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Special Report: FDA to Use EUA Pathway to Clear New Coronavirus Tests

The 2019 novel Wuhan coronavirus outbreak caught regulators and diagnostic test makers off guard. As the death toll mounts, the scramble is on to develop tests capable of detecting the virus. Here's a rundown of what the FDA is doing to achieve that objective.

The FDA's EUA Strategy

Because the coronavirus is so new, there are no FDA-approved commercial products for it in the US. So, on Jan. 28, the FDA unveiled its strategy for promoting the rapid development and availability of safe and effective investigational medical products "to address this urgent public health situation." As with previous infectious disease outbreaks like Zika, the centerpiece of the FDA strategy is expedited clearance of new coronavirus tests and treatment products via the Emergency Use Authorization (EUA) pathway. The FDA called on diagnostic test sponsors interested in potential EUA for detection tests to contact the Center for Devices

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HIPAA: OCR Clarifies Rules for Sharing Coronavirus Patient Medical Information During Current Health Emergency

The usual HIPAA Privacy restrictions on collecting, using and disclosing personal health information (PHI) are relaxed during public health emergencies. With this in mind, the Office for Civil Rights (OCR), the HHS agency charged with enforcing the HIPAA rules, issued 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 coronavirus outbreak. Here's a quick overview of the key points

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and Radiological Health (CDRH) (CDRH-EUA-Templates@fda.hhs.gov) for information and templates.

The CDC Test

On Feb. 4, the agency took the first step by issuing an EUA for a reverse transcriptase real-time PCR (rRT-PCR) assay (aka, the 2019 Real Time RT-PCR Diagnostic Test Panel) developed by the US Centers for Disease Control and Prevention (CDC) that's capable of detecting coronavirus from respiratory and blood serum samples, including nasal or oral swabs.

The test can be used in the US only by CDC-designated labs that are certified to perform high-complexity testing in accordance with agency protocol. The CDC published the test formula and created kits using the assay for distribution to state health departments and public health labs around the country.

Nancy Messonnier, director of the CDC National Center for Immunization and Respiratory Diseases, says that the agency deems the rapid development and distribution of the test a success. But while the agency has shipped the kits to all 50 US states (and 30 international sites), the kits can't be used unless and until they undergo quality assessment and validation by the public health labs of the particular state. "When a state gets the test kit, they have to verify that it works the same in their lab as it worked at CDC," Messonnier explained during a press conference. And, of course, some states will complete that process faster than others.

Already, the limitations of the assay have become evident. Thus, while a positive result is a pretty reliable indicator of coronavirus infection, the feedback suggests that a negative result can't be counted on to rule it out. Accordingly, the FDA has warned against relying on negative tests as the lone basis for treatment and patient management decisions. Negative results must also be evaluated along with clinical observations, patient history and epidemiological information, according to the agency. Meanwhile, the CDC acknowledged that it will probably need to remanufacture one of the kit reagents to address the test quality results issues.

Takeaway

While it has obvious flaws that need to be worked out, the CDC (rRT-PCR) assay is the only approved test for coronavirus currently available in the US, designed as a stopgap measure to hold down the fort until the private sector develops better alternatives.

The COVID-19 pandemic is a rapidly-developing story.
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Billing & Coding: Use New HCPCS Code U0001 to Bill Medicare for CDC Coronavirus Test

Good news for labs that are testing Medicare patients for SARS-CoV-2 using the newly approved Centers for Disease Control and Prevention (CDC) 2019 Real Time RT-PCR Diagnostic Test Panel (and physicians ordering the test). In billing for the test, you don't have to list an unspecified code. Instead, you can use the new Healthcare Common Procedure Coding System (HCPCS) code that CMS just created for labs and other providers to use in billing CDC tests for the virus, namely HCPCS code (U0001).

The Medicare claims processing system will be capable of accepting the new U0001HCPCS code on April 1 for dates of service on or after Feb. 4, 2020, the date FDA issued emergency use authorization for the CDC coronavirus test. (For more on the CDC test, see page 2).

CLIA: CMS Issues Guidance on How Labs Should Perform Coronavirus Testing

On Feb. 6, CMS issued guidance to labs and other providers on how to use the newly approved Centers for Disease Control and Prevention (CDC) test for coronavirus. Here are the key takeaways.

The CDC Test

As with other infectious illness outbreaks, coronavirus caught regulators, test makers and labs off guard. The only test for it currently available in the US is the real-time reverse transcription polymerase chain reaction panel, aka, the 2019-nCoV Real-Time RT-PCR Diagnostic Panel developed by the CDC using sequencing information made public by Chinese authorities. The FDA issued emergency use authorization (EUA) for the Panel on Feb. 4.

The Panel, which is capable of detecting coronavirus from respiratory and blood serum samples, including nasal or oral swabs. Test labs must use the kits and reagents supplied by the CDC to public health agencies in all 50 states but are allowed to use their RT-PCR equipment and extraction kits.

The CMS Guidelines

Two days after the test received EUA from the FDA, CMS published the guidelines telling state regulators in charge of enforcing the CLIA laws how to police use of the Panel by labs. The guidelines make four key points.

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CLIA: CMS Issues Guidance on How Labs Should Perform Coronavirus Testing, *from page 3*

1. Which Labs Can Perform

Only labs that are CDC qualified, and, CLIA certified for high complexity tests may perform the tests.

2. CLIA Applies

As with other assays that have received EUA from the FDA, use of the CDC panel and corresponding protocols remains subject to CLIA regulations. In other words, being CDC qualified doesn't exempt the lab from the need to meet CLIA requirements.

3. Need to Follow Manufacturer's Instructions (MI)

CDC qualified labs must also follow any and all applicable MI.

4. Need to Verify Performance Specifications

Upon receipt of the Panel assay and corresponding MI, CDC qualified labs must verify assay performance specifications in their lab per the manufacturer's instructions.

Takeaway

The guidance also instructs regulators to notify their CMS Location if they discover a lab using an assay without an EUA that is testing for the same agent for which the emergency has been declared, or a modified EUA assay. The CMS location will then relay the notification to CMS headquarters in Baltimore.

ACA Update: Uncertainty Will Continue as Supreme Court Passes Up Chance for a Quick Resolution

The agony of uncertainty over the fate of the *Affordable Care Act* will continue for at least another 12 months. The U.S. Supreme Court all but ensured that on Jan. 21, when it passed up the invitation from Democratic governors to fast-track the current federal case in Texas challenging the constitutionality of the law. Although the curt one-sentence refusal to hear the case on an expedited basis leaves the door open for a later change of mind, hopes for a Spring 2020 closure have now been dashed.

The Current State of the ACA

Barring a change of heart by the Court on early intervention, the ACA is and will remain valid law unless and until the following things happen:

- The Texas case runs its course, i.e., the U.S. Court of Appeals for the 5th Circuit issues a final decision on the merits; and
- The side that loses in the 5th Circuit appeals to the Supreme Court.

After that, things get iffy. Although everybody expects the Court to accept the case, it could deny the appeal and leave the 5th Circuit ruling intact. And that would spell doom for the ACA if, as many expect, the 5th Circuit turns thumbs down on the law. Of course, there's always the possibility that the 5th Circuit will uphold the ACA. In that case, a Supreme Court denial to hear the appeal would end the challenge and ensure the law's survival.

The punchline is that none of this will happen until the 5th Circuit makes its ruling. The decision the 5th Circuit issued on Dec. 18 is not such a ruling. On the contrary, the court punted on the chance to rule on the merits and sent the case back down to the lower court to revisit and explain its earlier decision finding the entire ACA law unconstitutional. Why strike down the whole law and not just the individual mandate, the 5th Circuit asked the court to clarify.

Takeaway

The Dec. 18, 2019 ruling from the 5th Circuit only prolongs the agony of ACA uncertainty since now the case has to go back down to the lower court, leaving the insurance market and millions of Americans to twist in the wind. The Democratic petition for fast-tracking was a chance for the Supreme Court to end the suspense, one way or another. But now that the Court has said no, the uncertainty will continue for at least another year.

Enforcement Trends: OCR Continues to Crack Down on HIPAA Right of Access Violations

On Sept. 9, 2019, the Office for Civil Rights (OCR), the HHS agency in charge of federal HIPAA enforcement, did something it had never done before by entering into a monetary settlement with a provider for a HIPAA right of access claim. And before the year was out, it did it again.

The OCR Right of Access Initiative

The actions are part of the Right of Access Initiative that the agency unveiled in Spring 2019. Although right of access has generated roughly one in three HIPAA complaints, privacy and security breaches have historically been the focus of OCR litigation and Phase 2 compliance audits. The first "trophy" yielded by this major enforcement policy change was the $85,000 September settlement with Florida's Bayfront Hospital for allegedly denying an expectant mother timely access to the protected

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Enforcement Trends: OCR Continues to Crack Down on HIPAA Right of Access Violations, *from page 5*

health information (PHI) of her unborn child. (See, *NIR*, Nov. 2019, for the details.)

The Most Recent Settlement

Coincidentally, the most recent Right of Access Initiative settlement also involved a Florida provider. The cases began in March when the OCR received a complaint about Korunda Medical's alleged failure to send a patient's PHI to a third party in a timely manner despite repeated requests. Then, when it finally did transmit the information, the primary care and interventional pain management services provider allegedly didn't do so in the requested electronic format and charged the patient excessive fees. Only after the OCR intervened for the second time did Korunda adequately fulfill the request. As in the Bayfront Hospital case, the settlement amount was $85,000. And like Bayfront, Korunda also had to implement a burdensome corrective action plan as part of the settlement.

Takeaway

The deadline for responding to a patient PHI access request is 30 days. To avoid potential audits and liability under the Right of Access Initiative, labs simply cannot afford to drag their feet in meeting the deadline (or charge excessive fees for processing PHI access requests). "For too long, healthcare providers have slow-walked their duty to provide patients their medical records out of a sleepy bureaucratic inertia," declared OCR Director Roger Severino. "We hope our shift to the imposition of corrective actions and settlements under our Right of Access Initiative will finally wake up healthcare providers to their obligations under the law."

In Brief: CMS Increases 2020 Maximum Civil Monetary Penalties

Every year, HHS adjusts for inflation the maximum civil monetary penalty (CMP) amounts that a lab or other provider can be fined. In 2020, CMP maximums will increase by 2.522%. The new higher CMP ceilings apply to penalties assessed on or after Nov. 15, 2019, if the violation occurred on or after Nov. 2, 2015.

Legislation Watch: Congress Moves One Step Closer to Passing "Surprise Billing" Legislation

Prospects for the passage of legislation banning "surprise billing" of patients before the presidential election advanced significantly on Feb. 12 with the powerful House Ways and Committee unanimously voting in favor of the *Consumer Protections Against Surprise Medical Bills Act*. The bipartisan bill would mandate that patients receive an upfront estimate of treatment services costs, along with notification about the provider's network status.

The Billing Dispute Resolution Controversy

The idea of protecting patients against surprise bills after they've been treated has a lot of traction with both parties. In the past two years, numerous bills have been proposed. For their part, providers don't object to the idea of ending surprise billing but differ on how that should be done. One of the key points of difference is with regard to settling disputed amounts.

Hospitals want disputes settled via arbitration rather than reference to benchmark rates. Accordingly, they support the Ways and Means bill because it would create an arbitration process for insurers and providers to work out disputed amounts.

Physicians are more skeptical on arbitration and want safeguards to ensure that the process takes into account into account physician data provided by an independent data collection entity in the interest of fairness. "We support the underlying mechanism for resolving these disputes, including the eligibility of all disputed claims for negotiation and mediation, noted American Medical Association president, **Dr. Patrice A. Harris**. "We also appreciate that the mediator must consider a wide range of supporting information submitted by physicians in rendering a final determination."

Physicians Advocacy Institute President **Robert W. Seligson** stated the case even more bluntly. "Using insurers' payment data to resolve disputes would undermine patients' access to important medical care, because, as the Congressional Budget Office recognized, unrestrained marketplace clout will drive rates down artificially, sometimes below the cost of medical services," he stated.

The Narrow Networks Concern

As the Institute's remarks reveal, the underlying concern for physicians is the prospect of further narrowing and reduced availability of health networks, which they contend is responsible for the surprise billing problem in the first place. Thus, the Association of American Surgeons

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Legislation Watch: Congress Moves One Step Closer to Passing "Surprise Billing" Legislation, *from page 7*

and Physicians came out against the Ways and Means bill, specifically its requirement to not allow patients to be charged more than the in-network cost-sharing amount which would narrow provider networks even further.

The Lab Industry Perspective

Of course, all of this has a direct impact on labs. At the heart of the surprise billing problem is "balance-billing," i.e., billing patients for the difference between what the provider charges for the service and the hospital's contract reimbursement rate with the payor. According to a recent study, clinical labs, anatomic pathologists, radiologists and anesthesiologists are among the providers that most frequently engage in balanced billing. In addition to imposing hardship on patients who thought they were receiving care from in-network medical facilities, this practice makes the industry look bad. All of this has fed the drive for surprise billing legislation.

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.

Compliance Corner: The HIPAA Right of Access Crackdown Continues

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HIPAA: OCR Clarifies Rules for Sharing Coronavirus Patient Medical Information During Current Health Emergency, *from page 1*

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. 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

You don't need authorization to disclose PHI to for legitimate purposes connected to public health and safety, including disclosure:

- 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 coronavirus;
- 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 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.

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

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HIPAA: OCR Clarifies Rules for Sharing Coronavirus Patient Medical Information During Current Health Emergency, *from page 11*

written authorization. See 45 CFR 164.508 for the requirements for a HIPAA 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.

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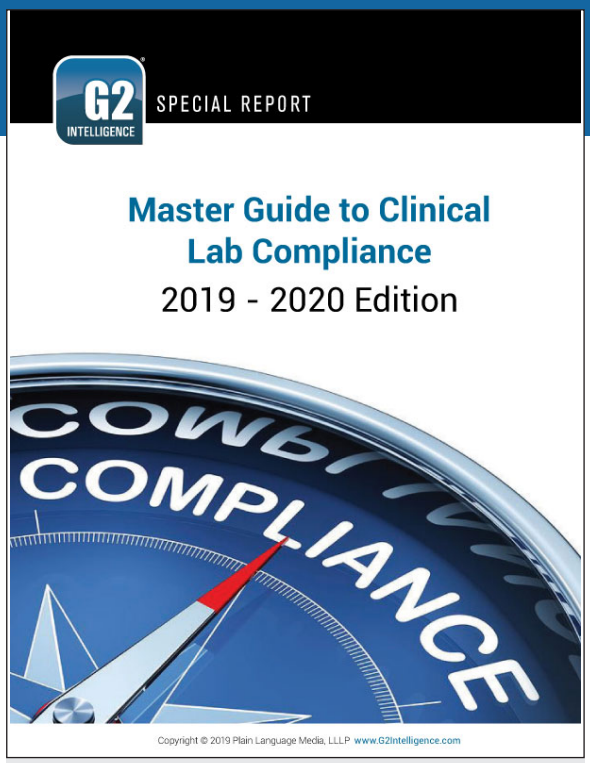

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Lab Compliance Essentials gives you the **practical, plain-language help** you need to understand the laws, and take **proven steps to protect your lab** from costly False-Claims, Anti-Kickback, Stark Law, and other legal and compliance violations.

For more information, please visit our website at **G2Intelligence.com/shop**

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