



Weekly Health Care Checkup: *COVID-19 and Beyond* July 20-24, 2020

IN BRIEF

What Happened This Week: Much of Washington was on standby this week waiting for Senate Republicans to drop their fourth and “final” COVID-19 response proposal, though internal party divisions over the size and scope of the bill ultimately [delayed](#) its anticipated release (more on this in the “Deep Dive” section of our report [here](#)).

Meanwhile, committee work resumed on both sides of the Capitol. The [House Oversight and Reform Subcommittee on Government Operations](#) kicked things off on Monday with a hearing on how COVID-19 has exposed outdated federal IT systems. On Tuesday, a group of pharmaceutical company executives testified before the [House Energy and Commerce Subcommittee on Oversight and Investigations](#) on the development of a COVID-19 vaccine. That same day, the [Senate Aging Committee](#) held a hearing looking at COVID-19’s impact on seniors, minority groups, and health disparities. On Wednesday, the [Senate Homeland Security and Governmental Affairs Committee](#) voted on several bills, including a handful of COVID-19 related proposals. And yesterday, the [House Education and Labor Subcommittee on Early Childhood, Elementary, and Secondary Education](#) heard from representatives from school districts in Texas and Tennessee, as well as the National Parent Teacher Association and the American Academy of Pediatrics during a hearing about how states can safely reopen public schools.

On the legislative front, the [lead Democrat on the Senate Finance Committee](#) and [House Republicans](#) both unveiled separate telehealth expansion proposals this week, and Senate HELP Committee Chairman introduced [legislation](#) to prepare for future pandemics.

In non-COVID news, the Senate voted 86-14 yesterday to approve its annual defense authorization legislation (NDAA) ([S. 4049](#)). The House passed its own NDAA bill ([H.R. 6395](#)) on Tuesday; however, in a [Statement of Administration Policy](#), the White House cited “serious concerns” with “several” provisions in the House bill and threatened to veto the legislation in its current form.

And later this morning, the House is expected to vote on a four-bill appropriations package ([H.R. 7608](#)) that includes Agriculture-FDA, Interior-Environment, Military Construction-VA, and State and Foreign Operations funding for FY 2021.

Over at the White House, HHS Secretary Azar [announced](#) yesterday that the COVID-19 National Public Health Emergency Declaration has been renewed for the next 90 days (through the end of October). President Trump resumed his daily COVID-19 news briefings this week after a three-month hiatus. In his [remarks](#) on Tuesday, the President acknowledged

that the situation will “probably, unfortunately, get worse before it gets better.” He also [announced](#) yesterday that plans to hold the GOP Convention in Florida later this summer would be scrapped due to the ongoing pandemic. And in non-COVID news, the President is also [expected](#) to sign a series of Executive Orders tied to prescription drug prices later today.

What to Expect Next Week: Though it’s possible the timeline could shift again, Senate Majority Leader Mitch McConnell (R-KY) [said](#) yesterday that he expects his party to release the details of their fourth COVID-19 response proposal on Monday. Should this scenario play out next week, the legislation still faces an uphill battle as the measure will need the approval of both the House and the Senate and – as it stands now – both parties are far apart on some of the major details in the bill.

The House is also expected to take up another appropriations package ([H.R. 7617](#)) next week that includes Defense, Commerce-Justice-Science, Energy and Water, Financial Services, Homeland Security, Labor-HHS-Education, and Transportation-HUD funding. This package is expected to pass; however, beyond that, it is unclear when both chambers will be able to move to conference as the Senate has yet to advance any of its own spending bills for FY 2021.

Click [here](#) for our full list of COVID / other health-related hearings slated for next week.

DEEP DIVE

Internal Party Divisions Delay Release of Senate GOP’s Fourth and “Final” COVID Response Bill: Much of Washington was on standby this week, waiting for Senate Republicans to drop their fourth and “final” COVID-19 response proposal; however internal party divisions over the size and scope of the bill ultimately [delayed](#) its anticipated release yesterday morning. In his remarks on the Senate floor later in the day yesterday, Senate Majority Leader Mitch McConnell (R-KY) said he now expects his party to release the details of their fourth COVID-19 response proposal on Monday. “The Administration has requested additional time to review the fine details, but we will be laying down this proposal early next week. We have an agreement in principle on the shape of this package,” he said.

But even if / when the Republicans unveil their bill next week, the proposal will merely serve as the opening salvo for negotiations between Republicans, Democrats, and the White House. As it stands now, some of the major sticking points between both parties include the bill’s price tag (Senate Republicans and the White House are reportedly eyeing a bill in the range of \$1 trillion, while House Democrats’ proposed fourth COVID bill – [HEROES Act](#) – was upwards of \$3 trillion), an [extension](#) of the CARES Act’s unemployment benefits (set to expire July 31), and the direct stimulus [payments](#) to individuals and families. With the dwindling number of legislative working days remaining before the monthlong August recess, it remains to be seen whether negotiators will be able to hammer out a deal and pass the legislation by the end of the month, or, if debate on this next response measure will spill over into August.

Drug Company Execs Testify Before House Subcommittee on COVID-19 Vaccine Development: Executives from AstraZeneca, Johnson & Johnson, Merck, Moderna, and Pfizer testified before the House Energy and Commerce Subcommittee on Oversight and Investigations Tuesday on the development of a COVID-19 vaccine. During the hearing, several Democrats – including Committee Chairman Frank Pallone (D-NJ) – expressed concern that the Trump Administration might pressure the FDA to forego standards of effectiveness in exchange for a quicker vaccine approval timeline. In response, all witnesses emphasized that they had not seen any evidence of the Agency lowering its efficacy standards and agreed that they themselves would not bring a product to market that was not found to be efficacious or safe. Dr. Menelas Pangalos, AstraZeneca’s Executive Vice President of Biopharmaceuticals R&D, added that because the

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vaccine will be used globally, it will be subjected to all other regulatory authorities around the world as well. A full summary of the discussion can be found [here](#).

Senate HELP Committee Chairman Introduces Pandemic Preparedness Legislation: On Monday, Senate HELP Committee Chairman Lamar Alexander (R-TN) formally introduced pandemic preparedness [legislation](#) which would:

- Provide new, sustained funding – \$5 billion over 10 years – to maintain onshore manufacturing for tests, treatments and vaccines.
- Provide new, sustained funding – \$10 billion over 10 years – for states to create and maintain their own stockpiles of supplies.
- Allow the federal government to work with companies to maintain additional supplies and manufacturing capacity for the federal Strategic National Stockpile.

The legislation was crafted following a June [white paper](#) from Alexander in which he solicited responses from stakeholders on preparing for the next pandemic. In a statement, Alexander said it was “imperative” that Congress act on the bill this year because “[e]ven with an event as significant as COVID-19, memories fade and attention moves quickly to the next crisis.” Earlier this spring, the HELP Committee conducted several pandemic preparedness hearings and issued a white paper soliciting feedback on recommendations to address future pandemics.

Senate Aging Committee Holds Hearing on COVID-19’s impact on Seniors, Minority Groups, and Health Disparities:

On Tuesday, the Senate Aging Committee held a [hearing](#) looking at COVID-19’s impact on seniors, minority groups, and health disparities. “There is still a great deal that we don’t yet know about COVID-19,” Chairwoman Collins (R-ME) said in her opening statement. “But we do know that individuals with chronic kidney disease, serious heart conditions, obesity, sickle cell disease, and Type 2 diabetes are at increased risk of severe illness from COVID-19, and that Black Americans experience these conditions at disproportionate rates.” In his own remarks, Atrium Health CEO Gene Woods testified that his company has had to “really rethink everything that we do as a health system” in order to respond to the challenges that minority groups in particular are facing during the pandemic. “We realize the road ahead is long, and there’s many challenges that remain.”

Senate HSGAC Approves COVID Legislation During Markup: On Wednesday, the Senate Homeland Security and Governmental Affairs Committee [approved](#) the following measures (by voice vote) during a markup:

- [S. 4204](#), Federal Emergency Pandemic Response Act, which would establish an interagency task force to analyze preparedness for national pandemics.
- [S. 4210](#), Securing Healthcare and Response Equipment Act, which would authorize the transfer of certain equipment during a public health emergency.
- [S. 4153](#), National Response Framework Improvement Act, which would require the Federal Emergency Management Agency to evaluate the National Response Framework based on lessons learned from the COVID-19 pandemic
- [S. 4157](#), National Infrastructure Simulation and Analysis Center Pandemic Modeling Act, which would expand the authority of the National Infrastructure Simulation and Analysis Center.
- [S. 4158](#), PPE Supply Chain Transparency Act, which would examine the extent of the reliance of the United States on foreign producers for personal protective equipment during the COVID-19 pandemic and produce recommendations to secure the supply chain of personal protective equipment.

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Lead Senate Finance Committee Democrat and House Republicans Unveil Separate Telehealth Proposals: On Monday, July 20, Senate Finance Committee Ranking Member Ron Wyden (D-OR) unveiled the details of a new telehealth bill ([S. 4230](#), the Telehealth Expansion Act) that would permanently expand mental health services and commonplace medical visits (known as evaluation and management (E/M) services) available via telehealth in Medicare beyond the COVID-19 pandemic by removing statutory geographic restrictions and expanding the available originating sites for those telehealth services. In a statement, Wyden said the pandemic “has been a trial by fire, but the experience to date has made clear that the health care system is ready for broader access to telehealth on a permanent basis.” That same day, House Ways and Means Committee Republicans released their own draft telehealth expansion [proposal](#). In a statement, Ways and Means Health Subcommittee Ranking Member Devin Nunes (R-CA) said: “[g]iven the success of increased access to telehealth for Americans during the pandemic, Congress should prioritize making increased access to telehealth a permanent function of our nation’s healthcare system.” Click [here](#) for the text of the discussion draft. Click [here](#) for the full summary.

House E&C Democrats Call on HHS Secretary Azar to Resign or Step Up on COVID-19: In a [letter](#) sent Monday, House Energy and Commerce Committee Chairman Frank Pallone (D-NJ) and Oversight and Investigations Subcommittee Chair Diana DeGette (D-CO) sent a letter to HHS Secretary Alex Azar expressing concern about the Trump Administration’s efforts to respond to the COVID-19 pandemic and calling on him to either step up in the fight against COVID-19 or step aside. “As the top health official in the country, you have a duty to protect the health and well-being of all Americans,” the lawmakers wrote. “Instead, you have spent the last six months promoting politics over science in our nation’s COVID-19 pandemic response. It is time for you to either stand up to protect public health or step aside as the nation’s top health official.”

Senate Democrats Urge White House to Reverse WHO Withdrawal Decision: A group of Senate Democrats – led by Senator Cory Booker (D-NJ) – sent a [letter](#) to President Trump urging him to reverse his decision to withdraw from the World Health Organization (WHO). “As it is now grimly clear, diseases do not respect borders. This is a crisis of global proportions, one that has painfully exposed the vulnerabilities and deficiencies of even the strongest economies and most competently governed societies,” the senators wrote. “This means in part continuing to collaborate and support the WHO, which is coordinating the global response to COVID-19.”

HHS Secretary Renews Public Health Emergency Through October: HHS Secretary Alex Azar [announced](#) yesterday that the COVID-19 National Public Health Emergency Declaration has been renewed for the next 90 days (through the end of October). In a tweet, Azar said the Administration “will continue its whole-of-America response to ensure Americans can get the care they need throughout the pandemic.”

HHS Begins Distribution of \$10 Billion in Additional Funding to Hospitals in High Impact COVID-19 Areas: Late last week, HHS’ Health Resources and Services Administration (HRSA) [announced](#) its intent to begin distributing an additional \$10 billion in funding to hospitals in areas hit hard by the COVID-19 pandemic beginning this week. This second round of funding will be distributed based on a formula for hospitals with over 161 COVID-19 admissions between January 1 and June 10, 2020, or one admission per day, or that experienced a disproportionate intensity of COVID admissions (exceeding the average ratio of COVID admissions/bed). Hospitals will be paid \$50,000 per eligible admission. In a statement, HHS Secretary Alex Azar said: “[b]ecause we’ve carefully targeted support, we can make payments to areas most in need as the pandemic evolves, like we are doing with this round of funds.”

Trump Administration Announces New Resources to Protect Nursing Home Residents Against COVID-19: In a press release on Wednesday, the Trump Administration announced several new initiatives tied to protecting nursing home residents during the pandemic. As part of the announcement, the Department says it plans to allocate \$5 billion of the

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CARES Act's Provider Relief Fund to Medicare-certified long term care facilities and state veterans' homes (nursing homes), to build nursing home skills and enhance nursing homes' response to COVID-19, including enhanced infection control. HHS says the money could be used to address a range of issues, including hiring additional staff, implementing infection control "mentorship" programs with subject matter experts, increasing testing, and providing additional services, such as technology so residents can connect with their families if they are not able to visit. In order to qualify for the funding, nursing homes must participate in the Nursing Home COVID-19 Training Program. In addition to the funding, HHS says it also intends to:

- Deploy Federal Task Force Strike Teams to provide onsite technical assistance and education to nursing homes experiencing outbreaks in an effort to help reduce transmission and the risk of COVID-19 spread among residents; and
- Begin to require, instead of recommend, that all nursing homes in states with a 5 percent positivity rate or greater test all nursing home staff each week (this announcement builds on CMS's recent [effort](#) to distribute rapid point of care testing at nursing homes in COVID-19 "hot spots" nationwide).

HHS Announces Publicly Available HHS Protect Data on HHS Protect Dashboard: On Monday, HHS announced that hospital-specific HHS Protect data (including inpatient bed utilization, ICU bed utilization, percentage of inpatient beds occupied by COVID-19 patients, and number of COVID-19 cases) would be publicly available via the HHS Coronavirus Data Hub. HHS says it built and launched the HHS Protect platform in April for authentication, amalgamation, and sharing of healthcare information. The [HHS Protect](#) platform then provides the data and analytics underlying the [HHS Coronavirus Data Hub](#). The public dashboards can be found [here](#). A FAQ document on HHS Protect can be found [here](#).

HHS Announces New COVID-19 Testing Implementation Forum: On Tuesday, HHS [announced](#) a new COVID-19 Testing Implementation Forum intended to capture feedback between federal officials and the private sector about SARS-CoV-2, the virus that causes COVID-19, testing and diagnostics. In a statement, HHS Assistant Secretary for Health ADM Brett Giroir said: "[g]aining private sector input is critical bringing novel technologies into widespread use by the public health and commercial sectors." HHS says forum participation will rotate in an effort to ensure diverse input. Federal participants will be led by the Office of the Assistant Secretary for Health, and include rotations from stakeholder groups, CDC, NIH, CMS, FDA, BARDA, and others.

FDA Issues First EUA for Sample Pooling in Diagnostic Testing: Earlier this week, the FDA reissued an emergency use authorization (EUA) to Quest Diagnostics for its [SARS-CoV-2 rRT-PCR test](#) for use with pooled samples containing up to four individual swab specimens collected under observation. The Quest test is the first COVID-19 diagnostic test to be authorized for use with pooled samples. In sample pooling, specimens are identified from populations based on positivity rate (for example, by county, zip code or by client). Up to four patient specimens are combined into a pool, and the pool is tested. If the pool is positive, inconclusive or invalid, then each of the constituent samples is re-tested as a separate individual specimen. If the pool is negative, then each constituent sample is reported as negative.

CDC Issues New Nursing Home Testing Guidance: The CDC recently released new [guidance](#) on COVID-19 testing in nursing homes. Within the document, the CDC stressed that testing conducted in nursing homes should be implemented in addition to [recommended IPC measures](#), and that facilities should aim for rapid turnaround times of test results.

OCR Issues Guidance on Civil Rights Protections Prohibiting Race, Color, and National Origin Discrimination During COVID-19: The HHS Office of Civil Rights recently issued [guidance](#) in an effort to ensure that recipients of federal financial assistance understand that they must comply with applicable federal civil rights laws and regulations that prohibit discrimination on the basis of race, color, and national origin in HHS-funded programs during COVID-19.

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NASEM and NAM to Develop Framework for Equitable Vaccine Distribution: The National Academies of Sciences, Engineering, and Medicine and the National Academy of Medicine (NAM) recently formed a [committee](#) to develop an [overarching framework](#) to assist policymakers in planning for equitable distribution of COVID-19 vaccines. As part of their effort, the groups say they will [consider](#): what criteria should be used to set priorities for equitable distribution among groups of potential vaccine recipients, taking into account factors such as population health disparities; individuals at higher risk because of health status, occupation, or living conditions; and geographic distribution of active virus spread. In addition, the committee will consider how communities of color can be assured access to COVID-19 vaccines in the US and recommend strategies to mitigate vaccine hesitancy among the American public.

CMS Releases FAQs on COVID-19 Medicare Provider Enrollment Relief: CMS recently issued an [FAQ](#) document on COVID-19 Medicare Provider Relief. Within the document, the Agency seeks to address issues related to waiver flexibilities for provider enrollment, hotline information, and information on options for providing care in alternative settings.

CDC Director Issues Statement RE: COVID-19 Infection Rate: In an effort to clarify recent media reports that there are 24 times more COVID-19 infections than reported cases, CDC Director Dr. Robert Redfield issued a [statement](#) this week, saying that the Agency's "retrospective estimate is that there were 10 times more cases than reported from the period where we've been examining antibody data: March through May."

CDC Updates Information on COVID-19 Contact Tracing: The CDC recently updated its interim COVID-19 contact tracing [communications toolkit](#) for health departments and issued a [guide](#) for conducting a COVID-19 case investigation (including operational questions that a jurisdiction should consider while planning their activities).

Noteworthy CDC Guidance on Reopening: Click [here](#) for updated information about going to the doctor and picking up medications during the pandemic. Click [here](#) for updated information to help employees make decisions about employee / customer protection. Click [here](#) for updated information for updated guidance for business owners. Click [here](#) for an updated FAQ document from the CDC regarding risk, infection control, transmission, testing, diagnosis, notification, treatment, management, etc. Click [here](#) for updated guidance from the CDC regarding the duration of isolation and precautions for adults with COVID-19. Click [here](#) for updated information from the CDC regarding separating yourself from others if you have COVID.

OTHER NOTEWORTHY HEALTH-RELATED ANNOUNCEMENTS COMING OUT OF WASHINGTON

House Poised to Approve its FY 2021 Appropriations Packages Ahead of August Recess; Senate Timeline for Action Still Unclear: The House is expected to move ahead with consideration of a four-bill appropriations package ([H.R. 7608](#)) today) that includes Agriculture-FDA, Interior-Environment, Military Construction-VA, and State and Foreign Operations funding for FY 2021. Next week, the chamber is expected to take up another appropriations package ([H.R. 7617](#)) that includes Defense, Commerce-Justice-Science, Energy and Water, Financial Services, Homeland Security, Labor-HHS-Education, and Transportation-HUD funding (the House bill would provide receive \$96.4 billion for HHS in FY 2021 – \$1.5 billion more than the FY 2020 enacted level and \$11.1 billion above the President's budget request). Both packages are expected to pass the House before the August recess; however beyond that, it is unclear when the House will be able to move to conference with the Senate as Senate appropriators have yet to advance any of their own spending bills for FY 2021 out of Committee. With very few legislative working days remaining before the September 30 deadline, a more likely scenario is that both chambers will move to instead take up a temporary spending bill, likely in the form of a continuing resolution in September to avoid a government shutdown.

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President Trump to Sign Executive Orders Tied to Rx Drug Prices: During an [event](#) at the White House later today, the President is expected to sign a series of Executive Orders tied to prescription drug prices. Although the details have not yet been released, reports have suggested that the Orders will attempt to address the so-called “favored nations rule” and Medicare’s 340B drug discount program.

FDA Issues New Labeling Requirements for Naloxone: The FDA [announced](#) yesterday that it will now require labeling for opioid pain medicine and medicine to treat opioid use disorder be updated to recommend that as a routine part of prescribing these medicines, health care professionals should discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. “Even during this global pandemic, we have continued to prioritize addressing the opioid crisis,” said FDA Commissioner Stephen Hahn. “Today’s action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose.”

Tracking Telehealth Legislation in the 116th Congress: Given the growing bipartisan interest in the use of telehealth during the pandemic, Mehlman Castagnetti has compiled a tracker of all telehealth-related legislation introduced this Congress. Please click [here](#) to view the tracker.

UPCOMING COVID / HEALTH-RELATED CONGRESSIONAL HEARINGS

Tuesday, July 28

10:00am

Senate Homeland Security and Governmental Affairs Committee Hearing
[Full Committee Hearing: Oversight of COVID-19 Financial Relief Packages](#)

10:15am

Senate Finance Committee Hearing
[Full Committee Hearing: Part 1: Protecting the Reliability of the U.S. Medical Supply Chain During the Pandemic](#)

2:30pm

Senate Homeland Security and Governmental Affairs Committee Hearing
[Subcommittee Hearing: Modernizing Telework: Review of Private Sector Telework Policies during the Pandemic](#)

2:30pm

Joint Economic Committee Hearing
[Full Committee Hearing: Reducing Uncertainty and Restoring Confidence during the Coronavirus Recession](#)

Wednesday, July 29

10:00am

House Committee on Energy and Commerce Hearing
[Subcommittee on Health Hearing: Improving Access to Care: Legislation to Reauthorize Key Public Health Programs](#)

- [H.R. 2075](#) to reauthorize school-based health centers;
- [H.R. 4078](#) to help improve the low-income housing credit;

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- [H.R. 4439](#) to give HHS Secretary permanent authority to issue priority review vouchers that would encourage treatments for rare pediatric diseases;
- [H.R. 4764](#) to reauthorize the "Stem Cell Therapeutic and Research Act of 2005; and
- [H.R. 5373](#) to reauthorize the United States Anti-Doping Agency.

10:00am

House Committee on Veterans' Affairs Meeting

[Subcommittee on Health Meeting: Examining Oversight of State Veterans Homes During the COVID-19 Pandemic](#)

10:00am

Senate Environment and Public Works Committee Hearing

[Full Committee Hearing: Lessons Learned from Remote Working during COVID-19: Can the Government Save Money Through Maximizing Efficient Use of Leased Space?](#)

3:00pm

Senate Veterans' Affairs Committee Hearing

[Full Committee Hearing: VA Telehealth During and Beyond COVID-19: Challenges and Opportunities in Rural America](#)

Thursday, July 30

Start Time TBD

Senate Finance Committee Hearing

[Full Committee Hearing: Part 2: Protecting the Reliability of the U.S. Medical Supply Chain During the Pandemic](#)

Friday, July 31

9:00am

House Select Subcommittee on the Coronavirus Crisis Hearing

[Select Subcommittee on the Coronavirus Crisis Hearing: Hybrid Hearing on The Urgent Need for a National Plan to Contain the Coronavirus](#)

ADMINISTRATION ANNOUNCEMENTS

Department of Health and Human Services

- [U.S. Government Engages Pfizer to Produce Millions of Doses of COVID-19 Vaccine](#)
- [OCR Resolves Religious Discrimination Complaint after Maryland Hospital System Ensures Patients Can Receive Religious Visitations During COVID-19](#)
- [OCR Resolves Complaint After Hospital Accommodates Medical Student's Religious Needs During COVID-19](#)
- [HHS Announces National COVID-19 Testing Implementation Forum](#)
- [OCR Issues Guidance on Civil Rights Protections Prohibiting Race, Color, and National Origin Discrimination During COVID-19](#)

Centers for Medicare & Medicaid Services

- [Trump Administration Announces New Resources to Protect Nursing Home Residents Against COVID-19](#)

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National Institutes of Health

- [NIH Leadership Details Unprecedented Initiative to Ramp Up Testing Technologies for COVID-19](#)

Food and Drug Administration

- [Click here for the full list of all new FDA updates.](#)

Noteworthy Guidance from the Centers for Disease Control and Prevention

- [Click here for the full list of all new CDC updates.](#)

QUICK LINKS

- [Mehlman Castagnetti's Infographics Analysis on Post-Pandemics Politics and Policy](#)
- [Additional Mehlman Castagnetti Resources on COVID-19](#)
- [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](#)

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