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Senate Finance Committee Hearing Addresses Potential Stark Law Changes

Earlier this summer, the Senate Finance Committee heard testimony from stakeholders arguing for changes to the Stark Law that could make compliance easier and facilitate new business models that promote value-based, coordinated health care services. The hearing followed a round table held last year and a recent Senate Finance Committee white paper on the self-referral law.

In December 2015, the Senate Committee on Finance and the House Committee on Ways and Means convened a group of experts to discuss the Stark Law, which prohibits physicians from referring Medicare patients for "designated health services (DHS)" to entities with which the physician has a financial relationship. The group considered changes that might be needed to facilitate implementation of the

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Pathology, Cytology Face Potential Cuts in 2017 Physician Fee Schedule

CPT Code 88305 is headed to the chopping block again. The Centers for Medicare & Medicaid Services (CMS) has suggested cutting the technical component of 88305—a tissue examination and a primary component within the practice of pathology—by 15 percent for calendar year 2017 as part of its proposed changes to the Medicare Physician Fee Schedule.

The pathology world was shaken to the core three years ago when the technical component of 88305 was cut by 57 percent. The decision by CMS to dramatically ratchet down reimbursement then led to the devaluation of many pathology practices. There have been other cuts since then, but they have remained below double digits percentagewise.

The proposed cut to 88305 would bring the technical portion of 88305 below $30, to $29.34. The proposed rate for professional interpretation remains essentially unchanged at $39.71.

The Physician Fee Schedule is a delicate ballet wherein CMS tries to reconcile the intellectual challenge of performing each task with how much time it takes to complete in order to compute how much Medicare will reimburse for each procedure. The agency tries to assign specific values to the work through what is known as relative value scale. The higher the value, the more laborious or complicated the task.

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Pathology, Cytology Face Potential Cuts in 2017 Physician Fee Schedule, *from page 1*

For this latest round of proposed cuts, the CMS said prices have dropped for some disposables to perform pathology services, particularly eosin stain supplies. That has also led to other smaller cuts to 14 other pathology-related CPT codes and G-code G0416, which pertains to prostate needle biopsies.

Another significant change is proposed reductions in payments around CPT code 88184, which pertains to flow cytometry/tc1 markers. The proposed cuts range from 3 cents to more than $5, depending on the work task related to the use of the assay. Each antibody flow cytometry test would be cut by $5.10 (input code SL186). But the dye sublimation printing attached to the task (input code ED031) would see just the smallest cut.

"For the second time in four years, another reduction on primary Pathology codes is being proposed. The first reduction was dramatic, this second would be catastrophic."

—Ana L. Viciana, M.D.

According to CMS, that is due to refinements connected to the amount of time such equipment is being used. However, the reductions total about a 20 percent cut in reimbursement around a significant amount of flow cytometry work.

The College of American Pathology and American Clinical Laboratory Association have yet to submit formal comments on the proposed rule, which impacts virtually every medical practice that accepts Medicare patients. CMS is accepting input through much of the next month.

The "proposals are intended to give a significant lift to the practice of primary care and to boost the time a physician can spend with their patients listening, advising and coordinating their care—both for physical and mental health," said CMS Acting Administrator Andy Slavitt in a statement.

Some pathologists have expressed displeasure in early comments submitted to the agency.

"For the second time in four years, another reduction on primary Pathology codes is being proposed. The first reduction was dramatic, this second would be catastrophic," remarked Ana L. Viciana, M.D., a pathologist in Miami, Fla. "Pathology services simply can barely afford to be provided adequately. The continued reduction in reimbursement results in an inability to maintain the level of professional services required to reduce medical errors!"

Megan Kressin, M.D., a pathologist in Austin, Tex., also expressed concern.

"These proposed fee reductions are extreme, and will challenge the ability of the pathology laboratory to accurately and quickly diagnose a patient's tumor. Histology is a delicate and time consuming art that can result in suboptimal tissue for diagnosis if rushed. Under the proposed fee codes, labs will be forced to reduce their histology workforce and overly burden an already stressed histology workforce," Kressin remarked. "Similarly, flow cytometry is the cornerstone of diagnosis for many leukemia and lymphoma cancers. A 20 percent reduction will challenge many labs to be able to continue to offer this vital and time-sensitive testing. My hospital must perform flow cytometry within an hour of sample collection in order to determine if there are enough cells for a bone marrow transplant; this is not a test that can be outsourced and it requires significant time, expertise, and equipment. This fee reduction would be devastating for the patients who depend on an accurate and timely pathology diagnosis for their treatment."

Takeaway: The CMS is proposing more significant cuts to the practice of pathology in its 2017 Physician Fee Schedule.

Congressional Leaders Query FDA and CMS about Theranos

Earlier this summer, ranking members of U.S. House of Representatives Committee on Energy and Commerce requested a briefing from Theranos to inform the committee about Theranos' efforts to comply with CMS inspection letters and FDA 483 inspection reports. Specifically, the letter requested the briefing address changes to policies and procedures the company has made, efforts to investigate the "root cause" of compliance issues, how it identified affected patients, and how the company is helping affected providers and patients. At the same time, the Centers for Medicare & Medicaid Services (CMS) notified Theranos had not provided a "credible allegation of compliance and acceptable evidence of correction" of deficiencies found during an inspection of its Newark, Calif., laboratory. Therefore, CMS threatened sanctions that include revocation of the CLIA certificate and barring founder Holmes from owning, operating or directing a lab for two years. See "Theranos Faces More Questions and Challenges and Ramps Up Efforts to Improve Compliance," *G2 Compliance Advisor*, July 2016, p.1. Theranos has announced that it is appealing CMS' sanctions. The announcement also indicated that the company has made "substantial progress toward correcting the deficiencies CMS identified" and will continue to work with the agency while the appeal is pending to try to achieve a "mutually agreeable resolution to the matter."

> ***"It is unclear whether the corrected blood tests reports issued by Theranos thus far capture the universe of inaccurate blood test results that the company has provided patients."***
>
> **— House letter to the FDA**

The same ranking committee members who requested a briefing from Theranos sent letters in late July to both the U.S. Food and Drug Administration and CMS expressing, concern about the number of tests Theranos had invalidated that had been performed on its platform. Theranos had said in June approximately 70,000 tests—slightly less than 1 percent of 7 million performed—had been invalidated. But the committee members noted prior statements by Theranos about the volume of patients who were tested using its new technologies to call into question those statistics. The committee also questioned an internal investigation undertaken by the company that concluded that no patients had been harmed by the inaccurate tests.

"It is unclear whether the corrected blood-test reports issued by Theranos thus far capture the universe of inaccurate blood test results that the company has provided patients," the House letter to the FDA said.

To add to the company's troubles, in a lawsuit filed in Arizona last month, a Theranos patient claimed he suffered a heart attack less than a month after undergoing routine lipid and A1C testing that showed no abnormalities, leading his doctor to make no changes to his medication or lifestyle. The test results were later invalidated by the company.

Meanwhile, Theranos began this month with an attempt to rehabilitate its image in the scientific community. In a widely anticipated special session at the American Society of Clinical Chemistry's 68th Annual Scientific Meeting and Clinical Lab Expo (July 31-Aug. 4, Philadelphia), Theranos CEO Elizabeth Holmes took the stage to discuss the company's technology—at least some of it. She opened by addressing the elephant in the room—government sanctions regarding Theranos' Calif. laboratory—but only to say that "we take full responsibility for our lab operations and we are working diligently to rectify all outstanding issues and to realize the highest standards of excellence in lab operations." What she really came to do, she said, was not to discuss lab operations but rather to introduce "key inventions" and "the associated science and results be-

"The architecture of Theranos' technologies, and the associated science and technology are sound, as was demonstrated ... at the AACC Scientific Meeting."

— Susan A. Evans, Theranos' Scientific and Medical Advisory Board

hind our technologies" and engage in an "exchange of scientific information about our inventions and technologies." Holmes did not address the Edison technology originally touted by the company but instead detailed the "architecture" of what the company has named the miniLab and the Theranos Virtual Analyzer (TVA), which facilitates testing across different methods in a miniature platform. The miniLab is a compact device (2.5 cubic feet) containing a mini-robot that processes single-use cartridges with the TVA remotely dictating protocols for processing. It contains a miniaturized luminometer and fluorometer, spectrophotometer and cytometer.

Holmes indicated the technology is not yet FDA approved but the company is working toward that goal. Following the presentation, AACC representatives Dr. Dennis Lo, Dr. Stephen Master, and Dr. Patricia Jones moderated a question and answer session. Dr. Master noted that the evidence Holmes presented "fell far short of" prior, very broad claims—for example, that Theranos technology could facilitate a "whole panoply of lab tests from a couple drops of blood." Holmes responded that this presentation was to begin engaging "in a scientific exchange" and discuss the architecture of one of its latest inventions. She did, however, acknowledge that "we fully understand … we have a lot of work to do to engage with this community … I wish that I had started earlier in the context of building the scientific and medical board that we've had the privilege to build and now working toward peer reviewed publications."

"The architecture of Theranos' technologies, and the associated science and technology are sound, as was demonstrated ... at the AACC Scientific Meeting," said Susan A. Evans, a member of Theranos' Scientific and Medical Advisory Board, in a statement released not long after Holmes presentation concluded. "Innovations like this are very exciting. The Theranos miniLab ... has the potential to increase access and bring laboratory testing to the patient, whether close to home or in remote locations that are currently underserved."

Takeaway: Members of Congress continue to press for details about Theranos' efforts to address deficiencies identified by the FDA and CMS. Meanwhile, the company has taken steps to increase transparency but with regard to a testing platform different than that which was the focus of their initial claims to disrupt the industry.

Job Interviews: How to Ask Personal Questions without Committing Discrimination

The job interview process is a breeding ground for discrimination complaints. One common mistake: asking job applicants inappropriate questions about their nationality, marital status, religion, disabilities and other characteristics that discrimination laws ban you from considering when making hiring decisions. Applicants on the receiving end of such questions are apt to come away feeling like you discriminated against them, especially if they do not get the job. Yet, it may also be legitimate to seek this kind of information to evaluate an applicant's credentials; the problem, in other words, is not necessarily the question but how you phrase it.

The bottom line: To avoid discrimination complaints, you need to know what questions you can and cannot ask. This article explains where to draw the lines.

You may consider personal characteristics protected against discrimination to the extent necessary to evaluate the applicant's ability to perform the essential functions of the job.

Why Certain Job Interview Questions Discriminate

"Are you pregnant?"

You don't have to be an HR manager to just know that this is a question that should not be asked during a job interview. The instinct is sound. But *why* is asking a job applicant if she is pregnant illegal?

Answer: Technically, it is not illegal. The anti-discrimination laws do not say employers may not ask questions about pregnancy. What the laws do say is that employers cannot *use* gender, including pregnancy, to make hiring decisions. The question "are you pregnant" suggests that you do factor pregnancy into your hiring decisions. The other problem with "are you pregnant" is that it is a question you would only ask female applicants.

When You May Ask Personal Questions

The rules are meant to combat the stereotype that women who want to have children are less dedicated to their jobs and ensure women equal hiring opportunity. But what if the employer has a legitimate, nondiscriminatory motivation to ask about pregnancy? For example, what if the job involves exposure to chemicals shown to cause miscarriages or birth defects?

The laws do allow employers leeway for these circumstances. **Rule of thumb:** You may consider personal characteristics protected against discrimination to the extent necessary to evaluate the applicant's ability to perform the essential functions of the job. The corollary is that you can ask questions during job interviews to obtain the personal information you need for your evaluation as long as you phrase your questions the right way.

The Questions You Can and Cannot Ask

Over the years, the EEOC has issued guidance explaining which pre-employment questions employers can and cannot ask. To make your life easier, we assembled the piecemeal guidance into a single, comprehensive chart.

COMPLIANCE PERSPECTIVES

Pre-Employment Inquiries

CAN'T ASK	CAN ASK	COMMENT
What's your maiden name?	■ What's your current name? ■ Have you ever been known by any other name?	Maiden name may indicate marital status, national origin or ancestry
■ Are you married/divorced/ single/ widowed? ■ Are you planning to get married? ■ Are you dating anyone? ■ Listing Mr/Mrs/Ms/Miss:		You may not ask women or men questions or seek to get information about their marital status
■ Name of spouse? ■ Where does your spouse work? May spouse get transferred? ■ Other questions about spouses	Describe travel/relocation requirements of job and ask applicants if they can meet them	Info on marital status and dependents required for payroll, etc., can be obtained after job offered
■ Are you pregnant? ■ Do you use birth control? ■ Are you planning to have children?	Describe the physical requirements and hazards of the job and ask applicants if there is any reason they cannot perform them	You may ask about pregnancy after offering the job to determine if the applicant needs accommodations
■ Do you have any children or dependents? ■ What are your childcare arrangements? ■ Any other questions about children or dependents	Describe the schedule and overtime requirements of the job and ask applicants if can meet them, e.g., "this job requires working on weekends—will that be a problem?"	Questions about children and dependents are evidence of intent to discriminate on the basis of gender and/or family status
Are you related to or friends with anyone who works for the company?	Describe company's anti-nepotism policy and ask applicants if their hiring would create any problems under it	Family relations and friendships with other employees have no bearing on an applicant's competence
■ How old are you? ■ What is your birth date? ■ Asking for a birth certificate ■ When did you graduate high school?	The law says you must be at least X years' old to work/do this job. Is that a problem?	Asking about age is evidence of discrimination unless an age limit or requirement is a bona fide occupational qualification
■ Are you a U.S. citizen? ■ What country are you from? ■ Where were you or your parents born? ■ List all previous addresses/military service.	■ Are you legally entitled to work in the U.S.? ■ Do you read, understand, speak and/ or write all the languages necessary to do the job as specified in the ad or job description?	You may not ask questions or seek information about an applicant's nationality or citizenship
What kind of military discharge did you receive?	■ Did you serve in the military? ■ What periods of service? ■ What training or work experience did you receive while in the military?	You can ask whether applicants served in the military but not about the kind of discharge they received

COMPLIANCE PERSPECTIVES

CAN'T ASK	CAN ASK	COMMENT
■ What is your race? ■ Questions about race or color including color of skin, hair, etc		Although race cannot be an occupational requirement, employers are allowed to collect racial information to implement affirmative action plans, recruit minorities and other legitimate, non-discriminatory purposes
■ What's your religion? ■ What church do you belong to? ■ Can you work on Sabbath, specific religious holidays, etc.? ■ Asking for a reference from the clergy		Asking about religion or even availability for work due to religious restrictions is evidence of religious discrimination except in very narrow circumstances
List names, dates and locations of all schools attended	List grade level completed/degrees obtained/courses taken	Okay to ask for names of technical, vocational and post-secondary schools unless it would reveal religious affiliation, nationality or race
■ Do you have any physical/mental disabilities? ■ Do you have X illness or disability? ■ Do you have any health problems? ■ Do you have a disability that would interfere with your ability to perform the job? ■ Are you in good health? ■ Have you ever been treated for alcohol or drug addiction? ■ How much alcohol do you drink each week? ■ What medications do you use? ■ Have you ever been treated for emotional or psychiatric problems? ■ Are you under a doctor's care? ■ Are you receiving counseling or therapy? ■ Do you have any allergies? ■ Have you ever received workers' compensation? ■ How many sick days did you take last year?	■ Describe essential requirements of the job, as specified in the job ad and job description and ask if applicant can perform them with or without reasonable accommodations ■ Describe or demonstrate how you would perform the essential functions of the job ■ Can you meet the attendance requirements of this job? ■ Do you use illegal drugs?	Medical questions, tests, evaluations may be appropriate after job is offered to determine need for accommodations

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COMPLIANCE PERSPECTIVES

CAN'T ASK	CAN ASK	COMMENT
■ Have you ever been arrested? ■ Have you ever been convicted of an offense? ■ Do you have a criminal record?	Asking about a conviction that is related to the job is allowed if the employer can prove that it has a business necessity to justify use of a conviction record based on 3 factors: ■ Nature and gravity of the offense ■ Amount of time elapsed since the conviction and/or completion of the sentence ■ Nature of the job being sought	■ Criminal records questions may violate state laws even if permitted by EEOC ■ Questions about *arrests* are never permitted ■ Criminal background and other checks might be allowed after the job is offered
■ Height: ■ Weight:		Height and weight requirements are considered discriminatory unless the employer can justify them as a bona fide occupational qualification
■ Do you own/lease your home/car? ■ Have your wages ever been garnished? ■ Have you ever declared bankruptcy?		Questions about a job applicant's financial situation violate fair credit and consumer credit laws unless those financial considerations are essential to the job in question

Note: In many cases, the ban on asking personal questions and seeking personal information during the pre-employment phase no longer applies after you make the applicant a job offer and before he/she starts work.

Takeaway: Labs, like all employers, need to make sure their hiring processes are compliant with the law and don't discriminate or otherwise violate federal and state law.

Get Practical Advice On Recruiting and Managing Staff and Developing Strong Leadership for Your Lab

The lab industry faces many challenges acquiring and keeping the right talent to meet the demands of a rapidly evolving diagnostics industry. In a pre-conference workshop at G2 Intelligence's 34th Annual Lab Institute a panel of experts will address hiring and compensation trends and issues related to recruiting the right talent, managing and retaining that talent while complying with all applicable laws and regulations, and developing strong leadership within the lab. The panel includes Leslie Loveless and Tara Kochis-Stach from Slone Partners, Lee Hubert from Voltage Leadership Academy and Miriam L. Rosen, Esq., from McDonald Hopkins.

For more information or to register for this workshop, "Recruiting and Managing the Lab Workforce of the Future," visit www.labinstitute.com or call customer service at 1-888-729-2315.

Have questions related to hiring, retaining and managing your laboratory's workforce? Send us your questions for our panel to address during this workshop. Submit questions to Editorial Director, Kelly Hardy Briganti at kelly@g2intelligence.com.

Senate Finance Committee Hearing Addresses Potential Stark Law Changes, *from page 1*

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and keep up to date with an industry shifting to alternative payment models.

Prior to the Senate Finance Committee hearing, the Committee released a white paper, "Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models," addressing potential revisions to the law that could make it easier for health care providers to collaborate and pursue alternative payment models that promote the government's Triple Aim. Senate Finance Committee Chairman, Orrin Hatch (R-Utah), explained in a statement: "This paper reflects critical feedback from the stakeholder community on the law's ambiguities, its unintended consequences and the need for reform, and I am hopeful it jumpstarts the discussion on how Congress can modernize the law to make it work for patients, providers, and taxpayers."

Suggested Changes/Improvements to Stark Law

Here are just some the suggestions raised in public comments and the Senate hearing for ways to address the Stark Law and its impact on efforts to reform the health care system.

- Repeal Stark Law entirely
- Repeal just the compensation arrangement requirements, limiting Stark's scope to ownership and investment interests
- Add new waiver or exceptions to the law to permit alternative payment models
- Keep existing exceptions but modify them to accommodate coordinated and integrated care delivery models
- Make exceptions correspond more closely to Anti-Kickback Statute exceptions
- Increase in advisory opinions and agency guidance on the law
- Distinguish technical violations from substantive violations with different sanctions for each
- Clarify meaning of key terms and definitions within the Stark Law such as fair market value, "takes into account the volume or value of referrals," "commercially reasonable," and "group practice"
- Add an intent requirement
- Change penalty determinations to incorporate mitigating factors such as technical versus substantive violations, inadvertent mistake rather than intentional act, corrective actions, emergency situations requiring physician services and harm to Medicare.

Summing up complaints in the public comments that the law is difficult to interpret and apply, the paper highlights the law's "strict liability regime, huge penalties, and the breadth, complexity, and ambiguities" as creating "what is often referred to as a minefield for the health care industry." The difficulty predicting when conduct will violate the law is impeding progress in developing alternative payment models said commenters.

The white paper notes the history and purpose behind Stark—to avoid improper influence on physician referrals—in the context of the current trend toward alternative payment methodologies focused on value rather than volume. This trend, commenters argued, alleviates some of the concerns, such as overutilization, that Stark was intended to address. Essentially, the argument is that because incentives are shifting toward coordination and less care rather than a focus on reimbursing based on volume, there should be less need for the Stark Law's restrictions in the new health care marketplace.

Public comments leading up to the white paper proposed several options for addressing the Stark Law ranging from complete repeal of the law to increased authority for advisory opinions (see box). The white paper indicates "commenters generally agreed" that there should be different consequences for "technical violations" and for substantive violations. It was suggested that technical violations could relate to documentation issues (such as whether the arrangement was in writing or met requirements for signatures or if there was a gap between a prior expired relation-

Health care lawyer Troy A. Barsky, Esq. a partner at Crowell & Moring, LLP, provided his perspective as counsel to health care providers, explaining the difficulty in complying with the Stark Law, grave consequences for even inadvertent technical violations, and how it is "diametrically opposed" to goals of new payment systems.

ship and a new arrangement) or perhaps compensation arrangements that violate Stark but don't violate the Anti-Kickback Statute or don't unduly influence physicians' decisions. But even this suggestion for less harsh consequences for technical violations raised complaints about difficulty in executing it and an increase of complexity rather than a move toward simplicity and clarity. Another suggestion recommended adding an intent requirement to the famously strict liability law to avoid punishing "purely accidental omissions."

At the July Committee hearing, health care executives Ronald A. Paulus, MD, President and CEO of Mission Health System, and Peter B. Mancino, Deputy General Counsel of The Johns Hopkins Health System Corporation explained how the Stark Law generates significant compliance costs due to its complexity and vagueness and complicates efforts to adapt to a changing health care environment. Paulus argued the law had "outlived its usefulness" and suggested the law's repeal would allow providers to do what the government has asked the industry to do—focus on patients and transform the fee-for-service reimbursement system. Mancino advocated revisions that would eliminate ambiguities, make penalties more reasonable and reform the law to allow innovative arrangements. Health care lawyer Troy A. Barsky, Esq. a partner at Crowell & Moring, LLP, provided his perspective as counsel to health care providers, explaining the difficulty in complying with the Stark Law, grave consequences for even inadvertent technical violations, and how it is "diametrically opposed" to goals of new payment systems. He argued Congress should consider repealing the law and if not, make "common sense" reforms such as removing technical requirements or limiting the consequences of technical violations and "removing barriers" to health care reform.

Takeaway: As the health care industry seeks to implement alternative payment models to improve quality and reduce costs, regulators are considering how current regulatory requirements could put up barriers to reform.

Liquid Biopsies Get FDA Attention

In addition to laboratory developed tests and next generation sequencing, could the FDA be looking to impose standards or guidance governing use of liquid biopsies? So-called "liquid biopsies" are increasingly becoming the future for precision medicine, often allowing deep analysis of a patient's medical condition without an invasive and uncomfortable medical procedure.

However, the regulation of liquid biopsies is also becoming inevitable, particularly as the U.S. Food and Drug Administration (FDA) has been taking aggressive actions toward the regulation of laboratory-developed tests.

And while the FDA has been on the receiving end of criticism from the laboratory community as being heavy-handed and potentially stifling regulation, the agency did hold a joint meeting in Washington, D.C., last month with the American Association of Cancer Research to discuss the future of liquid biopsies.

The meeting was co-chaired by Gideon Blumenthal, M.D., clinical team leader, for thoracic and head/neck oncology at the FDA's Center for Drug Evaluation and Research.

> *"We've heard there are some concerns or doubts, some uncertainties about whether different ways of evaluating liquid biopsy results agree."*
>
> —Abraham Tzou, M.D.

Although Blumenthal suggested that there may be room for some generalized public-private partnerships to develop liquid biopsies and protocols in the future, the daylong session was heavily weighted with discussion and debate over clinical issues. The presentations included 355 slides, most of which focused on how liquid biopsies are performed. FDA officials mostly gave the floor over to other presenters from institutions such as the Dana Farber Cancer Institute, the Memorial Sloan-Kettering Cancer Center and Johns Hopkins University.

For the most part, the FDA officials present at the session appeared to be in the exploratory phase as to how liquid biopsies and next-generation sequencing for such diagnostics are developing. The agency recently issued draft guidelines for some next-generation sequencing tests that are currently in the public comment phase.

"We've heard there are some concerns or doubts, some uncertainties about whether different ways of evaluating liquid biopsy results agree," said Abraham Tzou, M.D., an FDA medical officer and a pathologist by training. "Are they telling you the same thing, are they telling you different things? Obviously the best [outcome] would be to just have clinical outcome based on liquid biopsies. … I think most people would agree that is the ultimate answer. We've heard about different trials or proposals that are in progress where that is primarily the design. The question of course is [what to do] in the interim."

Takeaway: The Food and Drug Administration and various research institutions convened to discuss the emerging role of liquid biopsies, but the agency appears mostly in a preliminary examination stage for the new form of tests.

G2 Compliance Corner

Protecting Medical Records from Phishing Attacks

When asked why he robbed banks, the notorious outlaw Willie Sutton famously replied: "Because that's where they keep the money."

The same logic explains why labs have become a favorite target of hackers seeking to steal private information about patients. According to software security firm Trend Micro, more than 9 in 10 cyber-attacks against labs and other health facilities use a scam known as phishing. Typically, the hacker sends lab employees a fake email asking them to click on a link that infects their computer with a malicious virus providing the hacker access to the lab's electronic medical records.

The reason phishing is so effective is that it preys on the lab's weakest security link, its employees. Accordingly, the key to protecting your lab and its precious patient records is to train your employees about:

- What phishing is, how it occurs, and why it is such a threat;
- Red flags indicating that an email is a phishing barb, including common characteristics such as duplicating the image or using the name of a real company or person, promoting gifts, or threatening the loss an account; and
- How to properly check social media invites.

Do not confine your training to the class room or a web-based course. Run a mock phishing attack against your employees and see how many of them take the bait. In addition to assessing your vulnerability, the exercise will enable you to identify which employees to target for additional training.

News at a Glance

FDA Schedules NGS Workshop. The U.S. Food and Drug Administration (FDA) announced it will hold a public workshop Sept. 23 to solicit feedback on the two guidance documents it released in July 2016 addressing next-generation sequencing (NGS)-based in vitro diagnostics and the variant databases that support the clinical validity of such tests. The workshop will include presentations and moderated panel discussions addressing the guidance documents and questions posed in the related Federal Register notices. Stakeholders can attend in person or via webcast. Written or electronic comments related to the workshop can also be submitted by Oct. 6, 2016. See "FDA Guidance Addresses NGS Testing, Espousing Flexibility in Oversight," *G2 Compliance Advisor*, July 2016, p. 9 for more in-depth discussion of the guidance documents.

House Committee Studies CDC Laboratory Response Network. The U.S. House of Representatives Energy and Commerce Committee recently requested that the Centers for Disease Control and Prevention (CDC) provide information to the Committee about the capabilities of the CDC's Laboratory Response Network. Committee members emphasized the network's responsibility for ensuring the U.S. has the technology and resources to "test suspicious materials" and promptly detect and respond to potential incidents of bioterrorism or other public health emergencies. Specifically, the committee wants to know how many labs in the U.S. can participate in such activities and the extent of their capabilities. The committee also asked about the number and type of assays that have been developed to facilitate response to such public health emergencies and the network's ability to detect "emerging infectious diseases" such as Zika and Ebola.

HIPAA Turns 20! It's a milestone birthday for a law that is not generally celebrated among health care providers. The Health Insurance Portability and Accountability Act of 1996, better known as HIPAA, was enacted this month 20 years ago on Aug. 21, 1996. The law is perhaps best known for its imposition of privacy and security requirements intended to protect confidentiality of patients' health information. But another key objective of the law when enacted was to allow people to continue health care insurance even after losing a job and to prevent preexisting medical conditions from causing insureds to lose or have difficulty obtaining insurance. The U.S. Department of Health & Human Services issued a statement celebrating the occasion, lauding the legislation for also moving health care into the modern electronic age: "HIPAA simplified and encouraged the electronic transfer of information … and now 93.8% of all health care claims transactions today are conducted in standard form. The HIPAA standards have helped pave the way for interoperability of health data to enhance the patient and provider experience."

HIPAA's privacy and security rules also imposed standards identifying permissible and prohibited uses of patient information and required implementation of physical, technical and administrative safeguards to protect such information from improper disclosure. Modifications to the law have imposed requirements for dealing with and notifying affected patients about breaches of unsecured health information. HHS reports that since the law's requirements went into effect, the Office for Civil Rights (OCR), the agency charged with enforcing the law, has received 137,770 complaints under HIPAA—96% of which were resolved—and OCR has collected a total of $39,989,200 in settlements.

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