



Policy Brief

March 13, 2020



Government and Regulatory Updates as Hospitals Prepare for COVID-19

COVID-19, the novel coronavirus, has now been [declared a global pandemic](#) by the World Health Organization. In the U.S., the virus is a growing concern for federal and state governments, the public and health care providers. As providers are taking more precautions to prepare for possible outbreaks, they are facing more [strain on their resources](#), such as shortages of personal protective equipment. In response, the government has begun taking action to alleviate shortages and directing more resources to hospitals and other public health providers. Find the latest updates in the Resources section below.

Shortages Grow as Providers Prepare for COVID-19 Outbreaks

There are already growing shortages of safety equipment in hospitals as the [demand for respiratory masks](#) and other supplies needed to keep health care workers safe from the virus has spiked. The FDA has also reported [supply-chain disruptions](#) in China for other medical device supplies and active drug ingredients, which may lead to more shortages and further rising costs for hospitals.

Federal and State Governments' Response

Public health officials' concern on the potential impact of the pandemic, and the health care industry's capacity to deal with it, has prompted government action, including the following:

- President [Trump announced](#) a 30-day suspension of traveling from European countries to the U.S.

- The Administration has begun holding meetings between its Coronavirus Task Force, CMS and key health system leaders, including AHPA.
- Lawmakers are developing [emergency legislation](#) that includes a federal paid leave benefit program, coverage for COVID-19 testing and requiring that OSHA and the CDC provide more guidance within 30 days.
- An [\\$8.3 billion federal package](#) was finalized last week to help fund the response to COVID-19. Nearly \$1 billion is being allocated for the procurement of pharmaceuticals and medical supplies, support of health care preparedness and Community Health Centers, and to improve medical surge capacity.
- States are also taking action, with some declaring a state of emergency, setting up education centers or requiring that [insurers waive co-pays](#) for testing.

Federal Agency Resources

Below are recent resources from U.S. federal agencies to help health providers prepare for COVID-19:

- CMS [issued a memo](#) stating facemasks were an acceptable temporary alternative to respirators and issued guidance on the suspension of updating respirator fit test dates. Visit [CMS' website for more guidance](#).
- The CDC will implement a [new ICD-10 code](#) for cases of COVID-19 and [issued guidance](#) on the reuse of N95 respirators. Visit the [CDC's website](#) for more interim guidance.
- The FDA issued [new policies](#) for expedited laboratory testing for COVID-19. Visit the FDA's website for a [list of actions](#) the agency has taken in response to the virus.
- OSHA [released interim guidance](#) for employers of workers with potential exposure to COVID-19.

All of these websites are being updated daily (and some, even more frequently) with accurate, reliable information.



ACA Appeal Headed to the Supreme Court

The Supreme Court has agreed to hear the case against the Affordable Care Act (ACA), teeing up the law for its third major legal battle. Although a federal appeals court [ruled against](#) the individual mandate (the financial penalty for not having insurance), the remainder of the ACA was

left intact. Republican state officials then brought suit against the rest, claiming that the entirety of the law must now be unconstitutional. The case will be heard during the Court’s next term, which begins in October.

A Quick Refresher: What’s the Argument?

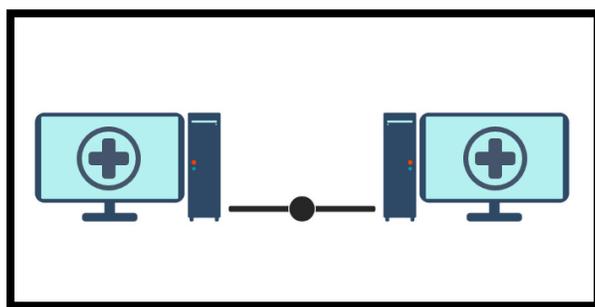
While the U.S. Fifth Circuit Court of Appeals decided that the individual mandate exceeded Congress’ taxing power, it left the question of severability unanswered. Severability—whether the rest of the law can stand without critical components—is at the heart of the Republican argument to repeal the ACA completely. Texas Attorney General Ken Paxton puts it this way: “Without the individual mandate, the entire law becomes unsupportable.”

What Does This Mean for States?

It’s important to remember that the ACA is still the law, even throughout these legal challenges. The ACA’s 2020 open enrollment period has passed, with the number of state insurers participating [continuing to increase](#). Patients who purchase insurance on the Health Insurance Exchanges already have their coverage locked in. Currently, political analysts think it is unlikely that the justices will release a decision before the end of the presidential election cycle.

Yes, But...

Many state and local governments make decisions about the upcoming years based on the coverage provided by the ACA. So do insurers, health care providers and local employers. Prolonged uncertainty around the law could have adverse consequences for individual patients and the broader health care economy.



CMS and ONC Release Interoperability Rules

On Monday, the Department of Health and Human Services (HHS) released its much-anticipated interoperability [final rules](#). In what the Administration calls the start of a new chapter in American health care, the rules released by the [Centers for Medicare and Medicaid Services](#) and the [Office of the National Coordinator for Health IT](#) (ONC) aim to simplify data exchanges between providers, prevent information blocking and increase patients’ access to their own data. Changes include standardizing application programming interfaces and requiring electronic notifications when patients are admitted, discharged or transferred. The Administration originally scheduled

the unveiling to coincide with the Healthcare Information and Management Systems Society (HIMSS) conference, however, the conference was [cancelled](#) due to COVID-19 concerns.



Election Watch 2020: News from the Campaign Trail

The journey to the 2020 presidential election continues. Below are the latest highlights from the campaign trail:

- [Super Tuesday](#) and “[Mini-Tuesday](#)” have come and gone. Both nights of voting ended in a [victory](#) for former Vice President Joe Biden.
- [Michael Bloomberg](#), [Pete Buttigieg](#), [Amy Klobuchar](#) and [Elizabeth Warren](#) have ended their presidential runs.
- National attention is now focused on the two major frontrunners: former Vice President Joe Biden and Senator Bernie Sanders. The next primary vote happens on Tuesday, March 17th, in the states of Arizona, Florida, Illinois and Ohio.
- The next debate, which will be between Biden and Sanders, is scheduled for this Sunday, March 15th. This will be the first debate during this cycle to not have a live audience.



A Look at the Federal Register

Advancing Interoperability and Patient Access to Health Data

CMS has released its [final rule](#) on interoperability and patient access. Highlights of the rule include requiring electronic exchange of data, public reporting of providers engaging in information blocking and requiring electronic notifications as a Condition of Participation.

21st Century Cures Act: Interoperability, Information Blocking and the ONC Health IT

The ONC has released its [final rule](#) on health information blocking, interoperability and the Health IT Certification Program. The rule clarifies definitions, provides specifics on application programming interface standards and adopts the U.S. Core Data for Interoperability (USCDI) standards.

Banned Devices: Electrical Stimulation Devices

The FDA has released a [final rule](#) banning the use of Electrical Stimulation Devices (ESDs) to treat self-injurious or aggressive behavior in patients, deeming such devices an “unreasonable and substantial risk.” ESDs are aversive conditioning devices that apply a shock to a patient’s skin in an attempt to discourage a harmful or unwanted behavior. **The ban is effective April 6th for new treatments; current treatment plans must be phased out by September 2nd.**

Health Professional Scholarship Program

The Department of Veterans Affairs (VA) has released a [final rule](#) on the Health Professional Scholarship Program (HPSP). The rule requires that the VA award 50 scholarships at minimum to mitigate the current provider shortage and extends the number of obligated service years for scholarship recipients. **The amended regulation is effective April 6th.**

IN OTHER NEWS

[Where That \\$8.3 Billion In U.S. Coronavirus Funding Will and Won't Go](#) – NPR

[Federal Court Strikes Down Michigan's Medicaid Work Requirement](#) – Michigan Radio

[Insulin Costs May Be Capped in a Medicare Program](#) – New York Times

[Discrimination: A Social Determinant of Health Inequities](#) – Health Affairs

[The U.S. Isn't Ready for What's About to Happen](#) – The Atlantic