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IN THIS ISSUE

COVID-19: New Report Sheds Light on Effectiveness of Federal Government's Response to Need for COVID-19 Testing

Labs, hospitals and other private sector providers have stepped up and performed heroic deeds in meeting the unprecedented demand for COVID-19 testing. State and federal health care agencies from across the country also stepped up to join in these efforts. And while the historic annals evaluating the overall success of these efforts remain to be written, a new report sheds light on the performance of the federal agencies. Here are the key takeaways:

The PRAC Report: Purpose and Methodology

The author of the report is the Pandemic Response Accountability Committee (PRAC), a new federal agency established by the CARES Act to promote transparency and perform independent oversight over spending of CARES Act and other related federal emergency

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Top of the News: Hospital Price Transparency Is Here—But How Will It Be Enforced?

With just three days left in 2020, last-ditch efforts to derail HHS' controversial new hospital transparency rules before they took effect on Jan. 1 failed when the U.S. Court of Appeals for the District of Columbia Circuit rejected The American Hospital Association's (AHA) lawsuit. As a result, hospitals are now officially required to post the rates they negotiate with private insurers online. But the inauguration of a new administration may yet prove to be the hospital industry's deliverance.

The Price Transparency Rule

The transparency requirements are contained in a final rule that HHS published in November 2019. They were supposed to take

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bill funds. PRAC's responsibilities include supporting efforts to "prevent and detect fraud, waste, abuse, and mismanagement [and] mitigate major risks that cut across program and agency boundaries."

Published on Jan. 14, 2021, the PRAC report, aka, Federal COVID-19 Testing Report: Data Insights from Six Federal Health Care Programs, is a first of its kind, multi-agency analysis based on data compiled from six different Offices of Inspector General associated with a specific federal agency involved in COVID-19 testing in the seven months after declaration of the public health emergency, i.e., from February through August 2020, including the OIGs from the U.S.:

- Office of Personnel Management (OPM);
- Department of Defense (DOD);
- Department of Health and Human Services (HHS);
- Department of Justice (DOJ);
- Department of Labor (DOL); and
- Department of Veterans Affairs (DOVA).

To assess the agency's COVID-19 testing performance, the PRAC Subgroup that wrote the report asked the OIGs six key questions:

- How many COVID-19 tests were administered, and when?
- Who was tested?
- What types of tests were administered?
- How much did the particular health care program pay for tests?
- In what health care settings did people access testing?
- How long did it take to return test results?

The 5 Key Findings

PRAC determined that, collectively, the six agencies paid for or administered 10.7 million COVID-19 tests, representing 12.7 percent of all coronavirus tests performed in the U.S. during the study period. Its findings with regard to testing characteristics are largely consistent with overall national trends. The five key insights:

1. People Tested

In terms of test subjects, the report found that the demographic characteristics, i.e., gender, age, and race or ethnicity of beneficiaries in two of the federal programs, Medicare Part B and the Bureau of Prisons, were generally proportional to the demographic characteristics of the populations those programs serve. Thus, for example, the 9 percent of

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Medicare Part B beneficiaries that identified themselves as Black/African American in the study data closely aligns with the nearly 10 percent of Black/African American Medicare Part B beneficiaries that received a COVID-19 test from all providers, i.e., other agencies, private labs, hospitals, etc. Similarly, the 33 percent of Bureau of Prisons subjects who self-identified as Hispanic/Latino in the study sample was just slightly above the 28 percent of all inmates who received a COVID-19 test that self-identified as Hispanic/Latino.

However, the other four federal health care programs analyzed (Veterans Health Administration, Federal Employee Health Benefits Program, DOL Workers' Compensation and DOD Medical Treatment Facilities) had varying levels of demographic information available.

2. Types of Tests Performed

COVID-19 test types performed or administered by the federal agencies in the study also mirrored national testing patterns. The vast majority of tests were molecular viral but most programs also covered a limited antibodies testing. The breakdown:

Types of COVID-19 Tests Paid for or Administered by Studied Federal Agency

Agency	Molecular Viral	Antibodies
OPM	81 percent	19 percent
HHS (Medicare Part B)	86 percent	14 percent
DOL (Workers' Comp)	95 percent	5 percent
VA (VHA)	95 percent	5 percent
DOD (Medical Treatment Facilities)	96 percent	4 percent
DOJ (Bureau of Prisons)	100 percent	0 percent

Source: PRAC

3. Testing Volume

Testing by the federal agencies in the study was consistent with overall U.S. testing patterns, with little done in the first months of the pandemic, followed by significant increases in volume through the spring and summer.

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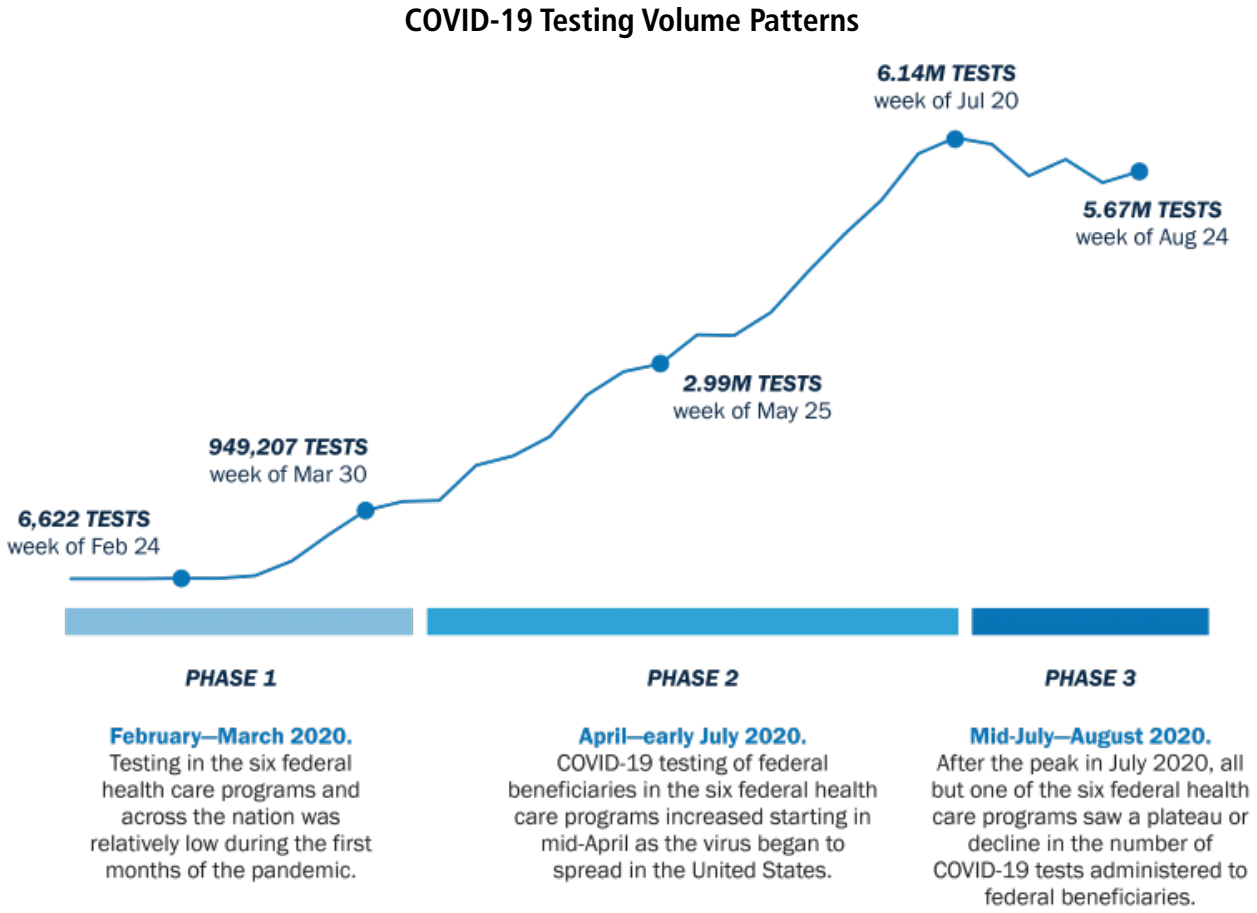


Source: PRAC

4. Test Reimbursement

During the study period, the six federal health care programs spent at least $659.5 million on COVID-19 tests for their beneficiaries. (This amount doesn't include testing at the VHA for which no spending data was available.) Average costs for COVID-19 viral tests, which accounted for the vast majority of those the federal agencies in the study administered or paid for, varied by program. Four of the six programs—Medicare Part B, the FEHBP, Workers' Compensation and the Bureau of Prisons—reported paying an average $69 to $130 per viral test processed at a commercial lab, with variances attributable to differences in product used, supplies involved and program reimbursement rules.

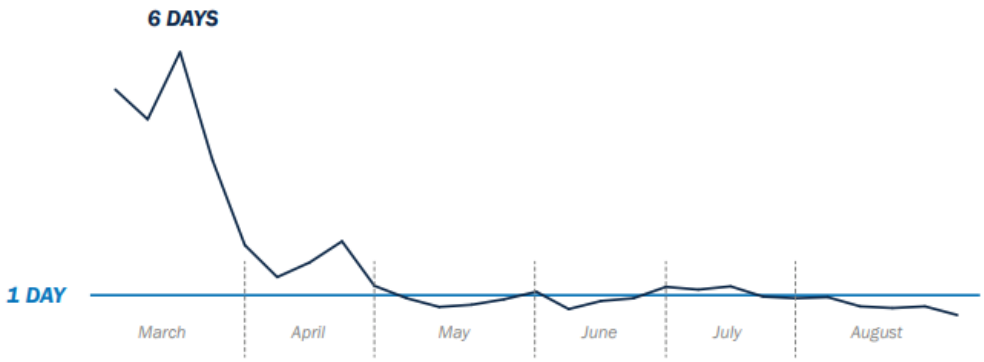
Of the programs that ordered and performed testing at facilities that they manage or operate, only two had data on average cost of viral tests. The DOD Medical Treatment Facilities' average per-test cost for viral tests ordered and performed at its facilities was $57. The Bureau of Prisons' average per test costs were $0 because tests were performed on site using

testing machines and supplies from the Strategic National Stockpile provided by HHS free of charge.

5. Test Turnaround Time

Only three of the agencies—Bureau of Prisons, VHA and DOD Medical Treatment Facilities— furnished data on COVID-19 test turnaround time. However, those data were also consistent with national testing trends. Thus, the VA and DOD reported turnaround times of more than four days and three days, respectively, in March 2020. But by the end of July, turnaround time had dropped to around one day. The Bureau of Prisons reported that at some sites, test turnaround took as long as two weeks in July and August as demand began to spike. The Bureau of Prisons also used rapid molecular testing, which returned results in as little as 15 minutes.

Exhibit 6. Veterans Health Administration reported that by July it took about a day to process results.



Source: PRAC analysis of COVID-19 testing data from six federal health care programs, February–August 2020.

Takeaway

While it's not a comprehensive review of the entire federal government testing response, the report does provide valuable insight enabling Congress, federal and state agencies, health care entities and other stakeholders understand and plan for current and future response efforts. "Testing for COVID-19 is a critical component of the federal government's pandemic response," noted PRAC Chair Michael Horowitz in a statement on the day the report came out. "Today's report examines the testing processes in multiple federal programs, providing a detailed look at testing trends, demographics, and spending."

Enforcement Trends: Has OSHA Done Enough to Enforce COVID-19 Workplace Safety Rules?

Even after the election and swearing in of the new President, federal government response to the COVID-19 pandemic remains a politically charged issue. One bone of contention involves whether OSHA has done enough to protect lab, hospital, nursing home and other workers exposed to the virus. On Jan. 8, the agency issued a statistical report documenting its COVID-19 enforcement efforts starting with the beginning of the pandemic and running through Dec. 31, 2020.

Lab Liability for COVID-19 Violations Under OSHA Laws

Nobody disputes that under OSHA, labs and other employers have a duty to protect workers from risk of COVID-19 infection. What may be less clear, is the source of that duty. Neither the *Occupational Safety and Health Act* (Act) nor the regulations say anything about COVID-19 or, with a few exceptions, infectious illnesses in general. Other hazards not mentioned include workplace violence, musculoskeletal and ergonomic injuries, cold and heat stress, to name just a few. And, yet, OSHA inspectors still hand out citations and fines against employers that fail to guard against these workplace hazards.

How can OSHA do this? Answer: OSHA's authority to issue fines for failing to control hazards not specifically mentioned in the law comes from Section 5(a)(1) of the Act, aka, the "general duty clause," which requires employers to furnish a workplace that's "free from recognized hazards" likely to cause death or serious physical harm to a worker. And coronavirus is clearly a "recognized hazard," especially in COVID-19 testing labs and other healthcare settings.

In addition, inspectors looking into coronavirus compliance can also cite employers for other kinds of OSHA violations, such as failing to comply with requirements pertaining to personal protective equipment (PPE) and respiratory protection.

OSHA Penalty Amounts for COVID-19 Violations

OSHA penalties vary in size, depending on how the inspector that hands them out characterize the violation. And while the agency indexes penalties every year, here were the penalty amounts during the pandemic year of 2020 covered in the OSHA report:

2020 OSHA Penalty Amounts

Type of Violation	Minimum Penalty	Maximum Penalty
Serious	$964 per violation	$13,494 per violation
Other-Than-Serious	$0 per violation	$13,494 per violation
Willful or Repeated	$9,639 per violation	$134,494 per violation

Type of Violation	Minimum Penalty	Maximum Penalty
Failure to Abate (i.e., fix a cited violation)	NA	$13,494 per day up to maximum of 30 days
Posting Requirements	$0 per violation	$13,494 per violation

OSHA COVID-19 Enforcement by the Numbers

According to the report, in 2020, OSHA carried out 300 COVID-19 inspections. To put those numbers into context, the agency performs an average of 32,000 total inspections per year. The other key number in the report is $3,930,381, the total amount in penalties that OSHA inspectors proposed against employers cited for COVID-19 violations. Keep in mind that employers cited for OSHA violations have the right to appeal the proposed penalty amount. The report also lists the types of violations for which employers were cited, including failure to:

- Comply with the general duty clause requirement to provide a workplace free from recognized hazards;
- Implement a written respiratory protection program;
- Provide a medical evaluation, respirator fit test, training on proper respirator use and PPE;
- Report a workplace injury, illness or fatality; and
- Record an injury or illness on OSHA 300 logs and other recordkeeping forms.

What the report doesn't address is the size of the penalties handed out. And to the extent OSHA is trying to make a point about how tough it's been in enforcing coronavirus safety rules, this omission was probably deliberate. Based on incremental reports listing fines against employers over a weekly period, we can discern that the highest proposed fine against an employer for a COVID-19 violation was a mere $26,988. The vast majority of proposed fines were at or below the $13,494 maximum for a serious violation.

One final note: The report includes only enforcement activity carried out by federal OSHA. Twenty-two states, including California, have their own state OSHA equivalent programs imposing requirements that are typically stricter than federal standards.

Takeaway

Although the fine totals sound impressive, the numbers support the contention that OSHA has been less than vigorous in its efforts to enforce COVID-19-related safety rules in the workplace. Inspections have been relatively few in number and the penalty amounts modest, particularly as compared to fines the agency hands out for fall protection, Hazcom, confined spaces, lockout, machine guarding and other common violations.

FDA WATCH

FDA Sounds Alarm on Potential Impact of Genetic Mutation on SARS-CoV-2 Molecular Test Accuracy

As if COVID-19 testing wasn't challenging enough, the emergence of new variants has made the SARS-CoV-2 virus a moving target. With this in mind, the FDA is warning clinical labs and health care providers of the risk that genetic mutations to the virus may lead to false negative test results. In its Jan. 8 letter, FDA identifies specific molecular tests that have received Emergency Use Authorization (EUAs) whose performance could be impacted by SARS-CoV-2 genetic variants.

The Diagnostic Challenge

The first and vast majority of tests with EUA for SARS-CoV-2 are molecular assay designed to detect specific RNA sequences found in the viral genome. However, the SARS-CoV-2 virus mutates regularly, resulting in several genetically unique variants, each with different RNA sequences. The presence of SARS-CoV-2 genetic variants in a patient sample can potentially change the performance of the SARS-CoV-2 test. If a molecular test isn't engineered to detect the sequences associated with these variants, it may miss the variant leading to the false conclusion that the test subject doesn't have the virus. The resulting false negative enhances the risk of infection by unwittingly unleashing people who should be in self-isolation on others.

Molecular tests designed to detect multiple SARS-CoV-2 genetic targets are less susceptible to the effects of genetic variation than tests designed to detect a single genetic target. The clinical impact of genetic variants on test sensitivity is influenced by the sequence of the variant, the design of test and the prevalence of the variant in the patient population. Tests that rely on the detection of multiple regions of the genome may be less impacted by genetic variation in the SARS-CoV2 genome than tests that rely on detection of only a single region.

The FDA Response

The FDA has been monitoring the potential effects of genetic variation in molecular tests that have received EUA on an ongoing basis throughout the pandemic. And on Jan. 8, it sounded the alarm. "The FDA reminds clinical laboratory staff and health care providers about the risk of false negative results with all laboratory tests," FDA wrote, including molecular tests. "No test is perfect. Laboratories should expect some false results to occur even when very accurate SARS-CoV-2 tests are used."

The FDA identifies three tests with EUA that could be impacted by mutations:

- The Mesa Biotech Accula SARS-Cov-2 Test, which received EUA on March 24;

- The Thermo Fisher Scientific TaqPath COVID-19 Combo Kit, which received initial EUA on March 15 and received subsequent expansions allowing for home collection and use with additional instruments and reagents; and
- The Applied DNA Sciences' Linea COVID-19 Assay Kit, first cleared on May 13 and subsequently cleared for use with robotic RNA extraction.

FDA Recommendations

The FDA recommends that clinical lab staff and providers who use molecular tests for the detection of the SARS-CoV-2 virus:

- Recognize that genetic variants of SARS-CoV-2 arise regularly and may result in false negative test results;
- Be aware that tests that use multiple genetic targets to determine a final result are less likely to be impacted by increased prevalence of genetic variants;
- Analyze negative results in combination with clinical observations, patient history and epidemiological information; and
- Consider ordering repeat testing with a different test with different genetic targets for patients who test negative after molecular testing if COVID-19 is still suspected.

Utilization Management: New Federal Regulations Streamline and Speed Up Payor Prior Authorization

In its final days, the Trump administration finalized (and, in the eyes of many in the health care industry, rushed) regulatory changes designed to ease prior authorization rules and improve provider and patient access to medical records. Specifically, the CMS final rule requires Medicaid, the Children's Health Insurance Plan (CHIP), Qualified Health Plans (QHPs) and other plans—but not Medicare Advantage plans—to build application program interfaces to support prior authorization and data exchange. In case you don't feel like reading the entire 433-page rule, here's a quick overview.

Does Prior Authorization Impede Medical Care?

Payors rely on prior authorization requirements to ensure program integrity and winnow out medically unnecessary lab tests and other covered health services. However, these requirements are administratively burdensome and time consuming. The all too frequent result is not only significant inconvenience but also actual harm to patients.

In 2018, the healthcare industry issued a consensus statement stressing the need for reform. But those calls seem to have gone unheeded. In a

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

The CMS Rule

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

1. Mandatory Payor APIs

The rule, which builds on the Interoperability and Patient Access final rule that CMS published in May 2020, calls for payors to create application programming interfaces (APIs) on their systems that enable electronic health records (EHR) and other information systems to talk to each other or third-party applications. Payor APIs would have to meet the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) standard. The FHIR standard is a technology solution that helps bridge the gaps between systems so that both systems can understand and use the data they exchange.

2. New Deadlines for Prior Authorization

The final rule also reduces the wait time for prior authorization decisions by requiring payors (other than QHP issuers on Federally Facilitated Exchanges (FFEs)) to issue decisions on urgent requests within 72 hours and non-urgent requests within seven calendar days. Payors must also provide a specific reason for any denial, to give providers some transparency into the process. To promote accountability for plans, the rule also requires payors to make public certain metrics that demonstrate how many procedures they're authorizing.

Operation Warp Speed?

CMS moved at warp speed to bring these rules to fruition by ending comments on the proposed rule on Jan. 4, 2021, a mere 22 days after posting it (a period that spanned the Christmas and New Year's holidays) and then finalizing the rule just eight days after that. So, provider groups can be forgiven for criticizing the agency with rushing through such an

important rule without giving them ample time to study and comment on it. The rule will be implemented in stages over two years, starting on Jan. 1, 2023.

Takeaway

Taken together, these policies could lead to fewer prior authorization denials and appeals while improving communication among payors, providers and patients, according to a CMS statement. The biggest criticism is the omission of Medicare Advantage plans, which creates the potential to create treatment misalignment and dysfunction for dual Medicare- and Medicaid-eligible patients. CMS indicated that it was planning to create a parallel rule for Medicare Advantage plans but, alas, never did—at least during this administration.

The other fly in the ointment is the use of APIs. This is far from the first time that the Trump administration pushed for adopting APIs for EHR communication and sharing purposes. However, APIs are also fairly controversial due to privacy concerns. As a result, key players in the healthcare industry have resisted their adoption. And now that a new administration has taken the reins, the rule's future remains in doubt. One possibility is that the next CMS will sever the controversial API requirements and leave the prior authorization deadlines and transparency reporting obligations intact, while potentially extending them to Medicare Advantage Plans.

Top of the News: Hospital Price Transparency Is Here—But How Will It Be Enforced? *from page 1*

effect on Jan. 1, 2020. But in response to industry protest, the agency agreed to push back the effective date for one year. While serving the laudable goal of furnishing consumers the pricing information they need to shop around and make informed decisions about medical care, the transparency requirements are also administratively burdensome and highly intrusive.

Specifically, they require hospitals to publish their "standard charges" for both gross charges and payer-specific negotiated charges for all items and services. Pricing information must also be available on the Internet in a machine-readable file and include information such as common billing or accounting codes used by the hospital, along with a description of the particular item or service. The pricing information must be presented in a "consumer friendly" way using "plain language" and include payer-specific negotiated charges for common "shoppable" services.

"Shoppable services" is defined as those that can be scheduled by a health care consumer in advance, theoretically in the interest of shopping out the best price or deal. That includes most lab tests, as well as x-rays, outpatient visits, imaging tests and bundled services like pre- and post-

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delivery care and cesarean deliveries. Hospitals must display negotiated charges for at least 300 services, including 70 selected by the CMS and 230 selected by the hospitals. Especially irksome is that those services cover inpatient and outpatient procedures offered to any and all patients, not just Medicare beneficiaries.

"Consumer-friendly" disclosure means making hospital charge information public in a prominent location online (or in written form upon request) that's easily accessible, without barriers and searchable.

"Plain language" Product and service descriptions must also be in "plain language" with the shoppable service charges displayed and grouped with charges for any ancillary services the hospital customarily provides with the primary shoppable service. Hospitals must also update their posted pricing information at least once a year.

What Hospitals Must Do to Comply

On Dec. 18, 2020, HHS issued instructions on how hospitals must disclose their prices, outlining two methods:

- **A machine-readable file** that contains standard charges for all charges and services at the hospital, including gross charges, discounted cash prices, payer-specific negotiated charges, and de-identified minimum and maximum negotiated charges; and
- **A consumer-friendly display** of at least 300 shoppable services, that can be scheduled in advance, including plain-language descriptions in a searchable format. This section must also provide gross and discounted cash prices, payer specific charges, and de-identified minimum and maximum negotiated charges.

The Legal Battle Over Transparency

AHA has vigorously fought the transparency rule almost from the moment HHS proposed the final version in November 2019, arguing that requiring disclosure of the closely guarded rates negotiated with payors violates hospitals' First Amendment rights. AHA President Rick Pollack also warned that the rules "could seriously limit the choices available to patients in the private market and fuel anticompetitive behavior among commercial health insurers in an already highly concentrated insurance industry."

In December 2019, the Association of American Medical Colleges, Children's Hospital Association and Federation of American Hospitals joined AHA in a lawsuit challenging the rules and HHS' statutory authority to require public disclosure of individually negotiated rates between commercial insurers and hospitals. The agency won the first round on June 27, when the U.S. District Court for the District of Columbia dismissed the case without a trial.

The appeal to the D.C. Circuit was the last hope of AHA and its allies. But it was not to be. The appeal judges upheld the lower court's ruling, finding that HHS' rule was: i. consistent with the First Amendment; ii. within the agency's power to issue under the *Affordable Care Act*; and iii. did not seek to expand, nor "otherwise affect traditional or ordinary economic regulation of commercial activity."

AHA had also argued that hospitals use different payment methodologies and store information across different systems, making it difficult to put into a single, comprehensive list. But the court noted that the rule's effective date had already been delayed by one year, that it only applies to base rates, and that HHS increased the burden estimate tenfold. They wrote that the newer, 150-hours-per-hospital estimate in the rule's first year is similar to one provided by the Healthcare Financial Management Association, a trade group for healthcare finance leaders, which filed an amicus brief in support of the AHA.

Finally, the judges also rejected the AHA's argument that the price transparency rule will mislead consumers, agreeing with HHS' contention that that it's actually the current system (i.e., pre-transparency rules in effect before Jan. 1, 2021) rule that's misleading.

Takeaway

The stakes are high. CMS declared its intention to enforcing the new rules aggressively via response to complaints and proactive monitoring and auditing. Hospitals that don't comply face the risk civil monetary penalties of up to $300 a day and more than $100,000 per year. However, on Dec. 21, the AHA wrote ***a letter*** *calling on the incoming Biden-Harris administration to "exercise enforcement discretion" with regard to the new rule. Given the popularity of the concept of empowering consumers to make informed decisions about their own health care, judicious and restrained enforcement rather than repeal may turn out to be a workable solution.*

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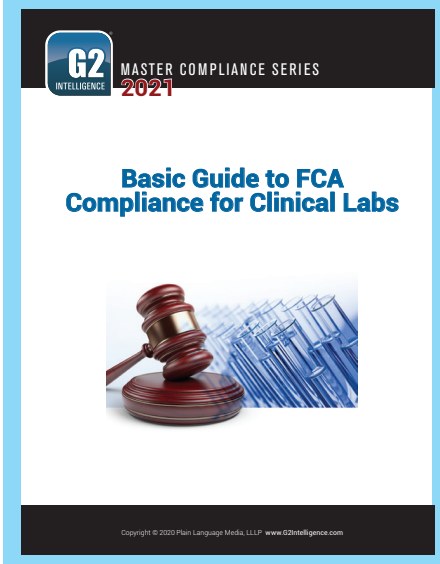

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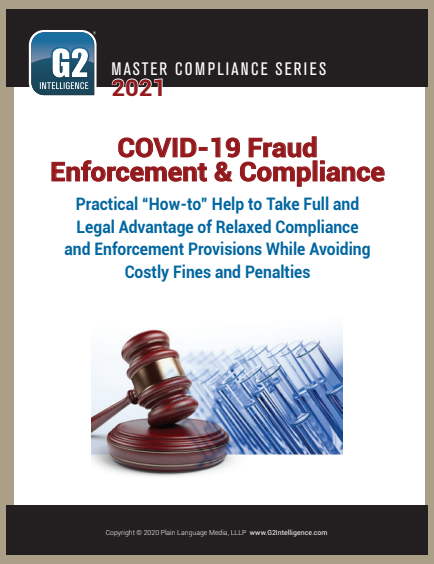

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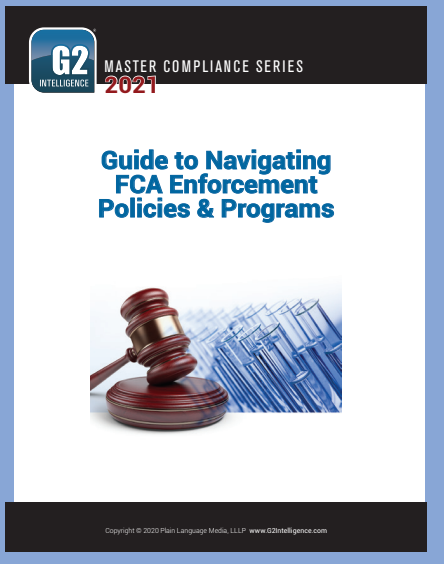

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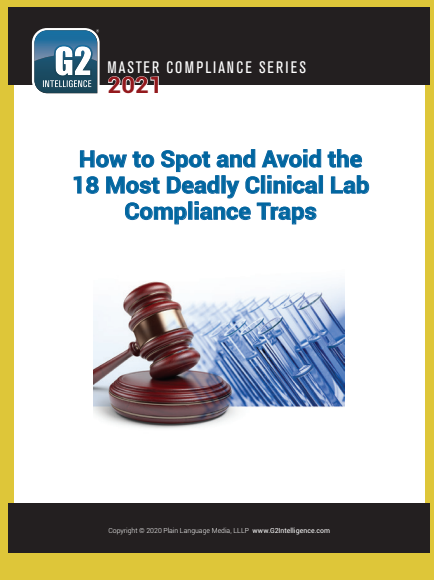

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