 12% |
| Understanding requirements governing custom test panels | 10% |
| Ensuring compliance with the False Claims Act | 6% |

*Survey participants could select top 3 concerns
Source: *LE Compliance & Policy Report Survey* (August 2023; n=51)

Fifty-eight percent of survey respondents said that UnitedHealthcare was the payer "most difficult to get payment from." Only 16% picked Cigna as being among the most difficult payers.

### Which Payers are Most Difficult to Get Payment from?*




*Survey participants could select more than one payer
Source: *LE Compliance & Policy Report Survey* (August 2023; n=51)

The survey also showed that the Beneficiary Inducement Statute (BIS) is one of the least understood federal healthcare regulations. The BIS prohibits an individual or entity from providing remuneration to patients who are eligible for Medicare or Medicaid benefits if that individual or entity knows (or should know) that doing so is likely to influence the patient's decision to order or receive a service from a particular provider. Only 8% of surveyed lab directors said they had an "excellent understanding" of BIS, while 24% said they "don't really understand it at all."

## Georgia Lab Owner Sentenced to 27 Years in Genetic Testing Fraud Case

The owner of a Georgia clinical laboratory was sentenced August 18 to 27 years in prison for his role in a scheme to defraud Medicare by submitting more than $463 million in genetic and other laboratory tests that his patients did not need and that were procured through the payment of kickbacks and bribes.

Minal Patel, 44, owned LabSolutions LLC in Atlanta. According to court documents, Patel conspired with patient brokers, telemedicine companies and call centers to target Medicare beneficiaries with telemarketing calls falsely stating that Medicare covered expensive cancer genetic tests. After the Medicare beneficiaries agreed to take a test, Patel paid kickbacks and bribes to patient brokers to obtain signed doctors' orders authorizing the tests from telemedicine companies.

To conceal the kickbacks and bribes, Patel required patient brokers to sign sham contracts that falsely stated that the brokers were performing legitimate advertising services for LabSolutions, when, as Patel well knew, the brokers were deceptively marketing to Medicare beneficiaries and paying kickbacks and bribes to telemedicine companies for genetic testing prescriptions.

"In one of the largest genetic testing fraud cases ever tried to verdict, today's sentence makes clear that the Department will seek justice for those who put profits above patient care, including owners and executives," said Acting Assistant Attorney General Nicole M. Argentieri of the Justice Department's Criminal Division.

Patel knew the telemedicine doctors robo-signed prescriptions for expensive genetic testing even though they were not treating the beneficiaries, often did not even speak with them and made no evaluation of medical necessity.

From July 2016 through August 2019, LabSolutions submitted more than $463 million in claims to Medicare, including for thousands of medically unnecessary genetic tests, for which Medicare paid more than $187 million. In that time period, Patel personally received more than $21 million in connection with the fraud, said the DOJ.

The case was brought forward as part of Operation Double Helix, a federal law enforcement action led by the Health Care Fraud Strike Force under the supervision of the Criminal Division's Fraud Section. This operation focuses on fraudulent genetic cancer testing that has resulted in charges against dozens of defendants associated with telemedicine companies and cancer genetic testing laboratories for their alleged participations in one of the largest health care fraud schemes ever charged.

## Supreme Court Decision Could Make It Easier to Dismiss Frivolous Whistleblower Complaints

A recent U.S. Supreme Court case could make it easier for clinical laboratories and other businesses to seek dismissal of frivolous whistleblower complaints brought under the False Claims Act (FCA).

In *United States ex rel. Polansky v. Executive Health Resources Inc.*, the high court on June 16, 2023, ruled that the federal government is entitled to "substantial deference" in seeking dismissal of a qui tam or whistleblower case, even if the government declined to intervene in the case before ordered to make an intervention decision.


*Lori Rubin Garber*

This is good news for FCA defendants, as defendants occasionally appeal to the government for dismissal when a relator pursues a meritless case against the defendant or otherwise pursues an FCA action the government has reason to oppose, according to Lori Rubin Garber, a partner with Foley & Lardner (Washington, D.C.).

"The key takeaway for clinical labs is that it can't hurt to see if the Department of Justice will move to dismiss the case if they agree it is without merit," she says. "It makes it an easier call for DOJ to dismiss a case knowing they can dismiss and the Supreme Court gives them substantial deference."

**Two Questions**

The first question the Supreme Court tackled in this case was whether the government could move to dismiss an FCA action after initially declining to intervene in the case at the outset of the litigation and leaving the relator to litigate the case on behalf of the government, explains Garber. Petitioner Polansky had argued the government should not have been able to move to dismiss his FCA case after initially declining intervention since the government had already declined to participate and was not an active litigant. The Supreme Court sided with the government, holding that so long as the government intervened in the case at some point – which a court can permit at any time upon a showing of good cause – the government may move to dismiss.

The second question was what standards applied in assessing a government motion to dismiss an FCA case. The Supreme Court ruled that "the Government's views are entitled to substantial deference" because [a] qui tam suit . . . is on behalf of and in the name of the Government." The court cautioned "a district court should think several times over before denying a motion to dismiss" brought by the government in an FCA case.

"If the Government offers a reasonable argument for why the burdens of continued litigation outweigh its benefits, the court should grant the motion," said the Supreme Court. "And that is so even if the relator presents a credible assessment to the contrary."

**Reasons for Dismissal**

Garber believes this ruling could result in an uptick in dismissals of meritless cases. She notes that a 2018 memo from the Department of Justice outlined seven factors for evaluating dismissal of qui tam cases: 1) non-meritorious cases, 2) cases that are duplicative of pre-existing investigations or cases, 3) cases that interfere with agency policies or programs, 4) cases that may interfere with ongoing government litigation, 5) cases involving potential adverse impact on protection of classified information, 6) burdensome cases where, for example, the costs of monitoring outweigh the potential recoveries, and 7) cases involving egregious procedural errors or interference by the relator.

**'Shoot Your Shot'**

The takeaway for clinical labs? "If you're worried about facing a qui tam suit that you think is incorrect, it can't hurt to see if the DOJ will move to dismiss the case if they agree," says Garber. "It makes an easier call for the DOJ to dismiss a case knowing they can dismiss and the Supreme Court gives them substantial deference."

The Supreme Court decision in Polansky does not change the law, but it more clearly explains the standards that courts can apply in allowing a dismissal, she explains.

"If you have a fair argument why the qui tam case should not go forward, I say shoot your shot," says Garber.

# COMPLIANCE 101:

## *Auditing and Monitoring of Policies and Procedures*

The Health and Human Services Office of Inspector General (HHS OIG) has made it clear that it does not look kindly on compliance plans and programs that exist on paper but are not earnestly implemented or enforced. In addition to education and training programs, policies and notices, a successful compliance program should require the thorough monitoring of its implementation and regular reporting to senior executives and members of the Board of Directors.

Although many monitoring techniques are available, an effective tool to ensure enforcement is the performance of regular, periodic audits of the laboratory's operations, with particular attention paid to billing, sales, marketing, notices and disclosures to physicians, requisition forms, pricing and activities of phlebotomists and others involved in the ordering of laboratory services. In addition, auditing should address issues related to contracts, competitive practices, marketing materials, CPT/HCPCS coding and billing, test information, reporting and record keeping.

Quality assurance and zero tolerance of fraud should be the goal of the compliance division, and auditing is a good tool to use to achieve that goal, says the OIG. Compliance audits should be conducted in accordance with pre-established comprehensive audit procedures and should include, at a minimum:

1. On-site visits.
2. Interviews with personnel involved in management, operations, billing, sales, marketing and other related activities.
3. Reviews of written materials and documentation used by the laboratory.
4. Trend analysis studies.

Formal audit reports should be prepared and submitted to the Chief Compliance Officer and the Board of Directors or other governing body to ensure that laboratory management is aware of the results and can take whatever steps necessary to correct past problems and prevent them from recurring. The OIG suggests that the audit or other analytic reports specifically identify areas where corrective actions are needed. In certain cases, subsequent audits or studies would be advisable to ensure that the recommended corrective actions have been implemented and are successful.

**Annual Compliance Audit**

Clinical laboratories should perform an annual compliance audit. According to CodeMap, the audit should review compliance with the following: Federal anti-kickback provisions; Stark self-referral prohibitions; CPT/HCPCS coding and billing; ICD-10 coding practices; and rules and regulations governing claims development and submission. The annual compliance audit should also include examination of whether the lab has adhered to its own compliance policies, such as conducting effective compliance training, operating a disclosure hotline and taking appropriate disciplinary actions.

The lab should retain outside auditors to perform the annual compliance audit, says CodeMap. The audit should include one or more on-site visits, interviews with personnel, questionnaires developed to solicit the impressions of a broad cross-section of the lab's employees and clients relating to compliance issues, reviews of requisition forms and other forms that support claims for reimbursement, review of written materials used in marketing, processing and billing of tests, and trend analysis studies (e.g., comparisons with previous year's findings and investigation of significant differences) that seek deviations in billing or ordering patterns.

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

## In Brief

### New Bill to Require Lab Price Transparency Under Medicare

Rep. Carol Miller (R-WV) on July 25 introduced the Clinical Laboratory Price Transparency Act, which she says will provide patients with clear price transparency when making healthcare decisions regarding clinical laboratory testing. The bill will require clinical labs under Medicare to publish their healthcare prices beginning Jan. 1, 2025, and the Centers for Medicare and Medicaid Services (CMS) to monitor compliance. In a statement, the American Clinical Laboratory Association (ACLA) says it supports healthcare price transparency efforts that are meaningful to patients, including the provision of information about the cash prices for clinical laboratory test services. "We also believe that a consumer's insurer is the best source about their out-of-pocket expenses, and insurers are required to have transparency tools in place to do just that," says ACLA. "We do not, however, believe it is useful to provide negotiated rates between providers and health plans as this information will not have any utility for consumers because it does not change the rate their own insurer has negotiated or the cash price."

### USPSTF Ponders Ongoing Insurance Coverage of Covid Screening

The U.S. Preventive Services Task Force (USPSTF) plans to discuss recommending Covid-19 screening, which is the first step in requiring insurers to permanently cover the tests at no cost to patients. Chair Michael Barry wrote in a letter to Sen. Elizabeth Warren (D-Mass.) that the task force would convene and "determine whether and how Covid-19 screening might be considered within the Task Force's scope." Under the Affordable Care Act, insurers are required to cover tests, screening and certain preventive medicines that the task force strongly recommends. During the public health emergency, all public and private insurers were required to cover Covid tests at no cost. But since the emergency ended in May, several large insurers have limited coverage of at-home tests or introduced copays on lab tests for Covid.



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