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For Clinical and AP Laboratories and Pathology Practices

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INSIDE THIS ISSUE

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Upcoming Events

Conferences:

Lab Leadership Summit: Designing, Implementing & Managing a High-Profit Lab Outreach Program
May 11, 2017 – 8 a.m.-5 p.m.
Holiday Inn Airport, Atlanta, GA
www.lableadershipsummit.com

Lab Institute 2017
October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

OIG and DOJ Offer Tips for Evaluating Compliance Effectiveness

Labs have two new compliance tools—from the Department of Justice (DOJ) and the Office of Inspector General (OIG)—focused on evaluating the effectiveness of compliance programs. The DOJ's resource addresses evaluation of a compliance program in the context of fraud prosecution while the OIG's tool has a more proactive objective, to measure programs periodically, even when no misconduct or investigation is at issue.

Both the OIG and DOJ caution that these resources are not "one-size-fits-all," nor are they meant to be a checklist or standard formula rigidly applied but instead the elements discussed should be applied on a case-by-case basis. Both resources share similar themes and concerns and demonstrate a faithfulness to the core principles of effective compliance programs first discussed nearly 20 years ago in the OIG's Compliance Program Guidance for Clinical Laboratories.

Continued on page 9

23andMe Gains FDA Approval for DTC Test

23andMe and the U.S. Food and Drug Administration (FDA) announced this month that the agency allowed marketing of 23andMe's Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases or conditions. "These are the first direct-to-consumer (DTC) tests authorized by the FDA that provide information on an individual's genetic predisposition to certain medical diseases or conditions, which may help to make decisions about lifestyle choices or to inform discussions with a health care professional," said the FDA in its statement.

In 2013, the FDA issued a warning letter to 23andMe requiring that it stop marketing its DTC Personal Genome Service. The FDA had concluded that the $99 saliva test was a class III medical device requiring FDA approval. But a little less than two years later, the company won FDA approval for a DTC genetic carrier test for Bloom Syndrome.

Now, the FDA has given 23andMe authority to market its DTC genetic testing report that indicates personal risk for certain diseases such as late-onset Alzheimer's, Parkinson's, and celiac. The approval was granted following de novo classification

Continued on page 2

23andMe Gains FDA Approval for DTC Test, *from page 1*

review—which can be used for low or moderate risk devices that are not substantially equivalent to existing devices. Tests reviewed under this approach will be subject to special controls regarding the test's "accuracy, reliability and clinical relevance." Future tests that are substantially equivalent to this DTC test will be able to utilize the 510(k) approval process.

"This is an important moment for people who want to know their genetic health risks and be more proactive about their health," declared 23andMe CEO and Co-founder Anne Wojcicki in a statement. "The FDA has embraced innovation and has empowered individuals by authorizing direct access to this information. It is a significant step forward for 23andMe and for the adoption of personal genetics."

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CASE OF THE MONTH

False Billing of Nuclear Stress Tests at Center of $50 Million Cardio Fraud Scheme

The feds arrested a cardiologist, neurologist and four others for their role in an elaborate fraud scheme. The government contends that over a 12-year period, the defendants' New York City medical practice billed Medicare and private insurers for $50+ million worth of cardiology and neurology tests and procedures that were either medically unnecessary or not actually provided, including nuclear stress tests (NSTs) on patients who didn't need them. In addition to prison time, the defendants face the risk of treble damages and civil penalties under the False Claims Act.

NST Billing & Coding

NSTs measure blood flow to the heart both when the patient is resting and stressed (either via exercise or chemical inducement). There are three possible CPT codes for billing the imaging part of the test:

- **Codes 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.

Lack of MD Options in Superbill

The problem was that the practice listed only one code for "Nuclear Studies" in its superbill: 78452. 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.

Takeaway: Although the case involved cardiology testing, the same "bundling" risks arise in physician ordering of laboratory tests, particularly with regard to test panels. To avoid "bundling" charges, labs must ensure that their requisition forms list not just the test panel but the

component tests it contains so that the physician has the option of ordering the test(s) individually. (For more compliance information regarding medical necessity and customized panels see "Spot the Compliance Mistake(s) Customized Test Panels & Medical Necessity" in the March issue of G2 Compliance Advisor.) See more at www.g2intelligence.com/spot-the-compliance-mistakes-customized-test-panels-medical-necessity.

Laboratory Safety: Making Laboratory Safety as Simple as ABC

By Dan Scungio, MT (ASCP), SLS, CQA (ASQ)

When it comes to safety in the laboratory, there are several rules, regulations, and guidelines to keep track of from multiple organizations. If your responsibilities for lab safety are shared with other job duties, that makes keeping track of these regulations even more difficult. If you're having a hard time keeping up as a lab safety professional, how are you getting the necessary information to your staff?

One way to simplify these regulations is to break them down into specific safety topics and focus on the three main inspection readiness points and training for each. Breaking down the readiness pieces into ABCs can help you use the information easily for your lab.

Safety in the Physical Environment

For our first example, let's look at the physical environment in the laboratory. The regulations for what was once known as the "environment of care" are concerned with the actual physical space. Is there adequate space for safe work to be performed in the lab? Is there adequate working space in the general lab for the medical director, charge techs, etc.? This is also where labs should consider space for staff lockers, rest rooms, and a meeting and break area. Work space is of course important as well. Is there adequate room in your lab for equipment, and storage of supplies, both room temperature and refrigerated?

To break this down, the ABCs of the lab physical environment are:

A = Arranged neatly. A culture of neatness and cleanliness is simply a better environment to work in, but it also helps most people to work in a better, orderly, safer fashion.

B = Below 18 inches from ceiling. Some fire locales may require 24-inch clearance, and it may only be required if there is a sprinkler system in place. Check with your local fire authority as they have the ultimate say in this.

C = Clear walkways and paths to exits.

Bloodborne Pathogen Safety

Bloodborne Pathogens is an important safety topic in the laboratory, and the regulations are not always understood. OSHA requires a full safety plan for your lab which includes education and training about the Exposure Control Plan, Personal Protective Equipment, food and drink in the lab, specimen transport, and spill clean-up.

If you are struggling with getting your hands around safety compliance, then start with some of the basics, the ABCs in each safety category.

Broken down to its basic form, the ABCs are:

A = Assess PPE. Perform risk and task assessments annually and visually assess the location of PPE and its use in the lab. Make it easy for people to comply with PPE use.

B = Ban food and drink from the lab. This also includes gum, candy, throat lozenges, etc. Why? OSHA is reducing hand-to-mouth contact in the lab to reduce the possibility of lab-acquired infections.

C = Carry specimens appropriately. Train staff for packing and shipping category A and B substances where needed, train how to transport specimens in house, via courier, etc.

Chemical Safety

Chemical management is another topic that can consume the time of a lab safety professional. So many regulations affect this area, and keeping up with chemical labeling, the inventory, and Safety Data Sheets (SDS) can seem daunting.

Let's break this subject down to its simplest ABC form:

A = Account for all chemicals. Update the lab chemical inventory at least annually, classify chemicals as carcinogen, reproductive or acute toxin, and ensure proper storage of chemicals.

B = Be ready for spills. Be sure you have the right types of spill kits (i.e., neutralizers for formaldehyde), and make sure they are ready for use. Staff need training on the use of spill supplies and spill drills are always a good idea.

C = Classify all chemicals. Label all primary and secondary containers properly, make sure you have access to SDS for all chemicals on site, and ensure that staff are trained on all present chemical hazards.

Conclusion

There are several other safety issues in the lab, such as waste management, ergonomics, fire safety, and compressed gas safety to name a few, and the regulations for safety surrounding some of these keep changing.

If you are struggling with getting your hands around safety compliance, then start with some of the basics, the ABCs in each safety category. Start there and build on your "safety alphabet," and from there you will see the improvement in your overall lab safety culture. Focus on the process today and you will reach your goals tomorrow.

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Editor's Picks

- www.g2intelligence.com//alert-emphasizes-leadership-sets-tone-for-safety-and-quality
- www.g2intelligence.com//lab-safety-compliance-match-your-ppe-to-the-hazard

8 Traps to Avoid When Investigating a Sexual Harassment Complaint

President Trump has declared April is National Sexual Assault Awareness and Prevention Month. Sexual harassment is a related problem that all employers must proactively address and prevent. While most labs, pathology practices and other health care employers are well aware of the need for sexual harassment policies, just having a policy isn't enough. If sexual harassment allegations arise, you need to know how to appropriately respond. Here are 8 potential mistakes your lab should be alert to and avoid making when conducting investigations of such allegations.

It's critical for labs and pathology practices to be aware of the mistakes that can mar your sexual harassment investigation and make your lab or practice liable—regardless of whether the accusation is actually true.

Don't Rush To Judgment—In Either Direction

Back in the bad old days when employers didn't take sexual harassment seriously, harassment complaints were ignored or swept under the rug. To the extent they were investigated at all, the tendency was to downplay the complaint as exaggeration, fabrication or oversensitivity on the part of the victim.

The good news: Today's employers "get it" and understand the implications of sexual harassment complaints and the liability and embarrassment they can bring to the organization.

The bad news: Employers are still rushing to judgment, only now they're going in the opposite direction. The modern tendency is to assume that employee sexual harassment accusations are true and swiftly discipline the accused to control the damage. Such hasty decisions not only fail to contain the problem but actually make it worse.

And that brings us to the moral of this story: Your liability for sexual harassment is based not only on your policies and attitudes but on how you investigate complaints. To conduct a reasonable investigation the inquiry must be not just thorough but fair and account for the rights of both accuser and accused.

It's critical for labs and pathology practices to be aware of the mistakes that can mar your sexual harassment investigation and make your lab or practice liable—regardless of whether the accusation is actually true. We've looked at court cases and Equal Employment Opportunity Commission rulings and identified eight things you need to be on the lookout for.

Mistake 1: Waiting too long

You must investigate promptly. Over time, memories fade, witnesses leave and physical evidence disappears. In addition to compromising the evidence, delaying an investigation undermines its effectiveness and puts additional strain on the accuser, accused and other parties involved.

- **Employer loses:** Court rules that an employer's investigation of sexual harassment was unfair because of "excessive" and "unreasonable" delay—the investigation didn't start until nearly six months after the complaint was reported.

- **Employer wins:** Court praises employer for starting investigation within a day of receiving the first allegation of sexual harassment from an employee who claimed a supervisor made unwanted sexual comments.

Practice tip: Keep in mind that while speed is important it isn't the paramount concern. Fairness is. Rushing an investigation is just as bad as foot dragging. So, for example, it was unfair for an employer not to give the accused enough time to respond to allegations in a rush to complete the investigation before the Christmas holiday.

Mistake 2: Using investigator who isn't objective

The person carrying out the investigation must be completely impartial and not related to or in any other special relationship with either the accuser or accused. That's why managers shouldn't investigate subordinates and vice-versa. Individuals also shouldn't investigate if they have a history of conflict with the accused or the accuser. Nor should the investigators have a personal or professional stake in the outcome, such as partners determined to use the investigation to cover up wrongdoing in their departments.

Of course, it's not always easy to find objective and impartial investigators, especially in small labs where everyone knows and may be affected by the outcome of the investigation. And persons who are objective might not be qualified to do a thorough and competent investigation. As a result, you may have to hire an external resource to do the investigation.

Mistake 3: Not getting both sides of story

One common mistake is talking only to the alleged victim. You can't have a fair investigation unless you also give the accused an opportunity to give his/her side of the story.

You must also give the accused the facts they need to know about the allegations, including dates and specific details, to respond effectively.

- **Employer loses:** Arbitrator rules that employee accused of sexual harassment was wrongfully fired because the investigation was unfair. *The biggest flaw:* Waiting three months before telling the employee what he was accused of.

Sexual harassment investigation DOs & DON'Ts

- ✔ **DO** select an impartial and objective investigator or investigative team
- ✔ **DO** let the accused answer allegations
- ✔ **DO** give the accused detailed information he needs to answer the allegations
- ✔ **DO** interview all relevant witnesses, including those the accused asks you to interview
- ✔ **DO** interview witnesses thoroughly
- ✔ **DO** thoroughly document each step of the investigation
- ✖ **DON'T** assume a person is guilty just because he or she has been accused
- ✖ **DON'T** unnecessarily delay the investigation
- ✖ **DON'T** put a speedy investigation ahead of a fair one
- ✖ **DON'T** interview witnesses in the presence of other witnesses
- ✖ **DON'T** deviate from company investigation policy and procedures without justification

- **Employer wins:** Arbitrator upholds firing for harassment because the investigation was fair and the accused employee got a six-page detailed summary of the allegations.

Document the results of interviews and when appropriate get written statements from third party witnesses.

Mistake 4: Not interviewing third parties

It's important to interview not only the accuser and accused but others who may have relevant information about the situation—especially in the all too common he said/she said situations.

- **Employer loses:** Arbitrator says investigation is flawed because the employer didn't talk to the two individuals the accused cited as witnesses who would support his side of the story.
- **Employer wins:** Court says investigation that included interviews of 40 employees is thorough and fair. The investigator started by interviewing the accuser and then interviewed other employees that the accuser mentioned in her story and additional employees identified in the investigation. The investigator also interviewed the accused four times and gave him an opportunity to respond to the allegations on each occasion.

Practice tip: Document the results of interviews and when appropriate get written statements from third party witnesses.

Mistake 5: Asking leading questions

It's not just how many interviews you do but how you do them. One common interview mistake to avoid is to lead witnesses—that is, phrase questions to set up the witness to respond in a certain way.

Example: Jane accuses the billing manager, Mike, of making inappropriate remarks about her tight clothes not only to her but to her colleague, Megan. So the investigator decides to interview Megan to see if she can confirm the story.

- **Bad interview question:** "Did Mike ever say anything to you about Jane's tight clothes?"
- **Good interview question:** "Did you ever hear Mike make any inappropriate comments about you or any of your colleagues?"

Mistake 6: Interviewing witnesses in each other's presence

Interviewing the accuser in front of the accused can intimidate the accuser, and vice-versa. Even third-party witnesses can be influenced by the presence or statements of others. *Result:* The testimony becomes less credible as evidence.

- **Employer loses:** Court slams investigators for failing to warn two witnesses not to confer when putting their complaints of sexual harassment in writing and allowing them to give their accounts together in the same room at the same time.

Sooner or later, one of your employees is bound to complain about being sexually harassed by a co-worker.

Practice tip: Be on the lookout for and take steps to minimize the risk of witness collaboration and intimidation. Witnesses should be interviewed separately and not in the presence of other witnesses.

Mistake 7: Not following your own procedures

A surefire way to taint an investigation is to deviate from your lab's investigation procedures. Although you can be flexible if the occasion demands it, make sure you have a solid justification any time you depart from normal policy and procedure.

- **Employer wins:** Court finds it reasonable for employer to have police investigate rather than follow its internal investigation procedure of having supervisors conduct internal and "discreet" investigations of sexual harassment allegations, to avoid appearance of bias when owner's brother was the accused.

Mistake 8: Not documenting investigation

As lawyers like to say, if it isn't documented, it never happened. It's critically important to thoroughly document each step of your investigation so you can retrace your steps and prove that the investigation was thorough and fair.

- **Employer loses:** Court rules employer's general synopsis of what each witness said, rather than detailed notes of witness interviews, wasn't adequate.
- **Employer wins:** Court says investigation is properly conducted, citing detailed notes of interviews and written statements taken from all of the key witnesses.

Takeaway: Sooner or later, one of your employees is bound to complain about being sexually harassed by a co-worker. Such complaints are emotionally disturbing and expose your lab or pathology practice to serious legal risks. How you respond to the complaint has just as much impact on your liability as whether the complaint is actually true. The best way to protect your lab or pathology practice is to:

- *Recognize that overreacting to a sexual harassment complaint is just as dangerous as ignoring it;*
- *Help management resist the temptation to "put out the fire" and rush to judgment;*
- *Remind the decision makers that being accused doesn't make an employee guilty of sexual harassment;*
- *Have somebody objective and qualified thoroughly and fairly investigate if the accusation is true; and*
- *Ensure that the investigation process accounts for the rights of not just the alleged victim but the accuser.*

OIG and DOJ Offer Tips for Evaluating Compliance Effectiveness, *from page 1*

Here's a summary of some key takeaways from each of these compliance resources.

The "intent of this exercise was to provide a large number of ideas for measuring the various elements of a compliance program." The result was a list that offers "measurement options to a wide range of organizations with diverse size, operational complexity, industry sectors, resources, and compliance programs."

OIG/HCCA Resource Guide

The OIG collaborated with the Health Care Compliance Association to produce a Resource Guide to help organizations evaluate the effectiveness of their compliance programs. This is one of several collaborations with the HCCA aimed at providing compliance assistance to the health care industry. Two years ago, they collaborated on guidance for boards of directors to assist in ensuring proper oversight of compliance programs. See "OIG & Industry Leaders Collaborate on Guidance Regarding Compliance Oversight" May 1, 2015.

The current Resource Guide is the fruits of a HCCA- OIG Compliance Effectiveness Roundtable held in January 2017 in Washington, DC. The roundtable involved compliance professionals, Department of Health and Human Services and Office of Inspector General staff. The "intent of this exercise was to provide a large number of ideas for measuring the various elements of a compliance program." The result was a list that offers "measurement options to a wide range of organizations with diverse size, operational complexity, industry sectors, resources, and compliance programs."

The Guide is organized around seven categories taken from the HCCA's *CHC Candidate Handbook: Detailed Content Outline*. Within these categories the Guide discusses what and how to measure a compliance program's effectiveness, suggesting steps to take in evaluating the program. Those seven categories are:

1. **Standards, Policies and Procedures**—The Guide suggests periodically reviewing these compliance resources to ensure they are updated, accessible to and understood by employees and enforced by the administration.
2. **Compliance Program Administration**—Organizations should assure there's adequate staffing and budget for compliance; review oversight committee's goals and functions; verify the role and authority of compliance officer, counsel, compliance committee and the governing board and review organizational structure; ensure development of risk assessment plans, internal controls, periodic compliance program reviews and annual compliance work plan.
3. **Screening and Evaluation of Employees, Physicians, Vendors and other Agents**—Ensure job descriptions and performance evaluations include compliance element, verify processes to identify conflicts of interest and background checks of staff and appropriate due diligence for third parties.
4. **Communication, Education, and Training on Compliance Issues**—Make sure compliance updates are communicated throughout

the organization and regular training and continuing education is provided and participation tracked.

5. **Monitoring, Auditing, and Internal Reporting Systems**—Develop audit plans and internal reporting mechanisms and measure accessibility and effectiveness, assure that regular monitoring and auditing is performed, verify that risks identified in such activities or through internal reporting are responded to/addressed in timely manner and retaliation is not occurring; and review corrective action activities.
6. **Discipline for Non-Compliance**—Ensure consistent and proportionate disciplinary action taken and properly documented.
7. **Investigations and Remedial Measures**—Review corrective action to be sure that noncompliance is appropriately handled, investigations are properly conducted and documented, remedial action taken to prevent future risk, organization appropriately cooperates with government entities, and overpayments are timely refunded.

DOJ Evaluation of Compliance Programs

The DOJ said it doesn't "use any rigid formula to assess the effectiveness of corporate compliance programs" and instead makes "individualized determination[s]."

The DOJ also released guidance for industry to help ensure compliance, titled Evaluation of Corporate Compliance Programs discussing the effectiveness of compliance programs--which is one of the so-called "Filip Factors" that federal prosecutors use when considering prosecution of a business. The document instructs that prosecutors consider those factors "in conducting an investigation of a corporate entity, determining whether to bring charges, and negotiating plea or other agreements."

The DOJ said it doesn't "use any rigid formula to assess the effectiveness of corporate compliance programs" and instead makes "individualized determination[s]." However, there are "common questions" to be asked about compliance programs and this new document "provides some important topics and sample questions that the Fraud Section has frequently found relevant in evaluating a corporate compliance program." The document's topics and questions are also described as related to topics in the U.S. Sentencing Guidelines and other criminal prosecution/fraud section guidance documents.

The document addresses 11 topics with specific questions to ask under each topic. The DOJ notes that not every question will be applicable in every case and this isn't a checklist or a formula. However, these topics and questions provide valuable insight for organizations to use in proactively evaluating the effectiveness of their compliance programs.

Here are some takeaways gleaned from a review of the document's 11 topics and related questions:

1. **Analysis and remediation of misconduct:** The government is concerned with whether organizations seek to find the root cause of misconduct and whether systemic issues were involved. Additionally, it's important to consider whether the misconduct could have been prevented, whether the company should have known about the miscon-

duct due to audits, internal reporting or investigations and if so, why it wasn't caught earlier. Most importantly, what does the company plan to do after the misconduct is discovered – how will it make sure it doesn't happen again?

2. **Management:** Following the often-discussed "tone-at-the-top" theme, the document focuses on whether senior leaders "encouraged or discouraged" misconduct and "modelled proper behavior." How does leadership communicate a commitment to compliance? The board of directors' resources and access to compliance expertise, use of external auditors, communication with compliance team and their oversight activities are all key concerns.
3. **Compliance resources and autonomy of compliance personnel:** Consider how the lab values its compliance functions. Does it pay as much attention and devote the resources to compliance activities and the compliance team as it does to other functions? The government is also concerned about whether resources are commensurate with risk of the organization and whether compliance team requests for resources have been met and if not why. The importance of compliance to "strategic and operational decisions" is also analyzed.

The document's questions emphasize the need for policies and procedures that can prevent misconduct and proper communication of these to employees, as well training and oversight of implementation.

The questions asked reinforce guidance included in other compliance resources that recommend the compliance team have direct reporting capability to the board of directors, meet directly with the board and have independence so they can adequately perform their function without influence from management. The questions probe whether compliance functions have reported concerns, and whether deals or transactions have been stopped or changed due to the compliance team's expressed concerns.

4. **Policies and procedures:** The document's questions emphasize the need for policies and procedures that can prevent misconduct and proper communication of these to employees, as well training and oversight of implementation.
5. **Risk assessment:** The questions focus on methods the company uses for detecting risks and misconduct.
6. **Training and communication:** The government is concerned about how well-tailored training is to employees based on their roles and risk level and how well the training is designed to be understood and effective.
7. **Reporting and investigation measures:** Relating back to initial topics on risk analysis and investigation, the government looks to see how well entities collect and use information from compliance reporting resources and whether reports are taken seriously, how an entity responds to compliance reports and investigates reports or actual misconduct, including "[h]ow high up in the company ... investigative findings go."

Due diligence is also a key concern regarding arrangements with other entities and whether such due diligence identifies risk of misconduct.

8. **Discipline and incentives:** Compliance programs should incentivize compliance and appropriately discipline non-compliance, including holding managers and supervisors accountable for allowing misconduct to occur.

9. **Continuous improvement:** Internal audits, control testing and updated risk assessments, policies and procedures should be part of efforts to continuously improve compliance.

10. **Use of third party management entities:** Consider whether and why the lab outsources functions, how they control the relationship with and conduct of the third party and whether due diligence is performed and third party conduct is monitored and disciplined when necessary.

11. **Compliance in merger and acquisition scenarios:** Due diligence is also a key concern regarding arrangements with other entities and whether such due diligence identifies risk of misconduct. Additionally, labs need to be concerned about how well they integrate compliance into the resulting entities.

Takeaway: Laboratories can benefit from two new compliance tools to evaluate their compliance programs and ensure their effectiveness.