



## Policy Brief

May 8, 2020

### CMS Provides New Flexibilities to Providers



CMS recently released [new waivers](#) for health providers to better serve patients during the pandemic. These waivers apply nationwide and are, generally, retroactive to March 1, 2020. An [interim final rule](#) released last week unpacks these provisions and provides additional flexibilities for certain providers. The rule focuses on expanding access to care through telehealth and reducing regulatory burden across the care continuum. It also institutes [new reporting requirements](#) for Long-Term Care Facilities. Below are key highlights on the new flexibilities provided. For a summary of the interim final rule, click [here](#).

#### **Telehealth**

- Allow health care professionals who were previously unable to furnish and bill for Medicare telehealth services (including physical therapists, occupational therapists, speech language pathologists and others) to receive payment for these services.
- Allow hospitals to bill the originating site facility fee for telehealth services furnished to Medicare patients registered as hospital outpatients, including when the patient is at home.
- Allow hospitals to bill for therapy, education and training services furnished remotely by hospital-based practitioners to Medicare patients registered as hospital outpatients, including when the patient is at home.

## **Teaching Hospitals**

- Allow teaching hospitals to claim residents that rotate to another hospital during the national emergency under the teaching hospital's full time equivalent resident count. It also does not penalize hospitals without teaching programs for accepting those residents.

## **Hospital Outpatient Departments**

- Allow provider-based hospital outpatient departments that relocate from on- to off-campus, or from one off-campus location to another, to *request* temporary payment at the full OPPS rate, rather than the PFS rate.
  - When the pandemic ends, if temporarily relocated off-campus hospital outpatient departments do not go back to their original location, they will be considered to be non-accepted and paid at the PFS rate.

## **Diagnostic Testing**

- Cover COVID-19 tests when ordered by any health care professional authorized under state law without requiring a written order from a treating physician or practitioner.
- Cover certain serology or antibody tests that beneficiaries self-collect at home.

## **Scope of Practice**

- Allow any member of the medical team to add documentation in the medical record as long as it is reviewed and signed by the appropriate clinician.
- Allow physician assistants, nurse practitioners and clinical nurse specialists to certify the need for home health services and order services.

## **Quality Reporting Programs (QRP)**

- For the Value-Based Purchasing (VBP) program, amend the extraordinary circumstances exception policy so that hospitals in an entire region or locale can receive an exception for quality reporting without the need to request one.
- Delay the compliance date for quality reporting for IRFs, Long-Term Care Hospitals (LTCHs), Home Health Agencies (HHAs) and Skilled Nursing Facilities (SNFs).

## **Medicare Shared Savings Program (MSSP)**

- Allow MSSP Accountable Care Organizations (ACOs) to delay for a year their movement to a higher risk track.
- Remove the cost of treating COVID-19 patients from ACO expenses.



## Updates on COVID-19 Regulations

AHPA continues to follow new COVID-19 regulations, guidance and other government actions. The updates below are the latest guidance and other developments since April 25<sup>th</sup> to help mitigate the impacts of COVID-19. For earlier COVID-19 regulations and guidance, visit the last [Policy Brief](#).

### **Paycheck Protection Program and Health Care Enhancement Act**

- Congress has passed the [Paycheck Protection Program and Health Care Enhancement Act](#), a \$484 billion COVID-19 funding package. The bill includes an additional \$75 billion for providers and an extra \$310 billion for small business loans.

### **Second Round of Waivers Released by CMS**

- CMS has issued [another round](#) of regulatory waivers to expand care and provide flexibility through the pandemic. These include making it easier for beneficiaries to obtain testing and further expansion of access to telehealth services.

### **Terms and Conditions Released for Provider Relief Fund**

- HHS has released the terms and conditions for receiving payments from the COVID-19 Provider Relief Fund. Those receiving automatic payments are required to [verify](#) revenue data within 30 days of receipt.

### **Advanced Payment Program Now Closed**

- CMS has [announced](#) that it will not be accepting any new applications for its Advanced Payment Program and is reevaluating the Accelerated Payment Program.

### **MIPS Credit for COVID-19 Clinical Trials**

- Clinicians who participate in a COVID-19 clinical trial and report their findings to a clinical data repository or registry may [earn MIPS credit](#) under the Improvement Activities performance category.

### **Interoperability and Patient Access Delays**

- CMS is [extending](#) the timeline for the *Admission, Discharge and Transfer Notification* Condition of Participation by an additional six months.

### HRSA's COVID-19 Uninsured Program Portal

- HRSA has launched a [portal](#) for health care providers to seek reimbursement for COVID-19 testing, treatment and related services for the uninsured, as dictated by the CARES Act.

### Workforce Flexibility Virtual Toolkit

- HHS has created a [virtual toolkit](#) to help health care decisionmakers maximize workforce flexibilities. The toolkit includes resources on funding, licensure, scope of practice, liability protections and workforce training.

### Updated Coronavirus Testing Guidance

- The White House has released its [blueprint](#) to increase testing capacity. The guidance includes recommendations for states looking to create their own testing plans.

### Maternal Opioid Misuse Model Delayed Until 2021

- CMS [recently announced](#) a postponement of the Maternal Opioid Misuse models' implementation due to the pandemic. Participants will now have until July 1, 2021 to screen and enroll beneficiaries.



### Reopening States: How Ready Are We?

More than half of all states are [considering reopening](#), in part due to the economic impact of prolonged stay-at-home orders. Some infectious disease models show that [peak periods](#) of demand for hospital resources are in the past; others predict a [sharp rise](#) in daily deaths over the next several weeks. Despite the President's [repeated tweets](#) calling for states' swift "liberation" from stay-at-home orders, the official White House guidance recommends a cautious, evidence-based approach. States, local governments and employers are all grappling with how to resume some business functions while still protecting public health.

### Which states have already begun reopening?

Many of the states in which AHPA has a presence have either already begun reopening or have a signed executive order that will lift the lockdown within the next two weeks. Florida, Georgia, Texas, North Carolina, Kansas and Colorado all have begun this process. Michigan Gov. Gretchen Whitmer remains cautious, saying, "As great as the price [is] that we have paid in this moment, we know we don't want to do it again."

### **How do these states know that they are ready?**

In general, governors are taking a tailored approach, carefully crafting their reopening strategies to meet the needs of their communities. As the shutdown is lifted, nearly all states are watching the rates of new infections to determine their readiness. The White House recommends a minimum of 14 days of downward trending cases before reopening. States are also using the amounts of tests performed and the number of positive cases as indicators. The [National Governors Association](#) believes states can be ready to reopen when they can perform a minimum of 750,000 tests per week, deploy [contact tracing](#) and expand their hospitals' surge capacity should a second wave of infections emerge.

### **Yes, but...**

Public health officials urge states to be cautious and conservative while reopening. The Institute for Health Metrics and Evaluation's death-toll projections, often used by the White House, [double](#) when adjusted for premature reopening. Dr. Anthony Fauci warns that a rebound in cases could be seen if social distancing is tossed aside due to the virus' ability to "spread like wildfire." In addition, [recent polls](#) show deep safety concerns from voters across the political spectrum. Only 27% of Republicans and 10% of Democrats polled felt a readiness to resume in-person daily activities, travel or attend crowded workplace events.



### **Policy Changes to Accelerate COVID-19 Therapeutics**

Due to COVID-19 therapeutics' potential for saving lives and reopening the economy, the government has been cutting through red tape to fast track their development. Normally, vaccine development [would take several years](#); FDA drug approvals alone can take [six to 10 months](#). The Administration is looking to find COVID-19 treatments in a fraction of that time, despite [potential risks](#) to patients. Key regulatory changes to accomplish this have focused on speeding up the clinical trials, allowing access to investigational drugs and information sharing.

#### **Streamline Clinical Trials**

The FDA developed the [Coronavirus Treatment Acceleration Program \(CTAP\)](#) to ensure COVID-19 studies get underway and treatments be brought to market as soon as possible. This includes streamlining FDA protocol review processes to 24 hours and identifying priority products, which can lead to a reduced [six-month approval](#) timeline.

## **Fast-Track Vaccine Development**

Pharmaceutical companies are leveraging the groundwork from past vaccines' development and other nontraditional methods to [meet an accelerated timeline](#) of a year to 18 months, or sooner, for a vaccine. These efforts are being aided by policy measures, such as the [NIH's initiative](#) to share clinical trial designs and prioritize potential vaccine candidates. Another controversial [proposed policy](#) to fast track vaccines is allowing volunteers to be [infected with COVID-19](#) to test a vaccine.

## **Access to Investigational Therapeutics**

The FDA can also invoke [Emergency Use Authorizations \(EUAs\)](#) to allow medical products without full FDA approval to be used for emergency treatment in certain situations. For example, remdesivir, an antiviral drug, was recently [granted an EUA](#) after an accelerated [adaptive clinical trial](#) revealed supporting evidence, giving clinicians access to this drug.

## **Safety Concerns**

Researchers still warn against the dangers of moving too quickly in therapeutic and vaccine development. In the past, [botched vaccines](#) have mistakenly infected people with a live virus or triggered an adverse immune response. If a potential vaccine causes harm to people, it could [further increase mistrust](#) of the scientific community.

## **Supreme Court Rules in Favor of Insurers**

The Supreme Court has ruled the withholding of risk-corridor payments from insurers to be unlawful. In an [8-to-1 decision](#), the Court is requiring that the federal government pay the \$12 billion owed to select insurers in the Affordable Care Act's (ACA) risk-corridor program. The risk-corridor program was a stabilization program established by the ACA to help offset the risk of selling same-premium coverage to all consumers, regardless of health status or preexisting conditions. In 2014, the government pulled back on this promise, prompting more than [50 lawsuits](#) from insurers.



## 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:

- The Democratic National Committee is scheduled to meet and weigh approvals for states who have postponed their primaries past June 9<sup>th</sup>, the original deadline for holding primaries. Kentucky is included in the list of states seeking this approval.
- Continued coronavirus safety concerns are prompting states to explore online voting, despite concerns from cybersecurity experts. Currently, [three states](#) plan to allow internet voting for select populations' summer primaries.



### A Look at the Federal Register

#### **21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking and the ONC Health IT Certification Program**

HHS and the ONC have released a [final rule](#) implementing certain health IT-related provisions of the 21<sup>st</sup> Century Cures Act. The rule finalizes requirements for developers, modifies certification criteria, outlines voluntary certification of health IT for use by pediatric providers, and “reasonable and necessary” activities that will not be considered information blocking. **The rule is effective on June 30, 2020.**

#### **CMS Interoperability and Patient Access Final Rule**

CMS has released a [final rule](#) on interoperability and patient access. The rule is intended to improve the quality and accessibility of health information, including data on health care prices and outcomes, while minimizing reporting burdens for providers and payers. **The rule is effective on June 30, 2020.**

### **New Mailing Standards for COVID-19 Related Category B Infectious Substances**

The Postal Service has issued a [temporary final rule](#) to support the regulation and rapid deployment of COVID-19 diagnostic tests using the mail. All shippers of these infectious substances must obtain authorization prior to mailing. **The rule is effective on April 27, 2020 through the duration of the PHE.**

### **Grants, Contracts and Other Agreements: Fraud and Abuse, Information Blocking, Civil Monetary Penalty Rules**

HHS has released a [proposed rule](#) that would amend the civil monetary penalty rules to incorporate new authorities, assessments and exclusions related to HHS grants or other agreements; incorporate new authorities regarding information blocking; and increase the maximum penalties for certain violations. **Comments are due on June 23, 2020.**

### **IN OTHER NEWS**

[The Politics and Price of Premature Reopening](#) – Washington Post

[A Terrible Price: The Deadly Racial Disparities of COVID-19 in America](#) – NY Times

[Welcome Back to the Office. Your Every Move Will Be Watched](#) – Wall Street Journal

[What is the Real Coronavirus Toll in Each State](#) – NY Times

[Trump's "Operation Warp Speed" Aims to Rush Coronavirus Vaccine](#) – Bloomberg

[What CMS's Response to COVID-19 Means for Front Line Clinicians](#) – Health Affairs