G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

March 2020

INSIDE THIS ISSUE

Coronavirus and Patient Privacy: How the HIPAA Rules Change During a Public Health Emergency

Coronavirus (COVID-19) has officially been declared a public health emergency. And the usual HIPAA Privacy restrictions on collecting, using and disclosing patients' personal health information (PHI) without consent are relaxed during public health emergencies. The bottom line: There may be situations where labs can and, in some cases, must take liberties with PHI. Here's a quick look at what you can and can't do based on Feb. 3, 2020 guidance from the Office for Civil Rights (OCR), the HHS agency charged with enforcing the HIPAA rules.

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Compliance Perspectives: The Employee Privacy Implications of Workplace COVID-19 Response

As concerns of pandemic grow, labs need to take measures to prevent and, if necessary, respond to workplace COVID-19 coronavirus infection. And as with any other infectious illness, COVID-19 risk management may require you to collect, use and disclose (which we'll refer to collectively as "use") private medical information about your employees, e.g., determine if they're infected to assess the need for quarantine measures. So, you need to be aware of your employees' privacy rights and adjust your emergency response measures accordingly. Here's how. (See page 6 for an analysis of COVID-19 and patients' privacy.)

What the Privacy Laws Require

While HIPAA is about patient rather than workplace privacy, it comes into play when labs use their employees' personal health information (PHI). Employees may also have privacy rights vis-à-vis their employers under:

- State personal privacy laws, both statutory and common law, i.e., case law;
- The collective bargaining agreements and individual employment contracts;

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The OCR Guidance

HIPAA doesn't go away during a public health emergency; but the restrictions on sharing PHI do loosen up, at least in certain situations. OCR issued the guidance to clarify the privacy rules that labs and other HIPAA covered entities (which, for simplicity's sake, we'll refer to collectively as "labs" unless the context requires otherwise) must follow during the COVID-19 outbreak. (See page 6 for an analysis of the employee privacy implications of COVID-19.)

Sharing Patient Information

The HIPAA Privacy Rule requirement that labs not disclose a patient's PHI without the patient's authorization is subject to exceptions, including disclosure necessary to treat the patient or another patient. This is true even when there's no public health emergency. Treatment, the guidance explains, includes coordination or management of health care and related services by one or more health care providers and others, consultation between providers, and the referral of patients for treatment.

Disclosure for Public Health Activities

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities to have access to PHI that's necessary to carry out their public health mission. Accordingly, it allows labs to disclose such PHI without individual authorization

- To federal, state or local health departments or other public health authorities for the purpose of preventing or controlling disease, e.g., reporting cases of patients exposed to, suspected of or confirmed as having COVID-19;
- At the direction of a public health authority, to a foreign government agency acting in collaboration with the public health authority; and
- To persons at risk of contracting or spreading a disease or condition where state or other law authorizes the lab to notify such persons as necessary to prevent or control the spread of the disease.

Disclosures to Individuals Involved in Patient's Care

Labs may share PHI with a patient's family members, relatives, friends or other persons: i. that patients identify as being involved in their care; or, ii. as necessary to identify, locate and notify family members, guardians, or anyone else responsible for the patient's care, of the patient's location, general condition or death, which may include via the police, press or public at large. But the guidance stresses that the lab should, if possible, get verbal permission or otherwise be able to reasonably infer that the patient doesn't object. A lab may also share PHI with disaster relief organizations like the American Red Cross, that are legally authorized to assist in disaster relief efforts.

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Lab Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
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Disclosures to Prevent Serious & Imminent Threat

Labs may share patient information with anyone as necessary to prevent or reduce a serious and imminent threat to the health and safety of a person or the public, subject to state and other applicable law and ethical standards of conduct.

Disclosures to the Media or Others Not Involved in Care

With limited exceptions, labs may not disclose PHI about the treatment of an identifiable patient, e.g., lab test results, without the patient's written authorization. But if a patient hasn't objected to or restricted the release of PHI, a covered hospital or other health care facility may, upon request, disclose information about a particular patient by name, may release limited facility directory information to acknowledge an individual is a patient at the facility, and may provide basic information about the patient's condition in general terms (e.g., critical or stable, deceased, or treated and released).

Minimum Necessary

For most disclosures, a lab must make reasonable efforts to limit the information disclosed to the "minimum necessary" to accomplish the purpose. (Exception: Minimum necessary requirements don't apply to disclosures to health care providers for treatment purposes.) Labs may rely on representations from a public health authority or other public official that the requested information is the minimum necessary for the purpose, as long as that reliance is reasonable under the circumstances. For example, a lab may rely on representations from the CDC that the PHI requested about all patients exposed to or suspected or confirmed to have coronavirus is the minimum necessary for the public health purpose.

Safeguarding Patient Information

In an emergency situation, labs must continue to implement reasonable safeguards to protect patient information against intentional or unintentional impermissible uses and disclosures. Labs (and their business associates) must also implement the administrative, physical and technical safeguards required by the HIPAA Security Rule for electronic PHI.

The COVID-19 situation is changing rapidly. For latest information affecting your lab, log in at www.G2Intelligence.com.

COMPLIANCE PERSPECTIVES, *from page 1*

- Your lab's internal HR policies and Code of Conduct; and
- Any other things you do to foster reasonable expectations of privacy in your employees.

The most significant privacy restriction for labs, is the need to get employees' consent to use their PHI. The consent form must be clearly written so employees know how you propose to use their PHI; and the decision to sign must be totally voluntary. Any signs of trickery or coercion nullify the consent. However, as a practical restriction, there are situations where you're allowed to use PHI without consent.

Rule 1: You Probably Need Consent to Use PHI for COVID-19 Planning

From previous pandemics, we've learned that it's unclear whether use of PHI for COVID-19 preparation and response would be exempt from consent restriction. Equally unclear, then, is whether employees must provide the PHI your lab needs to carry out preparation and response measures. Bottom Line: Unless clear guidance states the contrary, you should plan to get consent for COVID-19-related uses of employee PHI.

Rule 2: You Must Keep PHI to Minimum Necessary

Use of PHI must also be kept to the minimum necessary to accomplish whatever planning or response function you need the PHI to carry out. Thus, for example, it would be inappropriate to ask employees to undergo a physical exam or submit a complete medical record to assess their vulnerability to infection. Note that the minimum necessary restriction applies regardless of whether the use is consented to.

Rule 3: You Must Notify Employees of PHI Use

You must also notify employees of the PHI you use and why you need it for COVID-19 planning and response.

Rule 4: You Must Keep PHI Secure

You must maintain the security of any PHI you collect from employees, including use of:

- Physical barriers such as keeping files locked;
- Electronic measures such as password protection and encryption; and
- Administrative controls such as keeping the number of staffers with access to employee PHI limited to the minimum necessary.

Rule 5: You Must Properly Destroy PHI Information After Use

Finally, you must ensure that the PHI you collect from employees for COVID-19 planning and response is properly destroyed after it's no longer needed.

How to Handle 5 Key Situations

Here are some practical pointers based on government guidelines, expert opinions and privacy best practices from previous outbreaks.

1. Identifying Employees Needing Alternative Work Arrangements

Challenge: Although you can't generally ask employees who they live with, this may become crucial information for COVID-19 planning because it enables you to identify which employees may need alternative work arrangements.

Wrong: Asking: "Do you have young children or elderly parents that you might have to stay home and care for in the event of a COVID-19 pandemic?"

Right: Distributing a survey asking employees if they may have to make alternative work arrangements to care for kids or elderly parents. This way, you will be able to estimate how many employees may be absent without collecting detailed personal information.

2. Identifying Employees Who Might Be Susceptible to Infection

Challenge: You may want to identify employees with asthma, immunity deficiencies or other vulnerabilities to viruses so you can warn them to take special precautions against COVID-19.

Wrong : Asking employees for detailed information about their medical condition, e.g., asking if they have asthma.

Right: Letting all employees know that individuals with certain conditions are at risk and need to consider additional precautions.

3. Asking Employees for Personal Contact Information

Challenge: You need contact information so you can provide employees updates about a pandemic situation.

Wrong: Requiring or asking employees to give you their personal email or phone number.

Right: Asking employees how they prefer to be contacted and giving them alternative ways to get information from you without having to disclose their private contact information, e.g., having them call in to the office at agreed-upon intervals.

4. Asking Employees Who Call In Sick If They Have COVID-19

Challenge: In a pandemic situation, you'll need to keep track of how many employees are diagnosed with COVID-19.

Wrong: Asking employees who call in sick: "Do you have COVID-19?"

Right: Asking employees who say they're sick how long they expect to be out and when they plan to return. In short, you can ask for a prognosis but not a diagnosis.

5. Notifying Other Employees that a Co-Worker Has COVID-19

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COMPLIANCE PERSPECTIVES, *from page 5*

Challenge: If you learn that an employee has COVID-19, you might want to notify others at the lab, including the employee's co-workers.

Wrong: Disclosing an employee's diagnosis to somebody else.

Right: Letting others know that the employee isn't available, and if necessary, when he/she's expected to return.

COVID-19, Privacy & Practical Limits	
X What You CAN'T Do	**√ What You CAN Do**
Ask: "Do you have kids or older parents that you might have to stay home and care for?"	Hand out a survey asking employees if they might have to make alternative work arrangements without specifically asking who they live with.
Ask: "Do you have asthma or other medical condition that makes you at high risk of infection?"	Notify ALL employees that certain medical conditions heighten the risk of infection and advise any employee who has such conditions to take special measures to protect themselves.
Asking employees for personal emails or other contact information in case you need to notify them of developments.	Ask employees what contact arrangements they want to make and explore ways to maintain contact that don't involve getting private emails, e.g., letting employees call in themselves at agreed intervals.
Asking an employee who calls in sick: "Do you have COVID-19?"	Asking an employee who calls in sick: "How long do you expect to be out of work?"
Telling an employee's colleagues: "Joe has COVID-19."	Telling an employee's colleagues: "Joe has called in sick and isn't expected to return until Thursday."

Scorecard: SVT False Billing Settlements Near the $3 Million Mark

Urine drug testing for purposes of medical treatment is deemed medically necessary under Medicare billing and payment rules. The same is not true for specimen validity tests (SVT), a quality control process designed to catch drug test cheaters by verifying that a urine drug screen sample is consistent with normal human urine and hasn't been adulterated, diluted or substituted. In February 2018, the OIG issued a report contending that Medicare made $66.3 million in improper SVT payments to nearly 4,500

labs and physician offices.

In response, CMS ordered Medicare contractors to take measures to get that money back. Since then, at least 10 different urine drug testing labs, most of them from the Ohio Valley, have come forward to self-disclose improper SVT billing, generating over $2.8 million in total recoveries. Here's the settlement rundown as of the end of 2019.

Urine Drug Testing Lab SVT Billing Settlements in 2019

Date	Lab	Settlement Amount
Jan. 24	Northern Kentucky Center for Pain Relief	$126,799
Feb. 6	Wheelersburg Internal Medicine Group + Mohammad Mouhib Kalo, MD (Ohio)	$111,706
March 13	VerraLab JA, LLC (Louisville, KY)	$125,983
March 13	Medical Specialist of Kentuckiana, PLLC (Louisville, KY)	$69,776
May 30	Commonwealth Pain Associates, PLLC (Louisville, KY)	$88,214
June 28	Ethos Laboratory (Newport, KY)	$1,345,959
Aug. 7	Discover Diagnostic Laboratory, LLC (Oak Ridge, TN)	$95,882
Aug. 22	American Clinical Solutions, LLC (Boca Raton, FL)	$61,546
Oct. 4	Ohio River Laboratories, LLC (Houston, TX)	$49,493
Dec. 12	American Toxicology Lab, LLC (Johnson City, TN)	$175,889

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TOOL: MODEL SCREENING FORM FOR CORONAVIRUS COVID-19

We don't yet know how contagious coronavirus (COVID-19) is but we do know that it can spread via human-to-human contact. We also know that the risk of contracting the diseases is significantly greater if the person has lived or traveled to the Chinese city of Wuhan where the virus originated. Similarly, individuals who've been to other countries where cases of COVID-19 has been reported may also pose a greater risk. Accordingly, should it become necessary to implement quarantine measures to prevent spread of the disease, you need to be able to determine who at your workplace has been to high risk countries. And that's what the Screening Form below enables you to do.

XYZ Laboratories Coronavirus (COVID-19) Screening Form

Name: _____
Last First Middle

Date: _____

Please answer the following questions.

1. Have you traveled to any of the following countries within the past 14 days?

China	o Yes	o No
Cambodia	o Yes	o No
Thailand	o Yes	o No
Vietnam	o Yes	o No
Philippines	o Yes	o No
Japan	o Yes	o No
Korea	o Yes	o No
Hong Kong	o Yes	o No
Macao	o Yes	o No
Taiwan	o Yes	o No
Singapore	o Yes	o No
Malaysia	o Yes	o No
Australia	o Yes	o No
Nepal	o Yes	o No
Sri Lanka	o Yes	o No
India	o Yes	o No
UAE	o Yes	o No
Canada	o Yes	o No
UK	o Yes	o No
Spain	o Yes	o No
France	o Yes	o No
Belgium	o Yes	o No
Germany	o Yes	o No
Italy	o Yes	o No

Sweden o Yes o No
Finland o Yes o No
Russia o Yes o No

[This is a list of countries other than the US with confirmed reported COVID-19.]

2. If you answered Yes to any of the countries in the above question, were you in any farms, live animal markets or other areas where animals may have been slaughtered? o Yes o No

If Yes:

Did you make contact with any animals, live or dead? o Yes o No
Did you make contact with surfaces that had animal droppings or secretions on them? o Yes o No

Did you eat any raw or undercooked animal products? o Yes o No

Did you spend time in large crowds or crowded areas? o Yes o No

Did you have contact with sick people, especially those with a fever, cough or difficulty breathing? o Yes o No

3. Have you been in close contact or staying in the same household as someone with a known or suspected case of coronavirus? o Yes o No

4. Do you have any of the following symptoms:

Fever o Yes o No
Cough o Yes o No
Difficulty breathing o Yes o No

5. Have you been in close contact or staying in the same household as someone with any of the above symptoms? o Yes o No

Testing for coronavirus is considered on a case-by-case basis in consultation with local health departments. XYZ Laboratories reserves the right to restrict entry to its facility for any individuals it believes present a risk of infection. Entry will not be permissible without documentation indicating an absence of infection from an appropriate health care provider.

Labs IN COURT

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

Texas Lab Loses $30.6 Million Whistleblower Suit over False Billing of Technician Travel Mileage

Case: A case that began as a whistleblower complaint by a competing lab ended with a $30.6 million judgment against a Texas lab for falsely billing Medicare for travel reimbursements. In addition to billing for miles ostensibly driven by technicians to collect specimens that were actually shipped via airplane without any technician onboard, the lab failed to prorate mileage, treating a single shipment of multiple samples as though each sample had been shipped separately.

Significance: The lab claimed that it followed guidance from the CMS Manual suggesting that it could bill for the mileage. But the federal appeals court wasn't impressed. For one thing, CMS guidance isn't legally binding, especially when it contradicts clear billing laws. Besides, the lab misread the guidance which applied to billing for mileage that technicians *actually travelling somewhere*, which wasn't the situation in this case. The argument that it was a reasonable mistake to believe that it could bill for miles not travelled by anyone "borders on the absurd" [*United States ex rel. Drummond v. BestCare Lab. Servs., L.L.C.,* 2020 U.S. App. LEXIS 4904].

Failure to Give Documents to Hospital Auditor Costs Lab Its Right to Be Paid for Tests

What Happened: Blue Cross Blue Shield (BCBS) initiated a billing audit of an Alabama hospital after noticing its average urine drug tests had spiked from 30 to 1,100 per month. The hospital asked its lab provider to furnish the physician orders and other records BCBS auditors needed to verify the tests were medically necessary but the lab didn't provide them. As a result, BCBS denied the hospital's claims. In turn, the hospital withheld the $245,000 it still owed the lab under the lab services contract. The lab sued the hospital for breach of contract.

Ruling: The Alabama federal court ruled in the hospital's favor. When one side violates a contract, the other can recover as long as it can show was in "substantial compliance" with the agreement. The hospital's failure to pay was a clear contract violation; the problem was that the lab also violated the contract by not providing the records the hospital needed to give the auditors. The court ruled that this was a "material breach" justifying the hospital's refusal to meet its own contractual obligation to pay [*Riverboat Grp., LLC v. Ivy Creek of Tallapoosa, LLC,* 2020 U.S. Dist. LEXIS 27947].

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Chicago M.D. Convicted for Medically Unnecessary Allergen Tests

Case: A federal jury in Chicago convicted a physician on six fraud charges for approving medically unnecessary percutaneous allergen tests for Medicare patients over a four-year period starting in 2011. In most cases, the physician issued his approval after the tests had already been performed.

Significance: The physician was part of a larger fraud scheme involving several medical entities in an attempt to avoid attracting Medicare scrutiny by reducing the volume of billing by any single company. Upon receiving payments from Medicare, those entities sent the physician a check representing his cut of the proceeds.

Fired Lab Assistant Loses Defamation Lawsuit against Her Supervisor

Case: A lab assistant fired for poor performance claimed that her supervisor committed defamation by making the following oral remarks:

- "We're letting you go because we feel you're not a good fit for the lab"; and
- "You didn't do anything wrong, but you were slow and not keeping up with your work."

The federal court tossed her case. Even if the remarks were defamatory, you can't have defamation without publication and there was no allegation the supervisor published the remarks or that any third person heard them.

Significance: The assistant's second defamation claim, which the court also dismissed, pointed to the written statements containing those same remarks made by the supervisor for the HR files. But while being in writing satisfied the publication requirement, the written statements were

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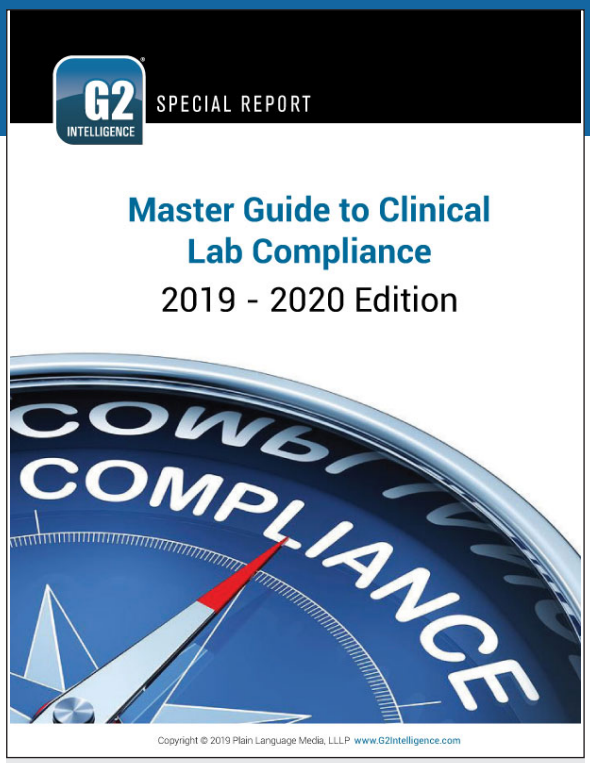
protected by qualified privilege because they were part of the termination process and accessible only to those with a legitimate interest or role in that process [*Nedrick v. Southside Reg'l Med. Ctr.*, 2020 U.S. Dist. LEXIS 20337, 2020 WL 534052].

Protect Your Lab against Growing Legal Risk!

Master Guide to Clinical Lab Compliance 2019-2020 Edition



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A Practical, Plain-Language Guide to Protecting Your Lab against Costly False-Claims, Anti-Kickback, and Stark Law Violations

For over two decades, clinical labs have been the target of a relentless stream of **investigations, audits, reviews, lawsuits**—and even **criminal prosecutions**—by the Centers for Medicare and Medicaid Services, and other Federal and State agencies.

Without a doubt, enforcement actions for **False-Claims violations** top the list. But the government has also systematically and aggressively grown the number of investigations into **Anti-Kickback** and **Stark Law violations.**

And that's just the tip of the iceberg. Investigations and **enforcement actions by state governments** have become increasingly aggressive... **whistleblower lawsuits** continue to grow sharply... and the ACA has earmarked **over $350 Million in funds for stepped up enforcement though 2020**, so you can be sure that labs like yours will come under increasing legal scrutiny.

Lab Compliance Essentials gives you the **practical, plain-language help** you need to understand the laws, and take **proven steps to protect your lab** from costly False-Claims, Anti-Kickback, Stark Law, and other legal and compliance violations.

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Or contact Andrea: **888-729-2315**, **Andrea@plainlanguagemedia.com**