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Special Report: The 5 Things Labs Need to Know about the Biden COVID-19 Testing Plan

Testing labs on the front lines of the COVID-19 battlefield are getting federal reinforcements. And it's not just money. The new administration is taking an entirely new line of attack that differs from the approach of its predecessor in almost every conceivable way. Perhaps the starkest contrast is with regard to urgency, with the new president unveiling his COVID-19 testing strategy on his very first day in office. Here's a quick overview of the five key elements of the Biden plan, aka, National Strategy for COVID-19 Response and Pandemic Preparedness.

1. Provide More Money

Let's start with money. The 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.

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Focus On: How the Transition from Trump to Biden Will Affect Federal Regulation and Reimbursement

"Meet the new boss. . . same as the old boss."

The Who's "Won't Get Fooled Again" is a rock classic; but as far as U.S. presidents and federal regulation are concerned, the "new boss" is almost never the same as the "old boss." The typical pattern: The outgoing administration recognizes that its opportunity to impose its political agenda is running out and generates a final spasm of new regulation; the ingoing

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2. Ensure Free COVID-19 Testing

The new administration is continuing the free testing policy of its predecessor but in a much 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 and among asymptomatic individuals. Further, technical assistance will support more widespread adoption of testing to improve timely diagnosis and public confidence in the safety of settings like schools.

3. Step 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 U.S. Centers for Disease Control and Prevention (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. It's not as much money as some experts believe is necessary to achieve maximum COVID-19 sequencing capacity, but it's 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. Step Up Production of Testing Supplies

Another cornerstone of the Biden Plan 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 the DPA and other applicable legal powers to get industry to accelerate the manufacturing, delivery and distribution of 12 categories of critical supplies, including taking action to increase the availability of supplies including:

- N95 masks, isolation gowns, nitrile gloves and other PPE;
- PCR sample collection swabs;
- Test reagents;
- Pipette tips;
- Lab analysis machines for PCR tests;

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- High-absorbency foam swabs and nitrocellulose material for rapid antigen tests;
- Rapid test kits;
- Low dead-space needles and syringes; and
- Necessary equipment and material to accelerate the manufacture, delivery, and administration of COVID-19 vaccine.

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

5. Fix the COVID-19 Testing Supplies Chain

In addition to hitting the gas on immediate production, the Biden plan 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 (See the related story below).

Takeaway

The point of this overview is not that the Biden plan is superior to the Trump COVID-19 testing strategy but that it's 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's the same approach that Lincoln and Franklin D. Roosevelt followed to confront the national emergencies they faced. Only time will tell whether it works for COVID-19.

Pandemic Logistics: Federal Agencies Reach Out to Manufacturers to Ramp Up COVID-19 Testing Supply Chain

Supply chain and logistics have bedeviled COVID-19 testing efforts on a national basis since the pandemic began. On Feb. 5, the federal government took steps to address the supply chain challenge via collaboration of key agencies. The first move: publication of an Area of Interest (AoI) notice

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soliciting proposals for the funding of projects designed to streamline, expand and scale the manufacture and distribution of diagnostic testing equipment and personal protective equipment (PPE).

The Federal Collaboration

Four federal government agencies with direct ties to the diagnostics supply chain are participating in the new initiative, including:

- The Department of Health and Human Services (HHS) (Office of the Assistant Secretary (OASH));
- The Biomedical Advanced Research and Development Authority (BARDA);
- The National Institute of Health (NIH) Rapid Acquisition of Diagnostics (RADx)); and
- The U.S. Air Force (USAF).

The mission of the collaboration is to understand and improve the diagnostics industry's capability "to rapidly mature and scale specific manufacturing capabilities within the diagnostic testing supply chain."

The AoI solicitation targets different stakeholders in the testing supply chain, such as sample collection and consumables makers, suppliers of raw materials and components, and developers of equipment, asking them to propose projects to expand manufacturing capacity and/or increase test throughput. Projects eligible for federal funding encompass a wide scope of products, including raw materials, resources, components and equipment for the production of analyzers, reagents, test kits and other preanalytical, analytical and post-analytical diagnostic materials for COVID-19 testing.

Who and How to Respond to the AoI

The AoI also provides general response guidelines and procedures. The agencies are seeking proposals from vendors that have developed or are developing products relevant to COVID-19 diagnostic tests, but also have potential for future use in diagnostics related to other pathogens and testing requirements, such as blood product testing. The supply chain products must also support *in vitro* diagnostics that have or are expected to receive Emergency Use Authorization (EUA) from the FDA by March 31, 2021.

Submissions should provide line of site from their manufactured items to the COVID-19 diagnostic activity they support or are integrated with. Although respondents don't necessarily have to be U.S.-based companies, all expansion of manufacturing efforts supported by the AoI must be carried out within the U.S. and/or U.S. territories.

The agencies will accept proposals until March 7, 2021, with evaluations expected to have begun within 48 hours of the posting of the AoI.

Interested companies should submit cost estimates with their proposals, and a USAF contracting team will respond to questions from developers directed to a dedicated email address. All questions concerning the AoI must be sent to the following email: supplychain.cso.dafact@afwerx.af.mil

FDA WATCH

FDA Clears the Way for Over-the-Counter Sale of COVID-19 Home Test Kits

Since the pandemic began, the FDA has granted Emergency Use Authorization (EUA) for more than 250 COVID-19 diagnostic tests. Among these, nearly 30 have received clearance for at-home collection; a couple have also been cleared for all-in-one use obviating the need for a lab at all. And recently, the FDA crossed a new boundary by clearing an all-in-one testing product that can be sold over the counter (OTC) without a prescription.

The Breakthrough

The breakthrough came on Nov. 17 when the FDA granted EUA to the Ellume COVID-19 Home Test, 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's 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's the first and, so far, only such kit cleared for OTC. 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. After the sample is analyzed, results are delivered to the user's smartphone via Bluetooth in 15 minutes or less.

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

Health Reform: Will Transition to a New Administration Be Enough to Save the ACA?

The *Affordable Care Act* (ACA, aka Obamacare) has gained a powerful new ally in its bid to stave off legal extinction at the hands of the Supreme Court: the U.S. Department of Justice (DOJ). On Feb. 10, the DOJ sent a letter to the Court declaring that the government had "reconsidered" its position on the law's constitutionality. The letter also urges the Justices to leave the rest of the ACA standing even if they find the individual mandate requiring individuals to obtain health insurance unconstitutional.

The Legal Case against the ACA

The politically-infused court battle over the ACA's constitutionality has been taking place since the statute's enactment in 2010. The Supreme Court seemingly settled the issue once and for all in 2012 by upholding the law in a case called *NFIB v. Sebelius*. But after capturing all three branches of the federal government in 2016, the Republicans decided to make one more run at the law. The actual case came from the states level with 20 GOP governors leading the charge. renewed appeared to be the decisive blow was struck in, the U.S. Supreme Court in found Obamacare's individual mandate constitutional. When Republicans got hold of all three branches of the Federal government, however, they zeroed out the individual mandate penalty. After that, 20 Republican state attorneys general and governors challenged the law's constitutionality again.

Republicans also had new legal ammunition. That's because the basis of the *Sebelius* ruling was that the ACA represented a constitutional exercise of Congress' right to tax. But in Dec. 20, 2017, Congress enacted the *Tax*

Cuts and Jobs Act establishing a $0 mandate penalty. The plaintiffs in the new case contend that a $0 penalty is *not* a tax and thus no longer supportable as an exercise of Congressional taxing powers. And since the individual mandate isn't severable from the rest of the ACA, they asked the federal court to strike down the entire law.

The case ping ponged around the Texas federal courts, with the district court siding with the Republicans, only to be rebuffed by the Fifth Circuit's order to go back to the drawing table. All the while, insurers, the health markets and especially individuals who depend on the ACA for health coverage twisted in the wind. So, in response to urgent pleas, the Supreme Court made the unusual decision to rule on the case without waiting for a final judgment from the lower courts.

Elections Have Consequences

When the Supreme Court heard oral arguments on the latest court challenge to the ACA back in November, the DOJ took the position that the entire law was unconstitutional and needed to be struck down. Of course, a lot has changed since then, most notably the management of the DOJ, whose boss was a part of the Obama administration that championed the enactment of the ACA.

Although the Biden DOJ can't end the case, it can and is determined to influence its outcome. With that in mind, new Deputy Solicitor General Edwin Kneedler sent the Justices a letter in early February arguing that "rather than imposing a new burden on covered individuals, the [individual mandate] preserved the choice between lawful options and simply eliminated any financial or negative legal consequence from choosing not to enroll in health coverage. Kneedler didn't request new oral arguments or additional briefing from the state attorneys general.

Takeaway

So, what happens next? As it was back in November, the answer is "we don't know." For what it's worth, Court watchers that observed the November oral hearings came away with the impression that all nine Justices appeared to be highly skeptical of the legal arguments for striking down the entire ACA. But predicting how Justices will rule on a case based on their line of questioning during oral hearings is anything but an exact science.

While not totally insignificant, the transition of the DOJ from Republican to Democratic leadership will likely have little effect on the ultimate ruling. Of greater potential significance is Democratic control over the White House and both houses of Congress, which provides a window for adopting new legislation in the event that the Court does find the entire ACA unconstitutional. Whether a new healthcare plan is a realistic sustainable resolution remains an unknown and perhaps ultimately moot issue.

Enforcement Alert: OIG to Audit Medicare Part B Lab Testing During the Pandemic

Fraudulent and abusive billing of lab services has long been a favorite target of OIG enforcers. And with the unprecedented surge of COVID-19 testing during the public health emergency, it's hardly surprising that the agency would once more turn its attention to labs. Accordingly, audits of Medicare Part B lab services during the pandemic are among the new items the OIG added to its Work Plan in February.

OIG Oversight of COVID-19 Testing

This isn't the first time that the OIG has incorporated review of COVID-19 testing into its Work Plan. Last July, the agency announced plans to look into potential abuses of add-on tests, e.g., to confirm or rule a diagnosis other than COVID-19. In the Work Plan item, the OIG agency said it had "program integrity concerns" related to add-on tests in conjunction with COVID-19, particularly the potential of fraudulent billing for associated respiratory pathogen panel (RPP) tests, allergy tests or genetic tests.

Adding to the concern, the OIG explained, was the decision of CMS to temporarily relax the rules requiring an order from the treating physician

or nonphysician practitioner (NPP) for COVID-19 tests during the public health emergency. Relaxation of physician ordering/NPP rules gives "unscrupulous actors more leeway for fraudulent billing of unnecessary add-on testing," the OIG warned. As of February, the agency has yet to release its report on the add-on testing audit.

The New OIG Initiative

However, the OIG audit item in the February 2021 Work Plan is a bit different from previous initiatives. The agency's normal inclination is to question whether commonly billed lab tests are really necessary; but this time, the OIG is wondering why more tests *are not* being performed—specifically, tests for conditions other than COVID-19. The "number of non-COVID-19 tests billed for Medicare Part B beneficiaries during the COVID-19 pandemic has decreased compared to the six-month period before the pandemic," the OIG notes. The agency also expresses a seldom seen sympathy for labs by acknowledging that "many independent labs have encountered challenges in providing COVID-19 testing."

As a result, the OIG says it will audit utilization of Medicare Part B lab services during the pand emic focusing initially on non-COVID-19 testing. Of course, the Work Plan item adds, the agency will also look into "aberrant billing of COVID-19 testing during the pandemic."

Takeaway

It was only a matter of time before the OIG took a good hard look into lab testing during the pandemic. But this latest audit initiative is different in tone and scope. While rooting out the bad apples is always will be the objective—including with regard to the still pending July Work Plan item targeting add-on tests for COVID-19 test subjects—this time it sounds like the OIG's primary motivation is genuine concern for and eagerness to assist testing labs in their efforts to survive pandemic struggles.

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administration then reviews and in, many cases, revises or cancels those midnight regulations, not only because of its policy differences but also due to the fact that these regulations are typically rushed into effect without following the required notice and comment procedures.

And that's exactly how things are playing out on the healthcare front under the Biden administration. On its very first day in office, the "new boss" issued an Executive Order imposing a freeze on any last-minute

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regulations finalized by the "old boss" pending further review. Here's a rundown of what for labs are four key midnight regulatory initiatives affected by the Biden freeze.

1. Easing of Payor Pre-Authorization Requirements

Initiative: On Jan. 15, CMS issued a final rule requiring Medicaid, the Children's Health Insurance Plan, Qualified Health Plans and other federal plans (but not Medicare Advantage plans) 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; and
- Issue prior authorization decisions on urgent requests within 72 hours and non-urgent requests within seven calendar days; and
- Provide a specific reason for any denials.

Status: CMS hasn't announced any decisions or timetables. However, it has quietly removed the final rule and associated press releases touting its virtues from its website. In addition to sending a negative signal, the removal of the publication will delay the final rule's effective date if the administration were to finalize it.

2. No Penalties for Violating Guidance Documents

Initiative: On Jan. 12, HHS finalized a rule banning the department from imposing penalties on individuals and organizations for failing to comply with a standard or practice that are set forth in a guidance document rather than an official rule or regulation. The rule also requires HHS to follow extensive new procedural rules to carry out civil enforcement actions for potential violations. The rule was purported to take effect immediately.

Status: A rule intended to advance the Trump agenda of cutting regulation and red tape doesn't seem likely to survive under Biden. In ordering the freeze, the new president went out of his way to stress that the administration's policy is "to use available tools to confront" and revoke "harmful policies and directives that threaten to frustrate" the federal government's ability to confront the nation's "urgent challenges." So, while no decisions have yet been made, this rule seems destined for the circular bin.

3. Medicare Coverage of Breakthrough Devices

Initiative: CMS issued a final rule on Jan. 12 providing for Medicare to cover medical devices that receive "breakthrough" authorization from the FDA for four years, with the potential to make coverage permanent based on clinical evidence and health outcomes among Medicare beneficiaries.

The rule, which addresses concerns that the existing Medicare coverage process is too slow and thereby denies beneficiaries access to cutting edge medical technology, was slated to take effect March 15.

Status: It's hard to predict what the administration will do with this rule, which is just as popular with the device industry as it is loathsome to the insurance industry and patient safety groups. The one thing that is sure is that if the rule does go into effect, it won't be on March 15.

4. Official Medicare Coverage Definition of "Reasonable and Necessary"

Initiative: The Trump regulatory change with arguably the widest and most direct impact on labs is the Jan. 14 final rule establishing a definitive definition for CMS to use to determine whether a service or item is "reasonable and necessary" for purposes of Medicare coverage. While it has long been the standard for coverage, the "reasonable and necessary" rule comes not from official regulation but the Medicare Program Integrity Manual. Under the final rule, a service or item would be deemed reasonable and necessary if it's considered:

- Safe and effective;
- Not experimental and investigational;
- Appropriate for Medicare patients to the extent it's: A. Furnished in accordance with accepted medical standards for diagnosis and treatment; B. Furnished in an appropriate setting; C. Ordered and provided by qualified personnel; D. Meets, but doesn't exceed, the patient's medical need; E. Is at least as beneficial as an existing and available medically appropriate alternative; or. F. Meets criteria to be created by CMS later measuring utilization and coverage of the service or item by commercial insurers.

The new rule was supposed to take effect on March 15.

Status: This one is perhaps the hardest to predict. Totally scuttling the rule might prove unwise given that the healthcare industry has been calling on CMS to adopt a clear and official definition of "reasonable and necessary" for 50 years. However, there are also concerns that the definition in the final rule departs from that of the proposed rule. Moreover, the final rule is a work in progress that will require sub-regulations to flesh out the criteria for commercial insurance coverage comparison (part F. of the bullet listed above). At the end of the day, there's a good chance that the administration will build on and tweak the work of its predecessor. But when and if a final definition does emerge, it will certainly take effect much later than March 15, 2021.

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Other Midnight Trump Regulations on the Chopping Block

Here are some of the other controversial healthcare regulations that were finalized in the last days of the previous administration that have been put on hold as a result of the Jan. 20, 2021 Biden Executive Order:

Medicare Part D Drug Rebates: A controversial rule that would replace the current system of basing rebates on a drug's list price with fixed administrative fees in a bid to cut drug prices and pharmacy benefit managers' profits;

Cuts in 340B Drug Discounts: Finalized in December, the rule would require community health centers to pass 340B drug discounts through to their patients;

Oversight of Accrediting Organizations: A rule designed to root out potential conflicts of interest among accrediting organizations that also offer consulting services to clients.

Medicare Outpatient Drug Prices: Defying a federal court ruling, the administration planned to go through with a pilot program to tie Medicare outpatient drug prices to how much foreign countries charge for the particular products.

Coverage of Dialysis Treatments: The rule would have required dialysis centers to tell patients about their coverage options and premium assistance programs.

Medicare Part A Coverage of Social Security Recipients: The administration wanted to change the current rule under which persons age 65 or older automatically apply for Part A coverage when they collect Social Security benefits to allow recipients of retirement benefits to decline Part A coverage.

Price Transparency for Insurers: The flip-side of the hospital transparency rule that would require health insurers and self-insured plans to disclose their in-network and out-of-networks to enable consumers to make better informed choices.

Green Light for Value-Based Drug Pricing: CMS gutted regulations banning private insurers, state Medicaid programs and prescription drug manufacturers from creating value-based payment arrangements tied to clinical outcomes.

Medicare Advantage Payments: CMS' new Medicare Advantage pay rates included a controversial new payment methodology for adjusting plan payments based on encounter data.

Privatization of ACA Exchanges: In the final days of the administration, CMS issued a rule to increase competition in Affordable Care Exchanges by allowing states to waive certain requirements for their exchanges via Section 1332 waivers and authorize web-based brokers to sell plans.