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The Business of Testing: Hospital Laboratories Take a Stand Against Controversial UnitedHealthcare Outpatient Reimbursement Policy

The cold war between hospital laboratories and the nation's third largest health insurer, UnitedHealthcare (UHC), over reimbursement of diagnostic tests is getting hotter by the day. At the center of the conflict is a controversial new UHC policy that would require laboratories to meet the standards of its homegrown provider care quality and efficiency program to qualify for reimbursement. Hospitals are pushing back against the policy and have now asked the federal government to intervene in the dispute.

The Reimbursement Challenge

Payors of all stripe have a rich tradition of griping about the high costs of laboratory tests. A turning point came in 2014 when Congress enacted the *Protecting Access to Medicare Act* (PAMA)

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Testing Strategy: The Biden Administration Initiates New Plan for National COVID-19 Testing

As with any other aspect of public life, the philosophy and views of the individual occupying the White House ultimately impact the direction of healthcare and diagnostics in the U.S. However, when a new president takes office in the midst of a pandemic, that impact becomes not only magnified but also more immediate. This is particularly true when the new president's views are diametrically opposed to those of his/her predecessor. The most dramatic illustration of these principles occurred on Jan. 20, 2021, the Biden administration's first day in office, with the rollout of a bold new plan for COVID-19 testing called the National Strategy for COVID-19 Response and Pandemic Preparedness (National Strategy).

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to mandate imposition of a market-based pricing regime for Part B Medicare laboratory test reimbursement. Although the laboratory industry embraced the concept of market-based pricing, it recoiled at the distorted methods that CMS used to implement the scheme. By excluding hospital laboratories from the calculation of market price, the CMS PAMA system artificially and unfairly slashed reimbursement rates across the board.

PAMA proved to be a double whammy for laboratories to the extent it inspired private payors to implement their own aggressive reimbursement systems. In many cases, payors tied laboratory test reimbursements not only to what had become the oxymoron of "PAMA market rates" but also opaque clinical quality standards under their exclusive control.

The UHC Reimbursement Policy

The main reason that excluding hospital-owned outpatient laboratories from PAMA pricing scheme is not simply because of how big their share of the market is but the fact that their affiliation with a hospital gives them the leverage to command higher reimbursement rates from payors. Of course, this situation is not lost on private payors.

UHC initiated its new hospital laboratory test reimbursement policy to address this disparity in pricing. In some cases, UHC was paying hospital laboratories up to 500 percent more than freestanding laboratories for the same tests, noted a UHC spokesperson. Thus, for example, a comprehensive metabolic panel costing about $10 when performed at freestanding facility cost $156 when done by a hospital outpatient facility. Blood glucose tests done by freestanding laboratories at $5 a pop cost an average of $80.

The new UHC policy is purportedly tied to care quality. It requires hospital laboratories to register as what are called Designated Diagnostic Providers (DDPs) by Feb. 28 to avoid losing their right to reimbursement when the policy officially take effect on July 1, 2021. Securing DDP status is not exactly a formality either. To qualify as a DDP, laboratories must complete a programmatic registration process and meet certain thresholds for quality and efficiency. UHC contends that the new requirements are necessary to ensure that laboratories are not overcharging. However, what is particularly irksome to laboratories is that the UHC's refuses to make its quality and efficiency criteria available for public review.

The Hospitals Fight Back

Leading the opposition to the UHC policy is the American Hospital Association (AHA). In addition to its lack of transparency, the AHA has expressed concerns about the lack of assurance that enough laboratories will qualify as DDPs for the payor to have ample numbers of laboratory

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providers in its networks to meet federal network adequacy requirements. AHA also notes that UHC plans to continue laboratories as in-network providers even if they do not qualify for DDP status. In addition to being deceptive to consumers seeking to evaluate the scope of network coverage, AHA argues that this practice may become a "new avenue" for surprise bills to the extent that patients who get tested from a laboratory listed as being in-network will not discover until after their tests are done that they will be responsible for 100 percent of the bill because the facility did not have DDP status.

In response, UHC says it intends to reach out to members to explain and ensure they understand the change and use a special icon to designate non-DDP laboratories in its provider directories. In addition, UHC will allow one-time exceptions and reprocess the claims of members that receive tests from non-DDP laboratories for the first time. The insurer also notes that the DDP policy applies only to outpatient tests and not tests performed as part of inpatient treatment.

The Conflict Escalates

On Feb. 4, the AHA raised the stakes by writing letters asking two key federal agencies to investigate UHC and bar it from implementing the new DDP policy. The AHA letter to the Centers for Medicare and Medicaid Services (CMS) calls on the agency not to allow UHC apply the policy to the plans in its jurisdiction, including Medicare Advantage, Medicaid managed care, Children's Health Insurance Program and health insurance marketplace plans. The CMS letter makes the case from the perspective of protecting patients and hospitals by pointing to its potential impact on care quality and limitation of patient treatment choices.

The AHA letter to the U.S. Federal Trade Commission (FTC) calls for action against UHC private plans in the name of consumer protection claims. It characterizes the UHC policy as "bait and switch" coverage constituting a deceptive trade practice and a form of anticompetitive conduct.

Takeaway

The current battle between the AHA and UHC over outpatient hospital laboratory test reimbursement, which is actually part of a wider conflict that also encompasses reimbursement of specialty drugs for outpatients, is notable not simply for its substance but also its dynamic. While haggling over reimbursement is as old as the healthcare market itself, the contract negotiation table has been its historic venue. What is troubling about this new episode is that it seems to represent a bid by a payor to rewrite the contract unilaterally after it has been signed and put into effect.

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This is the third time a major payor has resorted to this tactic to slash reimbursement for hospital outpatient diagnostic services. In 2017, Blues giant Anthem announced that it would no longer pay for MRIs and CT scans performed on an outpatient basis in hospitals. In 2020, Cigna imposed the same policy. In each case the payors positioned the policy as a defense against overcharges and cited how much more hospital outpatient facilities charge than freestanding facilities for imaging services. Hospitals have fought back and even gone to court. But this time they are upping the ante by taking their case directly to the regulators.

FDA WATCH

2020 Was a Record Year for New Medical Device Approvals—And Not Just for COVID-19

They say that necessity is the mother of invention. But, historically, invention has never been the problem for creators of novel medical devices; the real challenge for these inventors has been more about getting the regulatory approval necessary to bring their creations to market. And the necessity imparted by the pandemic offered unprecedented opportunity to meet that challenge with the U.S. Food and Drug Administration (FDA) authorizing a record-high number of novel medical devices in 2020.

The Emergency Use Authorization Factor

Despite a slight dip in 2019, new medical device approvals have been steadily trending upward over the past decade. Even so, what occurred in 2020 represents an aberration from previous patterns, as total FDA new medical device approvals completely crushed the previous high of 2017.

Of course, the major reason for the spike is that the 2020 totals include not just full-blown clearance but also emergency use authorization (EUA), a less rigorous pathway to approval that the FDA uses in response to public health emergencies. Although this was hardly the first time that the opening of the EUA pipeline benefited medical device makers, the COVID-19 crisis was—and remains—bigger and more urgent than any previous public health emergency to arise under the FDA's modern regulatory regime, paving the way for novel ventilators, laboratory tests, sample collection devices, personal protective equipment and other products to diagnose and treat the virus.

The Year in Device Approvals

A new article in the *New England Journal of Medicine* written by Jeff Shuren and William Maisel, respectively, the directors of the FDA's Center for Devices and Radiological Health (CDRH), and the CDRH Office of Product Evaluation and Quality documents what happened. The CDRH was stretched unusually thin during the year, the authors explain, due to a deluge of submissions coming, including both COVID-19 products coming through the EUA pathway. Shuren and Maisel said the agency Shuren and Maisel said the agency issued 625 EUAs for medical devices in 2020, including several designated as novel medical devices such as *in vitro* diagnostics for COVID-19.

Surprisingly, though, the deluge extended beyond coronavirus. The flow of submissions for non-COVID-19 products also exceeded previous years, with device makers seeking clearance via the 510(k), Breakthrough Device and De Novo pre-market approval channels, as well as the humanitarian device exemption. Non-COVID-19 novel medical devices products that the FDA cleared for the first time in 2020 included:

- The first liquid biopsy next generation-sequencing companion diagnostic test;
- The first cardiac ultrasound software using artificial intelligence to aid in capturing quality diagnostic images;
- An automated insulin delivery and monitoring system for young patients;
- An anterior cruciate ligament implant; and
- A game-based digital therapeutic to help children with attention deficit hyperactivity disorder.

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Here are some of the key new FDA EUAs and clearances announced in February:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Grifols	EUA for Procleix SARS-CoV-2 Assay
Immunodiagnostic Systems	EUA for IDS SARS-CoV-2 IgG automated chemiluminescent immunoassay
Thermo Fisher Scientific	EUA for Applied Biosystems TaqPath COVID-19, Flu A, Flu B Combo Kit
Becton Dickinson	EUA for BD SARS-CoV-2/Flu assay run on firm's BD Max platform
Bio-Rad	EUA for combined COVID-19, influenza A, and influenza B multiplex syndromic RT-PCR test

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Manufacturer(s)	Product
Roche	Breakthrough Device designation for Elecsys Growth Differentiation Factor-15 (GDF-15) test for use as companion diagnostic in patients with solid tumors for treatment with Pfizer's investigational drug PF-069446860
Roche	510(k) clearance for Cobas BKV test expanded to include use with stabilized urine samples (previously cleared for use with ethylenediaminetetraacetic acid (EDTA) plasma samples)
Visby Medical	EUA for single-use, rapid point-of-care COVID-19 PCR test
Clinomics	EUA for TrioDx RT-PCR COVID-19 Test
Princeton BioMeditech	EUA for Status COVID-19/Flu antigen test
Siemens Healthineers	510(k) clearance for Cobas Immulite, Immulite 1000, and Immulite 2000 analyzers and immunoassays for quantitative measurement of cortisol in serum
Ambry Genetics	EUA for Ambry COVID-19 RT-PCR Test

FDA News: FDA Clears Neutralizing Antibodies Detection Test for COVID-19

Innovative new COVID-19 tests continue to emerge from the pipeline. One of the novel diagnostic products that has flown slightly under the radar is the cPass SARS-CoV-2 Neutralization Antibody Detection Kit from Piscataway, NJ-based GenScript Biotech, which recently became the first commercial laboratory test using neutralizing antibodies to detect COVID-19 to gain Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA).

Neutralizing Antibodies Detection

Neutralizing antibodies prevent viruses from infecting cells, although questions remain about how long antibodies against COVID-19 actually last and how much protection from infection they actually provide. The new serology test will help researchers study the virus' neutralizing antibodies, noted Dr. Tim Stenzel, director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health.

"The ability to detect neutralizing antibodies can help us gain additional insight into what the existence of antibodies may mean for patients as we continue the fight against COVID-19," Stenzel noted in a statement. "There are still many unknowns about what the presence of SARS-CoV-2

antibodies may tell us about potential immunity, but [the GenScript cPass test] authorization gives us another tool to evaluate those antibodies as we continue to research and study this virus."

The Test

The GenScript cPass test is a blocking enzyme-linked immunosorbent assay (ELISA) designed to mimic the virus' neutralization process to detect total neutralizing antibodies to SARS-CoV-2 in human serum and plasma, with results provided in approximately one hour. The test does not require live virus, which enables it to be used in standard research or clinical diagnostic laboratories that do not have a biosafety level 3 rating.

In addition to detecting prior SARS-CoV-2 exposure and the presence of neutralizing antibodies in convalescent patients, GenScript said that the test is expected to help in the assessment of SARS-CoV-2 vaccine candidates where a standardized test that can detect neutralizing antibodies will be needed for large patient cohorts. It can also be used to screen animals for SARS-CoV-2 infection without modification.

Takeaway

The cPass test is authorized for use by any CLIA-certified laboratory to perform high-complexity tests, according to the FDA. The agency also clarified that testing positive for COVID-19 neutralizing antibodies does not necessarily mean that a patient is protected from COVID-19. So, patients and providers still need to follow public health precautions.

Genetic Testing: New Study Shows Viability of Using Ancestry to Compare Prostate Cancer Risk Across Populations

Ancestry has been shown to be a risk factor for prostate cancer. Unfortunately, we know very little about why men of certain races and ethnicities are more prone to get it, let alone how to use genetic information about ancestry to stratify risk across different populations. But according to a new report, a genetic risk score based on a multi-ancestry meta-analysis can stratify men by their risk of developing prostate cancer.

The Diagnostic Challenge

Black men in the U.S., and other men of African ancestry, are diagnosed with prostate cancer more than men of other races. By the same token, prostate cancer occurs less often in Asian-American and Hispanic/Latino men than in non-Hispanic whites. Ancestry affects not just susceptibility but the age a man is likely to get prostate cancer and whether he is likely

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to die from it. However, the reasons for these ancestry-based variants remains a mystery.

New Genetic Clues

Genome analysis may hold the key to unraveling this mystery. There are currently a total of 183 known genetic risk variants for prostate cancer. On Jan. 4, *Nature Genetics* reported that an international team of researchers had uncovered 86 more. According to the report, the team did this by performing a meta-analysis of genome-wide association studies of prostate cancer that included multiple ancestry populations. Specifically, they analyzed 107,247 prostate cancer cases and 127,006 controls from about a dozen cohorts, including:

Ancestries Included in Meta-Analysis

Populations	Cases	Controls
European	85,554	91,972
African	10,368	10,986
East Asian	8,611	18,809
Hispanic	2,714	5,239

The Findings

Combining the known 183 with the 86 they discovered, the researched used the 269 risk variants to create genetic risk scores (GRS) for prostate cancer, which they weighted based on ancestry effects. They then compared the risks of developing prostate cancer in men in the top 10 percent of GRS for each ancestry against men with average genetic risk for prostate cancer. Findings:

- Men of European ancestry had five times the risk of developing prostate cancer;
- Men of African ancestry had nearly four times the risk;
- Men of East Asian ancestry had nearly 4.5 times the risk; and
- Hispanic men had about four times the risk.

In addition, they found that the mean GRS of men of African ancestry was slightly more than two times the GRS of men of European ancestry and that men of East Asian ancestry had a mean GRS that was 0.73 times lower than that of men of European ancestry.

They also considered the impact of age on the association between GRS and prostate cancer risk, finding that men of European ancestry in the top 10 percent of GRS who are under age 55 had a 6.7 times increased risk, while men of European ancestry above age 55 had a 4.4 times higher risk.

Takeaway

While the researchers noted that there is no evidence to show that GRS can differentiate risk of aggressive prostate cancer, they also pointed out that roughly half the men with aggressive cancer were in the top 20 percent of GRS. "Genetic risk scores will soon be available for a number of diseases including prostate cancer," noted one of the researchers.

Informatics: Hologic Partners with Google Cloud to Enhance Cervical Cancer Screening

Hologic, Inc. announced on Feb. 1 that it has entered into a multi-year strategic collaboration with Google Cloud to augment the screening of cervical cancer by the integration of Google Cloud's machine learning technologies with Hologic's Genius™ Digital Diagnostics System. Hologic expects that Genius Digital Diagnostics System will derive more actionable insights from cytology slides for cytotechnologists and pathologists, as Google Cloud architecture further extends the system's capabilities. The company is promising "to transform screening and accelerate the eradication of cervical cancer across the globe."

The Collaboration

Hologic, Inc. is a medical technology company primarily focused on improving women's health and well-being through early detection and treatment. Genius Digital Diagnostics is a digital cytology platform that combines artificial intelligence (AI) with advanced digital imaging to help identify pre-cancerous lesions and cancer cells in women.

Hologic is enhancing the deep learning component of the Genius Digital Diagnostics system with Google Cloud. The expectation is that the Genius Digital Diagnostics System will derive even more actionable insights from cytology slides for cytotechnologists and pathologists. Google Cloud also provides a secure and reliable cloud data architecture to further extend the system's capabilities.

"Hologic has been at the forefront of cervical cancer screening for more than 30 years, and we are building on that legacy with this strategic collaboration," said Kevin Thornal, President of Hologic's Diagnostic Solutions Division in a press release. "Enhancing our use of AI with Google Cloud's machine learning capabilities and cloud architecture is the next natural step in this journey forward."

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The Diagnostic Challenge

Back on Jan. 20, 2020, COVID-19 coronavirus was only just beginning to transform from an Asian to global threat. Because the virus was novel, there was no proven laboratory test to diagnose it. In late February, the U.S. declared a public health emergency and the U.S. Centers for Disease Control and Prevention (CDC) secured the first ever Food and Drug Administration (FDA) emergency use authorization (EUA) for a test to detect the coronavirus. However, as we would learn later, the CDC assay was seriously flawed. And the efforts to distribute it to state laboratories and public health agencies was beset with roadblocks and administrative error.

The Trump administration policy was to assign top priority to developing new COVID-19 diagnostics and industry rose heroically to the challenge. By the end of March, more than a dozen COVID-19 tests had received EUA, including assays from Roche, Thermo Fisher Scientific, Hologic, Quidel, Abbott (two tests), Quest, DiaSorin, Cepheid, BioMérieux and Quidel. In addition to these RT PCR products, FDA loosened the rules to allow SARS-CoV-2 antibodies and antigen tests to reach the market on an expedited basis. And so they did, including many assays of dubious reliability.

But while the system succeeded in generating an adequate volume of test products, logistics, supplies and distribution proved to be the Achilles' heal. Laboratory scientific and trade associations urged the White House to take immediate and direct action to resolve the challenges; but the idea of exercising central control over the economy was anathema for an administration dedicated to cutting business regulation.

The National Strategy

In almost every aspect, the Biden National Strategy for COVID-19 testing is the diametrical opposite of the approach taken by its predecessor. Perhaps the most notable change is with regard to tone and sense of urgency. Here are the key changes with regard to substantive policy.

1. More Money for COVID-19 Testing

The first big difference between Trump and Biden is with regard to money for COVID-19 testing. The new administration's proposed $1.9 trillion American Rescue Plan includes $50 billion to expand COVID-19 testing by providing funding to purchase rapid tests, expand lab capacity and support regular testing efforts of schools and local governments.

2. Ensure Free COVID-19 Testing

The National Strategy calls for continuing the free testing policy of the previous administration but in a more direct and hands-on fashion. A

new Executive Order establishes the COVID-19 Pandemic Testing Board to oversee implementation of a clear, unified approach to testing and directs agencies to facilitate testing free of charge for those who lack health insurance and to clarify insurers' obligation to cover testing. The federal government will also provide testing protocols to inform the use of testing in congregate settings, schools, and other critical areas as well as among asymptomatic individuals. Technical assistance will support more widespread adoption of testing to improve timely diagnosis and public confidence in the safety of settings like schools.

3. Stepped Up Production of COVID-19 Tests

On Feb. 17, the White House COVID-19 Response Team announced that the administration will provide $1.6 billion to expand and improve COVID-19 testing and genomic sequencing. The CDC will invest almost $200 million to finance a threefold expansion of sequencing for the virus and its variants from 7,000 to about 25,000 samples per week. That is not as much money as some experts believe is necessary to achieve maximum COVID-19 sequencing capacity, but it is a nice start.

The sequencing initiative comes about two weeks after the Response Team announced that the administration is finalizing contracts with six undisclosed companies to increase domestic testing capability for at-home SARS-CoV-2 tests, which would lead to 61 million point-of-care or at-home tests by the end of the summer.

4. Stepped Up Production of Testing Supplies

Another cornerstone of the National Strategy is to promote production of vaccines, tests, PPE, reagents and other critical testing materials that have been in short supply. As with free testing, the most dramatic change is not in the policy but its execution, specifically the administration's willingness to invoke federal government control over industry under a law called the *Defense Production Act* (DPA). A new Executive Order directs federal agencies to exercise their DPA legal powers to get industry to accelerate the manufacturing, delivery and distribution of 12 categories of critical supplies, including:

- N95 masks, isolation gowns, nitrile gloves and other PPE;
- PCR sample collection swabs;
- Test reagents;
- Pipette tips;
- Laboratory analysis machines for PCR tests;
- High-absorbency foam swabs and nitrocellulose material for rapid antigen tests;
- Rapid test kits;
- Low dead-space needles and syringes; and

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- Necessary equipment and material to accelerate the manufacture, delivery and administration of the COVID-19 vaccine.

Meanwhile, the new Pandemic Testing Board is establishing regional coordinating centers to identify laboratory testing capacity and match it to specific areas of need. The coordinating centers will partner with laboratories, including academic and commercial laboratories, to collect specimens, perform tests and report results.

5. Fix the COVID-19 Testing Supply Chain

In addition to hitting the gas on immediate production, the National Strategy includes measures to fix the structural and systemic supplies and logistical bottlenecks that have bedeviled COVID-19 testing efforts during all phases of the public health emergency. The $1.9 trillion rescue plan provides $30 billion to the Disaster Relief Fund to help ramp up production of supplies including items like vials, reagents, and protective gear that are essential to collecting and running clinical samples. In addition, key federal agencies have been ordered to collaborate and work alongside industry to support projects to expand and improve production and distribution of PPE and testing supplies.

Takeaway

The point of this overview is not that the Biden plan is superior to the Trump COVID-19 testing strategy but that it is vastly different. An administration philosophically opposed to government regulation has been succeeded by a regime prepared to use any and every source of legal authority at its disposal to tackle the crisis. It is the same approach that Lincoln and Franklin D. Roosevelt followed to confront the national emergencies they faced upon taking office. Time will tell whether it succeeds for COVID-19.