G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

Dec. 2017 / Jan. 2018

INSIDE THIS ISSUE

www.G2Intelligence.com

PAMA-geddon: Lab Industry Takes CMS to Court

The nearly three-year struggle between HHS and the lab industry over PAMA has entered a new phase. On December 11, the American Clinical Laboratory Association (ACLA) filed a lawsuit asking the U.S. District Court for the District of Columbia to intervene and resolve the PAMA fee schedule fiasco.

What ACLA Is Claiming

ACLA's beef is not with the idea of basing Medicare Part B fees for lab tests on actual market rate but how CMS has gone about executing it, specifically its exclusion of hospital labs in determining market prices. The complaint asserts three basic claims:

1. CMS exceeded its statutory authority under PAMA to determine market prices by deliberately excluding hospital labs, which represent the vast majority of the lab market;
2. Not counting hospital labs was an unreasonable interpretation of PAMA—specifically the term "applicable laboratories"; and
3. The CMS pricing formula is "arbitrary, capricious" and an "abuse of discretion."

Continued on page 2

FDA Continues Easing DTC, Home Use Test Regulations

In a continued reversal of its 2013 crackdown on direct-to-consumer (DTC) genetic tests, the U.S. Food and Drug Administration (FDA) unveiled loosened regulations in November that will effectively enable growth in the DTC genetic test market, as well as ease restrictions on bringing other CLIA-waived tests to market.

Enabling DTC Tests for Genetic Health Risks

The FDA has slowly been approving DTC tests on a case-by-case basis. But new proposed regulations unveiled in November will allow genetic carrier screening tests, taken by prospective parents, and other genetic health risk (GHR) tests to enter the market without prior review. The new regulatory approach

Continued on page 17

PAMA-geddon: Lab Industry Takes CMS to Court, *from page 1*

What ACLA Wants the Court to Do

The ACLA is asking for "injunctive relief." *Interpretation:* Rather than award money damages, the ACLA wants the court to take action to resolve the problem, namely:

1. Bar CMS from putting its now final 2018 PAMA Clinical Laboratory Fee Schedule into effect (For the details, see "CMS Finalizes Controversial PAMA Fee Schedule, *GCA*, November 2017, page 1); and
2. Order CMS to obey PAMA by revising its pricing formula to include hospital labs as "applicable laboratories" for purposes of calculating market rates.

G2CA

Glenn S. Demby, Editor

Lori Solomon, Contributing Editor

Catherine Jones, Contributing Editor and Social Media Manager

Barbara Manning Grimm, Managing Editor

David van der Gulik, Designer

Randy Cochran, Corporate Licensing Manager

Myra Langsam, Business Development

Michael Sherman, Director of Marketing

Jim Pearmain, General Manager

Pete Stowe, Managing Partner

Mark T. Ziebarth, Publisher

G2 Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 1-888-729-2315
Fax: 1-855-649-1623
Web site: www.G2Intelligence.com.

LDTs, FDA-Approved Companion Diagnostics Perform Similarly; Off-Label Use of Companion Diagnostic Kits Common

One of the arguments for U.S. Food and Drug Administration oversight over laboratory-developed tests (LDTs) involves the need for greater assurances regarding the quality and consistency of these tests. A brief report published December 14 in *JAMA Oncology* may allay some of these concerns.

A study of close to 7,000 College of American Pathologists proficiency testing samples found that LDTs and FDA-approved companion diagnostics (FDA-CDs) had similarly high accuracy for detecting variants in three oncology-related genes—BRAF, EGFR, and KRAS. However, the researchers found that more than 60 percent of laboratories report modifying the intended use of FDA-CDs, essentially making them LDTs.

The researchers compared analytical validity and associated preanalytic practices for 6,897 proficiency testing responses. Combined, both LDTs and FDA-CDs exceeded 97 percent accuracy across all the samples.

- For BRAF mutations, LDTs outperformed FDA-CDs with a 96.6 percent acceptable rate while FDA-CDs results were significantly lower at 93.0 percent. The researchers attributed this difference primarily to analysis of the BRAF p.V600K mutation (88.0 percent for LDTs versus 66.1 percent acceptable rate for FDA-CDs).
- For EGFR, LDTs performed slightly, but significantly, less well than the FDA-CDs (97.6 percent acceptability for LDT versus 99.1 percent for FDA-CDs). This discrepancy was driven by detection of the EGFR p.L861Q mutation (91 percent for LDTs versus 100 percent for FDA-CDs).
- For KRAS, there was no significant difference between acceptability rates for LDTs and the FDA-CDs overall or by individual variants.

The researchers importantly found that more than 60 percent of participants using FDA-CDs report modifying the approved preanalytic methods to broaden clinical use. This off-label practice essentially turns the FDA-

> "The preanalytic questions highlight the fact that many FDA-CD laboratories conduct practices that are not in accord with their FDA-approved methods."
>
> — Annette Kim, M.D., Ph.D.

CDs into LDTs. Reported off-label practices include unapproved specimen types and tumor types, as well as accepting specimens with lower tumor content than are required for the approved assay and not quantifying DNA before performing the assay.

"The preanalytic questions highlight the fact that many FDA-CD laboratories conduct practices that are not in accord with their FDA-approved methods," write the authors led by Annette Kim, M.D., Ph.D., from Brigham and Women's Hospital in Boston, Mass. "Although this flexibility is advantageous for patient care, it is important to recognize that the use of specimens other than formalin-fixed paraffin-embedded samples of the specified tumor type for the FDA-CDs is off-label, resulting in reclassification of the assay as an LDT."

Several authors report financial ties to the diagnostics industry.

Takeaway: While it may be reassuring that LDTs and FDA-CDs perform with similar access for detection of oncology-related genetic mutations, it may concern regulators the extent to which FDA-approved in vitro diagnostic kits are being used off-label.

Brief Your CEO: 5 Takeaways from OIG's New Semiannual Report

Like many lab managers, you may provide a year-end compliance briefing to your executive team. If so, you will want to cover the new OIG Semiannual Report to Congress in which the agency explains what it thinks it accomplished in the past six months and what it hopes to do going forward. Here are the five key points about the most recent Report to touch on during your briefing.

1. Continued Growth of the Strike Force

By now, you should have made your executives aware of the fact that the National Strike Force Takedowns featuring coordination among the OIG, Department of Justice and local law enforcement have become the centerpiece of federal health care fraud enforcement. The new OIG Report makes it clear that this trend is still going strong. This July, witnessed the biggest Takedown in history resulting in charges against over 400 defendants in 41 federal districts involving schemes worth about $1.3 billion, not to mention 112 criminal actions.

2017 OIG Enforcement By the Numbers

The OIG report lists the following statistics on the agency's enforcement efforts from April through September 2017:

- **$4.13** billion in expected investigative recoveries;
- **881** criminal actions against individuals or entities relating to HHS programs;
- **826** civil actions; and
- **3,244** exclusions of individuals and entities.

2. Growing Focus on Opioids and Narcotics

While the extent of Takedown growth is a continuation of previous trends, the new focus on opioids represents a change in direction that your executives need to be aware of. Notably, over 120 of the 400+ defendants booked by the Takedown were involved in illegal pre-

scribing and distribution of opioid drugs, including 22 doctors. The OIG also issued 295 exclusion orders for opioid offenses. While not directly targeting lab testing, labs that provide urine testing to patients who are legally prescribed opioids are among the providers with a bullseye on their back.

3. Prioritization on Cybersecurity and EHR

Let the executives know that cybersecurity continues to figure prominently in OIG activities, as do related issues related to electronic health records (EHR) fraud. An OIG Medicare audit unearthed $729.4 million in EHR incentive payments to providers who failed to meet "meaningful use" requirements. CMS also made $2.3 million in incentive payments for the wrong payment year to providers who switched between incentive programs.

4. Internal Overpayment Cleanups

You may want to mention that the OIG did a lot of looking inward over the past six months, especially with regard to a continuing sore spot: recovery of Medicare overpayments. Although CMS has made marginal improvement since 2010 when it collected overpayments at a 7% clip, there is still plenty of work to be done. According to the OIG, collections reached 20% in 2014, leaving $386 million uncollected.

5. What the Fraud Investigators Are Looking for

The report notes that fraud investigations continue to focus on "patient harm; billing for services not rendered, medically unnecessary services, or upcoded services; illegal billing, sale, diversion, and off-label marketing of prescription drugs; and solicitation and receipt of kickbacks, including illegal payments to patients for involvement in fraud schemes and illegal referral arrangements between physicians and medical companies." Lab testing is specifically identified as types of fraud schemes of principle concern to the OIG.

Labs Figure Prominently in OIG's Newest Top 10 Challenges List

Although the OIG has its flaws, lack of transparency is not among them. Exhibit A: the agency's ongoing list of top 10 management and performance challenges facing the Department of Health and Human Services in the coming year. As it usually does, maintaining program integrity tops the newest list. And while not expressly spelled out, we all know that "program integrity" is code for billing and payment of lab and diagnostic services, among other things. Here's the entire Top 10. While most are re-runs, there are a few new items (denoted by the asterisk):

1. Ensure Medicare Program Integrity
2. Ensure Medicaid Program Integrity
3. Curb the Opioid Epidemic*
4. Improve Care for Vulnerable Populations
5. Ensure Integrity in Managed Care and Other Programs Delivered via Private Insurers
6. Improve Financial and Administrative Management and Reduce Improper Payments
7. Protect Integrity of Public HHS Grants
8. Ensure Safety of Food, Drugs and Medical Devices
9. Ensure Program Integrity and Quality in American Indian and Alaska Native Populations Programs*
10. Protect HHS Data, Systems and Beneficiaries from Cyber Threats

You Make the Call: Self-Disclosing Non-Compliant Arrangements with Large Physician Groups

SITUATION

Fictional Med (FM), a large physician-owned clinic, is one of your lab's biggest customers. So your heart sinks when during an internal compliance audit, you discover that your lab has been paying service fees to FM physicians at above market rates for years. Immediately recognizing that this constitutes an improper financial relationship, you persuade lab management to disclose the arrangement under the CMS Voluntary Self-Referral Disclosure Protocol (SRDP).

THE DISCLOSURE PROCESS

On June 1, 2017, CMS revised the SRDP process governing how would-be disclosers supply information involving financial relationships with physician organizations and the individual physician owners deemed to "stand in the organization's shoes." Specifically, you must fill out a series of specific forms, including the Physician Information Form (PIP Form) listing identifying information about each physician included in the disclosure (i.e., FM).*

THE QUESTION

Do you really have to submit a separate (and redundant) PIP Form for each FM owner?

THE ANSWER

No, as long as you follow the CMS's new streamlined submission process.

THE EXPLANATION

In an apparent effort to reduce redundancy, CMS published a new FAQ on its website in October to clarify that disclosing entities may submit a *single* PIP Form covering the entire physician organization, provided that they include a separate listing providing the following information for each physician that stood in the organization's shoes during the look back period:

- Each physician's name and National Provider Identifier (NPI);
- The period of noncompliance for the physician with regard to the improper compensation arrangement disclosed; and
- Any other information unique to the physician, e.g., the date the physician became an owner or left the group.

Note:

* The other required SDRP forms include the Financial Analysis Worksheet identifying potential overpayments based on a six-year look back period; and the SRDP Disclosure Form listing identifying information about the disclosing party (in this case, the lab).

Case of the Month: Feds Turn Up the Heat on False Billing of Nuclear Stress Tests

While the feds have made urine drug testing of opioid drug patients their number one target for lab-related *False Claims Act* (FCA) charges this year, nuclear stress tests (NSTs) ordered by cardiologists have also been garnering increasing attention. There are three things about NSTs, which use radioactive dyes to measure blood flow to the heart both when the patient is resting and stressed either via exercise or chemical inducement, that put them high on the list of FCA enforcement priorities in the diagnostics sphere:

1. NSTs are very expensive;
2. They expose patients to significant doses of radiation; and
3. They can generate false positives resulting in the ordering of medically unnecessary invasive procedures.

NST coding irregularities were at the center of one of the largest diagnostic fraud cases of 2017--the $50+ million scam allegedly perpetrated by a cardiologist, neurologist and four others associated with a New York City medical practice this spring.

Routine Ordering of NSTs: The CVC Case

For these reasons, NSTs are deemed medically necessary only in very limited circumstances. So the ordering of NSTs at abnormally high rates routine raises a bright red flag.

CVC Heart Center, a California cardiology clinic, and its physician owners just learned this lesson the hard way. The U.S. Attorney charged the defendants with falsely billing Medicare and Medicaid for medically unnecessary NSTs over a five-year period beginning in 2010. According to the indictment, CVC physicians automatically scheduled annual NSTs for patients without actually seeing them to determine whether the test was actually needed in violation of Medicare medical necessity rules and a CMS Local Coverage Determination banning use of NSTs as a screening procedure. On Dec. 5, the physicians agreed to settle the case for $1.2 million rather than risk a trial.

NST Bundling: The NYC Case

Coding of NSTs may also raise FCA red flags. There are three possible CPT codes for billing the imaging part of the test:

- **Code 78451** (SPECT) when only one set of images is taken, either at rest or stress;
- **Code 78543** (Planar) when only one set of images is taken, either at rest or stress; and
- **Code 78452** may only be used when two sets of images are taken.

NST coding irregularities were at the center of one of the largest diagnostic fraud cases of 2017—the $50+ million scam allegedly perpetrated by a cardiologist, neurologist and four others associated with a New York City medical practice this spring. Among other things, the defendants have been charged with NST coding abuses, specifically listing only one code for "Nuclear Studies" in the practice's superbill: 78452. As a result, physicians were forced to

indicate that they performed both a resting *and* stress study, even if they actually performed only one part of the study. (See *NIR*, June 19, 2017, for more details about the case.)

Takeaway: For clinical labs, none of this is new. Routine ordering, medical necessity and bundling of costly tests have been fundamental compliance challenges to labs for decades. However, now these same enforcement principles are being applied with increasing regularity to target not just NSTs but other elaborate diagnostic procedures.

FDA Warns About Biotin Interference With Lab Tests

In late November the U.S. Food and Drug Administration issued a safety communication warning that the supplement biotin (Vitamin B7) may interfere with laboratory testing results. The warning comes after Roche Diagnostics (Indianapolis, Indiana) published a study online Sept. 14 in the *International Journal of Pharmacokinetics* demonstrating that an eight-hour wait time or washout period is necessary for accurate test results when using streptavidin–biotin immunoassays following high doses of biotin (more than 5 mg/day).

High-sensitivity immunoassays made by companies like Abbott, Beckman Coulter, Ortho Clinical Diagnostics, Roche Diagnostics, and Siemens Healthcare Diagnostics are all susceptible to biotin interference.

The FDA says it has received a report that one patient taking high levels of biotin died following falsely low troponin results on a test for heart attacks known to have biotin interference. There have been previous case reports of biotin interference leading to incorrect diagnoses in both adults and children, particularly for cardiovascular diagnostic tests and hormone tests. However, there is increasing use of over-the-counter (OTC) biotin supplements that purportedly strengthen hair, skin, and nails. These products range in biotin doses from 50 µg in multivitamin to as high as 10 mg in some biotin-only products. The FDA notes these high-dose OTC products may contain biotin levels up to 650 times the recommended daily intake of biotin (30 µg/day). Additionally, physicians recommend extremely high doses for treatment of neuropathy and multiple sclerosis. Thus, there is increasing evidence that the risk of biotin interference with laboratory testing is also increasing.

High-sensitivity immunoassays made by companies like Abbott, Beckman Coulter, Ortho Clinical Diagnostics, Roche Diagnostics, and Siemens Healthcare Diagnostics are all susceptible to biotin interference. Excess biotin in patient samples can result in falsely high test results with competitive assay design and falsely low results with sandwich assay design. The study in the International Journal of Pharmacokinetics found that manufacturers provide a "spectrum of guidance" in package inserts ranging from no mention or vague generic warnings of biotin interference to comprehensive specification on serum biotin concentrations.

The Roche study sought to characterize the pharmacokinetic properties of biotin and establish a model simulating the effective half-life of biotin and biotin metabolites with different high-dose regimens (1 mg daily to 300 mg).

Participants were divided into three different dosing groups (5, 10 or 20 mg taken orally once a day) for five days. Participants were required to fast for 8 hours prior to and 1 hour after biotin intake and blood samples were collected prior to biotin intake on days 1, 2, and 7, and at 1, 3, 6, 8 and 12 hours postdose on days 3 and 7. Samples were analyzed using the cobas e 411 analyzer (Roche Diagnostics) using an in-house competitive Elecsys research assay. The researchers identified the necessary washout periods for biotin concentrations to reach thresholds ranging from 10 to 100 ng/mL.

"It is important for clinicians and pathologists to be aware of which immunoassays are streptavidin-biotin-based and therefore when an abnormal result may be the result of interference and require repeat analysis before a diagnosis is made," write the authors led by Paul Grimsey, from Roche Innovation Center in the United Kingdom. "It is important to understand the time taken for the serum biotin concentration to fall below a specific threshold, to allow calculation of the washout period required before collection of serum samples for assessment using biotin-streptavidin based assays."

The researchers found that biotin has linear pharmacokinetics over the range of doses studied, is rapidly absorbed with a maximum serum concentration of less than 1 hour, and has an effective serum half-life of 15 hours.

- For biotin doses up to daily doses of 1 mg (e.g., in a multivitamin) serum biotin levels fall below an in vitro threshold of 10 ng/ml (one of the lowest recommended biotin interference thresholds) after 2 hours.
- For doses of biotin of up to 10 mg/day, an in vitro serum biotin threshold of 30 ng/ml could be consistently reached after 8 hours of washout.
- For extremely high doses of biotin (more than 20 mg), the residual biotin serum concentration did not drop to 30 ng/ml until 31 hours after last intake and took 73 hours to drop to 10 ng/ml, indicating an extended washout periods would be needed for immunoassays with a low in vitro interference threshold (less than 30 ng/ml) and following extremely high doses of biotin.

The authors caution that the study is not able to give information as to the size of any potential effect of biotin interference on test results or the proportion of laboratory values that are potentially vulnerable to interference.

Takeaway: The potential for supplementary biotin consumption to interfere with test results is a real concern and is something that laboratories need to work with providers on to ensure accurate diagnosis.

FDA Recommendations for Laboratories

In order to cut the risk of adverse events associated with biotin interference with laboratory tests the FDA is recommending that laboratory personnel:

- Be aware that biotin levels higher than the recommended daily allowance may cause significant interference with affected lab tests
- Communicate with health care providers and patients regarding use of assays with biotin technology
- At draw centers, ask patients if they are taking biotin
- Educate health care providers about biotin interference with specific tests
- Communicate with the lab test manufacturer if you have questions about biotin interference

COMPLIANCE *PERSPECTIVES*

5 Common Sexual Harassment Policy Blind Spots & How to Fix Them

Recent weeks have witnessed the morphing of workplace sexual harassment prevention from legal requirement to moral imperative. And while the current fervor is a bit unnerving for employers, to the extent it shatters complacency, it's a positive and even necessary development. Sexual harassment has evolved dramatically in the past two decades—in terms of not just conduct but our understanding of it.

As a result, the traditional sexual harassment policy, of circa 2000, has become out of date and badly in need of revision. So reviewing your lab's current sexual harassment policy is not only a justifiable use of time but an imperative. Here are five common blind spots to look for in your review.

Ban sexual harassment not just "in the workplace" or "the lab" but all work-related settings, including offsite activities

1. Banning Sexual Harassment "in the Workplace"

Blind Spot: Typical policies ban sexual harassment "in the workplace." The problem is that sexual harassment occurs not just within the four corners of the physical workplace but also offsite—in vehicles, during business trips and even at home. Moreover, the employer's duty to prevent sexual harassment may follow employees wherever they go in the course of their job duties, especially when they are in the company of co-workers.

Examples:

- California court refuses to dismiss sexual harassment claim of employee/actor who was allegedly drugged and gang raped at home of co-worker/casting director;
- Male salesman's inappropriate sexual remarks to female co-worker at bar was sexual harassment even though it occurred away from work site;
- Failure to take action in response to employee's complaints about co-worker's harassing phone calls makes employer liable for creating hostile work environment even though calls were made from (and to) home after work hours.

How to Fix It: Ban sexual harassment not just "in the workplace" or "the lab" but all work-related settings, including offsite activities such as:

- Client and customer visits and service calls;
- Business travel;
- Conferences, training sessions and seminars;
- Company or client-sponsored social functions;
- Any other offsite work assignments.

2. Banning Sexual Harassment "by Co-Workers, Supervisors and Managers"

Blind Spot: As with setting, sexual harassment is personnel-agnostic. Employees can suffer it at the hands of not just individuals who work for the same organization but third parties like customers, clients and even outside service personnel.

Example: During a service visit, a photocopy technician smacks an employee on the butt with a rolled up newspaper as she bends over to pick up a fallen ink cartridge. The victim's employer is found liable for sexual harassment even though the technician is an employee of the service company and not the organization.

Old-school sexual harassment policies don't deal with what is rapidly becoming the face of sexual harassment in the 21st century: cyber bullying and revenge porn.

How to Fix It: Your commitment to protect lab employees from sexual harassment should extend to harassment from third parties that employees may encounter in the course of their job at least to the extent you have a reasonable degree of control over those parties, e.g., customers, clients, vendors and contract personnel. While it may be admirable in principle, seeking to extend this commitment to *all* third parties is neither reasonable nor realistic.

3. Omission of Cyber Harassment & Revenge Porn

Blind Spot: Old-school sexual harassment policies don't deal with what is rapidly becoming the face of sexual harassment in the 21st century: cyber bullying and revenge porn. The latter refers to vindictive and nonconsensual online posting of nude or sexually explicit photos, videos and other depictions of ex-lovers in an attempt to embarrass, humiliate and ruin lives. And it frequently happens in the workplace. Although the law is still evolving, the early cases indicate that it's only a matter of time before the employer's sexual harassment duties are extended to cyber bullying and revenge porn.

How to Fix It: Make sure your policy defines sexual harassment to include cyber bullying and stalking, non-consensual taking or posting of sexual activity and other forms of sexual abuse against co-workers via social media and other digital fora.

4. Omission of Other Forms of Sexual Misconduct

Blind Spot: While sexual harassment is the most common, it's not the *only* form of workplace sexual misconduct. And while using the term "sexual harassment" to refer to the whole enchilada may be clear enough for everyday parlance, it won't work in the context of an HR policy.

How to Fix It: Ban not just "sexual harassment" but all forms of sexual misconduct that employees may suffer in the course of their work, including:

- Non-consensual sexual contact or attempts to commit it (just be sure to include a clear definition of "consent");
- Dating violence or abuse, i.e., use of fear, degradation, humiliation and/or abuse against a dating partner to gain power and control in the relationship;
- Domestic violence;
- Stalking and cyber stalking;
- Sexually-based communication, i.e., in-person, phone, social media, electronic messages and other communications of a sexual nature that are unwelcome to the employee recipient;
- Invasion of an employee's sexual privacy;
- Exceeding the limits of consent, e.g., Bob lets a friend hide in the closet so he can watch Bob have consensual sex with his co-worker;
- Knowingly transmitting a sexual infection or disease to another person;
- Non-consensual sexual exposure.

5. Lack of Accountability for Bad Faith Accusations

Blind Spot: While most sexual harassment complaints are made in good faith, there's always the risk of employees' of abusing the system by making accusations they know to be baseless. Most sexual harassment policies aren't equipped to deal with these abuses.

- *Pattern 1:* The policy doesn't hold employees accountable for such abuses; or
- *Pattern 2:* The policy holds employees accountable for "false" accusations.

The first policy doesn't go far enough; and the second policy goes too far. Punishing employees for making "false" sexual harassment complaints exposes you to liability risks for retaliation if the employee made the accusation in good faith and sincerely believed he/she was harassed.

How to Fix It: Reserve the right to punish not false but bad faith complaints. Specify that you won't consider a complaint to be in bad faith merely because the evidence doesn't ultimately support the accusation and that bad faith requires a finding that the complaining employee acted maliciously either knowing that the accusation was false or recklessly without regard to whether the accusation was true.

Takeaway: The old-school sexual harassment policy, circa 2000, has become obsolete and needs to be revised to comport with modern times, technology, wisdom and understanding about how sexual harassment occurs.

TOOL: MODEL SEXUAL HARASSMENT POLICY

The sexual harassment policy has been a fixture of the HR manual for decades. And that's the problem. While lack of toleration for sexual harassment is decades-old, the conduct and our understanding of how to deal with it has evolved significantly in recent years. In the current environment, reviewing your current sexual harassment policy is not only a justifiable use of time but an imperative. Here's a Model Sexual Harassment Policy template you can use to conduct your review.

LABORATORY SEXUAL HARASSMENT POLICY

1. LABORATORY COMMITMENT & PRINCIPLES

XYZ Laboratory (Laboratory) is fully committed to providing employees a work environment that is positive, respectful and safe, one that recognizes, respects and embraces the individual dignity, worth and rights of all our employees regardless of gender. We will not tolerate sexual harassment in any form and we are committed to taking all complaints of such conduct seriously and responding as quickly as possible and holding individuals found to have engaged in such conduct fully accountable regardless of position.

2. PURPOSE

The purpose of this Policy is twofold:

a. To establish clear ground rules regarding sexual harassment and other forms of sexual misconduct so that all employees understand what is and is not acceptable and can thus behave accordingly; and

b. To describe the procedures that XYZ Laboratory follows for receiving, investigating and responding to complaints of sexual harassment, including imposition of discipline for those found guilty of offenses.

3. DEFINITION OF SEXUAL HARASSMENT

For the purposes of this Policy, sexual harassment in the workplace refers to a course of offensive, humiliating or intimidating comment or behavior based on sex or gender (typically but not exclusively by one employee—which may include a supervisor or manager) against another, that the person engaging in the behavior knows or ought reasonably to know is unwelcome. Sexual harassment negatively affects the work environment and can lead to negative work-related consequences for the victim. Sexual harassment may consist of a single incident of unwelcome behavior or multiple incidents over time. Sexual harassment is also form of discrimination that is prohibited under both federal and state discrimination laws.

3.1. What Constitutes Sexual Harassment

Sexual harassment includes, but is not limited to:

Physical Harassment. Examples:

- Leering or inappropriate staring;
- Invasion of personal space;
- Unwelcome and unnecessary physical contact (touching, grabbing, hugging, kissing, etc.);
- Sexual assault and violence.

Verbal Harassment. Examples:

- Making offensive comments or engaging in behavior towards a person based on their gender, gender identity, gender expression and/or sexual orientation;
- Making sex-related comments about a person's physical appearance or actions;
- Making comments or engaging in behavior because of a belief that someone does not conform to gender-role stereotypes;
- Making offensive comments about members of a specific gender or sexual orientation;
- Using vulgar, sexual or gender-related humor or derogatory language (such as slurs, jokes or innuendo);
- Asking unwelcome questions or engaging in unwelcome conversation about sexual activities;
- Spreading sexual rumors (including online).

Hostile Work Environment Harassment. Examples:

- Displaying or distributing pornographic or other sexual images, objects, jokes or sayings (including online);
- Making vulgar gestures.

Threats and Demands. Examples:

- Asking for sexual favors in exchange for workplace benefits;

- Repeatedly asking someone for dates or sexual favors even after they have said no;
- Threatening someone (e.g., with violence, termination or denial of other workplace benefits) if they refuse to comply with sexual advances;
- Making an employee dress or behave in a sexualized or gender-specific way;
- Threats of retaliation or reprisal if the victim makes a complaint under this Policy or exercises his/her recourse under employment discrimination or other laws.

3.2. Where Sexual Harassment Can Take Place
For the purposes of this Policy, the workplace or work environment refers to all workplace-related activities, including:

- Activities on Laboratory premises;
- Work assignments outside of Laboratory premises ;
- Work-related conferences, training sessions, or seminars;
- Work-related travel;
- Work-related social functions that Laboratory or its clients or associates sponsor or organize.

The above scope of activities in which sexual harassment can occur includes the job application and interview process, volunteer work and internships with Laboratory, and activities or events that take place outside regular business hours or locations but are linked to and may impact the workplace environment.

This Policy applies to all permanent and temporary employees at all levels, to those with whom Laboratory conducts business, and at all sites where Laboratory business activities take place.

3.3. Potential Victims of Sexual Harassment
Both women and men may engage in and experience sexual harassment in the workplace, but women are generally more vulnerable to it because they often hold jobs with lower pay, authority and status than men. That being said, even women in positions of authority can experience sexual harassment. Treating and portraying an employee, especially a woman, in a sexual way can undermine their status and image in the eyes of their co-workers.

In addition, sexual harassment can be perpetrated by women targeting men and by men or women targeting members of their own sex or gender. The offense is defined not by the gender of the victim and victimizer but the sexual nature of the conduct.

3.4. What Does NOT Constitute Sexual Harassment
The definition of sexual harassment and the Laboratory Sexual Harassment Policy are not intended to inhibit interactions based on mutual consent between employees, such as consensual conversation about sex in the workplace, or suggestive imagery, like a poster, that does not offend anyone. However, if you are offended by comments or imagery in the workplace even when no one else is, this does not mean that your concern is invalid. You should express your objections to those involved and file a complaint if the issue is not resolved.

4. OTHER FORMS OF PROHIBITED SEXUAL MISCONDUCT

4.1. Sexual Offenses Other than Harassment
Laboratory is committed to preventing and protecting employees against not just sexual harassment but a wide range of behaviors and conduct of a sexual nature that is nonconsensual or has the purpose or effect of threatening, intimidating or coercing. As with harassment, both men and women may be perpetrators as well as victims of sexual misconduct.

4.2. Definition of Consent
For the purposes of this Policy, consent means conscious, informed, fully voluntary agreement to, or permission for, an act. In determining whether consent has been given, the following principles will apply:

- Although consent may be implied verbally or nonverbally, it should never be assumed;
- Silence, inaction or absence of express denial of consent do not necessarily imply consent;
- Consent is valid only if it is given voluntarily without threat, force or duress;
- Consent is valid only if it is given by a person with adequate capacity—valid consent cannot be provided by a person who is asleep, drunk, high, physically or mentally incapacitated or otherwise judgment-impaired;
- Consent is not valid if it is provided by a person under the legal age of consent;
- Consent is limited in scope—consenting to one form of sexual activity is not implied consent to another form of sexual activity;
- Consent can be taken back at any time.

4.3. Forms of Prohibited Sexual Misconduct
Forms of sexual misconduct banned by this Policy include, but are not limited to:

a. NonConsensual Sexual Contact (or Attempts to Commit It), i.e., any intentional sexual touching, however slight, with any object by a person upon a person without consent and/or by force, including (without limitation):

- Contact with the breasts, buttocks, groin or genitals;
- Making another person touch the abuser, victim or a third party with or on any of those body parts; and/or
- Any other intentional bodily contact in a sexual manner not involving contact with/of/by breasts, buttocks, groin, genitals, mouth or other orifice.

b. NonConsensual Sexual Intercourse (or Attempts to Commit It), i.e., any sexual intercourse, however slight, with any object by a person upon a person without consent and/or by force, including (without limitation):

- Vaginal penetration by a penis, object, tongue or finger;
- Anal penetration by a penis, object, tongue, or finger, and/or
- Oral copulation (mouth-to-genital contact or genital-to-mouth contact).

c. Dating Violence, i.e., a pattern of assaultive and controlling behaviors by a person against a dating partner in an attempt to use fear, degradation, humiliation and/or abuse to gain or maintain power and control in the relationship.

d. Domestic Violence, i.e., use of physical, sexual or emotional abuse or threats to control a current or former spouse or other intimate partner, e.g., a person with whom the abuser is living or has lived with in the past.

e. Stalking, i.e., a pattern of repeated and unwanted attention, harassment, contact or other course of conduct directed at a specific person which would cause a reasonable person to become alarmed or fear harm or injury, including physical, emotional or psychological harm.

f. Cyber-Stalking, i.e., use of electronic media such as the internet, social networks, blogs, cell phones, texts or other similar devices or forms of contact to pursue, harass or make unwelcome contact with another person.

g. Sexual Exploitation, i.e., taking sexual advantage of another person for the advantage or benefit of the person committing the exploitation or a third person to the extent such behavior does not constitute sexual harassment or one of the other forms of sexual misconduct banned by this Policy. Examples:

- Invasion of sexual privacy;
- Prostituting another person;
- Photographing, video-or audio-taping sexual activity without consent;
- Exceeding the boundaries of consent, e.g., letting a friend hide in the closet so he can watch you have consensual sex with your partner;
- Voyeurism;
- Knowingly transmitting a sexually transmitted infection, disease or HIV to another person;
- Non-consensual exposure of genitals; and
- Sexually-based stalking.

h. Sexually-Based Communication, i.e., speaking to, or directing any kind of communication, words or images of a sexual nature at another person which is not welcomed by the receiving party, which may include interactions in person, by phone, social media, electronic messages and photos and written words or images such as graffiti.

5. ROLES & RESPONSIBILITIES

5.1. Duty of Management

Laboratory management is committed to:

- Treating all co-workers, seniors, subordinates, colleagues and others with whom they interact with professionalism, dignity and respect in adherence to this Policy;
- Providing satisfactory resources to deal with sexual harassment complaints;
- Taking complaints seriously and responding quickly; and
- Fostering a healthy environment where employees feel comfortable about raising complaints and are kept informed about and involved with actions taken in response.

5.2. Duty of Supervisors

Supervisors will:

- Treat all co-workers, seniors, subordinates, colleagues and others with whom they interact with professionalism, dignity and respect in adherence to this Policy;
- Ensure that all employees, including those in positions of responsibility, are made aware of sexual harassment policies as soon as they are introduced, as well as through training, orientation material and education on human rights issues; and
- Continually monitor the work environment to make sure it is free from sexually harassing behavior.

5.3. Duty of Workers

Workers will:

- Treat all co-workers, seniors, subordinates, colleagues and others with whom they interact with professionalism, dignity and respect in adherence to this Policy;
- Immediately notify a supervisor or manager if they experience or witness incidents of sexual harassment or other violations of this Policy.

6. REPORTING SEXUAL HARASSMENT & MISCONDUCT

6.1. Procedures

Laboratory wants to ensure all its employees feel safe, comfortable and encouraged to report any incident of sexual harassment or misconduct they have observed or experienced. Please file a complaint about any incident to your manager [*contact name and info*] or HR advisor [*contact name and info*]. If it is not appropriate to file a complaint with these individuals because they are involved in the incident, the employee should report the incident to any other manager of their choice.

Complaints need not be in writing but should include as much detail as possible, including the name(s) of the individual(s) involved and a description of the incident(s), including actions and/or comments made, place(s), date(s) and time(s).

The possibility of informal resolution may be explored and reached with the consent of all parties. If no informal resolution is sufficient, a formal and thorough investigation of the incident and surrounding circumstances will be undertaken, involving interviews with the complainant, the respondent, and any other individuals who may be able to provide information on the situation.

If the process within the workplace does not address or resolve the issue to your satisfaction, you can report it to the [*state*] Equal Employment Opportunity office [*contact info*].

Threats, attempts or actual incidents of physical or sexual assault are all criminal offenses and can be reported to your local police service.

6.2. Assurance of Non-Retaliation

Employees are reminded that Laboratory is committed to providing you a workplace free of sexual harassment and misconduct in accordance with OHS, human rights and other laws and this Policy. Making you feel free to come forward and report incidents or concerns of sexual harassment is an important part of our commitment. Accordingly, we wish to assure you that you won't be fired, demoted, reassigned, disciplined or subject to any other punishment or adverse treatment from Laboratory or its managers, supervisors and other representatives in retaliation for reporting sexual harassment or misconduct in good faith.

6.3. Bad Faith Complaints

To protect the innocent, Laboratory reserves the right to discipline any employee who knowingly and in bad faith files a false complaint or makes misrepresentations of sexual harassment or misconduct up to and including termination. For purposes of this Policy, a complaint is not considered bad faith merely because the evidence does not ultimately support the allegation. Bad faith requires an investigation finding that the employee who accused another person of sexual harassment or misconduct acted maliciously knowing the accusation was false or recklessly without regard to whether the accusation was true.

7. INVESTIGATION

All reports of sexual harassment, misconduct or other alleged violations of this Policy will be taken seriously and responded to immediately. Where it is determined that the report has merit, an internal investigation will be made by staff members not implicated or in any way involved in the complaint following the fair investigation procedures and protocols set out in the Laboratory Disciplinary Policy.

8. DISCIPLINE

Acts of sexual harassment or misconduct will not be tolerated and will be responded to with appropriate disciplinary action, up to and including termination, based on a thorough investigation of the incident and the surrounding circumstances. Such disciplinary action may include immediate termination, even if the person committing the act has committed no prior offenses or engaged in previous acts of sexual harassment or misconduct.

9. CONTRACTORS & SUBCONTRACTORS

To protect employees from risks of sexual harassment or misconduct by third parties they contact at work, Laboratory will ensure that any contractors and subcontractors hired to perform work at its lab sites are notified of and required to ensure their workers comply with the terms of this Policy and are held accountable for any violations they commit.

Labs IN COURT

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

$80K Is the Price for Accepting Free Testing Cups

Case: Those turned out to be some pretty expensive cups! A group of addiction centers (aka, AMC) probably did not think twice about accepting free point of care testing cups from Millennium Labs. But what looked trivial to AMC was valuable enough in the eyes of the OIG to constitute remuneration creating an improper financial relationship between the parties. *Result:* Subsequent AMC referrals to Millennium constituted illegal kickbacks. AMC doubtlessly disagreed with the OIG's theory but decided that discretion was the better part of valor and paid $79,880.50 to settle the case.

Significance: Those darned free Millennium Labs test cups! The exact same forbidden fruit was the damnation of Parallax Center, a New York City drug addiction treatment center earlier this fall. The settlement bill: $64,203. Neither case is all that big a surprise when you consider that over the years, the OIG has gone out of its way to remind labs (and other providers) that compensation need not be elaborate to establish an illegal relationship between the lab and referral source. And if the referrals are tainted, billing for the resulting claims amounts to submitting a false claim under the False Claims Act.

Processing & Handling Fees Cross Kickback Line

Case: Speaking of kickbacks, a North Carolina medical clinic and its physician order have agreed to pay $60K to settle charges of accepting illegal remuneration from labs to which it referred patients in the form of "process and handling fees."

Significance: Unfortunately, it is almost impossible to figure out what the physician did wrong since the OIG did not release the details of the case. But in general, paying fees to referring physicians for processing, handling and other services is an anti-kickback violation unless it qualifies for the so called "bona fide employee" exception:

- The services covered by the fee are clearly identified;
- The fee reflects fair market value for the provided services; and
- Volume or value of federal program referrals by the physician are not a factor in determining the fee amount.

Methadone Clinic & CEO Settle Improper Urine Testing Charges for $884K

Case: Improper billing for urine drug testing, 2017's biggest story in FCA lab enforcement, has struck again. On Dec. 8, a substance abuse clinic and its CEO settled claims of incorporating on-site testing of patients into the bundled weekly rate it charged the Connecticut Medicaid Program for all services rendered. The problem is that it was referring those tests to an independent lab in Massachusetts, meaning Medicaid was paying twice for those tests. *The settlement bill:* $883,859.

Significance: If you have been following these urine test cases throughout the year, you may notice that the settlement amount seems a bit high. And there's a good reason for that. The Connecticut Dept. of Services detected the "bundling" issue during an audit two years earlier. Continued non-compliance with the weekly rate payment rule would result in penalties later, the audit report warned. But the clinic apparently ignored the warning and ended up having to settle at above the usual going rate for these cases.

FDA Continues Easing DTC, Home Use Test Regulations, From Page 1

doesn't apply to genetic tests that inform treatment decisions (e.g., hereditary cancer tests for BRCA1 and BRCA2 genes).

In its November notice, the FDA said GHR test developers will face a one-time FDA review, but can subsequently expand their GHR-marketed tests without further review. The FDA acknowledged in a statement that consumers are increasingly embracing GHR tests to better understand their individual risk for developing diseases and possibly make lifestyle choices to counter these risks. However, the FDA cautioned, these tests can pose "their own risks" if they provide incorrect or misleading information to consumers in the absence of professional medical advice.

"The accelerated development of these innovative DTC genetic risk tests paired with the known safety considerations presents unique challenges to FDA regulation, as these technologies don't fit squarely into our traditional risk-based approach to device regulation," FDA Commissioner Scott Gottlieb, M.D., said in a statement. "In its consideration of GHR tests, the FDA seeks to strike a balance that provides for an efficient pathway to bring these tests to consumers, without sacrificing the assurances offered by FDA oversight."

Easing CLIA-Waiver Regulations

On Nov. 29, the agency issued two draft guidances proposing to reduce the burden of applying for CLIA waivers. The first draft guidance is in response to the Cures Act, which requires that FDA allow manufacturers of in vitro diagnostic devices submitting a CLIA waiver to demonstrate accuracy through comparable performance between a waived user and a moderately complex laboratory user, rather than based upon a gold standard. In addition to this statutory change, the draft guidance provides significant detail regarding demonstration of accuracy of a test for purposes of securing the "insignificant risk" waiver.

The second proposal would establish a dual submission pathway enabling test makers to use the same sets of studies to secure 510(k) approval and a CLIA waiver.

Takeaway: The FDA is sending strong signals it plans to continue to streamline regulations enabling easier market entry for innovative products, including DTC tests for GHR and CLIA-waived products.

OIG Work Plan Monthly Review: December 2017

None of the six items the OIG added to its Work Plan this month directly address labs or labs services. However, five of the new items, including the two dealing with opioid abuse, might affect labs indirectly.

1. Prescription Opioid Drug Abuse: Prescription Drug Monitoring Programs

Concern: HHS provides funding to states to prevent opioid abuse and misuse via CDC and the Substance Abuse and Mental Health Services Administration (SAMHSA).

What OIG Will Investigate: The OIG will do a series of audits focusing on states getting HHS funding that have a high or significant increase in the number of overdose deaths to determine: i. what state agencies did with their federal funds for enhancing prescription drug monitoring programs (PDMPs) to improve safe prescribing practices and prevent prescription drug abuse; and ii. whether state agencies complied with federal requirements.

2. Impact of Indian Health Service (HIS) Information Technology & Security Services on Opioid Prescribing Practices

Concern: The IHS's decentralized management structure and limited cybersecurity resources may be impairing its efforts to implement IT improvements, update its EHR system and combat opioid abuse.

What OIG Will Investigate: The OIG will analyze and compare IT/IS operations and opioid prescribing practices at five IHS hospitals to determine whether: i. IHS's decentralized management structure has affected its ability to deliver adequate IT/IS services; and ii. Hospitals prescribed and dispensed opioids in accordance with IHS policies and procedures.

3. Paper Check Medicaid Payments Made to Mailbox-Rental Store Addresses

Concern: CMS payments made by paper check to a mailed provider address carry the risk of theft, forgery or alteration. In addition, a recent Government Accountability Office report found that Medicare payments made to a provider who gives its address as a mailbox-rental store, vacant, or invalid practice address increase the potential risk of fraud, waste, or abuse.

What OIG Will Investigate: The OIG will determine whether similar problems exist with Medicaid payment focusing on whether Medicaid payments by paper check sent to providers with mailbox-rental locations were for unallowable services.

4. Status Update on State Medicaid-Provider Enrollment Efforts

Concern: A few years ago, the OIG found that many States hadn't yet completed fingerprint and background checks and site visits of providers seeking to enroll in Medicaid. But despite assistance from CMS and repeated deadline extensions, the enrollment problem remains unresolved.

What OIG Will Investigate: The OIG will do a Status Update to determine which States have completed the required checks and site visits and try to identify the roadblocks.

5. Review of CMS Medicare Advantage Organization Payment Systems

Concern: CMS is transitioning to a new data systems for making Medicare Part C payments to Medicare Advantage organizations to process risk-adjusted hierarchical condition category (HCC) payment increases.

What OIG Will Investigate: The OIG will review the transition from a data continuity perspective focusing on cases in which CMS made an increased payment to a Medicare Advantage organization for an HCC to determine if CMS systems properly contained a requisite diagnostic code mapping to that particular HCC.

Teaching Hospitals Consistently Order More Lab Tests Per Patient

A new study validates the long-held assumption that intensity of care is consistently higher at teaching hospitals, compared to nonteaching hospitals. Patients in Texas admitted to major teaching hospitals with two common conditions receive significantly more laboratory tests per day, compared to similar patients at nonteaching hospitals even after controlling for illness severity, length of stay, and patient demographics, according to a study published Nov. 13 in *JAMA Internal Medicine*. In an environment with increased focus on value-based care and appropriate test utilization, the authors say that studying cultural factors in the training environments that may lead to increased use of laboratory tests is essential.

Using a large statewide all-payer database, the researchers identified hospitalizations with a primary diagnosis of bacterial pneumonia (n = 24,118) or cellulitis (n = 19,211; from Jan. 1, 2014, to June 30, 2015) across 11 major teaching hospitals, 12 minor teaching hospitals, and 73 nonteaching hospitals in Texas each with 100 or more hospitalizations for each condition. These diagnoses were selected in part due to the fact that specialized laboratory testing is generally not required for these conditions and that they are cause for admission at both teaching and nonteaching hospitals.

The researchers found that the mean number of laboratory tests per day varied significantly by hospital type and was highest for major teaching hospitals for both conditions (bacterial pneumonia: major teaching hospitals, 13.21 versus 8.92 at nonteaching hospitals; cellulitis: major teaching hospitals, 10.43 versus 7.29 at nonteaching hospitals). This association held for all levels of illness severity for both conditions, except for patients with cellulitis with the highest illness severity level. The size of the effect amounted to approximately 3.6 additional laboratory tests per day for pneumonia and

Findings Applied to A Single Case

The authors offer the following illustration:

Patient: A 42-year-old African American man with Medicaid insurance coverage presenting to the emergency department with community-acquired pneumonia.

Hospitalization: A 4-night hospital stay with an illness severity of 2.

Laboratory Testing: Based on the study results, if this patient were admitted to a nonteaching hospital, he would receive 10 laboratory tests per day during his hospitalization, for a total of 40 laboratory tests versus if he were admitted to a major teaching hospital he would receive 13 laboratory tests per day, for a total of 52 laboratory tests, representing a 30 percent increase in use of laboratory testing.

2.6 additional laboratory tests per day for cellulitis. Hospitals that had more laboratory tests ordered for patients with pneumonia also had more laboratory tests ordered for patients with cellulitis.

Of the 11 major teaching hospitals, eight were above the mean number of laboratory tests performed across all hospitals for pneumonia and seven were above the mean number of laboratory tests performed across all hospitals for cellulitis.

"Our data also show that patients with pneumonia at major teaching hospitals are sicker, perhaps leading to learned behaviors by trainees of ordering more laboratory tests," write the authors led by Victoria Valencia, from University of Texas at Austin. "Perhaps higher rates of testing are justified for a substantial fraction of patients in teaching hospitals, but this behavior may then spill over to less acutely ill patients.... If this phenomenon exists it could complicate generalized efforts to reduce testing at academic medical centers and could even lead to harm if there is an overall nontargeted reduction in testing."

Takeaway: This study confirms a widespread pattern of increased laboratory test ordering in teaching hospitals, even for common conditions. In an environment with increased focus on value-based care, targeted test reduction interventions need to ensure sicker patients are receiving needed tests, but that less severely ill patients are not receiving unnecessary testing.