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Coronavirus: FDA Takes Unprecedented Measures to Promote Rapid Development of Coronavirus Diagnostic Tests

The FDA is following a two-prong strategy to promote and expedite development and validation of a test capable of safe, rapid and reliable detection of novel coronavirus (COVID-19), the disease caused by the SARS-CoV-2 virus. Here's an overview of the progress being made—and not made—on both fronts.

The Traditional EUA Pathway

The FDA is calling on test makers to seek rapid approval via the emergency use authorization (EUA) pathway the way it did with SARS, H1N1 and other previous outbreaks. The problem is that novel coronavirus isn't a known pathogen the way the previous outbreak viruses were. As a result, the diagnostics have to be created from scratch.

The other issue is time. Historically, it takes months to secure EUA

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Reimbursement: Congress Calls on Insurers to Cover Coronavirus Testing without Charging Patients

As labs scramble to come up with a coronavirus detection assay and CMS creates a billing and coding regimen, Congress is working to ensure that private payors provide coverage of SARS-CoV-2 testing. On March 6, the U.S. House of Representatives passed a bill requiring insurers to cover all testing without passing costs on to patients.

The Bill

The coronavirus provisions are part of a larger appropriations bill called the Families First Coronavirus Response Act (HR 6201).

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clearance. The good news is that the FDA has streamlined its application process by implementing a rolling process using an electronic template. The agency reports that it has already contacted more than 70 test makers interested in seeking EUA for coronavirus detection tests.

In fact, the agency has already broken its own speed record by issuing its first EUA on February 4, less than a week after mobilizing the pathway, for a reverse transcriptase real-time PCR (rRT-PCR) assay (aka, the 2019 Real Time RT-PCR Diagnostic Test Panel) developed by the U.S. Centers for Disease Control and Prevention (CDC). The test was approved for use only by CDC-designated labs certified to perform high-complexity testing in accordance with agency protocol.

The CDC has distributed test kits to state health departments and public health labs around the country. But reagent, instrumentation and lab staff shortages, coupled with questions about the test's reliability in ruling out infection, has made the pace of test validation and deployment frustratingly slow. As of March 10, the CDC reports that that 78 public health labs are now running the test. Those labs have the current capacity to test 75,000 people, which is not nearly enough.

To address the reagent bottlenecks, the FDA extended the CDC's EUA to cover kit lots from reagent two manufacturers validated at CDC labs, including two kit lots from Integrated DNA Technologies (IDT), which is owned by Danaher, and one kit lot from LGC Biosearch Technologies. But the shortages continue.

In addition to the CDC assay, the FDA has recently issued EUA for two commercial tests:

- On March 12, EUA was granted to the Cobas SARS-CoV-2 rRT-PCR assay from Roche for qualitative detection used with the Cobas 6800 and 8800 systems; and
- On March 13, the FDA provided EUA clearance to Thermo Fisher Scientific's TaqPath COVID-19 Combo Kit, is for the qualitative detection of SARS-CoV-2 nucleic acid in nasopharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage specimens from individuals suspected of having COVID-19 by their healthcare provider.

As of March 16, Thermo Fisher had 1.5 million tests available to ship under the EUA label and expects to increase production to reach 2 million tests per week. Based on available raw materials and the installed instrument base, the firm expects to ramp up production to up to 5 million tests per week in April. Thermo Fisher plans to initially ship those tests to approximately 200 laboratories in the U.S. and "will continue to work in partnership with government agencies and private partners to expand access," according to a company statement.

In addition, to the two commercial assays, the FDA gave EUA to the

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Wadsworth Center, New York State Department of Public Health's New York SARS-CoV-2 RT-PCR Diagnostic Panel authorized for emergency use by a pair of public laboratories in the state.

The flow of EUA tests is expected to accelerate with Qiagen and GenMark Diagnostics among the manufacturers with assays in the pipeline.

Non-EUA Pathway

For the first time, emergency development of new pathogen testing in the U.S. isn't confined to the EUA pathway. The FDA is also pursuing a second strategy of allowing high-complexity CLIA labs (of which there are a reported 300 to 400 across the country) to develop and start using validated coronavirus tests before the agency even completes review of their EUA applications. High-complexity labs are required to strictly follow CDC testing protocols, notify the FDA of test validation and submit a complete EUA request within 15 days after validation.

Among the first labs to follow this unprecedented pathway is LabCorp, which launched its LabCorp 2019 Novel Coronavirus (COVID-19) NAA test on March 6. Like the EUA tests, the LabCorp assay uses PCR technology to qualitatively detect the SARS-CoV-2 virus from respiratory samples collected at the point of care. Other major labs planning to launch their own SARS-CoV-2 tests prior to completion of EUA review include Quest Diagnostics, BioReference Laboratories (part of Opko Health) and Enzo Biochem.

SCORECARD: CORONA TESTING & THE EUROPEAN MARKET

While the pace of approval for new coronavirus diagnostic tests in the U.S. is faster than in any previous infectious illness outbreak, it's still far behind Europe where have already reached the market. Such tests include:

Coronavirus Assays Receiving CE-IVD Marking in Europe
(in rough chronological order of approval date)

Test Maker	Coronavirus Detection Test
Primerdesign (owned by Novacyt)	Molecular SARS-CoV-2 virus test for research-use-only
Co-Diagnostics	Logix Smart Coronavirus COVID-19 test
Snibe Diagnostic	Maglumi 2019-nCoV (SARS-CoV-2) IgM/IgG kits
BGI	Real-Time Fluorescent RT-PCR kit for detecting SARS-CoV-2 virus
EliTech Group	GeneFinder COVID-19 RealAmp kit for SARS-CoV-2 detection
Genomica (owned by PharmaMar Group)	qCOVID-19 and CLART COVID-19 kits
CerTest BioTec	ViaSure SARS-CoV-2 Real Time PCR Detection Kit
Genematrix	Neoflex COVID-19 coronavirus test kit

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FDA Takes Unprecedented Measures to Promote Rapid Development of Coronavirus Diagnostic Tests, *from page 3*

Takeaway

Creating tests capable of detecting new pathogens is always a slow process. What makes the coronavirus situation different is that the pathogen was previously unknown, meaning that test makers didn't get the benefit of the head start they had with previous outbreak viruses. The speed of the coronavirus spread and growing urgency of the public health crisis makes the delay in test development all the more frustrating, not to mention dangerous. The good news is that it's not business as usual. The imperative for rapid test development is unprecedented; and so are the regulatory strategies being followed to ensure the development and deployment of a reliable coronavirus detection test as soon as possible.

Billing & Coding: CMS Sets Rules for Medicare Coronavirus Testing Reimbursement with Private Payors Expected to Follow Suit

Good news for labs that are testing Medicare patients for the SARS-CoV-2 virus that causes coronavirus using the Centers for Disease Control and Prevention (CDC) 2019 Real Time RT-PCR Diagnostic Test Panel or the other commercial assays that have recently received Emergency Use Authorization (EUA) from the FDA. Instead, you can use the new Healthcare Common Procedure Coding System (HCPCS) codes that CMS created for labs and other providers for use in billing the brand-new tests:

- HCPCS code U0001 for the CDC test, which CMS announced will be reimbursed at between $35.91 or $35.92 per test; and
- HCPCS code U0002 for other SARS-CoV-2 virus assays that have received EUA from the FDA, e.g., from Roche and Thermo Fisher Scientific, which will be reimbursed at between $51.31 and $51.33 per test.

Takeaway

The CMS claims processing system will be capable of accepting the new HCPCS codes on April 1 for dates of service on or after Feb. 4, 2020, the date the FDA issued EUA authorization for the CDC coronavirus test. Reimbursement rates vary slightly by region subject to the determination of the local Medicare Administrative Contractor. Commercial insurers haven't yet announced their reimbursement rates, but are expected to align their own prices with Medicare's.

(See page 4 for information about the diagnosis coding of coronavirus and page 6 for a summary about new legislation requiring coverage of coronavirus testing).

Coronavirus: How COVID-19 Public Health Emergency Offers Potential for Temporary Stark Relief

On Jan. 31, 2020, the U.S. Department of Health and Human Services declared novel coronavirus, aka, COVID-19, a public health emergency (PHE). While it might sound like the highest level of government policy, declaration of a PHE might have a direct and immediate practical impact on your lab and in a manner you probably would have never thought of. Specifically, the PHE offers the potential for temporary relief from the Stark Law, freeing you up to make business arrangements with referring physicians related to coronavirus testing that would be completely illegal during periods of normalcy.

The Laws of PHEs

The Stark Law bans physicians from referring Medicare or Medicaid patients to labs or other health care entity with which they or an immediate family member have a financial relationship. Ensuring adherence to Stark restrictions when dealing with referring physicians is an everyday and pressing imperative for labs and their compliance managers.

But there's another law that may come into play, namely, the Public Health Service Act, which empowers the HHS Secretary to declare a PHE. While it may feel like public relations, the reason the Secretary made such a declaration was to activate his powers to take broad response measures to deal with the coronavirus and protect the public, which may include educating the public and disseminating information about the coronavirus, encouraging research and development of diagnostic and treatment techniques, improving screening and detection efforts; and supporting state and local government efforts to control the virus.

One application of these powers involves setting aside or relaxing health care regulations to deal with the emergency. Specifically, while a declared PHE is in effect, HHS may waive or modify Medicare, Medicaid, State Children's Health Insurance Program and HIPAA requirements under Section 1135 of the Social Security Act (SSA), including:

- Conditions of participation;
- The need of preapproval for medical items or services;
- Restrictions on telemedicine; and
- Stark Law restrictions.

Section 1135 Waivers

Section 1135 waivers aren't automatic or self-activating. To get one, you need to actually apply to CMS, which reviews each application on a case by case basis. The waiver can take effectively retroactively to the start of the

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emergency period or to any other subsequent date CMS determines. The waiver ends upon termination of the PHE or 60 days after the waiver or modification is first published. If the PHE is still in effect after 60 days, it can be renewed for additional 60-day periods.

Takeaway

During the current coronavirus emergency, labs need to recognize that they may have additional latitude to enter into temporary arrangements with physicians to promote public health. More precisely, seeking a Section 1135 waiver may make a lot of sense if your lab has an opportunity to provide coronavirus testing or other related services for Medicare or Medicaid beneficiaries in collaboration with a physician or medical group that has ownership interests in or other financial ties to your lab that would normally be prohibited under the Stark Law.

Reimbursement: CDC Issues ICD-10-CM Coding Guidance for Coronavirus Encounters

The U.S. Centers for Disease Control and Prevention (CDC) issued official guidance to labs and other health care providers on which ICD-10-CM diagnosis codes to use for 2019 novel coronavirus (COVID-19) patient encounters. Specifically, encounters with patients presenting with certain signs and symptoms, but where a definitive diagnosis has not been made, should be coded as follows:

- R05 – Cough;
- R06.02 – Shortness of breath; and
- R50.9 – Fever, unspecified

For pneumonia cases confirmed as due to COVID-19: Code J12.89, Other viral pneumonia, and B97.29, Other coronavirus as the cause of diseases classified elsewhere.

For acute bronchitis confirmed as due to COVID-19: Code J20.8, Acute bronchitis due to other specified organisms, or J40, Bronchitis not otherwise specified. In both instances, the provider should also use B97.29.

For lower respiratory infection or acute respiratory infections not otherwise specified that are documented as being associated with COVID-19: Code J22, Unspecified acute lower respiratory infection, with B97.29.

For COVID-19 is documented as being associated with a respiratory infection not otherwise specified: Code J98.8, Other specified respiratory disorders, with code B97.29.

Acute respiratory distress syndrome: Code J80, Acute respiratory distress syndrome, with code B97.29.

For a patient is evaluated following concern of possible exposure to COVID-19, but where COVID-19 is ruled out: Code Z03.818, Encounter for observation for suspected exposure to other biological agents ruled out.

For a patient that has actual exposure to COVID-19: Code Z20.828, Contact with and (suspected) exposure to other viral and communicable diseases.

B97.29 should not be used where the provider documents "suspected," "possible" or "probable" COVID-19.

ACA Update: SCOTUS Agrees to Rule on Obamacare for the Third Time

Before the coronavirus outbreak, the health care issue that kept millions of Americans up at night was the future of Obamacare, aka, the Affordable Care Act (ACA or Obamacare). Having already having survived two legal challenges, the ACA is now set to come under the U.S. Supreme Court's scrutiny for a third time. The announcement came in early March.

Obamacare in Court: Rounds 1 and 2

The first time Obamacare was found constitutional was in 2012 when the Supreme Court held that the law's requirement that most Americans obtain insurance or pay a penalty was a legal exercise of Congress's power to assess taxes. But the fun was just beginning.

In 2015, the high court held that the federal government can provide nationwide tax subsidies to help poor and middle-class people buy health insurance, rejecting an argument that the subsidies were available only in states that had created marketplaces, known as exchanges, to allow people who lack insurance to shop for individual health plans.

The Latest Court Case

A new election and change in Court personnel inspired the third and latest challenge, this one from a group of twenty Republican state attorneys general and governors. The new challenge zeroed in on the elimination of the mandate penalty to $0 in 2019. The argument: To the extent previous rulings upholding the ACA were predicated on Congressional taxing power, elimination of the mandate undermined the law's constitutionality.

In Dec. 18, 2018, a U.S. district court in Texas agreed with the argument and proceeded to rule that the entire ACA law should be struck down. On appeal, a federal appeals court agreed that, without the penalty, the individual mandate was unconstitutional; however, it sent the case

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back to the district court to once again decide if the entire ACA was unconstitutional. By remanding the case to its point of origin, the court of appeals' non-decision decision likely prolonged the case for at least one more year.

The Appeal for SCOTUS Intervention

With the insurance market and millions of Americans twisting in the wind, the U.S. House of Representatives and political leaders from a group of blue states asked the Supreme Court to fast-track review in an attempt to bypass a lengthy legal battle, so that a decision on the case would be made before the elections in November. But in January, the Court refused finding that the question wasn't yet ripe for high court intervention.

So, the House and blue staters tried a different legal tactic. Having lost their bid for fast-track review, the asked the Court to hear their appeal in the ordinary course, contending that Supreme Court review was warranted because part of a federal law had been held to be unconstitutional, which is often reason enough for the justices to agree to hear a case. They added that the lower courts' rulings had created doubt about the balance of the law.

In urging the court to deny review, the Trump administration called on the justices to wait for a definitive ruling from the lower courts. "Immediate review is unwarranted in the case's present posture," according to the administration's brief, "because the court of appeals did not definitively resolve any question of practical consequence." But the Supreme Court brushed the argument aside and agreed to hear the case.

What Happens Next?

While the Court has not announced a definitive schedule, legal experts expect that the case is likely to be heard sometime in the Fall of 2020, maybe even before the election. Any decision on the case, however, is not likely until the spring or early summer of 2021.

Of course, it's impossible to predict how the Supreme Court justices are going to rule. The fact that it has previously rescued Obamacare from legal challenges is no guarantee that it will do so again, especially given the addition of two conservative leaning justices appointed by President Trump since then. Defenders of Obamacare are hanging their hopes on the fact that Chief Justice Roberts twice sided with justices upholding the law. Some legal scholars suggest that he would not have taken the case if he thought the votes were there to have it declared unconstitutional. However, even if that is true, there is always the chance that the Chief Justice might have miscalculated.

And yet another variable is the health of Justice Ruth Bader Ginsburg. What if she should again fall ill in the next few months and leave the

Court? And what if President Trump were to appoint her successor before the case reached the time of judgment? Would there be any hope left of saving the law in those circumstances?

There's one more thing to consider, namely, the possibility that the Court will choose to overturn the mandate and only a few other select provisions, like the preexisting conditions rules, which were very much linked to the mandate when the law was drafted. But that's not what the Republican states or the Trump administration are asking for. They want the whole law tossed out.

Takeaway

What Happens If ACA Is Found Unconstitutional?

If the Court ultimately declares Obamacare unconstitutional, it would be as if Congress repealed Obamacare without any replacement law. Everything would go including:

- *Protections for preexisting conditions;*
- *Subsidies that help people purchase insurance;*
- *The Medicaid expansion; and*
- *Provisions unrelated to insurance, like nutrition requirements for food labels.*

*According to the **Urban Institute**, repeal of Obamacare would leave large swaths of the country uninsured. The number of uninsured would increase by approximately 20 million, or 65 percent nationally. The increase would be most heavily concentrated among:*

- *People with the lowest incomes (below 200 percent of the federal poverty level);*
- *Young adults; and*
- *Residents of the South and West.*

States that expanded Medicaid would also bear the brunt. The Urban Institute projected their uninsured rates would nearly double if the law were overturned. The uninsured rate for black Americans would increase from 11 percent to 20 percent, and there would also be a dramatic spike in the uninsured rates among Hispanics.

Laboratory Developed Tests: The VALID Act is Back

With all the attention commanded by the coronavirus crisis, a potentially huge development affecting the future of the lab industry has flown under the radar. What's at stake is the issue that has been at the center of the industry's agenda for nearly a decade: FDA regulation of laboratory developed tests (LDTs). Here's the rundown of recent developments.

The New VALID Act

In early March, legislators in the U.S. House of Representatives and Senate introduced a bill outlining a modernized framework for LDT regulation. U.S. Reps. **Larry Bucshon** (R-IN) and **Diana DeGette** (D-CO) introduced the bipartisan legislation to regulate in vitro clinical tests (IVCTs). The re-introduced legislation, the Verifying Accurate Leading-edge IVCT Development Act (VALID), would create a new product category for diagnostic and lab tests to be reviewed and approved by the FDA. An identical version of the bill also was introduced by U.S. Sens. **Richard Burr** (R-NC) and **Michael Bennet** (D-CO).

Prequel to VALID

Because lab tests weren't part of the original FDA legislation, the agency currently clears LDTs through its 510(k) pathway for medical devices. The legislative forebear of VALID was a bill called the Diagnostic Accuracy and Innovation Act (DAIA) that would have removed diagnostic tests from the definition of a medical device and thus outside the scope of the 510(k) pathway. After getting input from the lab and diagnostics industry, legislators submitted the DAIA draft to FDA for technical assistance. Instead of the usual technical edits, however, the FDA proposed an entirely new framework to overhaul the 510(k) premarket review program.

After the FDA's scheme received a thumbs down from the industry, DAIA's sponsors incorporated the FDA's ideas, including pre-certification, into a discussion draft of a new bill called VALID introduced in December 2018. However, VALID went nowhere in 2019. So, now the lawmakers are reintroducing it.

What VALID Would Do_

If enacted, VALID would create a new product category for diagnostic and lab tests, putting their review and approval under the FDA. It would also overhaul how the FDA reviews and approves diagnostic tests while giving labs greater flexibility in responding to public health emergencies.

Essentially, VALID creates a risk-based framework for IVCT regulation, with high-risk tests, like novel assays, required to go through premarket review; lower-risk tests could go to market after passing through technological certification. Specific features that VALID would implement:

- Establishment of a technology certification program for lower-risk tests;
- Requirement that high-risk tests undergo premarket review to verify analytical and clinical validity;
- Authority of the FDA to require that any test undergo premarket review after providing the developer an opportunity to address issues identified by the agency; and
- Creation of a new system to allow hospitals and labs to submit their tests electronically to the FDA for approval, a move that would speed up the approval process and increase the quality and reliability of the testing, according to the bill summary.

The law would also grandfather in existing LDTs being used clinically.

Lab Industry Reaction

In a press release American Clinical Laboratory Association President **Julie Khani** indicated that the organization will be reviewing VALID with members and engaging members on the Hill and the broader health care community. She noted: "Over the past several years, ACLA and our members have been actively working with stakeholders to advance meaningful comprehensive diagnostic reform for patients. As we've consistently stated, a modernized regulatory framework must ensure sustained innovation for patients and providers and support continued access to the laboratory tools necessary for the diagnosis, monitoring and treatment of disease."

Specifically, noted Khani, ACLA has consistently pushed for three main priorities:

- Reform that recognizes diagnostics as separate and distinct services from medical devices, and that also distinguishes between LDTs and IVDs;
- Grandfather and transition policies that protect patient access to currently available lab tests; and
- A regulatory system that balances the needs of innovation and appropriate regulatory oversight to ensure the accuracy, reliability and access of these tests.

However, she stated, in the short term, ACLA and its member companies are focused on responding to the growing demand for COVID-19 testing capacity, and would be turning to closer review of the new version of VALID in the near future.

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Among other things, it instructs insurers that offer group and individual health plans to cover SARS-CoV-2 diagnostics with Emergency Use Authorization (EUA) from the FDA. HR 6201also calls on insurers to waive deductibles, copayments and coinsurance for patients and refrain from following their usual prior authorization and other utilization management requirements for such tests. The bill covers costs associated with tests provided during the course of a patient's visit to a doctor, urgent care center or emergency room.

Takeaway

The Senate is now considering its own version of the bill and President Trump has suggested that he will support it.

A Potential Loophole: Non-EUA Tests

The way HR 6201 is written, it applies only to tests that have received EUA from the FDA, including assays from the U.S. Centers for Disease Control and commercial tests from Roche and Thermo Fisher. But under the FDA's coronavirus response strategy, the agency is permitting high-complexity labs to validate and administer their own tests while seeking EUA within 15 days. It's unclear whether HR 6201 would apply to those tests, which have been launched by LabCorp and Quest Diagnostics, among others. Is the inclusion of just EUA tests an oversight or deliberate? Industry organizations have called on to Congressional leaders to revise the language to fix the omission, if that's, in fact, what it is.

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As you know, American business is being hit hard by the COVID-19 pandemic.

The impact upon the publishing and media industry, and our critical suppliers and vendors, is growing increasingly severe. We are uncertain of our ability to continue to produce and deliver print versions of our publications, and we see no clear timeframe for resolution.

Therefore, G2 Intelligence has made a decision to move to a Digital-Only publishing format for the immediate future. All G2 newsletters, reports, and other information services will continue to be available in digital format to help support the lab industry during this crisis, but print versions will be discontinued.

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