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NATIONAL LAB REPORTER™

Formerly: National Intelligence Report

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 42nd Year of Publication

Vol. 21, Iss. 4, April 2021

IN THIS ISSUE

Health Care Reform: New COVID-19 Relief Law Aims to Ease the Health Insurance Crisis

Even by U.S. government standards, $1.9 trillion is a lot of money. But that's the money value of the COVID-19 relief under the *American Rescue Plan Act* of 2021 (ARPA) signed by President Biden on March 12. ARPA is an ambitious law that tackles the nation's economic, healthcare, insurance and other challenges across a broad front. Key elements include:

- $1,400 stimulus checks for most adults and their dependents;
- $300-per-week unemployment supplements;
- Increased child tax credits; and
- Money for vaccination programs, state and local governments and schools.

The aspect of ARPA of particular significance for labs and other providers are its measures to address the nation's health insurance crisis. Here's an overview.

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Kickbacks: Federal Court Upholds $114.1 Million Judgment against Principles of HDL and Singulex Scam

The Health Diagnostics Laboratory, Inc. (HDL) and Singulex kickback saga continues. In recent years, most of the action has been centered not so much on the labs themselves but on others involved in the scheme, including BlueWave Healthcare Consultants, their marketing firm and the downstream physicians to whom the labs directed their kickbacks. But this most recent action turns the spotlight back on the principles of HDL. It occurred on Feb, 22, 2021, when the U.S. Court of Appeals for the Fourth Circuit upheld a massive $114.1 million jury verdict against a former blood lab chief executive officer and two sales consultants in a whistleblower case.

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Health Care Reform: New COVID-19 Relief Law Aims to Ease the Health Insurance Crisis, *from page 1*

COVID-19 & the Health Insurance Crisis

In addition to wreaking economic havoc from coast to coast, the COVID-19 crisis exposed and exacerbated fundamental problems in the U.S. healthcare insurance system. According to the most recent National Center for Health Statistics (NCHS) report, some 30 million Americans were uninsured between January and June 2020. In all too many cases, loss of employment also meant loss of health insurance. Even the fortunate ones with *Consolidated Omnibus Budget Reconciliation Act* (COBRA) coverage weren't spared from this one- two-punch to the solar plexis since many simply couldn't afford to pay their COBRA premiums.

The *Affordable Care Act* (ACA), aka, Obamacare, was supposed to fix the problem of dependence on employer for health insurance. One way it does that is by providing tax credit subsidies to help individuals offset the costs of buying health plans. But under the current ACA rules, people who earn 400 percent of the federal poverty level aren't eligible for the tax credits. In real world terms, this effectively excludes a single person who earns more than roughly $51,00; it also excludes families of three earning $87,000.

The new president has taken steps to address the systemic health insurance challenges. In January, he ordered the ACA's health insurance marketplaces reopened to give people who lost insurance due to the pandemic another chance to get insurance coverage. He also initiated measures to restore coverage mandates that had been weakened by the previous administration, including protecting persons with pre-existing medical conditions.

In pursuit of that strategy, the new ARPA law makes important changes to the ACA and COBRA designed to benefit healthcare providers and insurers.

ACA Changes

ACA changes contained in ARPA, among the most significant made to the ACA since was adopted in 2010, is intended to fulfill Biden's campaign promise to expand Obamacare and make health insurance affordable for lower-class and middle-class Americans. Among these is a provision long supported by Democrats and the healthcare industry that expands eligibility criteria for ACA subsidies to include people with incomes above 400 percent of the federal poverty level. It also limits the amount households pay to only 8.5 percent of their income on healthcare while boosting subsidies to lower-income consumers.

ARPA also includes new incentives to entice holdout states, most notably Texas, Georgia and Florida, to expand Medicaid to the in-betweeners, i.e., people who make too much money to qualify for the federal health program for the poor but not enough money to be able to afford private health insurance coverage.

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National Lab Reporter
(ISSN 2332-1466) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

These changes will last only for two years, but many Democrats are already signaling their determination to find a way to make them permanent. For example, the Congressional Budget Office (CBO) estimates that a 64-year-old earning $58,000 would see monthly ACA payments decline from $1,075 under current law to $412.

It's estimated the changes will lower payments for almost 14 million people currently insured on the individual market. Furthermore, CBO estimates that the ACA changes will extend coverage to 2.5 million uninsured and cost about $34 billion.

COBRA Subsidies

ARPA also provides for free COBRA coverage over a six-month period for individuals who've lost group health coverage due to involuntary termination or reduced hours of employment. Any employee who lost coverage as of April 2020, is eligible for the entire six-month subsidy. Even employees who lost health coverage as far back as November 2019 may benefit from the subsidy, to the extent that their 18-month maximum COBRA period doesn't expire until the end of April 2021. However, individuals who are eligible for other group health coverage or Medicare aren't eligible for the new COBRA subsidy.

Significantly, the subsidy is available to employees who didn't elect COBRA coverage during their original election period, as well as to those who initially did exercise their COBRA elections but let their coverage lapse. Those individuals must be offered an additional window of at least 60 days to elect COBRA coverage. Most notably, the special election opportunity allows these individuals to make a prospective COBRA election for the period beginning April 1, 2021, without requiring payment of premiums retroactive to the original loss of coverage. This is a significant departure from the normal COBRA rules. The maximum COBRA period, however, is not extended and is still counted from the date of the original qualifying event.

Plan administrators are required to begin notifying eligible individuals of the COBRA subsidy within 60 days of April 1, 2021. The U.S. Department of Labor is required to issue model COBRA notices addressing the subsidy.

Proposed HIPAA Privacy Rule: The 9 Changes That Will Have an Immediate Impact on Lab Operations

On Dec. 10, with just a few weeks remaining in its tenure, the HHS Office for Civil Rights (OCR) proposed a series of changes to the HIPAA Privacy Rule. Public comments on the proposed rule were scheduled to close on March 22. Unlike many of the other midnight healthcare regulations adopted by the Trump administration, the Privacy Rule changes remain on track. But the new administration wants a little more time to study them. So, on March 9, the OCR announced that it was extending the comment period on the proposed rule for 45 days until May 6.

The 9 Key Changes

The point of the proposed rule, which takes up nearly 100 pages worth of 3-columned Federal Register text, is to give individuals greater access to their protected health information or electronic protected health information (which we'll refer to collectively as "PHI" except where the context requires otherwise) while at the same time making it easier for providers to use and share that PHI to coordinate treatment, respond to emergencies and transition to value-based care. For most lab managers, the key part of the rule are the changes likely to have an immediate impact on operations. There are three groups of such changes affecting:

- Patient PHI access rights;
- Access fees; and
- Notice of privacy practices.

A. Patient PHI Access Rights (Changes 1 to 4)

There are four changes that would have a direct impact on your HIPAA compliance efforts with regard to patient access rights:

1. Less Time to Respond to Access Requests

The proposed rule would cut the time of covered entities, including labs to meet patient requests to copy and access their records from 30 to 15 days. As under current rules, patients could request an extension. However, the extension period would also be reduced from 30 to 15 days.

2. Need for Urgency Access Prioritization Rules

To comply with the proposed rule, labs will have to create written policies for prioritizing health and safety and other urgent requests. Although the 15-day response limit and extension periods would still apply, the policies must be designed to meet the request within the first 15-day period and thus eliminate the need for the extension.

3. New Limits on Requests to Direct PHI to Third Parties

Some of the changes in the proposed rule would actually reduce your administrative load and simplify compliance. An example is the new set of

limits on individuals' right to direct you to transmit their ePHI to a third party in an electronic health record (EHR).

4. New Access Request Submission Procedures

The proposed rule would require labs to submit an individual's access request to another health care provider and get back the requested electronic copies of the person's ePHI in an EHR. The requirement wouldn't be automatic but would apply only if the individual made a "clear, conspicuous, and specific" request (which could be oral). Upon receiving such a request, the lab would have to submit it to the other provider within 15 calendar days.

B. Fee Limits & Disclosure for Third Party Requests (Changes 5 to 7)

The next group of changes likely to have an immediate operational impact involve the fees you can charge and the information you must disclose to individuals who ask you to direct their PHI to a third party.

5. Revised Fee Limits

The proposed rule would impose limits on fees for responding to requests to direct records to a third party. Fees would also have to be "reasonable" and "cost-based." However, you would be able to charge less restricted fees when fulfilling requests to send non-electronic copies of PHI in an EHR, or electronic copies of PHI that's not in an EHR, to third parties.

6. Free Access

Under the proposed rule, you'd also have to provide access to and copies of PHI free of charge when individuals:

- Inspect PHI about themselves in person; or
- Use an internet-based method to view or obtain a copy of PHI maintained by or on behalf of the lab).

7. Posting of Fee Schedule

The proposed rule requires labs and other covered entities to post estimated fee schedules on their websites for access and for disclosures with an individual's valid authorization. If individuals request it, you must also provide individualized estimates of fees for an individual's request for copies of PHI, along with itemized bills for completed requests. In addition, upon request, you must make the fee schedule available in paper or electronic form at the point of care or at an office that's responsible for releasing medical records.

C. Notice of Privacy Practices (NPP) (Changes 8 and 9)

When and if the proposed rule becomes final, you'll have to revise your NPP and procedures for distributing it.

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Proposed HIPAA Privacy Rule: The 9 Changes That Will Have an Immediate Impact on Lab Operations, *from page 5*

8. NPP Text Revisions

The proposed rule includes a number of detailed revisions to current rules governing the content of the NPP, including statements about individuals' rights PHI rights and how they exercise them. over their PHI and how to exercise those rights. In addition to incorporating the new language into the NPP, you'll have to designate a person who'll be available to discuss the NPP with the patient and list his/her contact information in the NPP.

9. Signature No Longer Required

One change that would make life easier for you and your lab staff is the proposed elimination of the requirement to get an individual's written acknowledgment of receipt of a direct treatment provider's NPP.

Takeaway

If the proposed rule is finalized, it would take effect on July 4, 60 days after publication of the final rule in the Federal Register.

Reimbursement: CMS Closes the Free COVID-19 Tests Coverage Loophole

Getting Republicans and Democrats to agree on anything these days is a Herculean task, even during a global pandemic. One of the rare points of consensus is with regard to the notion that all Americans should be able to get free COVID-19 testing. Accordingly, the mandate that payors pick up the full costs of testing without charging copayments was baked into the bipartisan relief legislation that Congress adopted in response to the crisis last spring. Of course, things didn't exactly go according to plan. Aided by CMS guidelines, payors were able to exploit an enormous loophole in the coverage policy to avoid paying for a crucial aspect of COVID-19 testing: screening of the asymptomatic. But now CMS has closed that loophole. Here's a briefing of the new developments and their impact on lab reimbursement.

The FFCRA & CARES Acts

On March 18, 2020, Congress enacted the *Families First Coronavirus Response Act* (FFCRA) requiring group health plans and health insurers offering group or individual health insurance coverage (but not short-term health plans) to provide benefits for certain items and services related to diagnostic testing for SARS-CoV-2. To ensure that testing is free, (Section 6001 of) FFCRA banned plans and insurers (which, for simplicity's sake,

we'll refer to collectively as "payors") from relying on standard methods of controlling costs and utilization, including:

- Cost-sharing requirements like deductibles, copayments and coinsurance; and
- Prior authorization and other medical utilization requirements.

Exactly one week later, FFCRA was amended via passage of the *Coronavirus Aid, Relief, and Economic Security Act* (CARES) which, among other things, broadened the range of diagnostic items and services subject to the Section 6001 coverage without cost-sharing or prior authorization mandate. CARES also required payors to reimburse providers of COVID-19 diagnostic testing an amount equal to their negotiated rate with the provider; if there was no negotiated rate, reimbursement had to be at the cash price for such service listed by the provider on a public website. CARES also gave payors the greenlight to negotiate for—but not unilaterally impose—a rate lower than the provider's listed cash price.

The "Medically Appropriate" Loophole & CMS Guidance

But the free SARS-CoV-2 testing plan —at least as most labs and other providers perceived it—veered off in an unexpected direction. The problem stemmed from the seeds of a loophole embedded within Section 6001 in the form of qualifying language specifying that the ban on cost-sharing payment applies only to tests that a healthcare provider deems "medically appropriate."

On April 11, CMS issued guidance explaining how the private payor lab test reimbursement scheme would work. Tests subject to the Section 6001 no-cost-sharing-coverage rule, according to the guidance, include those ordered as a result of urgent care visits, emergency room visits and in-person and telehealth visits to a doctor's office, according to the guidance. Tests performed on asymptomatic persons were conspicuously absent from this list.

Was that omission an oversight or a deliberate policy? The answer came on June 23 when CMS issued FAQs to explain the guidelines. In FAQ 5, CMS made it clear that it interpreted the "medically appropriate" language of Section 6001 as excluding "testing conducted to screen for general workplace health and safety (such as employee "return to work" programs, for public surveillance or any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19."

Sure enough, payors took the position that they didn't have to cover—or at the very least, could charge cost-sharing amounts—for testing the asympomatic. Some insurers cited the "medically appropriate" language and CMS guidance to refuse paying for testing performed on pooled samples. (See, *Diagnostic Testing and Emerging Technologies*, September 3, 2020.)

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Reimbursement: CMS Closes the Free COVID-19 Tests Coverage Loophole, *from page 7*

The Loophole Closes

The lab industry has argued that exploitation of the "medically appropriate" loophole to not cover COVID-19 screening undermines the FFCRA/CARES free testing policy and has repeatedly urged CMS to close it. Those pleas fell on deaf ears. But that all changed when the Biden administration took control.

On Feb. 26, 2021, CMS issued new guidance to make it clear that private payors generally can't use medical screening criteria to deny coverage for COVID-19 testing for asymptomatic people with no known exposure to the virus. The test must be covered if a licensed or authorized healthcare provider administers or has referred a patient for the test regardless of whether a person has symptoms or has been exposed. Coverage must be offered without cost sharing, prior authorization, "or other medical management requirements imposed by the plan or issuer," according to CMS. However, the guidance continues, payors may but aren't required "to provide coverage of testing such as for public health surveillance or employment purposes."

The new CMS guidance also confirms that insurers must cover point-of-care COVID-19 tests and diagnostic tests administered at state or local sites. This reinforces the existing policy that allows providers to seek federal reimbursement for providing COVID-19 diagnostic testing or vaccines to people who are uninsured. Providers can get reimbursed for COVID-19 diagnostic testing and vaccine administration through the Health Resources and Services Administration COVID-19 Uninsured Program, part of the Provider Relief Fund.

According to CMS, the new guidance should also make it easier for people to access COVID-19 diagnostic testing. For instance, the agency said people can get tested for COVID-19 before visiting a family member and pay no additional out-of-pocket costs. It reaffirms that payors are prohibited from requiring prior authorization or other medical management for COVID-19 diagnostic testing."

Takeaway

Industry reaction to the coverage clarification provided by the new guidance was swift and highly positive. For example, the American Clinical Laboratory Association praised CMS for taking "critical steps to close coverage gaps and protect access to the COVID-19 testing patients need."

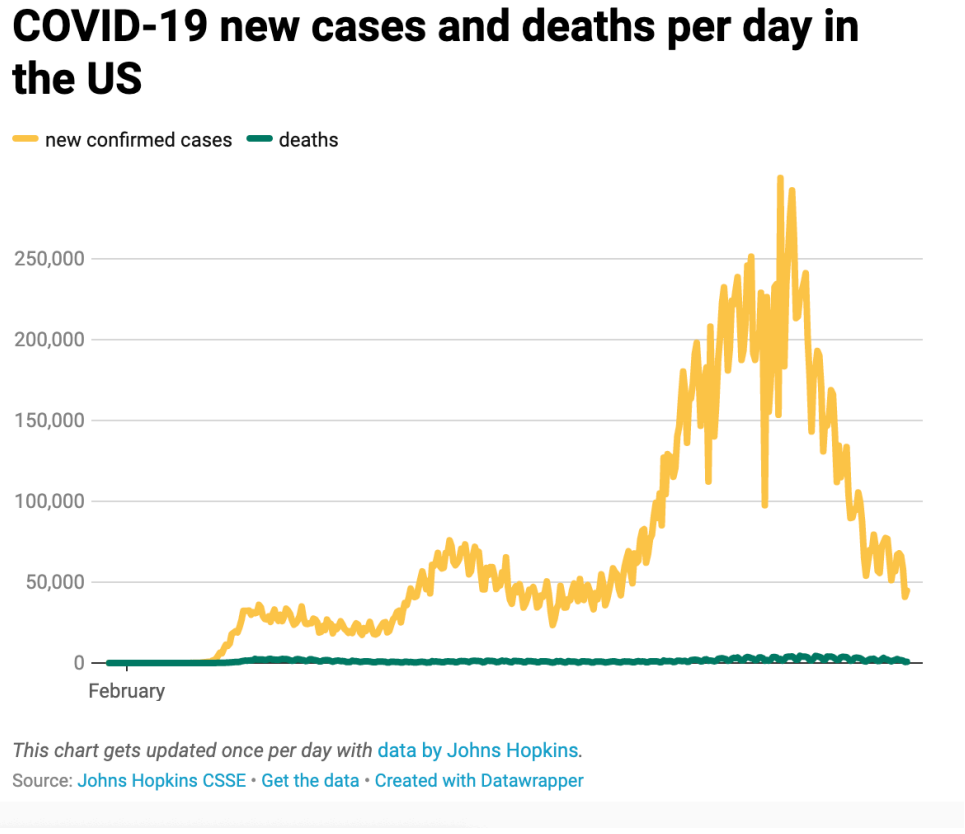
Utilization: Why Falling Demand for COVID-19 Testing May Be a Mixed Blessing

We all understood that the massive spike in COVID-19 testing was unsustainable and bound to gradually peter out. But now it appears that the decline is coming steeper and faster than anybody expected. From a public health standpoint, that sounds like great news; however, it may actually not be an entirely positive development.

The COVID-19 Testing Roller Coaster

Last year at this time, labs were just beginning to feel the pressure of what would become unprecedented demand for COVID-19 testing and test products. And after a brief lull in the spring, testing just kept climbing and climbing all through 2020. The recent spate of record breaking fourth quarter earnings reported by Thermo Fisher, Perkin Elmer, LabCorp, Quest, Hologic and other COVID-19 testing firms is testimony to just how fast a service that didn't even exist when the year began had ballooned so much by the time the year ended.

But in 2021, things seem to be headed in the opposite direction. From January through the end of February, the number of COVID-19 cases in the U.S. declined 70 percent. Even better was that COVID-19 hospitalizations and deaths were also sharply down.



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Utilization: Why Falling Demand for COVID-19 Testing May Be a Mixed Blessing, *from page 9*

Of course, these trends were accompanied by a significant fall off in demand for COVID-19 testing. Across the country, COVID-19 testing sites are closing down or rolling back hours of operation due to decreased testing demand. In Los Angeles county, more than 180 testing sites were operating at a third of capacity.

So, What's the Problem?

Of course, every silver lining has a cloud. Falling case, hospitalization and death rates are an unqualified good. The problem is that it may be impossible to sustain the declines if testing falls off too much. As it has since the pandemic began, testing remains critical to coronavirus containment and preventing new surges, particularly as new and more transmissible variants like the strain discovered in the United Kingdom emerge. The other red flag is pandemic fatigue, complacency and a false sense of security.

Ominously, the downward trend in COVID-19 cases, deaths and hospitalizations exhibited in the first two months of the year have leveled off. In fact, rates have actually increased slightly in March.

Takeaway

Even though it feels like things may be slowing down a bit in this pandemic, it's crucial for the country to remain vigilant and keep getting tested for COVID-19, especially but not exclusively people displaying symptoms of the virus.

Kickbacks: Federal Court Upholds $114.1 Million Judgment against Principles of HDL and Singulex Scam, *from page 1*

The HDL Scandal

The U.S. Anti-Kickback Statute (AKS) makes it illegal to offer, pay, solicit or receive remuneration to induce referrals of items or services covered by federally funded programs, such as lab tests. The point of the AKS is to ensure that physicians make medical treatment decisions based on the best interests of the patient without being influenced by bribes and improper financial incentives.

For sheer dollars involved, the HDL scheme is the biggest AKS prosecution ever undertaken against a lab. Some have even described it as the mother of all clinical lab frauds. For those of you unfamiliar with it, the case began as a *qui tam* lawsuit accusing HDL, Singulex and one other lab (the now defunct Berkeley Heart Lab) of working with BlueWave to induce blood testing referrals, including medically unnecessary large multi-assay panels, by paying physicians sham specimen processing and handling fees of between $10 to $17 per referral and routinely waiving copayments and deductibles. Then, by billing Medicare and TRICARE for tests provided under the arrangement, the labs violated the False Claims Act (FCA).

In April 2015, HDL paid $47 million to settle the charges against it; Singulex settled for $1.5 million. Both labs also entered into corporate integrity agreements with the government. The settlement forced HDL into Chapter 11 bankruptcy, but the embattled lab giant's legal woes continued. In addition to its creditors, HDL was sued by Cigna for $84 million in damages the private payer allegedly suffered as a result of the scheme. Adding insult to injury, BlueWave also sued its former partner for millions in unpaid consulting fees.

The $114.1 Million Verdict against the HDL Principles

But the HDL crackdown was just heating up. The 2015 settlement covered just the labs themselves. And it was and is U.S. Justice Department policy (known as the Yates Memo after the author who codified it) to target corporate principles and hold them personally accountable for an organization's wrongdoing. In this case, the principles were HDL's former CEO and a pair of individuals involved in marketing HDL and Singulex tests. Unlike the labs they led, the individual defendants decided to fight it out in court.

It turned out to be an unwise decision. In May 2018, after a two-week trial, a South Carolina U.S. District Court jury found the three defendants liable for AKS and FCA violations. In May 2018, the U.S. obtained a judgment against three individuals for paying kickbacks for laboratory referrals and making claims for medically unnecessary tests. The dimensions of the scheme were staggering. Consider these numbers:

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Kickbacks: Federal Court Upholds $114.1 Million Judgment against Principles of HDL and Singulex Scam, *from page 11*

- **35,074:** The number of false claims by HDL the defendants were responsible for submitting to Medicare and TRICARE;
- **$16,601,591:** The total value of those claims;
- **3,813:** The number of false claims by Singulex the two marketing defendants were responsible for submitting to Medicare and TRICARE; and
- **$467,953:** The value of those claims.

Having established liability, the court then had to decide on a damage award. As the FCA allows, the court trebled the damage amounts, offset settlement payments received from HDL and Singulex for the same claims, and awarded $63.8 million in penalties requested by the U.S. Total judgment amount: $114,148,661.86.

The Appeal

The defendants cried foul, claiming that the government didn't prove that they "knowingly and willfully" violated the AKS. All we did was pay salespeople commissions, they insisted. But on Feb. 22, the U.S. Court of Appeals for the Fourth Circuit rejected the appeal and upheld the verdict—all $114.1 million of it.

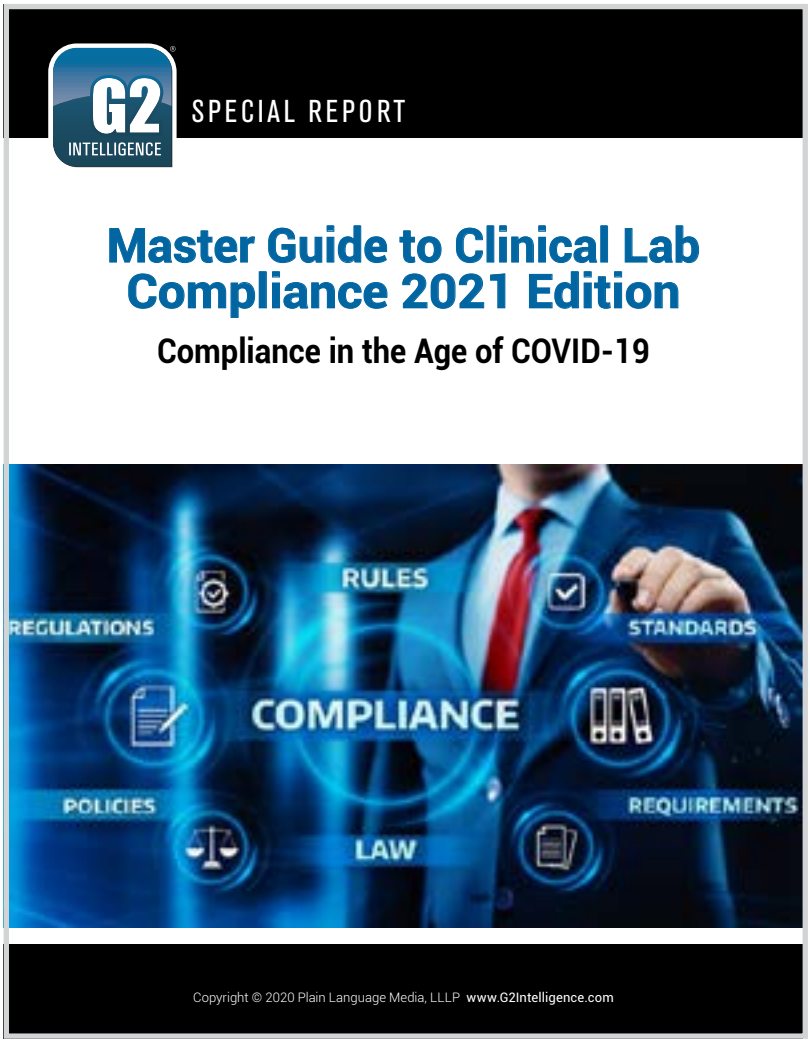
So, now the defendants face the task of coming up with the money. Making their situation even more precarious is that their liability is "joint and several." In other words, the government can collect some, all or any amount of the judgment from any one or combination of the defendants. That basically means they can go after whoever has the deepest pockets.

Takeaway

The HDL case is still not over. There are still other principles to prosecute. In addition, in the past couple of years, the DOJ has collected over $1 million in settlements from physicians who allegedly accepted the bogus specimen collection fees and other kickbacks from HDL and Singulex.

Master Guide to Clinical Lab Compliance 2021

Compliance in the Age of COVID-19



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