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Top of the News: What a Biden Administration Might Portend for Regulation of Laboratory Developed Tests

The roller coaster that has become FDA regulation of laboratory developed tests (LDTs) is about to get even more topsy-turvy now that **Joseph Biden** has been elected President of the United States. Here's a look at where things stand and what we might expect from the Biden administration.

FDA Review of LDTs

One of the new administration's first orders of business will be to ensure a robust pipeline of COVID-19 molecular, antibody and antigen tests. To accomplish that objective, the Biden FDA will likely consider the reversing the controversial LDT policy changes recently announced by the Trump administration. In August, HHS announced that the FDA would no longer require premarket review for LDTs but that labs could still voluntarily seek approval, clearance or emergency use authorization (EUA). But in October, the FDA pulled the rug out by announcing that it would no longer

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Enforcement Trends: Feds Bust Labs for Telemedicine Testing Scams

So much for the pandemic's dulling the momentum of federal fraud enforcement. Dubbed "Operation Rubber Stamp," the new nationwide enforcement action revealed by the Department of Justice (DOJ) on Sept. 30 is the largest "takedown" in Department history involving 51 federal districts, 345 defendants, including over 100 doctors, nurses and other licensed medical professionals, and $6 billion in false claims. And, while not necessarily the primary target, medical labs have been pulled in to the "Rubber Stamp" dragnet.

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What a Biden Administration Might Portend for Regulation of Laboratory Developed Tests, *from page 1*

perform EUA review of COVID-19 LDTs so that it could concentrate its resources on "innovative" new tests in the interests of public health.

The announcement came as a stunner, particularly since many of the most innovative new COVID-19 tests were LDTs from companies like Abbott and LabCorp. And it's not just COVID-19. The policy shift reversing the FDA's long-established approach applies to all LDTs, including badly needed cancer tests. So, it would not be shocking at all if the Biden administration reverses these policy changes and restores the pre-August status quo.

Legislative Reform

A divided Congress and semi-toxic partisan political environment will make it very difficult to enact new healthcare legislation. However, President-elect Biden was Vice President for an administration that did make an active attempt to modernize and reform the LDT regulatory system. Although the lab industry was far from enamored of them, the proposals put forward by the Obama FDA advanced the debate and provided impetus to legislative reform.

In early March, legislators in the House and Senate introduced a bill for regulating in vitro clinical tests (IVCT) called the *Verifying Accurate Leading-edge IVCT Development Act* (VALID) that 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. Key provisions:

- 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.

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Prospects for Change

The fact that VALID has bi-partisan support makes it a viable framework for legislative reform of LDTs regulation, if the will to enact such legislation it exists. But at least from a lab industry perspective, it needs a lot of fine tuning. In its initial response to VALID, the American Clinical Laboratory Association expressed support for reform legislation and outlined three principle priorities:

- Reform that recognizes diagnostics as separate and distinct services from medical devices, and that also distinguishes between LDTs and in vitro devices;
- 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.

Takeaway

The inauguration of a new president is generally a cause for optimism and an opportunity to bring new energy to tackle old healthcare challenges, especially during times of pandemic. And while LDTs aren't on the top of its agenda, they will no doubt command significant attention during the early days of the Biden administration. The most immediate action could be the rollback of the recent FDA premarket regulatory policy changes. The long-term efforts to reform the system are also likely to continue, both on the regulatory and legislative fronts.

Business Trends: Labs Partner with Airlines to Offer COVID-19 Testing to Travelers

COVID-19 has greatly complicated air travel from country to country and even state to state. While entrance rules vary from place to place, a number of jurisdictions are allowing travelers to avoid quarantine and self-isolation if they can prove they tested negative for the virus. As a result, some airlines have teamed with lab companies to offer customers with travel plans the chance to be tested before their flights. And now one airline has taken the model to the next level by providing, at-home saliva-based testing.

The JetBlue Collaboration with Vault Health

On Sept. 30, JetBlue announced that it has teamed with Vault Health, a men's healthcare technology platform offering in-home and personalized treatments, to provide COVID-19 testing for travelers. While it's hardly

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Labs Partner with Airlines to Offer COVID-19 Testing to Travelers, *from page 3*

the first such deal, the partnership is something of a game changer to the extent that the Vault Health test is a RT-PCR test run by the Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics using technology that has received Emergency Use Authorization (EUA) from the FDA for use on saliva samples collected at home.

The way it works: Customers go to Vault Health's dedicated landing page and enter their JetBlue confirmation code to start the process and also receive a discount on the test. After receiving test materials by overnight mail, they collect their own saliva samples from home while a Vault Health supervisor looks on by Zoom video to ensure everything is done properly. The sample is then sent overnight to a lab, with results provided in 72 hours or less. There are no swabs or need for in-person interaction. The test, a modified version of a Thermo Fisher Scientific assay that received EUA in April, is highly accurate and capable of detecting fewer than 10 copies of SARS-CoV-2 genes per milliliter of saliva, according to Vault Health.

"We are so happy to be able to provide JetBlue customers peace of mind during their travels," said Vault Health founder and CEO **Jason Feldman** in a statement. "This saliva test is one of the most reliable and accurate COVID tests available in the country with fast turnaround time to results."

Other Airline-Lab COVID-19 Testing Arrangements

Other airlines offering COVID-19 testing to travellers seeking to avoid quarantine and self-isolation include:

United Airlines was the first to offer testing. But while the airline plans to expand the program to other airports, testing is currently limited to customers traveling form San Francisco International Airport to Hawaii. There are two test options:

- A $250 rapid Abbott ID NOW COVID-19 test performed by GoHealth Urgent Care at San Francisco International Airport on the day of travel; or
- An $80 mail-in test administered by Color that travelers must complete 72 hours before travel.

American Airlines has partnered with CareNow. The test options:

- A $150 in-person testing at designated CareNow urgent care locations, which are open every day and after-hours; or
- A $249 on-site rapid testing on the day of the flight administered by CareNow at DFW (Dallas Fort Worth) International Airport with results expected in 15 minutes on average.

American has also entered a partnership with a second provider, LetsGetChecked, which allow passengers to order tests before flying from

five locations, three of which are in Hawaii (cost: $129) and two in Costa Rica (cost $109).

Hawaiian Airlines has tabbed Worksite Labs to offer testing at labs near Los Angeles and San Francisco International airports, with more locations to come. Cost: $150 for day-of travel express service and $90 for results within 36 hours.

Alaska Airlines has partnered with Carbon Health to offer passengers in Seattle who are traveling to Hawaii testing at a downtown pop-up clinic that promises test results within two hours at the cost of $135.

Medicare FFS: CMS Says Improper Medicare Fee-for-Service Payments Are Down $15 Billion Since 2016

CMS is claiming that its "aggressive corrective actions" have saved taxpayers over $15 billion in improper Medicare Fee-For-Service (FFS) payments over the past four years. According to the Nov. 16 report, the FFS improper payment rate has significantly declined under the Trump administration and has been below 10 percent for four straight years since 2016.

Home Health and SNF Initiatives Drive Savings

According to the CMS report, the FY 2020 Medicare FFS improper payment rate was 6.27 percent, representing $25.74 billion in improper payments, as compared to a rate of 7.25 percent accounting for $28.91 billion improper payments in FY 2019, and marking the fourth straight year the rate has been below the 10 percent threshold mandated by the *Payment Integrity Information Act of 2019*. CMS cites progress in the following areas as the principle driver of this year's decline in Parts A and Part B:

- **Home health improvements:** Initiatives to clarify documentation requirements and educating providers via the Targeted Probe and Educate program resulted in a $5.9 billion decrease in estimated improper payments from FY 2016 to FY 2020; and
- **Skilled nursing facility claims:** A policy change related to the supporting information for physician certification and recertification for skilled nursing facility services helped drive a $1 billion reduction in estimated improper payments in the last year.

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CMS Says Improper Medicare Fee-for-Service Payments Are Down $15 Billion Since 2016, *from page 5*

CMS Pats Itself on the Back

The CMS report isn't shy about claiming credit for these positive developments, saying they were the result of the agency's "steadfast efforts to identify the root causes of improper payments, implement action plans to reduce and prevent improper payments, and extend the Agency's capacity to address emerging areas of risk through work groups and interagency collaborations."

The CMS Strategy

To be fair, it's not just bluster. As the report notes, CMS has developed a five-pillar strategy to reduce the FFS improper payment rate:

1. Stop the Bad Guys

CMS works with law enforcement agencies to crack down on "bad actors" who have defrauded federal health programs.

2. Prevent Fraud Before It Happens

Rather than the expensive and inefficient "pay and chase" model, CMS prevents and eliminates fraud, waste and abuse on the front end by proactively strengthening vulnerabilities before they're exploited.

3. Mitigate Emerging Programmatic Risks

CMS is exploring ways to identify and reduce program integrity risks related to value-based payment programs by looking to experts in the healthcare community for lessons learned and best practices.

4. Emphasize the Carrot Over the Stick

To assist rather than punish providers who make good faith claim errors, CMS is reducing burden on providers by making coverage and payment rules more easily accessible to them, educating them on CMS programs, and reducing duplicative or unnecessary documentation requirements.

5. Leverage New Technology

CMS is working to modernize its program integrity efforts by exploring innovative technologies like artificial intelligence and machine learning, which could allow the Medicare program to review compliance on more claims with less burden on providers and less cost to taxpayers.

COVID-19: CDC Knowingly Shipped Flawed COVID-19 Test Kits to Public Labs in Early Days of Crisis, Says Report

Early missteps characterized the federal government's initial efforts to ensure a supply of reliable COVID-19 diagnostic tests in response to the public health emergency. And now a new National Public Radio (NPR) report contends that the U.S. Centers for Disease Control and Prevention (CDC) deliberately sent test kits to public labs despite knowing that they were apt to fail to 33 percent of the time.

The CDC's Decision

The Nov. 6 report's conclusion is based on a "root-cause analysis" internal review that the CDC conducted to understand why its early RT PCR coronavirus test didn't work properly, costing scientists precious weeks in the early days of a pandemic.

The CDC test, the first to receive FDA emergency use authorization for COVID-19, was designed and built in record time. According to NPR, the tests were all boxed up and ready to go on Feb. 6 when a scientist in an infectious disease lab on the CDC's Atlanta campus discovered the high failure rate while putting the test kit through its final paces.

Normally, a failure rate of that magnitude would have precluded releasing the test. But the CDC apparently caved to the intense pressure and proceeded to distribute the test to about 100 public labs across the country, including the New York City Public Health Laboratory.

Problems with the CDC Lab

The CDC's deliberate decision to release a flawed test kit wasn't the only thing the root-cause analysis uncovered. The reviewers also determined that the CDC's Respiratory Viruses Diagnostic Laboratory was beset with problems, including "process failures, a lack of appropriate recognized laboratory quality standards, and organizational problems related to the support and management of a laboratory supporting an outbreak response."

The problems with the Respiratory Viruses Diagnostic Laboratory were reported last month by ProPublica. NPR's story is the first time the CDC internal review's findings have been made public. The CDC declined to discuss the review with NPR.

Takeaway

The decision of the CDC to rush an unproven if not faulty COVID-19 test kit to public labs in response to enormous public pressure is a cautionary tale that the agency and other scientific authorities will have to bear in mind when releasing a vaccine for the virus.

Enforcement Scorecard: The HIPAA Information Access Rights Crackdown Continues

The face of federal HIPAA enforcement has changed in a subtle but significant way in the past 18 months. Historically, the focus has been all about keeping personal health information (PHI) private and secure. But now enforcement has broadened to include the part of the HIPAA Privacy Rule that requires labs and other providers to provide persons timely access to their PHI at a reasonable cost. As of September 2019, no provider had ever been fined for failing to meet their PHI access responsibilities. As of press time, nearly a dozen such fines have been imposed. And those numbers are growing literally every week. Here's the latest rundown of settlements.

OCR Right of Access Initiative Settlements Scorecard

Provider	Settlement Amount*	Allegations
St. Joseph's Hospital and Medical Center	$160,000	Phoenix hospital refused to provide PHI to patient's mother even though she was his legal representative
NY Spine Medicine	$100,000	Neurology practice refuses patient's multiple requests for copies of specific diagnostic films
Bayfront Hospital	$85,000	Florida hospital didn't provide expectant mother timely access to the PHI of her unborn child
Korunda Medical	$85,000	After first refusing to provide it at all, Florida primary care and interventional pain management services provider sent patient's PHI to third party in the wrong format and charged him excessive fees
Beth Israel Lahey Health Behavioral Services	$70,000	Massachusetts provider ignored request of personal representative seeking access to her father's PHI
Housing Works Inc.	$38,000	New York City non-profit services provider refused patient's request for a copy of his medical records
Riverside Psychiatric Medical Group	$25,000	California medical group didn't provide patient copy of her medical records despite repeated requests and OCR intervention
Dr. Rajendra Bhayani	$15,000	NY physician didn't provide patient her medical records even after OCR intervened and closed the complaint

Provider	Settlement Amount*	Allegations
All Inclusive Medical Services, Inc.	$15,000	California multi-specialty family medicine clinic refused patient's requests to inspect and receive a copy of her records
Wise Psychiatry, PC	$10,000	Colorado psychiatric firm refused to provide personal representative access to his minor son's medical record
King MD	$3,500	Virginia psychiatric practice didn't provide patient access to her medical records even after OCR intervened, provided technical assistance and closed the complaint

* In addition to the monetary settlement, each accused provider had to agree to implement a corrective action plan and allow the OCR to conduct close monitoring for one to two years.

Whistleblowers: Lab that Ignores Employee's Billing Concerns Settles FCA Case for $43 Million

One of the costliest *False Claims Act* settlements involving lab tests in recent years is still one more cautionary tale of how dismissing the reports of lab employees who come forward to express internal compliance concerns can fester into a devastating whistleblower lawsuit.

The Whistle Blows

The concerned-employee-turned-whistleblower in this case was the board-certified physician hired by North Carolina-based Genova Diagnostics as Chief Medical Order tasked with responsibility to develop medical necessity evidence for IgG allergen, NutrEval and GI Effects, three of the firm's unconventional test profiles. Over time, he realized that there was no such evidence and advised the lab not to bill Medicare, TRICARE and private insurers for the tests.

The Lab Plugs Its Ears

He claims that Genova dismissed his concerns as "overly conservative," and then cut his department's budget, before excluding him from management meetings and eventually firing him over what he contended were trumped up employment misconduct charges. So, the whistleblower

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Lab that Ignores Employee's Billing Concerns Settles FCA Case for $43 Million, *from page 9*

took his case to federal court [*United States ex rel. Darryl Landis, M.D. v. Genova Diagnostics, Inc., et al.*, No. 1:17-cv-341 (W.D.N.C.)].

The Feds Get Involved

The DOJ entered the scene, charging Genova with falsely billing for IgG allergen, NutrEval and GI Effects tests, citing the lack of published, peer-reviewed or high-quality clinical studies demonstrating the effectiveness of the tests. And since the tests weren't scientifically proven effective at diagnosing any medical conditions, they weren't deemed medically necessary under Medicare coverage rules. The DOJ also accused Genova of falsely coding the tests and paying compensation to phlebotomy vendors in violation of the Stark Law.

The Price of Settlement

After doing its own internal assessment, Genova concluded that it had done nothing wrong. But facing the risk of litigation and prosecution, it decided that discretion was the better part of valor and settled the case. The price tag could run as high as $43 million, including:

- Over $17 million in Medicare and TRICARE payments forfeited; and
- Additional penalties of13% of any net annual revenue above $100 million and 20% of any asset sales over $1 million over the next five years, subject to a $26 million cap.

The whistleblower stands to collect up to $6.5 million of this award.

Enforcement Trends: Feds Bust Labs for Telemedicine Testing Scams, *from page 1*

The Takedown Target

Of the $6 billion in false and federal claims submitted to federal health care programs and private insurers involved in Operation Rubber Stamp, $4.5 billion is connected to telemedicine. And that makes perfect sense. Long touted as the future of health care, telemedicine utilization has taken off during the public health emergency by enabling care to continue without breaching the walls of social distancing. Public and private payors immediately recognized this and have temporarily expanded coverage of telemedicine services, with the expectation that coverage will become permanent before too long.

But as other segments of the health care industry can attest, with profit and payment comes scrutiny. While it may be the biggest, Operation Rubber Stamp isn't the first major federal enforcement action targeting

telemedicine. For example, in April 2019, the DOJ announced the indictments of 24 individuals and telemedicine companies for allegedly accepting kickbacks from durable medical equipment (DME) suppliers and using telemedicine visits to persuade Medicare beneficiaries to accept DME that wasn't medically necessary. Similar charges were filed against other telemedicine providers in August 2019.

As Operation Rubber Stamp reveals, federal and state health care law enforcement has been stepping up the scrutiny of telemedicine since very early in the COVID-19 public health emergency.

Telemedicine Fraud and Lab Services

Nor is Operation Rubber Stamp the first time that telemedicine abuse has been connected to ordering of lab tests. One notable case concluded on Jan. 10, 2020, when the owner of two genetic testing labs in Pennsylvania pleaded guilty to conspiring with the operator of a Florida-based telemedicine company to carry out schemes to submit false claims to Medicare for cancer genomic testing (CGx) and pharmacogenetic testing (PGx). The labs paid the operator kickback fees based on the percentage of Medicare reimbursement to obtain CGx and PGx prescriptions from physicians who were contracted by the telemedicine company to review the beneficiaries' personal and familial medical histories. According to the DOJ, the contract physicians authorized testing for greater than 95% of beneficiaries even though they didn't conduct a proper telemedicine visit, weren't treating the beneficiaries for cancer or cancer symptoms, didn't use the test results for treatment of the beneficiaries, and generally weren't qualified to understand and interpret the test results.

Not surprisingly, many of the defendants in Operation Rubber Stamp are labs and telemedicine operators charged with paying kickbacks to doctors to order medically unnecessary tests for patients with whom they never actually had televisits.

The Other Targets of "Rubber Stamp"

Although 75% of the ill-gotten gains came from telemedicine abuses, Operation Rubber Stamp also targeted two other forms of more traditional fraudulent activity:

Illegal Opioids Distribution and Prescription

The takedown resulted in charges against 240 defendants for allegedly participating in illegal schemes to prescribe and distribute more than 30 million doses of opioids resulting in over $800 million in false claims. In addition to billing for services that weren't medically necessary or actually provided, in many cases, patient recruiters, beneficiaries and others received cash kickbacks in return for providing beneficiary information to providers, which the providers then used to submit fraudulent claims to

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Enforcement Trends: Feds Bust Labs for Telemedicine Testing Scams, *from page 11*

Medicare. Urine and other drug testing labs were named as defendants in a number of these cases.

"Sober Homes" Abuses

More than a dozen criminal defendants were also charged in connection with more than $845 million of allegedly false and fraudulent claims for tests and treatments for vulnerable patients seeking treatment for drug and/or alcohol addiction. Prosecutors contend that physicians, labs, owners and operators of substance abuse treatment facilities and patient recruiters, aka "body brokers" participated in schemes involving the payment of illegal kickbacks for referring patients to substance abuse treatment facilities, where they were prescribed medically unnecessary opioids and subjected to medically unnecessary drug testing. In many cases, payors were billed thousands of dollars for a single test. The patients were then often discharged and admitted to other treatment facilities, or referred to other labs and clinics, in exchange for further kickbacks.

Takeaway

Health care fraud is huge business even in the midst of a global pandemic. Thus, while utilization of routine and non-COVID medical treatment has slowed down, fraudsters have effectively pivoted their business models to take advantage of the newly expanded telemedicine and coverage rules adopted in response to the public health emergency. Operation Rubber Stamp makes it clear that the enforcers are onto the scammers and determined to bring them to justice. It also represents continuation of pre-pandemic patterns of massive joint federal-state takedown campaigns targeting specific forms of fraud. Rubber Stamp is the biggest takedown so far. But don't be surprised if that distinction ends by an even bigger campaign in the months or even weeks ahead.

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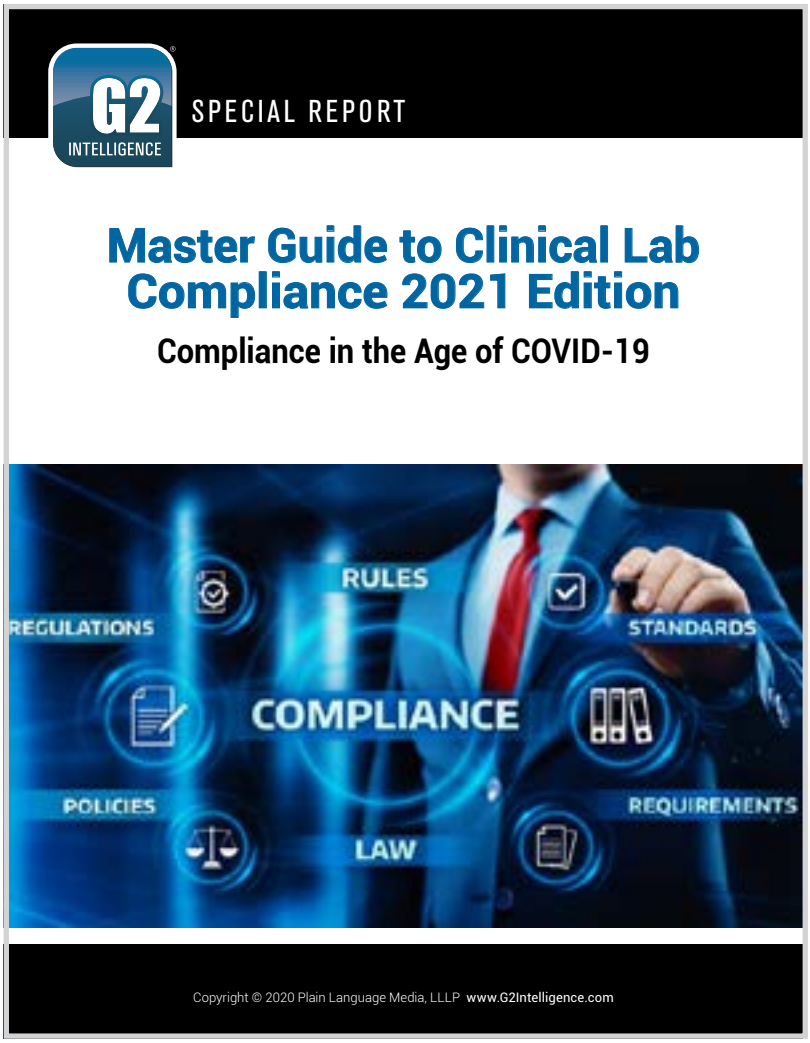
Compliance in the Age of COVID-19



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