

COVID-19: A Weekly Health Care Update from Washington
March 30 – April 3, 2020

IN BRIEF

What Happened This Week: With three major pieces of COVID-19 legislation now enacted, government agencies got to work this week to implement new programs and issue guidance for individuals, businesses, states, and health care providers. The Trump Administration extended its social distancing guidelines through the end of April, and announced a handful of temporary regulatory changes aimed at maximizing the flexibility of health care providers responding to the pandemic.

What to Expect in the Weeks and Months Ahead: Although Congress is not expected to be physically present in Washington until at least April 20, efforts to respond to the pandemic legislatively are far from over. Looking ahead, we can expect lawmakers to continue working remotely on additional measures tied to the pandemic.

DEEP DIVE

President Signs Third Major COVID-19 Emergency Supplemental Funding Bill Into Law; House Democrats Unveil Their Priorities for Future COVID-19 Legislation

Last Friday, Congress passed and the President signed, the bipartisan Coronavirus Aid, Relief, and Economic Security (CARES) Act ([H.R. 748](#)). The \$2.2 trillion emergency supplemental funding bill is the largest relief package in U.S. history and the third in a series of bills Congress has passed since the beginning of March to address the COVID-19 pandemic. In this [separate document](#), Mehlman Castagnetti summarizes the key provisions of the CARES Act, and attempts to put in one place some of most helpful resources the government has made available on COVID-19.

Looking ahead, it is almost certain that Congress will move to take up additional measures to deal with the crisis, although the timeline for passage and the details of any subsequent legislation are still unclear at this point. On Wednesday, House Democrats held a [press conference](#) to discuss their priorities for the next coronavirus response package (the so called “fourth package”). The list included infrastructure investments (which they said would build off of their [Moving Forward](#) infrastructure proposal from January), increased health care worker protections and additional aid for states to deal with the pandemic. President Trump has also [expressed interest](#) in some form of infrastructure investment, although Senate Majority Leader Mitch McConnell (R-KY) suggested that Congress hold off on taking up any major stimulus bill until the effects of the first three response bills are more fully realized. “Let’s see how things are going and respond accordingly,” he [said](#) Tuesday during a media

interview. Lawmakers are not expected to be in Washington until at least April 20, although negotiations are expected to continue remotely.

Speaker Pelosi Announces Formation of New House Select Committee on the Coronavirus Crisis

House Speaker Nancy Pelosi (D-CA) sent a “Dear Colleague” [letter](#) to all Members of the House yesterday announcing the formation of a House Select Committee on the Coronavirus Crisis. Within the letter, the Speaker explained that the bipartisan oversight Committee will be tasked with “ensur[ing] that the over \$2 trillion that Congress has dedicated to this battle – and any additional funds Congress provides in future legislation – are spent wisely and effectively.” The Committee will be chaired by House Majority Whip Jim Clyburn (D-SC).

Trump Administration Announces Regulatory Changes Aimed at Addressing Patient Surge

Using the authority provided under President Trump’s Emergency Declaration and emergency rule making, the Centers for Medicare & Medicaid Services (CMS) [announced](#) a handful of temporary regulatory changes intended to maximize the flexibility of health care providers responding to the pandemic. The Administration’s temporary changes include:

- *Increase Hospital Capacity* – Under the new guidance, CMS will allow communities to use local ambulatory surgery centers that followed federal recommendations to cancel elective surgeries. According to CMS, surgery centers will now be permitted to contract with local healthcare systems to provide hospital services, or they can enroll and bill as hospitals during the emergency declaration as long as they are not inconsistent with their State’s Emergency Preparedness or Pandemic Plan.
- *Expand the Healthcare Workforce* – CMS will temporarily permit local private practice clinicians and their trained staff to be available for temporary employment since nonessential medical and surgical services are postponed during the public health emergency. This temporary guidance is intended to allow hospitals and healthcare systems to increase their workforce capacity without violating Medicare rules.
- *Reduce Regulatory Burden* – CMS will temporarily eliminate paperwork requirements (such as extending reporting deadlines and suspending documentation requests) during the President’s Emergency Declaration. Medicare will also cover respiratory-related devices and equipment for any medical reason in an effort to better help patients get the care they need (under normal conditions, Medicare only covered these devices under certain circumstances).
- *Promote Telehealth in Medicare* – In an effort to build on its [previous action](#) to expand reimbursement for telehealth services, CMS says it will now allow for more than 80 additional services to be furnished via telehealth. Providers will be permitted to bill for telehealth visits at the same rate as in-person visits. And patients will be permitted to use apps with audio and video capabilities to visit with their clinician for a broader range of services, and providers will also be permitted to evaluate beneficiaries who have audio phones only (under normal

circumstances, CMS required clinicians to interact with the patient using both audio and visual).

For additional background information on the waivers and rule changes, click [here](#). For more information on the COVID-19 waivers and guidance, and the Interim Final Rule, click [here](#).

FCC Chairman Announces New Plan for Telehealth Program

Federal Communications Commission (FCC) Chairman Ajit Pai [announced](#) the Commission's plan for new COVID-19 Telehealth Program intended to support health care providers responding to the coronavirus pandemic by providing them with the support to purchase telecommunications services, information services, and devices necessary to enable the provision of telehealth services. The program is being funded using the \$200 million that was appropriated to the FCC in the CARES Act. Selected applicants will be provided with full funding for the eligible telehealth services and devices. Providers interested in participating will be required to submit an application to the FCC, and the Commission would then award funds on a rolling basis until the funds are exhausted or until the current pandemic has ended. In addition to this new telehealth program, the Chairman also announced the Commission's plans to implement a longer term Connected Care Pilot Program, intended to provide universal service support to help cover health care providers' qualifying costs of providing connected care services. Chairman Pai said this program would specifically focus on benefitting low-income or veteran patients.

HHS Announces Blanket Waivers of Physician Self-Referral Law During COVID-19 Pandemic

Earlier this week, the Department of Health and Human Services (HHS) [announced](#) it will issue blanket waivers of the physician self-referral law (Stark law) for the duration of the President's COVID-19 national emergency [declaration](#). According to the guidance document, the waiver only applies to financial relationships and referrals related to the COVID-19 outbreak in the United States. The Stark law was enacted in the late 1908s with the intent of preventing Medicare physician's financial interests from interfering with clinical decisions; however, in recent years, many providers have argued that it should be updated to alleviate regulatory burden.

CMS to Provide Financial Relief to Medicare Providers During COVID-19 Outbreak

The Centers for Medicare & Medicaid Services (CMS) recently [announced](#) it has expanded its accelerated and advance payment program for participating Medicare health care providers and suppliers during the COVID-19 pandemic. In order to qualify for the accelerated / advance payments, the Medicare provider / supplier must:

- Have billed Medicare for claims within 180 days immediately prior to the date of signature on the provider's/ supplier's request form,
- Not be in bankruptcy,
- Not be under active medical review or program integrity investigation, and
- Not have any outstanding delinquent Medicare overpayments.

The Agency says it expects the payments to be issued within seven days of the provider's request. An informational fact sheet on the accelerated/advance payment process and how to submit a request can be found [here](#).

Trump Administration Extends Social Distancing Guidelines Through End of April

The Trump Administration [announced](#) an extension of social distancing guidelines through April 30. While speaking at a press conference in the White House's Rose Garden, the President said the decision was made "based on modeling that shows the peak in fatalities will not arrive for another two weeks." He added that the modeling also showed that "vigorously" following the guidelines "could save more than 1 million American lives."

Trump Administration Expected to Update Guidelines on Face Masks in Public

Trump Administration officials [suggested](#) earlier today that the US could soon be updating its guidance on masks to recommend that all Americans – particularly those in the "hot spots" – wear masks in addition to continuing to practice social distancing while in public. However, officials were also quick to emphasize that Americans should opt for a bandana or cloth covering in lieu of the medical grade masks that health care workers and first responders need to protect themselves.

Former FDA Officials and Health Care Experts Propose "Roadmap" for Reopening America

In a new [report](#) titled, "National Coronavirus Response: A Road Map to Reopening," a handful of former FDA officials are proposing a four step plan to "reopen" America, including:

- **Phase 1 – Slow the Spread:** "These measures will need to be in place in each state until transmission has measurably slowed down and health infrastructure can be scaled up to safely manage the outbreak and care for the sick."
- **Phase 2 – State-by-State Reopening:** "Individual states can move to Phase II when they are able to safely diagnose, treat, and isolate COVID-19 cases and their contacts. During this phase, schools and businesses can reopen, and much of normal life can begin to resume in a phased approach. However, some physical distancing measures and limitations on gatherings will still need to be in place to prevent transmission from accelerating again."
- **Phase 3 – Establish Immune Protection and Lift Physical Distancing:** "Physical distancing restrictions and other Phase II measures can be lifted when safe and effective tools for mitigating the risk of COVID-19 are available, including broad surveillance, therapeutics that can rescue patients with significant disease or prevent serious illness in those most at risk, or a safe and effective vaccine."
- **Phase 4 – Rebuild Our Readiness for the Next Pandemic:** "After we successfully defeat COVID-19, we must ensure that America is never again unprepared to face a new infectious disease threat. This will require investment into research and development initiatives, expansion of public-health and health care infrastructure and workforce, and clear governance structures to execute strong preparedness plans."

The plan was authored by:

- Scott Gottlieb, resident fellow at the American Enterprise Institute and former FDA Commissioner from 2017 to 2019.
- Mark McClellan, director of the Duke-Margolis Center for Health Policy and former FDA Commissioner from 2002 to 2004.
- Lauren Silvis, senior vice president at Tempus Inc. and former Deputy Director of the FDA's Medical Device Center and the agency's Chief of Staff from 2017 to 2019.
- Caitlin Rivers, epidemiologist and assistant professor at the Johns Hopkins Center for Health Security.
- Crystal Watson, health security expert and assistant professor at the Johns Hopkins Center for Health Security.

Trump Administration Engages Hospitals in Data Sharing

Over the weekend, the Centers for Medicare & Medicaid Services (CMS) sent a [letter](#) to US hospitals requesting they report data in connection with their efforts to combat COVID-19, specifically citing testing data in addition to daily reporting regarding bed capacity and supplies to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) COVID-19 Patient Impact and Hospital Capacity Module. In a statement, CMS Administrator Seema Verma said the additional data will "help us better support hospitals to address their supply and capacity needs, as well as strengthen our surveillance efforts across the country." Click [here](#) for a press release from CMS.

ADMINISTRATION ANNOUNCEMENTS

Department of Health and Human Services

- [DOJ and HHS Partner to Distribute More Than Half A Million Medical Supplies Confiscated from Price Gougers](#)
- [HHS OCR Announces Notification of Enforcement Discretion to Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities During The COVID-19 Nationwide Public Health Emergency](#)
- [Optimizing Ventilator Use during the COVID-19 Pandemic](#)

Centers for Medicare & Medicaid Services

- [Trump Administration Issues Key Recommendations to Nursing Homes, State and Local Governments](#)
- [Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge](#)
- [Trump Administration Makes Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge](#)
- [Trump Administration Engages America's Hospitals in Unprecedented Data Sharing](#)

Centers for Disease Control and Prevention

- [Strategies to Optimize the Supply of PPE and Equipment](#)
- [CDC's role in helping cruise ship travelers during the COVID-19 pandemic](#)
- [Information for Healthcare Providers: COVID-19 and Pregnant Women](#)
- [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 \(COVID-19\)](#)
- [Collection and Submission of Postmortem Specimens from Deceased Persons with Known or Suspected COVID-19, March 2020 \(Interim Guidance\)](#)
- [Interim Guidance for Administrators of US K-12 Schools and Child Care Programs](#)
- [Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 \(COVID-19\) in Healthcare Settings](#)
- [Cleaning and Disinfection for Community Facilities](#)
- [Public Health Recommendations for Community-Related Exposure](#)
- [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#)
- [Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease \(COVID-19\)](#)

Food and Drug Administration

- [FDA Requests Removal of All Ranitidine Products \(Zantac\) from the Market](#)
- [FDA Provides Updated Guidance to Address the Urgent Need for Blood During the Pandemic](#)
- [FDA Continues to Accelerate Development of Novel Therapies for COVID-19](#)
- [FDA Expedites Review of Diagnostic Tests to Combat COVID-19](#)
- [FDA on Signing of the COVID-19 Emergency Relief Bill, Including Landmark Over-the-Counter Drug Reform and User Fee Legislation](#)

QUICK LINKS

- [Johns Hopkins University Map of Global Cases of Coronavirus](#)
- [CDC Map of Coronavirus Cases in the US](#)
- [CMS COVID-19 Stakeholder Call Recording/Transcripts](#)
- [Kaiser Family Foundation: State Data and Policy Actions to Address Coronavirus](#)
- [CRS Report: COVID-19 – Global Implications and Responses](#)