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For Clinical and AP Laboratories and Pathology Practices

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IN THIS ISSUE

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Compliance Alert: Be Sure You Can Document Medical Necessity of COVID-19 'Add-On Tests'

Memo to Lab Compliance Managers: Brace yourself for what may become the next big federal false billing crackdown against labs, specifically labs performing COVID-19 tests. The OIG has let it be known that it suspects that labs may be taking advantage of the unprecedented demand for COVID-19 testing to bill Medicare for high reimbursing and medically unnecessary add-on tests. As a result, one of the new items listed in the agency's June work plan is an investigation of recent test billings to confirm whether its suspicions are warranted.

What the OIG Is Worried About

The objective of COVID-19 testing is to determine whether an individual has the virus. However, as the OIG points out in the

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Compliance Perspectives: How to Create and Implement a Mandatory Face Mask Policy at Your Lab Facilities

What began as a CDC guideline is evolving into a legal duty with more than 20 states and countless municipalities across the country adopting laws requiring individuals to wear masks or face coverings in enclosed indoor public spaces, including medical testing labs. As a result, labs must adopt and enforce mandatory mask policies at their facilities. While mask requirements vary slightly by jurisdiction, here are the 10 basic elements they should include. Go to the G2 website for a Model Policy that you can adapt.

Defining Our Terms

This analysis is about non-medical face masks that people at medium at low risk levels are required to wear, as opposed

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work plan item, labs can also perform add-on tests, e.g., to confirm or rule a diagnosis other than COVID-19. In the new work plan item expresses, the agency says it has "program integrity concerns" related to add-on tests in conjunction with COVID-19, particularly the potential of fraudulent billing for associated respiratory pathogen panel (RPP) tests, allergy tests or genetic tests.

The OIG Game Plan

To address these concerns, the OIG plans to perform a study analyzing Medicare claims data for lab testing to identify trends in the use of RPP, allergy and genetic testing and identify billing patterns indicating that labs may be committing fraud and abuse.

How to Protect Yourself—Do a 3-Part Medical Necessity Documentation Audit

If your lab is performing tests in conjunction with COVID-19 testing, be sure that you have clear and complete records documenting that those tests are medically necessary for the particular patient. Consider performing an internal audit to verify you have the documentation to satisfy not just Medicare Administrative Contractors but private payors of the medical necessity of those tests, focusing on the following three core elements.

1. Document Test Order

The first key element to support medical necessity is documentation that the treating physician ordered the test, which may include:

- A signed requisition;
- An electronic signature through email; or
- Signed documentation in the patient's chart.

Caveat: Documenting orders for add-on tests will be tricky due to the fact that during the public health emergency CMS has relaxed the rules requiring an order from the treating physician or nonphysician practitioner (NPP) for COVID-19 tests. And, according to the OIG, relaxation of physician ordering/NPP rules gives "unscrupulous actors more leeway for fraudulent billing of unnecessary add-on testing." If you don't have any of the three forms of documentation listed above, you may need to get a signed attestation from the ordering physician or NPP documenting the test order.

2. Document Need for the Test

Make sure you have documentation that the test is medically necessary. The patient's medical record must contain information indicating why not just the COVID-19 test but all of the additional tests performed to rule out or confirm a COVID-19 diagnosis is necessary. Don't offer such tests in automatic, prepackaged panels because it will raise a bright red flag

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with the OIG. Simply putting a statement on your requisition forms that declares that the physician/NPP agrees that by ordering the COVID-19 test, he/she considers the additional tests as medically necessary won't work, either. Remember, it's not the recitation of the sentence that's important but the reason why it's medically necessary.

3. Document Use of Test Results

Last but not least, you need documentation of the usage of the test results. Medicare and other payors will likely want to see documentation of review and/or use of the information by the ordering physician/NPP. After all, if the physician didn't need to review and act on the test results, the payor is apt to question whether the test was medically necessary.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Magnolia Wins Round One of False Advertising Suit against Rival Collection Device Maker

Case: Score one, maybe two, for Magnolia Medical Technologies, Inc. in its ongoing litigation war with rival blood and bodily fluid collection device maker Kurin, Inc. In addition to patent infringement, the firms have accused each other of false advertising. Kurin began the suit by claiming Magnolia misrepresented the capabilities of its Steripath collection device; Magnolia countersued Kurin for falsely advertising its Kurin Lock device. On July 23, a Southern California US District Court handed Magnolia a double win, dismissing all of Kurin's false advertising claims against Magnolia while allowing Magnolia to take its own claims against Kurin to trial.

Significance: The court found that Magnolia's claims about Steripath's "virtually eliminating" blood culture contamination were appropriately supported by controlled clinical studies demonstrating that the device eliminates "all but less than 1% of false positives." Corresponding claims about Steripath's demonstrated 92% and 93% reductions in the contamination rate were also backed by clinical studies, the court said. By contrast, it held that the "blended rate" results that Kurin uses in advertising the Kurin Lock device are "the opposite of controlled study results, because the study does not control for the use of the relevant device."

Can Lab Suing Vendor for Defective MS Equipment Change Its Legal Theory at the Last Minute?

Case: A Brooklyn medical lab purchased turn-key mass spectrometry equipment and support services from a New Jersey vendor for $534,000

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Labs in Court: A roundup of recent cases and enforcement actions involving the diagnostics industry, *from page 3*

so it could begin providing clinical toxicology services. But kinks in the equipment/service package caused the lab to fail its initial Proficiency Tests with the New York Department of Health and sued the vendor for conspiracy, fraud and falsely misrepresenting the capabilities of the package. Five years into the litigation with the discovery completed and the case set to go to trial, the lab wanted to add a new claim to its complaint: breach of contract. The vendor cried foul, noting that this was the third time the lab had changed its legal case; but the New York federal court shrugged off the vendor's objections and let the lab amend its claim.

Significance: The new claim would delay the trial, the court acknowledged, but it wouldn't be an "undue delay" or cause the vendor "undue prejudice." A lot of extra discovery wouldn't be necessary given how frequently issues of contract had already been addressed during the previous depositions, the court reasoned. And the breach of contract claim wouldn't be futile since it had sufficient merit and would probably survive a motion to dismiss, the court concluded [*Lenco Diagnostic Labs., Inc. v. McKinley Sci., Inc.*, 2020 U.S. Dist. LEXIS 119922, 2020 WL 3840562].

Rhode Island Health System Fined +$1 Million for Failure to Encrypt Laptops

Case: The trouble began when Lifespan Corporation, the parent company of a Rhode Island-based non-profit health system filed a breach report after a laptop containing medical record numbers, medication and other electronic protected health information (ePHI) on more than 20,000 individuals was stolen from one of its hospital employees. HHS Office for Civil Rights (OCR) officials called in to investigate uncovered a slew of systemic HIPAA Rules violations at Lifespan, including not only widespread failure to encrypt ePHI on laptops but also a lack of device and media controls. In addition to a $1,040,000 fine, Lifespan had to sign a corrective action plan that included two years of monitoring.

Significance: Laptops, cellphones and mobile devices are stolen every day. That's why it's so critical to ensure that those devices are encrypted so that thieves can't use the ePHI they contain to commit identity theft. While these might seem like obvious points, the Lifespan case is a reminder that systemic breakdowns remain all too common at large healthcare entities and how costly to patients and providers alike they can be when they occur.

LDTs: FDA Cracks Down on Improper Marketing of SARS-CoV-2 Antibody Tests

Bloated and unsubstantiated marketing claims about the capabilities of unproven serologic SARS-CoV-2 antibody tests have been a problem almost since the public health emergency began. After playing nice and calling on the test producers to police themselves, the FDA has and is now exercising its enforcement powers to crack down on companies for improperly marketing antibody tests.

A 180º Pivot

When the public health emergency first began, the FDA allowed producers to introduce antibody tests immediately upon self-validation without Emergency Use Authorization (EUA) via its newly created "Policy D" pathway. Predictably, the US market was soon awash with unproven tests deceptively touted as having FDA approval. The agency sounded the alarm and called on test makers to submit their products to federal labs for independent evaluation. Few did.

The turning point came in early May when, in response to a scathing Congressional investigational report, the FDA put its foot down, ending Policy D and making independent evaluation mandatory for all SARS-CoV-2 antibody tests, including those with EUA. Less than two weeks later, nearly 30 Policy D tests were either delisted or voluntarily withdrawn by their manufacturers.

On June 16, the agency revoked the EUA of one of the first serologic SARS-CoV-2 antibody tests to receive authorization, Chembio Diagnostic's DPP COVID-19 IgM/IgG test, citing concerns about its sensitivity and specificity. According to the agency, Chembio and independent laboratory evaluation data showed that the test "generates a higher than expected rate of false results and higher than that reflected in the authorized labeling for the device."

The Warning Letters

Even so, while the FDA had threatened, it hadn't actually initiated any enforcement actions. But that changed on June 17, when the agency announced that it had issued three warning letters to companies for improper marketing of SARS-CoV-2 antibody tests:

- Medakit, which is based in Hong Kong;
- Antibodiescheck.com and Yama Group in the United Arab Emirates; and
- Chicago-based Jason Korkus and Sonrisa Family Dental, doing business as www.mycovidtest19.com.

The FDA claims the companies were selling tests directly to consumers for at-home use without proper regulatory clearance, approval, or

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LDTs: FDA Cracks Down on Improper Marketing of SARS-CoV-2 Antibody Tests, *from page 5*

authorization. Among the tests that were improperly marketed, one actually has received EUA, namely, the Cellex Test Kit from Cellex which is sold by Sonrisa. However, the EUA for the test covers only labs certified to perform moderate- and high-complexity tests under CLIA.

The agency asked the three firms to immediately correct the violations, including stopping the sale of the products or preventing future sales, or face possible legal action, such as seizure and injunction.

Takeaway

It's no more Mr. Nice Guy from the FDA as far as marketing of SARS-CoV-2 serology tests is concerned. The FDA has now issued a fourth warning letter, this one to KBMO Diagnostics, demanding that it cease selling a test that uses at-home blood sample collection for COVID-19 serology testing. The agency contends that KBMO made claims on its company website that its BloodSpot fingerstick test was now available for doctors to order and offering to send collection kit to patients' home.. The website also includes a "BloodSpot Collection Tutorial" demonstrating how to self-collect and mail a blood sample. The problem, of course, is that the FDA hasn't granted EUA for the product.

Enforcement Trends: After 5 Down Years, ROI on Federal Enforcement Increases—But Just a Tad

Like any other business, federal health care fraud law enforcement has to account for its return on investment (ROI). And for the previous six years, that ROI had been in steady decline. But ROI reversed directions and began moving north again in Fiscal Year 2019. That's the main takeaway of the new joint HHS and DOJ report on the financial performance of the Health Care Fraud and Abuse Control Program (Program) during the past fiscal year. While federal fraud fighting is still not nearly as profitable as it was six years ago, FY 2019 may at least signal a positive change in trajectory.

After Years of Trending Down, ROI Ticks Slightly Up

The *Health Insurance Portability and Accountability Act of 1996* (HIPAA) established the Program under the joint direction of the Attorney General and HHS Secretary, acting through the OIG, to coordinate federal, state and local law enforcement activities with respect to health care fraud and abuse. The Annual Report describes the Program's financial performance in the previous fiscal year.

Arguably, the most significant metric in the report is Program ROI, which measures how much money the Program returns for every dollar invested. Program ROI is calculated by dividing the total monetary results to the Federal government (not including relator payments) by the annual appropriation for the Program Account in a given year (not including portions of CMS funding dedicated to the Medicare Integrity Program.

And since FY 2013 when ROI peaked at $8.10, ROI has been trending steadily down, with five consecutive years of decline. FY 2019 finally saw the losing streak come to an end, with ROI increasing from $4.00 to $4.20 in 2019.

Annual Program ROI, FY 2013 to FY 2019

FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
$8.10	$7.70	$6.10	$5.00	$4.20	$4.00	$4.20

By the Numbers

During FY 2019, the federal government won or negotiated over $2.6 billion in health care fraud judgments and settlements. That's up from $2.3 billion in FY 2018, even though the number of convictions during the same period actually declined from 872 to 578. Of course, civil actions have traditionally been the cash cow of federal enforcement efforts.

Metric	FY 2019	FY 2018
Total recoveries	$2.6 billion	$2.3 billion
New DOJ criminal health care fraud investigations	1,060	1,139
New DOJ civil health care fraud investigations	1,112	918
New criminal cases filed	485	572
Convictions	528	872
Criminal action resulting from OIG Investigations	747	649
Exclusions issued by OIG	2,640	2,712

Takeaway

Because the annual Program ROI can vary from year to year depending on the number and type of cases that are settled or adjudicated during that year, DOJ and HHS use a three-year rolling average ROI for results contained in the report," the agencies explain in their report. But while rolling averages and a modest gain in FY 2019 may take off some of the edge for a particular year, they can't conceal the long-term trend. Simply put, the return on enforcement dollars is only about 50% of what it used to be just seven years ago.

Quiz: Can Lab Give Medical Group Free Telehealth Equipment for Non-COVID Treatment and Diagnosis?

SITUATION

A local physician group in an underserved rural community wants to establish a telehealth capacity enabling it to examine and treat elderly patients who are observing social distancing or are in isolation or quarantine. The problem is that it can't afford to buy or lease the necessary telehealth equipment. XYZ Laboratories has surplus telehealth equipment that it would love to donate to help the community. However, the group refers a lot of Medicare patients to the lab and XYZ is afraid that giving it free equipment would violate the Stark Law and Anti-Kickback Statute (collectively, the "kickback" laws).

QUESTION

Can XYZ donate the telehealth equipment to the physician group?

A. Yes, because the arrangement meets the criteria for the current blanket kickback waivers

B. Yes, because the kickback laws have been waived during the public health emergency

C. No, because free telehealth equipment is remuneration banned by the kickback laws

D. No, because the telehealth equipment may be used for services not related to diagnosis and treatment of COVID-19

ANSWER

A. Yes, XYZ can provide the group the free telehealth equipment because the donation satisfies the waiver criteria.

EXPLANATION

During normal times, providing free telehealth equipment to a referring physician would get your lab into trouble under the kickback laws. However, the Blanket Waivers issued by CMS in response to the current Public Health Emergency (PHE) temporarily allow labs to offer remuneration to referring physicians as long as the arrangement is made in good faith and for the sole purpose of COVID-19 diagnosis and treatment.

The Blanket Waivers expressly list telehealth equipment allowing for medical care of patients who are social distancing, or in isolation or quarantine as a permissible arrangement. As a result, A is the right answer.

WHY WRONG ANSWERS ARE WRONG

B is wrong because the normal kickback rules are still in effect during the PHE. The only exceptions are for the arrangements that satisfy the criteria set out in the Blanket Waivers, which the telehealth equipment freebies arrangement in this case does.

C is wrong because while giving the physician group free telehealth equipment would be illegal remuneration during times of normalcy, the normal rules can be set aside during a PHE. And that's exactly what happened when CMS issued the Blanket Waivers.

D is wrong but it sounds right. The Blanket Waivers are, in fact, limited to good faith arrangements "related solely to" COVID-19. But the language is defined broadly as covering any health services in response to individual and community needs due to the COVID-19 outbreak, not just the actual diagnosis and treatment of COVID-19, including a telehealth arrangement allowing for social distancing and treatment of people in self-isolation.

Takeaway

Should You or Shouldn't You

The Blanket Waivers apply automatically if the arrangement meets the criteria and you don't have to get pre-review and clearance from the OIG. However, the OIG reserves the right to review any arrangement and impose penalties if it determines that it doesn't satisfy the requirements. The OIG is also willing to issue an Advisory Opinion if parties do want a green light before entering into the arrangement.

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to N95 particulate respirators and more elaborate respiratory equipment, eye and face shields other personal protection equipment (PPE) required for lab workers who handle COVID-19 testing specimens, draw blood from potentially infected patients or are otherwise at high risk of infection.

1. Policy Statement

Start by stating that all lab entrants must wear a proper mask or face covering and that failure to comply will be grounds for denial of entrance or immediate removal and, if the violator is an employee, discipline up to and including termination (Policy, Sec. 1).

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2. Statement of Purpose

Indicate that the purpose of this policy is to prevent COVID-19 infection and ensure compliance with regulatory requirements and public health guidelines (Policy, Sec. 2).

3. Definition of "Mask"

Include a specific definition of what constitutes a mask, namely, a non-medical face mask, bandana or other covering that:

- Goes over the nose and mouth;
- Ties around the ears or back of the head;
- Fits snugly against the sides of the face and;
- Is secured under the chin.

Just as importantly, clarify what a mask does not include, namely, the N95 type filtered medical mask required by healthcare workers nor a face shield that protects only the wearer (Policy, Sec. 3).

4. Whom the Policy Covers

Explain that the mandatory mask policy covers not just lab employees but all facility entrants, including patients, couriers, contract workers, health professionals, vendors, visitors and guests, unless an exemption applies (Policy, Sec. 4).

5. Where the Policy Applies & Doesn't Apply

Clarify that the policy covers not just all indoor spaces but also outdoor work areas where proper social distancing can't be maintained, as well as in lab vehicles. Also list exceptions where people don't have to wear a mask, which may differ by jurisdiction but typically includes:

- Work or time spent alone in a personal office or workspace;
- Walking, exercising or other outdoor activity where individuals are at least six feet apart;
- Driving a single-occupancy vehicle;
- Telework; or
- Other operations, conditions or situations where people are alone in a personal room or space or assembled but still maintain the required social distancing boundaries (Policy, Sec. 4).

6. Masks Don't Replace Required PPE

Clarify that wearing a mask in no way relieves employees of their duty to use the job-specific PPE required by your lab's safe work procedures and OSHA policies (Policy, Sec. 5).

7. Exemptions

Establish legitimate exemptions where wearing a mask could actually endanger the user, such as when:

- A medical professional has advised that wearing a mask may pose a health risk or impair the user's breathing;
- Wearing a mask would create a health or safety risk to the wearer under federal, state or local regulations or guidelines;
- The user can't put on or take off the mask without assistance;
- The user is deaf or hard of hearing and relies on facial and mouth movements to communicate; or
- The user is under 2-years-old (Policy, Sec. 5).

8. Accommodations

In addition to health and safety exemptions, the Americans with Disabilities and other federal and state antidiscrimination laws require you to make reasonable accommodations for disabilities, religious beliefs and other protected characteristics to the point of undue hardship (Policy, Sec. 6).

9. Employer Responsibilities

List the roles and responsibilities of different stakeholders under the Policy, starting with lab management as employer. Under OSHA laws, employers must supply required PPE at their own expense, except for personal items like safety boots. While it's unclear which side of the line COVID-19 masks fall, best practice seems to dictate that employers furnish the masks but allow employees to pay for and use their own masks instead. Other employer responsibilities include ensuring signs are posted, proper disposal or cleaning is arranged and training is provided (Policy, Sec. 7.1).

10. Other Roles & Responsibilities

Other roles and responsibilities to address:

- Department heads should assess and identify mask supply needs, ensure signs are posted and rules are followed in their work area (Policy, Sec. 7.1);
- In addition to carrying out the responsibilities exercised by department heads at smaller labs without departments, supervisor should also deliver the necessary mask training and instruction and enforce the mask rules (Policy, Sec. 7.3); and
- Employees should be responsible for properly using and either disposing of or laundering/storing their masks, depending on what kind of masks you use (Policy, Sec. 7.4).

See the Model Mandatory Face Mask Policy on page 12

MODEL TOOL MANDATORY FACE MASK POLICY

Model Mandatory Face Mask Policy

More than 20 states have enacted laws requiring the use of face masks or coverings in indoor public places, which would include workplaces like medical testing labs. Here's a Model Policy incorporating current legal requirements and public health guidance that you can adapt for your own lab.

XYZ LABORATORIES
Mandatory Mask and Face Covering Policy

1. POLICY

Until further notice, no person may enter XYZ Laboratories facilities unless they wear a mask or face covering that covers the nose and mouth. Failure to comply with this rule and the terms of this Policy will be grounds for denial of entrance or immediate removal and, if the violation is committed by an XYZ employee, discipline up to termination in accordance with XYZ Laboratories' progressive disciplinary policies and procedures.

2. PURPOSE

The purpose of this Policy is to prevent the spread of the COVID-19 virus, protect the people present at XYZ Laboratories facilities and ensure compliance with public health guidelines, federal and state laws, local bylaws and other applicable requirements and standards.

3. DEFINITION OF "MASK"

For purposes of this Policy, "mask" means a non-medical facemask, bandana, scarf or any other non-surgical face covering that covers the nose and mouth, ties around the ears or the back of the head, fits snugly against the sides of the face, is secured under the chin and is designed to protect persons other than the wearer. "Masks" **do not** include N95 and other filtered masks required by lab workers nor face masks that protect only the wearer.

4. SCOPE OF POLICY

This Policy applies to all XYZ Laboratories personnel regardless of employment or pay status, couriers, healthcare professionals, patients, contract workers, vendors, customers, clients and visitors (unless they are subject to a specific exemption under Section 5 below) who are present: (i) inside any XYZ Laboratories building or facility, including vehicles and equipment; and/or (ii) in the outdoor areas of such buildings or facilities owned by XYZ Laboratories where people cannot maintain social distancing of at least six feet apart.

Masks are not required for:

- Work or time spent alone in a personal office or workspace;
- Walking, exercising or other outdoor activity where individuals are at least six feet apart;
- Driving a single-occupancy vehicle;
- Telework; or
- Other operations, conditions or situations where people are alone in a personal room or space or assembled but still maintain the required six feet social distancing boundaries.

5. EXEMPTIONS

The obligation to wear a mask does not in any way replace or eliminate employees' obligation to use respirators, surgical masks, face shields or any other job-specific personal protection equipment (PPE) required by XYZ Laboratories safe work procedures or OSHA policies. However, face masks are **not required** when:

- A medical professional has advised that wearing a mask may pose a health risk to or impair the breathing of the wearer;
- Wearing a mask would create a health or safety risk to the wearer as determined by federal, provincial or local regulators or OSHA or public health guidelines;
- The person is physically unable to put on or take off the mask without assistance;
- The person has trouble breathing, is unconscious or cannot remove the mask without help;
- The person is deaf or hard of hearing and relies on facial and mouth movements to communicate; or
- The person is a baby or toddler under two years of age.

6. ACCOMMODATIONS

In additions to the above exemptions, XYZ Laboratories will make reasonable accommodations to the point of undue hardship on a case-by-case basis as required by the *Americans with Disabilities Act* and other

applicable antidiscrimination and human rights laws.

7. ROLES & RESPONSIBILITIES

7.1 Employer

XYZ Laboratories is responsible for overall implementation of this Policy and will ensure that:

- An ample supply of masks is provided based on an assessment of requirements;
- Mask notification and warning signs are conspicuously posted at facility entrances and other locations;
- Safe and sanitary mask disposal procedures and receptacles are in place; and
- All persons receive proper training and instruction on how to use and launder/dispose of masks; and
- All persons are held accountable for following mask rules.

7.2 Department Heads
Department heads are responsible for:

- Performing an assessment to determine the mask needs of their departments;
- Developing conservation and disposal/laundering procedures and systems for the department; and
- Ensuring that all personnel and visitors to their department have and properly use required masks.

7.3 Supervisors
Supervisors are responsible for

- Instructing workers and visitors in the proper mask fitting, use, conservation and laundering/disposal;
- Serving as a role model by following the rules themselves;
- Answering employees' mask-related questions; and
- Enforcing mask rules, including via use of discipline when necessary.

7.4 Employees
Employees are responsible for:

- Using the masks supplied by their department—although employees may also buy their own masks at their own expense;
- Following the proper mask use instructions;
- Laundering their own masks/Dropping used masks in designated receptables for laundering/Properly disposing of their masks;
- Recognizing that masks are in short supply and take the proper steps to conserve them; and
- Reporting mask violations to their supervisors.

8. DURATION OF POLICY

This is Policy will remain in effect until public health officials and/or regulators determine that wearing a mask is no longer necessary to prevent the spread of COVID-19 and may be modified by XYZ Laboratories as necessary as the public health emergency and guidelines and regulatory requirements evolve.

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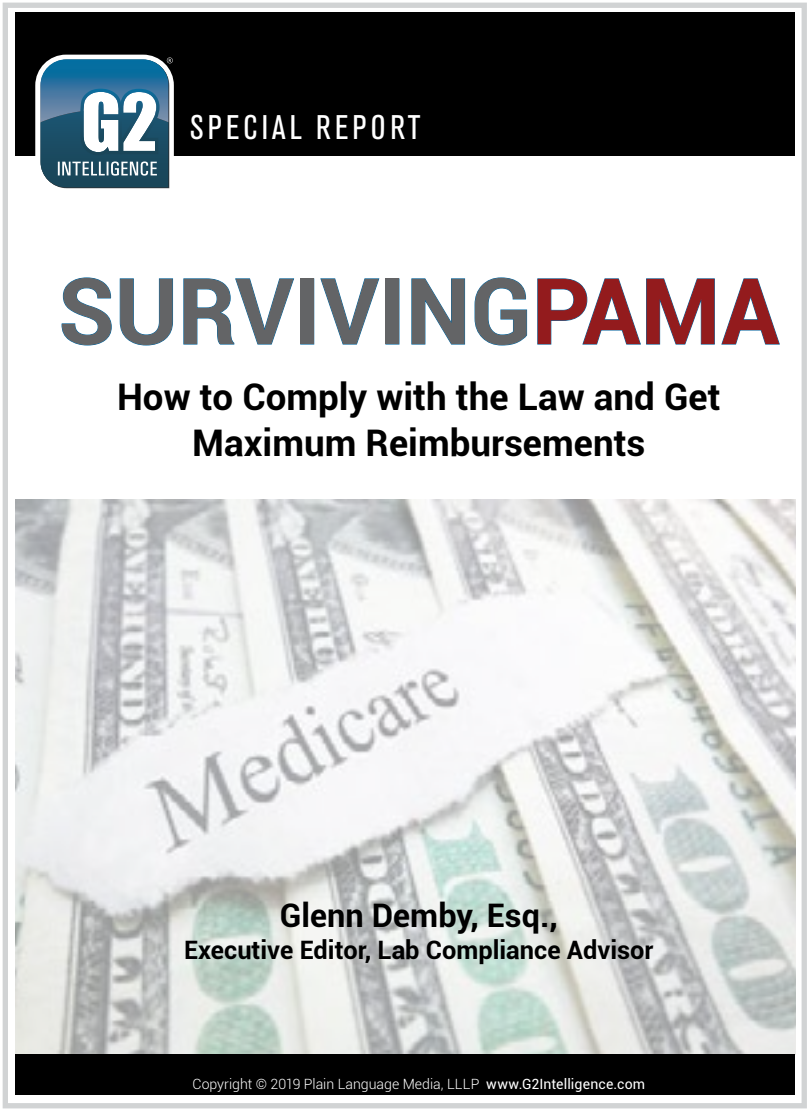

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