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New Trends, Applications, and IVD Industry Analysis

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Innovation: New Saliva-Based CRISPR Smartphone Assays May Fill Need for Mass and Rapid COVID-19 Testing

One of the few positive things to come out of this deadly global pandemic is how it has accelerated the pace of diagnostic innovation to hyperdrive levels. The latest example of this phenomenon is the rapid development of technology that enables individuals to use their smartphones to find out if they have COVID-19 via analysis of a saliva sample.

The Diagnostic Challenge

- Should we shut down the schools?
- How much progress are we making toward general immunity?
- Should we open the workplace?
- Is it safe for me to leave the home and go to the grocery store?

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Utilization Management: CMS Proposes New Regulations to Streamline and Speed Up Payor Prior Authorization

As its days dwindle down, the Trump administration proposed regulatory changes designed to ease prior authorization rules and improve provider and patient access to medical records. Specifically, the Center for Medicare and Medicaid Services (CMS) proposed rule would Medicaid, the Children's Health Insurance Plan (CHIP), Qualified Health Plans (QHPs) and other payors to build application program interfaces to support prior authorization and data exchange. Here is a quick briefing on the 347-page rule.

The Diagnostic Challenge

Payors rely on prior authorization requirements to ensure program integrity and winnow out medically unnecessary laboratory tests

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Innovation: New Saliva-Based CRISPR Smartphone Assays May Fill Need for Mass and Rapid COVID-19 Testing, *from page 1*

Mass rapid COVID-19 testing provides the critical data government regulators, scientists, employers and individuals need to make sound decisions about how to keep COVID-19 from spreading.

Molecular real-time reverse transcription polymerase chain reaction (RT PCR) testing represents the current gold standard for COVID-19 testing. But while it is capable of accurate detection, RT PCR test methods do not generate this kind of data. Because tests must be performed at an off-site laboratory using complex RNA extraction methods, individuals who get tested have to wait for days to find out if they are positive or negative. RT PCR tests are also dependent on supplies that are currently hard to get, including nasal swabs that must be inserted into the patient's nostril to obtain a sample from the sinus cavity, a process that is uncomfortable and, in many cases, must be carried out by a trained health professional.

The good news is that since the public health emergency began, researchers, universities and commercial laboratory companies have made significant progress in developing rapid, accurate and point of care COVID-19 diagnostics. Such progress has been manifested across a number of different fronts.

Home Sample Collection

One of the pathways to mass and rapid COVID-19 testing is the development of products allowing for home collection of test samples. Early in the pandemic, there was understandable skepticism about whether patients are actually capable of swabbing their own nostrils. However, a number of influential studies, including by researchers at the Stanford University School of Medicine published in *The Journal of the American Medical Association* in June provided critical evidence that patients can, in fact, be trusted to swab themselves.

On April 21, Laboratory Corporation of America's COVID-19 RT PCR test became the first assay to receive U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for use on home-collected samples. A month later, Quest Diagnostics received EUA for its own COVID-19 self-collection kit. And as 2020 comes to a close, dozens of other COVID-19 molecular tests have been cleared for home sample collection.

Saliva Based Testing

A variation on this same theme has been the development of COVID-19 tests that can be performed on saliva samples thereby obviating the need for nasal swab collection altogether. While nobody disputes that saliva testing is cheaper, simpler and easier on the supply chain, there were concerns about its accuracy as compared to testing on samples obtained by

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nasopharyngeal swabs. But as with home collection, evidence indicating that COVID-19 saliva-based is at least as reliable and accurate as swab-based testing was soon to emerge.

A Yale University study published in *The New England Journal of Medicine* on Aug. 28 found that the Yale saliva test actually detected the SARS-CoV-2 virus more frequently in patients known to have COVID-19, with 81 percent of the tests coming back positive in the first five days of infections, compared to the 71 percent rate got nasopharyngeal tests. The saliva test also detected more copies of the virus's genetic material.

A second study from the University of Ottawa published in the *Annals of Internal Medicine* the very same day was also supportive of saliva testing. The researchers tested nearly 2,000 people who had either mild symptoms of the virus or no symptoms but were at a high risk of infection. Participants collected their own saliva and also underwent the traditional swab test: 34 came back positive in both tests. In 14 cases, the virus was detected in the saliva sample, but not the nasal sample. In 22 cases, the opposite was true.

Even before these studies appeared, the FDA granted its EUA for a COVID-19 for use on saliva samples on April 13. The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay test is based on the Thermo Fisher Scientific Applied Biosystems TaqPath COVID-19 Combo Kit previously approved for the detection of specific genomic regions of the SARS-CoV-2 nucleocapsid gene, spike gene and ORF1ab region in nasopharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage specimens. But it was modified for use on additional specimen types, including saliva.

Of the roughly 250 COVID-19 assays to gain EUA by year's end, over a dozen have been approved for use on saliva samples.

Smartphone Testing on Saliva Samples

The next phase in the evolution was the marrying of these simplified sample collection methods with consumer-based, mobile technology allowing for rapid and accurate testing at the point of care. And because just about everybody owns a smartphone, this device would serve as the central node. However, instead of RT PCR, smartphone tests would be built around Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) gene-editing technology.

As with RT PCR, CRISPR diagnostics require the conversion of RNA to DNA, which then must be amplified to improve the accuracy of detection. That would have barred use of CRISPR with smartphones. But researchers were able to clear this hurdle by developing a novel approach allowing CRISPR to be used to detect viral RNA directly, thereby eliminating the need for conversion and amplification.

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Innovation: New Saliva-Based CRISPR Smartphone Assays May Fill Need for Mass and Rapid COVID-19 Testing, *from page 3*

The California Assay

In a study published in the scientific journal *Cell*, a team of researchers from Gladstone Institutes, University of California, Berkeley, and University of California, San Francisco outlined the technology for a CRISPR-based test for COVID-19 that uses a smartphone camera to provide accurate results in under 30 minutes.

The researchers built a prototype assay chip that uses the CRISPR/Cas12a enzyme to enhance an amplified viral RNA target's signal within a saliva sample. They integrated the chip into a smartphone-based fluorescence microscope readout device, which captures and analyzes images to determine whether the virus is present above a threshold concentration. They then tested the technique on 12 people infected with COVID-19 and six healthy controls. **Result:** The test was just as effective as RT PCR in distinguishing between people with and without the virus. "We believe this smartphone platform, a similar future application, offers the potential to rapidly expand COVID-19 screening capacity, and potentially simplify the verification of contact tracing, to improve local containment and inform regional disease control efforts," the authors wrote.

The Tulane Assay

A week after the *Cell* study describing the California 30-minute test, researchers from Tulane University raised the bar by a quarter of an hour when they unveiled their own version of a saliva-based test for COVID-19 that delivers results via a smartphone in 15 minutes. Like the California test, the Tulane assay is based on CRISPR technology capable of detecting SARS-CoV-2 virus RNA directly without the need for conversion and amplification. The researchers say the new saliva-based test is not only faster and more user-friendly but also more sensitive than standard RT PCR tests. "The sensitivity and simplicity of this test, its straightforward sample collection procedure, and the inexpensive nature of the readout device should permit the rapid translation of this approach to COVID-19 testing efforts," noted one of the Tulane researchers.

Takeaway

Although neither test has yet received FDA approval, the development of CRISPR-based assays capable of rapid and accurate COVID-19 diagnostics at the point of care via the use of consumer technology is the culmination of innovation across a number of fronts that the pandemic set into motion. The new assays essentially cut out the laboratory middleman making them more efficient and scalable. And if it they truly are as sensitive and reliable as RT PCR tests the way the researchers suggest, they could be a breakthrough in the effort to bring mass and rapid COVID-19 testing to the masses.

FDA WATCH

Agency Authorizes First OTC All-in-One At-Home COVID-19 Testing Kit

Since the pandemic began, the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for more than 225 COVID-19 diagnostic tests. Among these, 25 have been cleared for home collection of samples. On Nov. 17, the agency broke new ground by clearing Lucira Health's COVID-19 All-in-One Test Kit, the first all-in-one COVID-19 diagnostic enabling people to test themselves in their own home to receive EUA. On Dec. 15, the agency went one step further by issuing EUA for a full at-home testing kit for the virus that does not require a prescription.

The Ellume COVID-19 Home Test

The distinction of being the first went to the Ellume COVID-19 Home Test, is a rapid antigen test capable of detecting fragments of the SARS-CoV-2 virus. Although the assay is performed on samples taken from nasal swabs, it is a nasal mid-turbinate (NMT) test, which makes it less invasive than tests performed on samples taken using the much longer nasopharyngeal (NP) swabs that require a trained a health care provider to administer.

More significantly, it is an over-the-counter rather than a prescription test. Accordingly, FDA Commissioner **Stephen M. Hahn**, MD, hailed the approval as "a major milestone" in COVID-19 testing. "By authorizing a test for over-the-counter use, the FDA allows it to be sold in places like drug stores, where a patient can buy it, swab their nose, run the test, and find out their results in as little as 20 minutes," Hahn suggests.

Costing about $30, the Ellume test kit includes a sterile nasal swab, dropper, processing fluid, and a Bluetooth-connected "Analyzer," that pairs with an app providing step-by-step video instructions that users can upload to their smartphone. Step-by-step video instructions for taking the test are provided on the app. After the sample is analyzed, results are delivered to the user's smartphone via Bluetooth in 15 minutes or less.

The test is pretty accurate, having correctly identified 96 percent of positive samples and 100 percent of negative samples in individuals with symptoms, according to the FDA. The test also correctly identified 91 percent of positive samples and 96 percent of negative samples in asymptomatic persons.

However, because antigen tests are generally prone to both false negative and positive results, the FDA recommends that patients who are not displaying COVID-19 symptoms treat positive results as "presumptively positive until confirmed by another test as soon as possible." This is likely to be particularly relevant for communities with fewer infections,

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FDA Watch: Agency Authorizes First OTC All-in-One At-Home COVID-19 Testing Kit, *from page 5*

because false positive results can be more common when antigen tests are used in populations where there is low prevalence of COVID-19.

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Here are the other key new FDA EUAs and clearances announced in December:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Abbott	EUA for BinaxNow COVID-19 Ag Card rapid test
Quidel	EUA for QuickVue SARS Antigen test for COVID-19
MatMaCorp.	EUA for MatMaCorp COVID-19 2SF Test run on firm's Solas 8 portable nucleic acid analysis system
Acon Laboratories	EUA for ACON SARS-CoV-2 IgG/IgM Rapid Test
Hologic	EUA for Aptima SARS-CoV-2/Flu RT PCR assay
Hologic	Clearance for HIV-1 viral load monitoring Aptima HIV-1 Quant Dx assay, first dual-claim assay for diagnosis and viral load monitoring in U.S.
Genetworx	EUA for Genetworx Covid-19 Nasal Swab Test including self-collection kit materials
PacificDx	EUA for COVID-19 Test including use with nasal swab specimens self-collected at home using RapidRona's self-collection kit
Ellume	COVID-19 Home Test, first EUA for emergency COVID-19 test that can be completed at home without a prescription
Horiba Medical	Clearance for Yumizen C1200 next-generation clinical chemistry system
Applied BioCode	EUA for SARS-CoV-2 Assay expanded to include use with pooled samples
Siemens Healthineers	510(k) clearance for Epoc NXS Host mobile computer
LabCorp	EUA for over-the-counter version of firm's Pixel by LabCorp COVID-19 Test Home Collection Kit
Mesa Biotech	510(k) clearance and CLIA waiver for Accula Strep A molecular test
Luminostics	EUA for Clip COVID Rapid Antigen Test
BioFire Defense	EUA for SARS-CoV-2 assay expanded to allow use with pooled samples
Quest	EUA for RC COVID-19 +Flu RT-PCR test for use with firm's Self-Collection Kit for COVID-19 +Flu
Quest	EUA for RC SARS-CoV-2 Assay, which is performed using Roche's authorized Cobas SARS-CoV-2 RT-PCR test, expanded to include use with pooled samples

Manufacturer(s)	Product
Rheonix	EUA for SARS-CoV-2 assay expanded to include use on saliva samples
CDC	EUA for CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel expanded to include use with pooled samples
Innovita Biological Technology	EUA for Innovita 2019-nCoV Ab Test (Colloidal Gold) serology test
Cepheid	EUA for Xpert Omni SARS-CoV-2 RT PCR assay
Roche	EUA for Elecsys Anti-SARS-CoV-2 S electrochemiluminescence immunoassay run on firm's Cobas E analyzers
Lucira Health	EUA for Lucira COVID-19 All-in-One Test Kit, first fully at-home test authorized for COVID-19
GenScript Biotech	EUA for cPass SARS-CoV-2 Neutralization Antibody Detection Kit, first SARS-CoV-2 neutralizing antibody test to receive EUA

Testing Trends: Roche, Siemens Healthineers Score Big on FDA SARS-CoV-2 Antibodies Test Reliability Evaluation

While real-time reverse transcription polymerase chain reaction (RT PCR) assays are the primary diagnostic for COVID-19, the U.S. Food and Drug Administration (FDA) has also granted Emergency Use Authorization (EUA) to dozens of antibody tests since the pandemic began. And that begs an important question: Which of these tests is most reliable? The FDA recently published comparison data purporting to answer that question.

The Role of Antibody Testing

Serology-based tests detect antibodies the body produces to fight SARS-CoV-2 rather than the virus itself. The problem is that it takes several days for people who are infected to develop antibodies to the virus. This limits their reliability in diagnosing COVID-19. But while they should not be used as the sole basis for diagnosis, antibody tests help healthcare professionals identify individuals who may have developed an immune response to SARS-CoV-2 and determine who can donate convalescent plasma to treat patients with infections.

The FDA Performance Evaluation Methodology

As with any other assay, some SARS-CoV-2 antibodies tests are more reliable than others. The FDA set out to evaluate performance of 64 EUA tests on the basis of data provided by the respective test manufacturers and using two key metrics:

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Testing Trends: Roche, Siemens Healthineers Score Big on FDA SARS-CoV-2 Antibodies Test Reliability Evaluation, *from page 7*

- "Sensitivity" measures the ability of a test to identify persons with antibodies to SARS-CoV-2 (true positive rate); and
- "Specificity" measures the test's ability to identify persons without SARS-CoV-2 antibodies (true negative rate).

To measure sensitivity, the FDA evaluated whether a test was able to detect antibodies in blood samples from patients confirmed as having COVID-19 via nucleic acid amplification test (NAAT). A test's specificity can be estimated by testing large numbers of samples collected and frozen before SARS-CoV-2 is known to have circulated to demonstrate that the test does not produce positive results in response to the presence of other causes of a respiratory infection, such as other coronaviruses.

Because every test returns some false positives and negatives, tests are also measured by their Positive and Negative Predictive values (PPV and NPV), which are calculated using the test's sensitivity and specificity based on "prevalence," i.e., an assumption about the percentage of individuals in the population who have SARS-CoV-2 antibodies.

The Evaluation Results

Companies from central Europe garnered the bragging rights. One of the highest scoring tests was the Elecsys Anti-SARS-CoV-2 tests from Switzerland-based Roche Diagnostics. Applied to over 6,000 samples, including 233 positives, the semi-quantitative test correctly determined if SARS-CoV-2 antibodies were present in almost every case. When applied to a population in which 5 percent of samples had antibodies, the test had PPV of 99.7 percent and NPV of 99.8 percent. However, the qualitative version of the Elecsys test, while still among the top performers, was slightly less impressive.

Tests from Germany-based Siemens Healthineers also fared quite well, including a semi-quantitative test with a PPV of 98 percent and NPV of 100 percent at an antibody prevalence of 5 percent based on more than 1,000 samples.

Although several other tests had higher PPV and NPV, their scores are less impressive because they were based on smaller sample sizes. Thus, for example, an assay from Hangzhou Biotest Biotech posted 100 percent for both PPV and NPV but only tested 110 samples. Based on the 95 percent confidence interval, the real PPV for the test could be as low as 51 percent. By contrast, the lowest confidence interval the Roche and Siemens tests could dip would be PPV of, respectively, 93 percent and 88 percent.

Like Roche and Siemens, Abbott assessed most of its antibody tests on at least 1,000 samples. The PPVs of the three most comprehensively assessed Abbott tests were approximately 92 percent, with the lower and upper bounds of the confidence intervals of approximately 85 percent and 95 percent. While below the Roche, Siemens and other top tier tests, these

performance numbers are comparable to kits from Beckman Coulter and other big diagnostics firms.

Siemens Healthineers SARS-CoV-2 Test Wins Bouquets on the Other Side of the Atlantic

The new FDA comparison is the latest in a series of wins for the Siemens Healthineers. In July, the UK Department of Health and Social Care published a study evaluating the sensitivity and specificity of four coronavirus antibodies assays available in the UK market: Abbott Laboratories' SARS-CoV-2 Immunoassay, DiaSorin's Liaison SARS-CoV-2 S1/S2 IgG assay, Roche's Elecsys Anti-SARS-CoV-2 test, and Siemens' SARS-CoV-2 Total (COV2T) test. The study found that the Siemens' test was the only one to meet its 98 percent sensitivity and specificity standard. (See "Battle of the SARS-CoV-2 Antibody Immunoassays: Only One Test Meets Both UK Sensitivity and Specificity Targets," see Diagnostic Tests and Emerging Technology (DTET), Aug. 12, 2020.

On the downside, Thermo Fisher Scientific's OmniPATH COVID-19 Total Antibody came in with a disappointing PPV of 67 percent, far below those of its peers; but the smallness of the sample size—only 110 samples—creates a wide confidence interval that may belie the reliability of these results and make comparisons with tests evaluated on the basis of larger samples unreliable.

Takeaway

Available data suggests that almost all of the SARS-CoV-2 antibody tests that have received EUA from the FDA are at least 90 percent sensitive and specific. However, as the FDA evaluation illustrates, small differences in those figures can translate into big differences in PPV and NPV.

Testing Strategies: Studies Show Blood Testing May Be Just as Good If Not Better than PET Scans in Detecting Early Alzheimer's Disease

For decades, researchers have worked to create a cost-effective and accurate blood test for early detection of Alzheimer's disease. A new study suggesting that elevated levels of the protein tau phosphorylated at threonine 217 (p-tau-217) is an accurate biomarker for early onset of Alzheimer's offers new hopes of achieving that goal.

The Diagnostic Challenge

Alzheimer's damages brain cells well before it impairs cognitive ability. And by the time patients manifest symptoms of impaired thinking, it is too late to treat them. That makes it critical to identify Alzheimer's as early as possible before patients suffer cognitive impairment.

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Testing Strategies: Studies Show Blood Testing May Be Just as Good If Not Better than PET Scans in Detecting Early Alzheimer's Disease, *from page 9*

Alzheimer's patients generate abnormally large amounts of certain proteins in the brain that clump together to form plaques, strangling nerves and severing nerve connections. Current diagnosis of Alzheimer's relies largely on the use of positron emission tomography (PET) scans to detect buildups of these proteins. But PET scans are relatively expensive and only about 70 percent accurate. What is needed is a more accurate, easier and less costly detection test—like a blood test.

The AAIC Study

One potential biomarker for early Alzheimer's is an elevated level of the p-tau-217 protein. A study discussed at the annual Alzheimer's Association International Conference (AAIC) in July and reported online in *JAMA Neurology* in November found that blood tests for detecting abnormal tau metabolism in the brain were able to detect pathology earlier than PET scans in patients with preclinical Alzheimer's disease.

Tests for p-tau-217 were performed on 490 people, including healthy controls and those with subjective cognitive decline or mild cognitive impairment. Researchers compared the various methods of early Alzheimer's detection for their effectiveness in detecting preclinical disease. They found that plasma p-tau-217 levels were elevated during the early preclinical stages of Alzheimer's when PET scans were not yet capable of detecting insoluble tau aggregates. In other words, blood tests were the only way to detect the critical p-tau-27 biomarker as this early stage.

The data reported in the *JAMA Neurology* piece derive from a cohort of a Swedish, which is partly supported by Eli Lilly, finding plasma p-tau-217 effective for discriminating Alzheimer's from other neurodegenerative conditions, with better performance than p-tau-181, neurofilament light chain, and other biomarkers.

The Washington University at St. Louis Study

In another study reported at the AAIC, researchers at Washington University of St. Louis evaluated a mass spectrometry test for assessing p-tau-217 and other tau fragments using blood samples as small as 4 mL. The study included two cohorts—a discovery cohort with 36 participants and a validation cohort with 92 participants. The researchers paired nano liquid chromatography with tandem mass spectrometry for plasma testing. They also evaluated p-tau-217 levels in cerebrospinal fluid (CSF).

The results, which were published in the *Journal of Experimental Medicine* on July 28, show that p-tau-217 (and p-tau-281) were both highly specific for amyloid pathology evident on PET scans in both cohorts. "Importantly, plasma and CSF p-tau-217 measures distinguished amyloid-positive, tau PET-negative participants from controls," the researchers wrote.

The results suggest that plasma tau could be developed as a highly sensitive screening tool for individuals at risk of having amyloid pathology and a lower-cost alternative to PET imaging, the researchers concluded. Tau blood tests could also be complementary to beta-amyloid 42/40 ratio blood tests.

Takeaway

Evidence continues to emerge that blood testing patients for elevated levels of different proteins is a viable method of detecting the onset of early Alzheimer's disease, especially vis à vis PET scans. Blood tests that can be performed in a physician's office or other point of care settings are not just more affordable and accessible than PET scans but they may actually be more reliable. Even so, the development and regulatory approval of such tests remains years away.

Utilization Management: CMS Proposes New Regulations to Streamline and Speed Up Payor Prior Authorization, *from page 1*

and other covered health services. However, these requirements are administratively burdensome and time consuming. The all too frequent result is not only significant inconvenience but also harm to patients.

In 2018, the healthcare industry issued a consensus statement stressing the need for reform. But those calls seem to have gone unheeded. In a June 2020 American Medical Association (AMA) survey, more than 9 in 10 physicians said that prior authorization rules regularly delays patient access to medically necessary care. Nearly one in four physicians reported that at least one of their patients had suffered a serious adverse event as a result of prior authorization rules. Another 16 percent said that prior authorization delays resulted in the hospitalization of a patient. "These survey results highlight that practices continue to devote significant time—an average of nearly two business days per week per physician—navigating prior authorization's administrative obstacles," sometimes resulting in harm to patients, noted AMA President **Dr. Susan Bailey** in a statement.

The CMS Proposal

The strategy behind the CMS proposal is not to eliminate payor authorization requirements but make them more transparent and easier to maneuver. The new interfaces would enable providers to determine in advance the documentation each payor requires, streamline documentation processes and facilitate the electronic transmission prior authorization information requests and responses. It contains two key elements:

1. Mandatory Payor APIs

The plan, which builds on the Interoperability and Patient Access final rule that CMS published in May, calls for payors to create application programming interfaces (APIs) on their systems that enable electronic health records (EHR) and other information systems to talk to each other or third-party applications. Payor APIs would have to meet the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) standard. The FHIR standard is a technology solution that helps bridge the gaps between systems so that both systems can understand and use the data they exchange.

2. New Deadlines for Prior Authorization

The proposed rule would also reduce the wait time for prior authorization decisions by requiring payors (other than QHP issuers on Federally Facilitated Exchanges (FFEs)) to issue decisions on urgent requests within 72 hours and non-urgent requests within seven calendar days. Payors would also have to provide a specific reason for any denial, which

will allow providers some transparency into the process. To promote accountability for plans, the rule also requires them to make public certain metrics that demonstrate how many procedures they are authorizing.

Next Steps

Comments on the proposed rule close on Jan. 4. CMS' plan is to finalize the rules and have them go into effect on Jan. 1, 2023. The agency is also reportedly considering making a parallel proposal for Medicare Advantage plans.

Takeaway

Taken together, these policies could lead to fewer prior authorization denials and appeals while improving communication among payors, providers and patients, according to a CMS statement. But there is a fly in the ointment, namely the use of APIs. This is far from the first time that the administration has pushed for adopting APIs for EHR communication and sharing purposes. However, APIs are also fairly controversial due to privacy concerns. As a result, key players in the healthcare industry have resisted their adoption. And with a new administration set to take the reins, the proposed rule's future remains very much in doubt. One possibility is that the next CMS will sever the controversial API requirements and leave the prior authorization deadlines and transparency reporting obligations intact.

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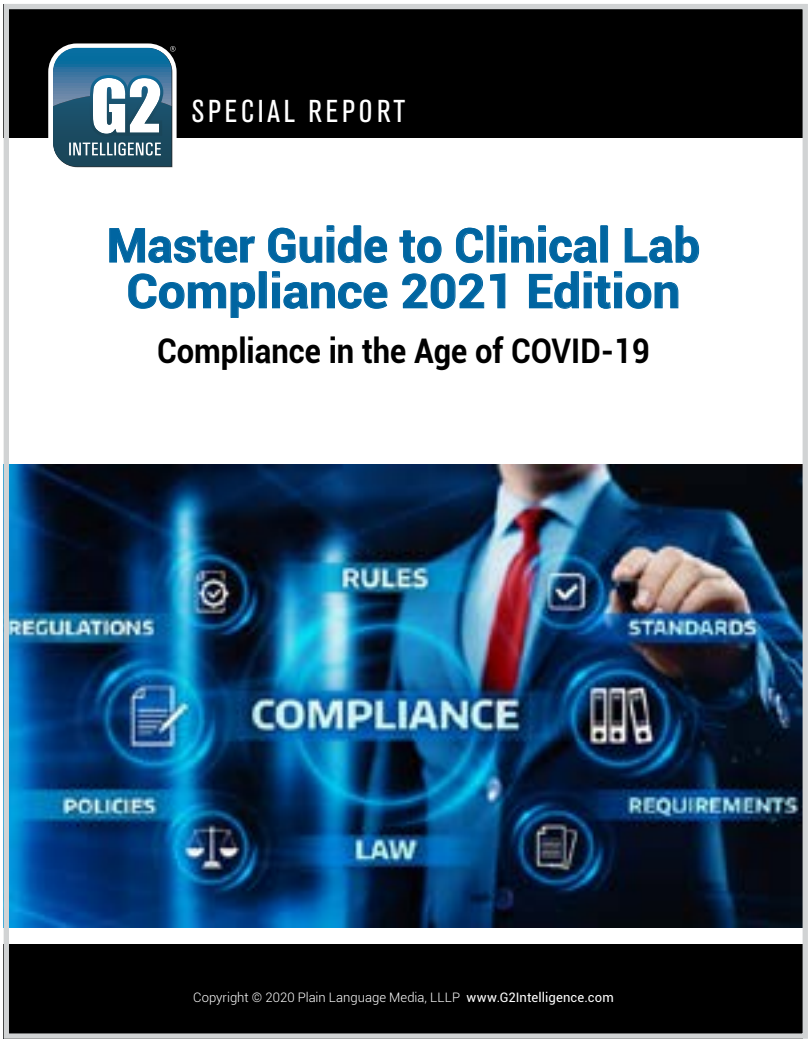
Compliance in the Age of COVID-19



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