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Kimberly Scott, Editor, kscott@laboratoryeconomics.com

# COMPLIANCE & POLICY REPORT

*Compliance and Regulatory Analysis for Lab Directors and Managers*

## CMS Says Its Policy Already Allows Nurses to Perform Moderate- and High-Complexity Testing

Despite widespread opposition to a CLIA proposal from the Centers for Medicare and Medicaid Services (CMS) to allow nurses to perform moderate- and high-complexity testing, they are allowed to do so under CMS policy guidance that's been in effect for more than seven years. *Continued on page 2.*

## Tips on Assessing, Mitigating Compliance Risk Under EKRA

In the four years since the Eliminating Kickbacks in Recovery Act (EKRA) was enacted, the federal government has not issued any regulations nor provided any guidance. As a result, many clinical laboratories are uncertain just what steps they should take to ensure compliance with the statute. *For tips on how to assess and mitigate compliance risk under EKRA, see pages 4-5.*

## OIG Clarifies Use of Gift Cards to Encourage Screening Tests

A new explanation by the Health and Human Services Office of Inspector General (OIG) on arrangements involving cash and cash equivalents to Medicare and Medicaid beneficiaries may open the door for arrangements previously thought likely to violate the beneficiary inducements provisions of the Civil Monetary Penalty Law (CMP) and the Anti-Kickback Statute (AKS), says Shannon DeBra, an attorney with Epstein Becker Green. *Details on page 7.*

## Are You in Compliance with the No Surprises Act?

Although the No Surprises Act (NSA) has been in effect since January 2022, many providers—including pathologists—may not be fully aware of their obligations under the law, particularly concerning good faith estimates and provider requirements for public disclosure.

Elizabeth Sullivan, a healthcare attorney with McDonald Hopkins (Cleveland), tells *LECPR* that the firm still encounters pathology groups, laboratories, and other providers that are not aware of the requirements under the law or that are unsure of how to fulfill such obligations. *See page 9 for key responsibilities under the NSA.*

## CONTENTS

## CMS Policy on Nurses Performing Moderate- and High-Complexity Testing

(*cont'd from page 1*)

Under a 2016 memorandum to state survey agency directors (16-18-CLIA), CMS states that "bachelor's and associate's degrees in nursing meet the requirement for earning a degree in a biological science for, respectively, high-complexity testing personnel and moderate-complexity testing personnel."

Sarah Bennett, Technical Director, Division of Clinical Laboratory Improvement and Quality for CMS, confirms that the policy allowing nurses to perform moderate- and high-complexity testing is still in effect.

"We are operating under the policy outlined in QSO-16-18-CLIA," Bennett writes in an e-mail to *LECPR*. She goes on to say that comments on a 2022 proposal to modify the Clinical Laboratory Improvement Amendments (CLIA) "are being evaluated to determine what, if any, proposed rule provisions will be finalized." (*For more on the proposed rule, see the March LECPR issue.*)

CMS sought further input on the issue on Jan. 5, 2018, when it issued a request for information (QSO-18-11-CLIA) asking for public comment on personnel requirements, proficiency testing, histocompatibility, compliance and additional fees.

**Confusion About Current Policy**

Dennis Weissman, a laboratory industry thought leader and consultant, says there appears to be some confusion in the industry about what the CLIA policy on nurses performing testing is, but notes that some labs have been utilizing nurses to perform testing since the 2016 memo was issued. Weissman points out that the 2022 CLIA proposed rule cites the 2016 memo but does not clearly state what the current policy is.

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In the proposed rule published July 26, 2022, CMS says it is proposing to add an earned doctoral, master's or bachelor's degree in nursing as a means to qualify as testing personnel (TP).

"In Survey and Certification memo 16-18-CLIA, we stated that a 'bachelor's in nursing meets the requirement of having earned a bachelor's degree in biological science for high-complexity TP' and that 'an associate's degree in nursing meets the requirement of having earned an associate's degree in a biological science for moderate-complexity TP,'" says CMS in the proposal.

"We appreciate all comments received in response to the 2018 RFI and agree that a nursing degree is not equivalent to a biological or chemical science degree. We also concur with some commenters' recommendation that nursing degrees be used as a separate qualifying degree for TP…We do not have any reason to believe that nurses would be unable to accurately and reliably perform moderate- and high-complexity testing with appropriate training and demonstration of competency," says CMS.

Weissman believes CMS essentially is proposing to change the rationale for allowing nurses to perform moderate- and high-complexity testing. "They're now saying a degree in nursing is not equivalent to a biological or chemical science degree, but we will accept it anyway as a qualifying condition for testing personnel," he says.

**Extensive Opposition**

A number of individuals and organizations submitting comments on the CLIA proposal oppose allowing those with nursing degrees to perform moderate- and high-complexity testing. Many of the commenters argue that while nurses have long performed point-of-care (POC) testing, they do not have adequate training to perform more complicated types of testing.

The Association of Public Health Laboratories (APHL) in its comments reiterated that it stands by its 2017 position statement that CMS "should immediately rescind its directive that an associate's or bachelor's degree in nursing is equivalent to an associate's or bachelor's degree in a biological science for a high-complexity laboratory."

APHL notes in its 2022 comments that there has been no change to the issues raised in the 2017 statement. "The disparity between the academic credentialing for biological or chemical sciences and nursing are too significant to be remedied by appropriate training," the group says.

**Guidance Is Not Rulemaking**

Jim Flanigan, Executive Vice President for the American Society for Clinical Laboratory Science (ASCLS), tells *LECPR* that CMS had told the organization that allowing nursing degrees to serve as a substitute for medical laboratory sciences degrees was an "unwritten rule" that had been in place since the beginning of CLIA and that the 2016 memo was simply bringing that to light.

*CMS told ASCLS that allowing nursing degrees to serve as a substitute for medical laboratory sciences degrees was an 'unwritten rule' that had been in place since the beginning of CLIA.*

ASCLS and the American Society for Clinical Pathology made several attempts to convince CMS that this was bad policy, including submission of thousands of signatures on petitions and holding meetings with senior CMS officials.

"Sub-regulatory guidance, which is the April 2016 memo, is different than formal rulemaking," says Flanigan. "CMS is essentially attempting to create federal law that bachelor's nursing degrees are equivalent to MLS degrees, when they are demonstrably not. They have entirely different coursework for entirely different professions that perform entirely different work."

In formal comments submitted to CMS on the 2022 proposed CLIA changes, ASCLS argues that CMS's proposal to add a bachelor's degree in nursing as a qualifying degree for high-complexity testing personnel "is incongruent with the narrative used to justify it," adding that the proposed rule omits any requirement for training and demonstrated competency to perform high-complexity testing relative to those who have four-year degrees in clinical laboratory science, chemistry or biology.

In fact, the Clinical Laboratory Improvement Advisory Committee (CLIAC) commissioned a CLIA personnel regulations workgroup, and at its April 2019 meeting stated, "Individuals with nursing degrees should qualify based on having satisfied educational requirements for courses with a clinical laboratory science component."

ASCLS says it is stunned that the agency had equated the experience with waived testing in point-of-care settings as somehow similar to high-complexity testing. CMS paints a rosy picture of how waived testing is performed in point-of-care environments, but basic waived testing deficiencies (as CMS notes are mostly performed by nurses) are regularly among the most cited by CMS and other deemed status surveyors under CLIA.

"This proposed rule, which opens a new vector for diagnostic error, is a reckless attempt to cover for a decades-old decision by CMS administrators to allow nurses to function in these roles as an 'unwritten rule,'" states ASCLS in its comments. "After it was added to the CLIA interpretive guidance via Survey and Certification memo 16-18-CLIA in April 2016, industry experts provided ample and convincing evidence that this was inappropriate. Still, CMS has persisted in this misguided course, benefiting no one and harming patients."

ASCLS is urging CMS to reverse the proposed rule and disallow individuals with nursing degrees without appropriate education and training to perform high-complexity clinical laboratory testing.

## Tips on Assessing, Mitigating Compliance Risk Under EKRA (*cont'd from page 1*)

There have been a number of prosecutions under EKRA since it went into effect. Some of the earliest cases prosecuted involved clinical treatment facilities and recovery homes while more recent cases involve laboratory testing, including Covid-19 testing. (*For more on EKRA rulings, see the April issue of LECPR.*)

*Myla Reizen*

Myla Reizen, a partner with K&L Gates (Miami), tells *LECPR* that it's fair to anticipate further EKRA enforcement due to the lack of regulatory guidance on the statute, along with recent government activities. Clinical laboratories should assess their current compensation arrangements to ensure they are in compliance with EKRA and other laws, says Reizen, who suggests that labs take the following steps:

1. **Take inventory of what compensation arrangements your lab currently has in place, particularly commission-based payments.** For instance, sales rep compensation, particularly percentage-based commission payments, can implicate EKRA, as well as the Anti-Kickback Statute and other related laws.

2. **Analyze these arrangements** internally with legal counsel or with an outside law firm to ensure they comply with applicable federal and state laws.

3. **Ensure that you are aware of all payments that are being made.** In some recent settlements, labs were still making payments under a commission structure that they had understood had been restructured. Genotox, which recently agreed to pay $5.9 million to the federal government to settle False Claims Act allegations, in 2019 had begun transitioning its marketing compensation structure from percentage to fixed rate due to EKRA concerns. However, at least three sales reps continued to get paid on a percentage basis through 2022. (*For more on the Genotox settlement, see p. 6.*)

4. **Decide if you need to make any modifications to your compensation arrangements**. Terminate any current practices and/or make any disclosures to the federal government. For example, the Health and Human Services Office of Inspector General has a healthcare fraud self-disclosure protocol under which providers can voluntarily identify, disclose and resolve instances of potential fraud involving federal healthcare programs. (The protocol was last updated in 2021. The revised protocol is available at www.oig.hhs.gov).

   "In some cases, compensation arrangements need to be restructured," says Reizen. "In other cases, they need to be terminated altogether."

5. **Determine what guidance, such as policies and procedures, need to be put into place to ensure compliance with EKRA and other laws.** The General Counsel and Compliance Officer should develop policies and procedures and submit them to the Board's Compliance Committee and full board. Once the lab's governing body has signed off on the policies, they should be implemented across the organization.

6. **Train all staff on the compliance policies of the organization.** Training should be conducted upon hire and at least once a year. In fact, education and training is one element of the HHS OIG's model compliance plan for clinical laboratories. According to the OIG, the training should cover the laboratory's compliance policies and should reinforce the fact that strict compliance with the law and laboratory policies is a condition of employment.

"This is not legal advice, but rather some general information that might be useful for clinical laboratories," says Reizen. "It's best if labs either consult with their own legal counsel or seek outside legal advice regarding the particular facts and circumstances in determining if arrangements comply with federal and state laws."

## Feds Bring 18 Charges in Covid Crackdown, Lab Implicated

The Department of Justice on April 20 announced criminal charges against 18 defendants in nine federal districts for their alleged participation in various fraud schemes involving healthcare services that exploited the Covid-19 pandemic and allegedly resulted in more than $490 million in Covid-19 related false billings.

In the Central District of California, a lab owner was charged for allegedly submitting more than $358 million in false and fraudulent claims to Medicare, the Health Resources and Services Administration (HRSA) and a private insurance company. The indictment alleges the defendant's lab performed Covid-19 screening testing for nursing homes and other facilities with vulnerable elderly populations, as well as primary and secondary schools. But to increase its reimbursements, the defendant allegedly added claims for respiratory pathogen test panels even though ordering providers and facility administrators did not want or need them.

Charges also have been brought against suppliers of Covid-19 over-the-counter tests who allegedly repeatedly supplied patients with dozens of Covid-19 tests that they did not want or need.

The charges come weeks after the White House announced it was seeking congressional approval for a $1.6 billion plan to deal with Covid-related fraud.

"The charges demonstrate that the federal government continues to focus on Covid-19 healthcare fraud, which is no surprise given the large volume of funds distributed as a result of Covid-19," says Karen Lovitch, chair of the Health Law Practice at Mintz Levin (Washington, D.C.). "One matter involved allegations of criminal fraud related to the uninsured program administered by HRSA, and we are likely to see more of those cases announced in the months ahead."

# EKRA Cited in Genotox Case; Whistleblower Gets $1 Million

Genotox Laboratories (Austin, TX) has reached a $5.9 million agreement with the federal government to resolve False Claims Act and Anti-Kickback Statute (AKS) violations related to unnecessary drug testing claims, the U.S. Department of Justice announced on April 4.

The agreement was signed by Matthew McCarty, MD, Founder and Chief Executive Officer of Genotox. McCarty, who is a board-certified anesthesiologist, is also owner of Balcones Pain Consultants (Austin) and GenoRite Pharmacy (Austin).

The government's investigation was prompted by whistleblower Alex DiGiacomo. As part of the $5.9 million settlement, DiGiacomo will receive about $1 million (17%). DiGiacomo worked as Genotox's billing manager from April 2016 to June 2020. DiGiacomo filed his whistleblower lawsuit in U.S. District Court for the Southern District of Georgia in September 2020.

**Some of the allegations contained in DiGiacomo's initial complaint included:**

- Genotox recruited medical practice employees to be specimen processors (SPs) for Genotox within their practices. Genotox paid commissions to these SPs as independent 1099 contractors based on the number of tests or revenue generated for Genotox. These arrangements violated The Eliminating Kickbacks Recovery Act (EKRA) because they were volume-based payments designed to induce referrals of lab tests, including tests paid for by Medicare.
- Genotox paid kickbacks to its medical practice clients in the form of "rent" for office space for its SPs in violation of AKS or EKRA.
- Genotox routinely used standing orders for custom toxicology profiles signed by its clients and kept on file with Genotox. The custom toxicology profiles were all designed to be billed under code G0483 (definitive drug testing for 22+ classes; Medicare rate of $247)—the most comprehensive and highest reimbursed urine drug test. Genotox's standing orders for custom toxicology profiles were used without regard to medical necessity.

"FCA cases are tough. I don't ever go into them with any expectation of success, so it was nice to get this one done," says Robert Snyder, attorney at Butler Wooten & Peak (Atlanta), which represented DiGiacomo.

According to Snyder, the defense disputed whether the anti-kickback statute applied to independent contractors working off commission in medical testing, but that the EKRA statute made the illegality of their actions "crystal clear."

*The defense disputed whether the anti-kickback statute applied to independent contractors working off commission in medical testing, but the EKRA statute made the illegality of their actions 'crystal clear.'*

After securing the settlement against Genotox, the plaintiffs dropped their complaints against several medical practices, including McCarty's other companies (Balcones Pain Consultants and GenoRite Pharmacy). "I do think [those claims had] merit; there were just questions of collectability, time spent by lawyers and the client, and just wanting to have closure and move on," Snyder says.

In connection with the settlement, Genotox has also entered into a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The CIA requires, among other things, that Genotox maintain a compliance program, implement a risk assessment program, and hire an Independent Review Organization to review Medicare and Medicaid claims at Genotox. Finally, Genotox is required to pay $225,000 to Butler Wooten & Peak to cover DiGiacomo's legal expenses.

## OIG Clarifies Use of Gift Cards to Encourage Screening Tests (*cont'd from page 1*)

In a FAQ posted to the OIG's website on March 29, 2023, the OIG explained how it distinguishes between "cash," "cash equivalents" and "in-kind" gift cards.

The OIG explained that "cash" means "monetary payments in the form of currency." The OIG also added that funds transferred electronically, such as through a peer-to-peer application (Venmo, CashApp, PayPal or Zelle) are also cash.

**Cash Equivalents**

Historically, the OIG interpreted the phrase "cash equivalent" to mean items convertible to cash, such as a check, or items that can be used like cash, such as a general-purpose prepaid card like a Visa or a Mastercard gift card. In recent years, however, the OIG expanded its interpretation of what qualified as a cash equivalent to also include gift cards from retailers it referred to as "big-box stores"—large retailers or online vendors that sell a wide variety of items that, in the OIG's view, "could easily be diverted from their intended purpose or converted to cash."

"This interpretation proved to be difficult to apply in real-world situations because while we all might think of Amazon and WalMart as big-box stores, it was not clear what other stores might also fall into this category and present a compliance risk," says DeBra.

For example, it was unclear whether gift cards from large grocery store chains whose stores sold items like household appliances, electronics and clothing would be included. If so, which items in particular made the store cross the line from permissible gift card to prohibited cash equivalent? Another common question was whether a gift card from one of these stores that limited the type of item purchased could avoid being treated as a cash equivalent.

**Subset of Gift Cards**

According to DeBra, the OIG provides some much-needed clarification to at least one of these questions in the new FAQ by identifying a subset of gift cards, including gift cards from big-box retailers, that it considers to be "in-kind" remuneration and not cash equivalents. The OIG stated that gift cards that can be redeemed for a limited category of items, such as a gas card or food delivery service gift card or voucher, would be considered in-kind remuneration.

*Shannon DeBra*

The OIG also confirmed that a gift card to a big box retailer that, by its express terms, may only be used to purchase a particular item or select categories of items would also be considered in-kind remuneration. As an example, the OIG cited a gift card to a big-box store that can only be used to purchase fresh food items such as produce.

The OIG noted that understanding how it views these different categories of gift cards is important to the application of certain AKS safe harbors and beneficiary inducements CMP exceptions. Citing the patient engagement and support safe harbor as an example, the OIG noted that the safe harbor only protects the provision of in-kind items, goods and services.

"That means that a Visa and MasterCard gift card or an unrestricted gift card to a big-box store would not qualify for safe harbor protection, but a gas card, a gift card to a fitness center or a restricted big-box store gift card could qualify under that safe harbor (assuming all other safe harbor requirements are met)," says DeBra.

**Instruments Convertible to Cash**

The OIG also clarified for the first time that the term "instruments convertible to cash" is not a synonym for "cash equivalent." Rather, the OIG explained that "instruments convertible to cash" refers to a subset of "cash equivalents" and noted, as an example, that while a prepaid Visa or MasterCard gift card is a "cash equivalent," it is not an "instrument convertible to cash."

"This distinction is relevant for applying the Preventive Care Exception to the Beneficiary Inducements CMP and may allow for a greater variety of incentives to be given to Medicare and Medicaid beneficiaries when the other requirements of that exception are met," says DeBra.

**Advisory Opinion 23-03**

Advisory Opinion 23-03 is the OIG's first opportunity to apply its newly announced clarification of the difference between a "cash equivalent" and an "instrument convertible to cash." In this opinion, the OIG considered a proposal by a laboratory to provide a prepaid card, such as a Visa or MasterCard gift card, with a value of up to $75 to certain individuals. These include federal healthcare program beneficiaries to encourage those individuals to return the sample collection kit associated with a stool-based DNA colorectal cancer screening test.

Under the proposed arrangement, a patient's prescriber would order the test and submit an order to the laboratory, which would then ship the test sample collection kit directly to the patient. The lab would make at least two patient contacts via telephone, text message, email or letter to encourage patients to return the kit to the laboratory.

If the lab does not receive the patient's sample following the two patient contacts, then the laboratory would send the patient a reminder letter that informs the patient that if they return the sample within a specified period of time, the lab will send the patient a prepaid gift card, such as a Visa or MasterCard gift card, with a value of up to $75. The gift cards would not be redeemable for any items or services provided by the lab and would only be available to patients once per 36-month period to align with Medicare's coverage rules for the test.

The availability of the gift card would not be advertised in any patient-focused promotions, nor would it be advertised or marketed to prescribers. The proposed arrangement also would not include any offer or payment of remuneration to prescribers. Additionally, the proposed arrangement would not apply if the prescriber orders the test through the laboratory's website.

*Relying in part on its newly clarified definition of 'instruments convertible to cash,' the OIG concluded that the offer and transfer of a Visa or MasterCard gift card in the proposed arrangement satisfied the requirements of the Preventive Care Exception under the Beneficiary Inducements CMP.*

In its analysis, the OIG noted that the proposed arrangement implicated both the Beneficiary Inducements CMP and the AKS. However, relying in part on its newly clarified definition of "instruments convertible to cash," the OIG concluded that the offer and transfer of a Visa or MasterCard gift card in the proposed arrangement satisfied the requirements of the Preventive Care Exception under the Beneficiary Inducements CMP.

"Noting that more than 30% of patients fail to return the kit to the laboratory, the OIG stated that the proposed arrangement could promote patient compliance with a screening test that has been recommended by the USPSTF and the American Cancer Society to screen for colon cancer and that CMS has said would benefit the patient and also the Medicare program," says DeBra.

AO 23-03 is available at https://oig.hhs.gov/documents/advisory-opinions/1109/AO-23-03.pdf. The FAQs are available at https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/.

## ARE YOU IN COMPLIANCE WITH THE NO SURPRISES ACT? (*cont'd from page 1*)

**Good Faith Estimates**

Under the NSA, uninsured and self-pay patients have the right to request a good-faith estimate (GFE) of what a procedure will cost before they have it. The facility where the primary procedure is performed must provide the estimate, but the NSA requires providers involved in the procedure, including pathologists and laboratories, to assist. The estimate must include charges for the items or services that are reasonably expected to be provided in conjunction with the primary item or service. The document must be a stand-alone document and can be either electronic or paper.

If a procedure is scheduled to take place within three business days, the facility must give the GFE to the patient no later than one day after scheduling. If the procedure is scheduled at least 10 business days before the procedure is to be performed, the facility must give patients an estimate no later than three business days after scheduling. If the actual bill is $400 or more above the good-faith estimate for a given provider's service(s), the patient may be able to dispute that portion of the bill.

Sullivan notes that providing a GFE can be especially challenging for pathologists given the nature of the work. "It is difficult for pathologists to put estimates together because it's difficult to anticipate what subsequent tests might be needed," she says. "We recommend that providers try to make this as standardized as possible in advance so they can provide this information quickly to the facility when requested." Appreciating the practical limitations on the recommendation, Sullivan suggests that providers prepare charge information in advance for as many situations as possible so that the information can be quickly accessed and combined for GFE requests.

*Elizabeth Sullivan*

For the first year that the law was in effect, the Department of Health and Human Services (HHS) exercised discretion in enforcement of GFEs. Actual enforcement was to begin at the end of 2022, but HHS said in an FAQ posted in December that it would extend enforcement discretion and anticipated further rulemaking on the issue.

"By extending this exercise of enforcement discretion, HHS aims to promote further interoperability across the healthcare industry and encourage providers, facilities and other industry members to focus resources towards adopting interoperable processes for exchanging information," the agency said in the FAQ, available at https://www.cms.gov/files/document/good-faith-estimate-uninsured-self-pay-part-3.pdf.

Sullivan recommends that providers take steps now to comply with the GFE requirement so they will be prepared when strict enforcement begins.

"Providers should organize a working group to come up with an estimated payment list and standardize it in some way," she advises. "If there's not a long implementation period, it could be a heavy lift for providers. At some point, we expect that the GFE to be enforced, and that could be a real administrative burden for providers that are unprepared."

**Public Disclosure Obligations**

According to Sullivan, some providers are still unaware that they have specific public disclosure obligations under the NSA. The NSA disclosures are intended to notify patients of the key protections under the NSA. The disclosures are also intended to provide information on how to notify the government if the patient believes the NSA has been violated. Specifically, providers are required to provide notice in three separate ways:

1. **Website disclosure.** Providers must post a disclosure on their website that is easily accessible.
2. **Print disclosure.** If the provider has a patient-facing area, such as a clinical laboratory, a notice should be posted in a prominent location.
3. **Notice sent to patient.** A one-page notice must be provided to patients either before billing or enclosed with the bill.

Importantly, the Centers for Medicare and Medicaid Services (CMS) has disclosure templates available to guide providers in preparing the required disclosures. More information is available at:

https://www.cms.gov/files/document/model-disclosure-notice-patient-protections-against-surprise-billing-providers-facilities-health.pdf.

https://www.cms.gov/files/document/standard-notice-consent-forms-nonparticipating-providers-emergency-facilities-regarding-consumer.pdf.

**Independent Dispute Resolution Process**

Provider groups continue to have concerns about the independent dispute resolution (IDR) process, arguing that the process benefits the payers and handicaps the providers. Under the final rule issued Aug. 19, 2022, the IDR entity is to give more weight to the qualifying payment amount (QPA), which is defined as the median contracted rate as of Jan. 31, 2019, adjusted for inflation.

"As a result of the original rulemaking, the QPA was skewed to what payers were already paying," says Sullivan. "Not only did the rule establish a presumption in favor of contracted rates, it also downplayed other information that providers feel is important in establishing reimbursement. The rule assumed that the QPA was credible and undermined the value of alternate information that would be submitted by the provider."

*While the NSA does take the patient out of the middle in the dispute between payers and providers, the law does have unintended consequences for providers.*

Many provider groups, including the College of American Pathologists, oppose relying on the QPA during the IDR process. In addition, a number of lawsuits have been filed challenging the IDR process. A Texas judge in February of this year ruled that the federal government's revised independent dispute resolution process for determining payment for out-of-network services under the NSA skews the arbitration results in commercial insurers' favor.

As a result of the decision, CMS in March 2023 revised IDR instructions to arbitrators, and arbitrators are instructed to decide cases based on merit and not on the instructions contained in the final rule. [It is interesting to note that in a report released in January 2023, the government said it had received more cases for arbitration than it had anticipated. From April 15 through September 30, 2022, payers and providers initiated more than 90,000 disputes through the federal IDR portal. The government had only estimated about 17,000 claims per year.]

Several lawsuits are still pending, including one challenging the definition of QPA and one challenging an increase in the fee charged to file arbitration cases (from $50 to $350).

While the NSA does take the patient out of the middle in the dispute between payers and providers over payment, the law does have unintended consequences for providers, notes Sullivan. "I believe the rule is functioning to protect patients, but as an unintended consequence, it has created challenges for providers in obtaining fair reimbursement from payers," she notes.

# COMPLIANCE 101:
## *Program Basics for Clinical Laboratories*

### Does Your Lab Have a Chief Compliance Officer?

Under the compliance program guidance from the Health and Human Services Office of Inspector General (HHS-OIG), all clinical and anatomic pathology laboratories should have a Chief Compliance Officer (CCO) or an equivalent, such as a Compliance Committee, to oversee and manage every aspect of the lab's compliance program.

The Chief Compliance Officer or committee should be delegated sufficient authority by the Board of Directors or governing body of the organization to undertake and comply with these responsibilities and should have open access to senior management and the governing body.

The following job description for a Chief Compliance Officer is adapted from CodeMap's ***Compliance Policy Manual for Clinical Laboratories, 2023 Edition***. According to CodeMap, a consulting company based in Chicago, a sample job description for a CCO should include, but not be limited to, the following responsibilities:

1. Oversee, coordinate and monitor the day-to-day compliance activities of the laboratory and the operation of the laboratory compliance program.
2. With the assistance of outside consultants (and legal counsel if required), establish a regulatory compliance manual. Maintain and supplement the manual as necessary.
3. Develop and coordinate appropriate compliance training and educational programs for all appropriate employees. Ensure that all employees understand the laboratory's commitment to comply with all laws, regulations, compliance program policies and ethical requirements applicable to the conduct of its business.
4. Develop, coordinate and oversee internal and external audit procedures for monitoring and detecting any misconduct or non-compliance. If misconduct or non-compliance is detected, recommend a solution and follow up to ensure that recommendations have been implemented.
5. Develop a system that enables employees to report any noncompliance without fear of retribution, ensuring that the reporting system is adequately publicized and that allegations of noncompliance are investigated and responded to promptly.
6. Ensure that a mechanism is in place for disciplining instances of noncompliance (including the failure to prevent, detect or report any noncompliance) appropriate to the nature and extent of the deviation, and ensure consistency in the application of disciplinary actions.
7. Ensure a workforce with high ethical standards by establishing a minimum standard of conduct and performing appropriate background and reference checks of potential employees.
8. In conjunction with legal counsel and outside consultants, interface, and when appropriate, negotiate with external regulatory agencies and federal and state contractors.
9. Report to the President or the Board of Directors as may be necessary concerning any significant compliance issues and ensure that appropriate action is taken.
10. Ensure that providers who order testing and services from the lab are informed of the laboratory's compliance program standards with respect to coding, billing and marketing.

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

## In Brief

### CDC Lab Workgroup Releases Report on Covid-19 Test Shortcomings

The Centers for Disease Control (CDC) has issued 10 recommendations on how to respond to future public health emergencies. The recommendations are contained in a report from the CDC's Advisory Committee to the Director Laboratory Workgroup following a review of the shortcomings of the agency's first Covid-19 test. Among the recommendations: appointment of a senior leader for laboratories reporting to the CDC director, consolidation of CDC's laboratory support functions into a new center and creation of exercise plans for developing tests for novel public health challenges. The report is available at https://www.cdc.gov/about/pdf/workgroup/EnhancingCDCLaboratoryPoliciesPracticesSystems.pdf.

### NGS Quality Initiative Identifies 12 System Essentials

The Next-Generation Sequencing (NGS) Quality Initiative, which is a collaboration between the CDC, the Association of Public Health Laboratories and state and local PHLs, has developed a number of tools for use by labs, including 12 quality system essentials. The initiative was created to develop an NGS-focused quality management system; create a toolkit to prevent duplication of efforts, increase efficiency and save costs; and harmonize quality standards for NGS across public health. More information is available at https://www.cdc.gov/labquality/ngs-quality-initiative.html.

### FDA Offers Transition Guidance for Covid-19 Tests Issued Under EUA

The Food and Drug Administration has issued two guidance documents to assist with transition plans for medical devices and tests that were issued emergency use authorization in response to the Covid-19 pandemic. The guidance provides recommendations and expectations for manufacturers that may or may not want to continue to distribute their test after the end of the public health emergency (PHE). EUAs may remain in effect even after the end of the PHE. The guidance documents are available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.



Jondavid Klipp, Publisher Kimberly Scott, Editor Jennifer Kaufman, Chief Copy Editor