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Covering Government Policy For Diagnostic Testing & Related Medical Services

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INSIDE THIS ISSUE

FDA Watch: Agency to Allow DTC Marketing of Genetic Tests *without* Premarket Approval

The FDA's longstanding policy of restricting direct-to-consumer (DTC) marketing of products without formal premarket approval is well known. But while it always applied to lab tests, the policy initially crafted for pharma and devices didn't become a big factor for *in vitro* diagnostics until 2013 when the FDA issued a warning letter to 23andMe over the marketing of its DNA analysis services. Since then, other consumer genomics firms have received similar warning letters about DTC marketing of genetic tests without premarket approval.

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Enforcement Trends: 5 Takeaways from OIG's New Semiannual Report

Veteran OIG semiannual report aficionados will find little in the most recent edition to distinguish it markedly from its predecessors. But while a new administration has done little to change the fundamental tone, extent, direction or tenor of OIG federal health care fraud enforcement activities, the 2017 semiannual report is rife with insight about what happened between April and September and what is likely to happen in 2018. Here are the five key takeaways for labs and pathologists.

1. Continued Growth of the Strike Force

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 in recent years. 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.

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. Notably, over 120 of the 400+ defendants booked by the Takedown were involved in illegal prescribing and distribution of opioid drugs,

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Agency to Allow DTC Marketing of Genetic Tests *without* Premarket Approval, *from page 1*

FDA Proposes Marketing without Premarket Approval

But 2017 has witnessed a thaw. The FDA signalled the new approach earlier in the year when it settled with 23andMe. Under the settlement, the agency not only issued premarket authorization of 10 genetic health risk (GHR) tests from 23andMe; more significantly, it gave the green light for future DTC launches of other tests without premarket review provided that the firm followed specifically listed controls.

On Nov. 6, the FDA proposed extending the 23andMe treatment to the entire industry. According to the agency's notice for public comment, premarket authorization is not necessary for certain class II (moderate risk) devices, including vitamin D mass spectrometry-based test systems and GHR assessment test systems.

The catch: GHR test manufacturers will need first time FDA marketing authorization; after that, though, they will be allowed to commercialize new GHR tests without additional review.

The limitation: The new approach doesn't apply to diagnostic genetic tests that *inform treatment decisions*, e.g., hereditary cancer tests analyzing BRCA1 and BRCA2 genes to decide if a woman should have a prophylactic mastectomy.

Takeaway: When and if the FDA finalizes the proposal, test makers will have to implement the same controls the FDA ordered 23andMe to use as part of the settlement, including:

- *Labeling outlining test limitations;*
- *Information about how the test works and its accuracy vis-à-vis a comparative baseline;*
- *References to applicable clinical guidelines and disease risks; and*
- *Information on obtaining a genetic counselor.*

The New FDA CLIA Waiver Policy

The proposed new DTC policy was hardly the end of the FDA's new largesse toward *in vitro* diagnostic product development. On Nov. 29, the agency issued draft guidance proposing to reduce the burden of applying for CLIA waivers allowing for the performance tests involving "insignificant risk of an erroneous result" without CLIA certification. The draft guidance is actually two proposals in one:

The first proposal would make it easier for test makers to demonstrate the accuracy of a test for purposes of securing the "insignificant risk" waiver; and

The second proposal would establish a dual submission pathway enabling test makers to use the same sets of studies to secure Section 510(k) approval and a CLIA waiver, effectively killing 2 FDA regulatory birds with one stone.

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New Lawsuit Tests Limits of Medical Malpractice in Age of Precision Medicine

Is a health care provider's failure to refer a cancer patient for genetic counseling grounds for medical malpractice?

One patient claims it is and wants $1.8 million in damages because she never got it.

The Case

The novel case involves a 36-year-old Oregon woman who underwent genetic testing for hereditary cancer risk (Myriad's MyRisk) due to her family history—her mother and grandmother had cancer. While the genetic test report found that "no clinically significant mutation has been identified," it also flagged a variant of unknown significance (VUS) in the MLH1 gene (MLH1 c.191A>G) associated with Lynch syndrome.

Ultimately, a court or jury will have to decide whether the providers committed malpractice.

Another doctor later determined that the diagnosis was wrong—but not before the patient had undergone a preventive double mastectomy and hysterectomy based on the diagnosis. The patient is now suing for $1.8 million in damages. Her medical malpractice lawsuit against her doctors and a southwest Oregon medical center cites not only "negligent diagnosis and treatment" resulting from misinterpretation of her genetic test results by a nurse practitioner, gynecologist, and a surgeon but a novel claim: the providers' failure to refer her to a genetic counsellor.

Does She Have a Valid Malpractice Claim?

Ultimately, a court or jury will have to decide whether the providers committed malpractice. Like any other plaintiff, to prove medical malpractice the patient will have to show that the providers failed to meet a recognized standard of medical care in failing to refer her for genetic counseling. To make that case, her attorneys will no doubt rely on 2015 guidelines from the American College of Medical Genetics and Genomics for the interpretation of sequence variants stating that a VUS should not be used in clinical decision making. The guideline goes on to say that additional patient monitoring may be advisable while efforts to reclassify the variant are underway.

Takeaway: While not ascribing too much significance to any single case, this litigation takes place against a fascinating backdrop of 21st century precision medicine in which genetic counseling plays an increasingly important role. Although it may not yet be recognized as a standard of medical practice, it's important to keep in mind that as medicine evolves, so does the standard of legal care. Thus regardless of the ultimate outcome, this case highlights the importance of appropriately counseling patients about genetic risk factors particularly when non-genetic experts are ordering tests.

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.

COMPLIANCE CORNER

Big Drop in Improper Medicare Payments

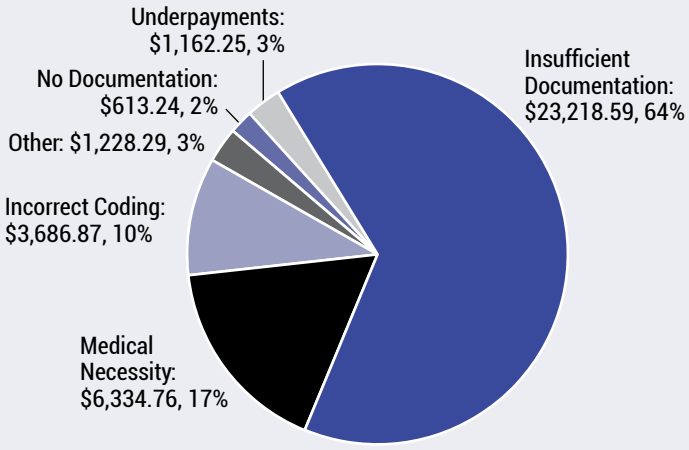
The rate of improper Medicare Fee-For-Service (FFS) payments dipped below the 10% threshold for the first time since 2013. Here are the key findings listed in the Nov. 15 CMS report:

- **9.5%:** 2017 Medicare FFS improper payment rate;
- **11%:** 2016 Medicare FFS improper payment rate;
- **$36.2 billion:** Total amount of 2017 Medicare FFS payments;
- **$4.9 billion:** Total amount of 2017 improper payment decrease;

Reasons for Improper Payments

Here are the reasons for improper FFS payments by percentage and dollar value:

Improper FFS Medicare FY 2017 Payments by Monetary Loss & Type of Error
(in millions)



Medicare Reimbursement: CMS Finalizes Controversial PAMA Fee Schedule

It's official. CMS is going forward with its controversial 2018 PAMA Clinical Laboratory Fee Schedule (CLFS). Regrettably, the final version closely tracks the preliminary one (See *GCA*, Oct. 24, 2017, for the details) with just a few minor adjustments:

1. Phase-In Reduction Cap of Cuts Over 10%

Situation: The National Limitation Amount (NLA) for a lab test HCPCS code is based on a percentage of the median of all local fee schedule amounts, including $0. Medicare pays whichever is lowest among the billed amount, local fee schedule amount or NLA.

Preliminary CLFS: The 23 HCPCS codes with a $0 NLA and a local fee schedule amount of over $0 in 2017 were slated for the full NLA treatment rather than the 10% reduction cap.

Final CLFS: The $0 local fee schedule amount test rates have been recalculated. *Result:* 16 of the 23 tests will qualify for the phase-in reduction cap.

2. Payment Floor for Diagnostic or Screening Pap Smear Lab Tests

Situation: The national minimum payment amount for a diagnostic or screening pap smear lab test is $14.60 for tests furnished in 2000. The national minimum payment amount for later years is then annually adjusted. The CY 2017 floor for these tests was $14.49. The CY 2018 update factor is 1.1%, which yields a CY 2018 floor of $14.65.

Preliminary CLFS: CMS didn't apply the national minimum payment amount floor to the 24 diagnostic or screening pap smear laboratory HCPCS codes for CY 2018.

Final CLFS: The minimum applies for eight of these codes; the remaining 16 will be paid the higher private payor rate-based payments, with the phase-in reduction cap where applicable.

3. Payment for Home Use Hemoglobin A1c (HbA1c) Kits

Situation: The payment rate for a diagnostic test for HbA1c labeled for home use by the FDA must equal the payment rate for HCPCS Code 83036 glycated hemoglobin test (and subsequent codes).

Preliminary CLFS: The CMS proposed rate of $22.50 for HCPCS code 83037 didn't apply the private payor rate-based payment for code 83036 of $11.99 even though 83037 is a home use test.

Final CLFS: The CY 2018 payment rate for HCPCS 83037 has been reduced from $22.50 to $11.99.

4. Removal of General Health Panel Code (HCPCS 80050)

Situation: HCPCS 80050, a bundled code that includes a comprehensive metabolic panel (HCPCS code 80053), thyroid stimulating hormone test (HCPCS code 84443) and a complete blood count (HCPCS code 85025), is not payable under Medicare.

Preliminary CLFS: CMS listed 80050 as a payable code.

Final CLFS: HCPCS 80050 has been removed from the list of payable codes.

Labs IN COURT

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

Using Nuclear Stress Tests as Screening Procedure = Medical Necessity Violation

Case: A California cardio clinic and its physician owners will pay $1.2 million to settle charges of falsely billing Medicare and Medicaid for medically unnecessary nuclear stress tests (NSTs). The feds claim that clinic physicians automatically scheduled annual NSTs for patients without actually seeing them to determine the necessity of the costly procedure in violation of medical necessity rules and a CMS Local Coverage Determination banning use of NSTs as a screening procedure.

Significance: This is at least the second time this year that NSTs played a central role in a major False Claims Act action. This spring, a cardiologist, neurologist and four others associated with a New York City medical practice were arrested for falsely billing millions of dollars in medically unnecessary NSTs, which measure blood flow to the heart both when the patient is resting and stressed. 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.

The practice got into hot water for listing 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. (See *NIR*, June 19, 2017, for more details about the case.)

Doctors Busted in $2.2 Million Opioid Drug Testing Scheme

Case: The year of the opioid crackdown continues. The most recent scheme involves a South Florida network that offered free rent and other kickbacks to physicians in exchange for referrals of insured drug addicts to reside in their sober homes. Residents were then subjected to regular drug testing. Four defendants were involved, including the network medical director who was sentenced to 48 months in prison and one year of supervised release. And as is becoming increasingly common in these cases, the doctor had to pay $2.198 million to make restitution for the money he stole.

Significance: While opioid scams involving drug tests have become common fare, this one seems to have been particularly egregious. The medical director created a drug testing regimen for each resident, including many he never actually examined, based on the bribes he got from the testing lab. He then used higher paying codes to bill Medicare for the exams. Adding to the harm, residents were allowed to continue doping as long as they kept their mouths shut.

FDA Dishes Out Warning Letters for Marketing of Genetic Tests

Case: Direct-to-consumer (DTC) marketing of genetic tests has been a sore spot with the FDA since 2013 when the agency issued a warning letter ordering 23andMe to quit marketing its consumer testing kits. This fall, two other consumer genomics firms received DTC-related warning letters from the FDA, including:

- DNA-Cardiocheck for selling its DNA-CardioCheck DTC test screening for genetic markers associated with heart disease and stroke; and
- Interleukin for selling consumer tests identifying people with genetic predisposition for increased risk of heart attack, diabetes and obesity.

Significance: The timing of these new warning letters is ironic but far from coincidental. The FDA issued these warning letters right after it settled with 23andMe and announced a proposed new policy loosening up the restrictions on DTC marketing of non-FDA-approved consumer genetics tests. (See the related story on page 1.)

Two Different Labs Get the Medicare Boot

Case: On Oct. 24, Total Lab Care, LLC accepted permanent exclusion from all federal health programs over allegations that it billed for testing urine toxicology samples referred by a physician to whom it paid improper financial remuneration. Just five days later, an independent lab in Southern California called Prohealth Neurodiagnostic, Inc. and its owner agreed to a five-year exclusion for allegedly billing nerve conduction studies listed in its Local Coverage Determination as screening exams and thus not billable under Medicare medical necessity criteria.

Significance: Exclusion of a clinical lab from participating in Medicare or other government health program is a relatively rare penalty. The occurrence of two of them in the span of less than a week is an even quirkier oddity.

BLS Conviction Count Continues to Mount

Case: At 38, the number of doctors convicted in the Biodiagnostic Laboratory Services LLC (BLS) scheme is enough to run a nice mid-size practice. Here is a profile of the latest two physician convictions.

Name	Practice	Allegations	Sentence
Aiman Hamdan	Cardiologist, Patterson, NJ	After accepting a $500K loan from BLS, referred approximately $53,000 of Medicare patient blood samples to lab for testing from Oct. through Nov. 2008 (his wife also convicted of paying bribes)	Potential penalties of: 30 years prison, one year supervised release + $1 million fine + $15K restitution
Ahmed El Soury	Internal Medicine, Staten Island, NY	Accepted more than $66K in bribes for referring roughly $650K in patient blood specimens from March 2011 through April 2013	33 months in prison

Significance: The latest BLS scoresheet: 53 convictions, 38 of them doctors and over $13 million recovered via forfeiture. At least one more doctor is also awaiting sentencing.

Employment Law Update: The Weinstein Edition

By Mike O'Brien

Harvey Weinstein all over our news feeds

Your news feed, like mine, has exploded with references to someone named Harvey Weinstein for the past couple of months. What's up? Weinstein is a well-known American film producer and former film studio executive. He and his brother co-founded Miramax, which produced several popular independent films. Several women who have worked with/for Weinstein have accused him of various forms of sexual misconduct, ranging from rape to requests for sexual favors to inappropriate comments. Many of the allegations involve workplace-related behaviors and, because of his success, wealth, and power in the entertainment industry, many felt obligated to comply with or at least not complain about his alleged misbehaviors.

The recent news is reminiscent of other past high profile discussions of the same general topic…Donald Trump grabbing you-know-what, Bill Clinton not having sex with "that woman," the dangers of accepting mixed drinks from Bill Cosby, and the whole Clarence Thomas/Anita Hill Supreme Court confirmation battle of the 1990s.

Now, as in the past, the headline news is providing another teaching moment when employers can talk to employees about inappropriate behavior and harassment on the job. Maybe you should seize this opportunity to have this important discussion with your employees? Why? Keep reading.

The hashtags #metoo and #Ihave

These hashtags also are appearing all over my news feeds. The #metoo hashtags are a collection of very disturbing stories from women who say they have suffered sexual harassment at work or various forms of sexual predation. The #Ihave hashtags are some stories from men admitting to sexual misbehavior and apologizing for it. There even are #metoo stories from male victims. Accordingly, this is an issue that likely is on the minds (and on the social media) of your employees right now. Your employees are talking about these very issues right now. There may never be a better time for you to talk with them too. You have their attention.

What the law says

We should all know this by now, right? Federal and Utah state law prohibit discrimination and harassment based on race, color, religion, age (40 and over), sex, gender, sexual orientation, gender identity, pregnancy, disability, national origin, ethnic background, genetic information (including of a family member), military service, and/or citizenship. Harassment is unwelcome or unsolicited verbal, physical or sexual conduct which interferes with an employee's job performance or which creates an intimidating, hostile work environment. Examples of possible harassment include:

- questions or comments that unnecessarily infringe on personal privacy, or offensive, sexist, off-color or sexual remarks, jokes, slurs, or propositions or comments that disparage a person or group on the basis of characteristics protected by law;

The EEOC also recently issued a report suggesting that employers should consider taking a different approach to preventing harassment in the workplace.

- derogatory or suggestive posters, cartoons, photographs, calendars, graffiti, drawings, other material, or gestures;
- inappropriate touching, hitting, pushing, or other aggressive physical contact or threats to take such action, and
- unsolicited sexual advances, requests, or demands, explicit or implicit, for sexual favors.

When an employer is aware of possibly-unlawful conduct, it has a legal duty to investigate and promptly remedy and problems. An employer can be held financially responsible for violations of these laws.

There are many faces to the problem

By the way, this is not just woman vs. man stuff, although many claims are framed that way. Today, claims of workplace harassment are filed with federal (Equal Employment Opportunity Employment Commission—EEOC) and state agencies (Utah Labor Commission Antidiscrimination and Labor Division—UALD) by men against women, by women against men, by women against women, and by men against men.

EEOC report questions employer anti-harassment efforts

The EEOC also recently issued a report suggesting that employers should consider taking a different approach to preventing harassment in the workplace. The report, resulting from an EEOC task force study over 2015-16, notes that despite ongoing employer efforts, harassment claims remain a major problem in today's workplaces. Thus, the report says employers should "reboot" their prevention efforts. The report calls for a renewed commitment from management to provide a respectful workplace without harassment, development of better policies regarding reporting and investigation, and an investment in effective training. The report says the best training focuses on preventing harassment rather than limiting liability, and suggests that live, plain-language and interactive training is best. You can read an executive summary of the report here and read the full report here.

What should an employer do?

To prevent harassment and discrimination and minimize legal risk, I tell my employer clients to focus on five basic goals:

1. Have clear policies regarding professional workplace behavior with effective mechanisms that encourage employees to raise issues and complaints;
2. Conduct employee/supervisor training, focus on establishing a workplace of civility, respect, and effective communication, and remember that supervisors must set a good example;
3. Try to head off possible problems proactively by investigating complaints and enforcing policies; deal with the "aftermath" to minimize the risk of retaliation claims;
4. Be consistent in decision-making and carefully document the same;
5. Focus on job relatedness—that is qualifications, demonstrated job performance, skills, etc., in decision-making, not on factors such as sex, race, etc.

Conclusion

Harvey Weinstein made movies, but the misbehaviors he is accused of also are real life problems in most workplaces today. As employers, we all get the chance to write the positive ending to this particular story, so get to it.

Disclosure: These updates are merely updates and are not intended to be legal advice. Receipt of this information does not create an attorney-client relationship.

Mike O'Brien is an experienced and accomplished employment attorney, media lawyer and courtroom litigator. He is listed in "Best Lawyers in America" for First Amendment (news media) law and employment law and in "Who's Who Legal USA" as one of the country's leading attorneys in management employment law. He was also cited in the 2007 editions of "Super Lawyers" for media law and "Chambers USA" for labor and employment law. Mike partners with employers in many industries to prevent and solve employment problems. Mike is also a recognized media and First Amendment lawyer.

Enforcement Trends: 5 Takeaways from OIG's New Semiannual Report, *from page 1*

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 bull's eye on their back.

3. Prioritization on Cybersecurity and EHR

Cybersecurity, information security continue 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

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 lots 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.

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.

Cybersecurity: New Bill Would Make Lab Employees Criminally Liable for Concealing Data Breaches

While massive data breaches have existed as long as massive data itself, legal accountability for organizations that commit them is a relatively recent phenomenon.

Breach Liability of Labs

Because so many data breaches involve health care, it's not surprising that the industry was among the earliest targeted for liability in the form of 2013 HIPAA amendments requiring labs and other covered entities to report breaches affecting 500 or more people immediately and smaller breaches by the end of the calendar year. In January 2017, Illinois health system Presence Health became the first provider penalized for failing to meet HIPAA breach notification requirements. (See *GCA*, Jan. 26, 2017, for the details.)

Potential data breach liability may include not just HIPAA fines but risks of private litigation. A notable example with national ramifications is the pending lawsuit against CareFirstBlueCross Blue Shield by members whose personal data was compromised in a 2014 data breach. The case, which involves the rights of individual victims to sue for money damages under the Fair Credit Reporting Act may be the first data breach case ever decided by the U.S. Supreme Court. (See *NIR*, Nov. 21, 2017, for the details.)

Extending Breach Liability to All Sectors

Even though data breaches also happen outside health care, most other industries have managed to fly under the radar. But recent high profile breach cases like Uber and Equifax have underlined the need for companies to respond more swiftly and effectively to breaches. So on Dec. 1, a trio of Democratic Senators introduced a bill to make breach notification an obligation of all companies. Under the so called Data Security and Breach Notification Act, a company would have to notify its consumers of data breaches within 30 days.

"Only stiffer enforcement and stringent penalties will make sure companies are properly and promptly notifying consumers when their data has been compromised," U.S. Sen. Richard Blumenthal (D-CT), a member of the committee on a sponsor of the bill, said. "Uber's stunning announcement of a data breach—made public a year after the fact—is yet another example of corporate carelessness in the face of a cyber intrusion that put their customers and

employees' personal and financial information at risk. Our legislation will give the FTC real teeth to hold accountable businesses that refuse to implement reasonable security practices."

Future Growth Opportunities

The key strategic takeaway from the report is the finding that the physician office business is the most profitable market segment for outreach and its most promising opportunity for future growth.

Takeaway: The Impact on Labs

The bill would also affect labs and other providers even though these entities are already required to provide breach notification under HIPAA.

1. New Liability Risks for Lab Employees

In addition to HIPAA penalties imposed on the lab, the bill would expose lab employees to the risk of criminal penalties for concealing data breaches. Specifically, employees that "intentionally and willfully conceal" a data breach causing any person $1,000 or more in harm would be subject to criminal fines and/or up to five years in prison.

2. Potential for New Data Security Requirements

The bill also directs the Federal Trade Commission to create security standards to help companies protect the personal and financial information of their customers. *Result:* The new FTC standards may impose new regulatory burdens on labs that go beyond their current HIPAA obligations.