



Weekly Health Care Checkup: *COVID-19 and Beyond* August 10-14, 2020

IN BRIEF

What Happened This Week: In response to the [stalled negotiations](#) on the next COVID-19 response package, President Trump announced last weekend that he would be taking action administratively through a series of Executive Orders. As expected, several Democratic – and some Republican – lawmakers [questioned](#) the legality and effectiveness of the President’s move; however, it is unclear when – or if – lawmakers will be able to reach a deal on the next package as both parties are seemingly still far apart on some of the major details in the bill.

On Tuesday, HHS Secretary Alex Azar met with Taiwan’s President and various health officials to praise the country’s response to the pandemic. In his [remarks](#), Azar emphasized that Taiwan’s “openness, transparency and cooperation” stands in “stark contrast” to that of China. The following day, President Trump held a [briefing](#) (stateside) to discuss reopening the nation’s schools. And yesterday, HHS [announced](#) a combined investment in two commercial diagnostic laboratories to expand capacity to conduct up to 4 million additional COVID-19 tests per month. The investments – totaling \$6.5 million – were awarded to Aegis Sciences Corporation and Sonic Healthcare USA.

In other non-COVID, but still health-related news, CMS [announced](#) a new Community Health Access and Rural Transformation (CHART) Model this week aimed at improving access to quality care while reducing costs.

And in major political news this week, presumptive Democratic Presidential candidate Joe Biden [declared](#) Kamala Harris as his running mate in the 2020 election.

What to Expect Next Week: The 2020 Democratic National Convention is scheduled to take place next week (August 17–20), although most events will be held virtually given the ongoing pandemic.

Meanwhile, over at the Capitol, both chambers are expected to be in recess for the next few weeks (through September 8 in the Senate and through September 14 in the House), although party leaders in both chambers have told their members to be on standby for votes in the event that an agreement on the next COVID response package is reached.

DEEP DIVE

COVID-19 Stimulus Negotiations at Standstill, President Trump Signs Series of Pandemic-Related Executive Orders: In response to the [stalled negotiations](#) on the next COVID-19 response package, President Trump announced last weekend that he would be taking action administratively through a series of Executive Orders. “I’m taking executive action,” the President said Saturday. “We’ve had it. And we’re going to save American jobs and provide relief to the American workers.” In summary, the President signed the following memorandums instructing his Administration to do the following:

1. [Postpone Federal Payroll Tax Collection](#): Although the President acknowledged that only Congress can permanently take action to cut taxes, this Executive Order would suspend collection of payroll taxes from September 1 through December 31 for Americans earning under \$100,000 a year.
2. [Consider Reinstating Expired Eviction Moratorium](#): The CARES Act’s eviction moratorium expired July 24. The President’s Executive Order instructs the HHS Secretary and the CDC Director to “consider” whether an eviction ban is necessary going forward and directs the Treasury Secretary to identify federal funding that could be used to provide temporary financial assistance to renters / homeowners.
3. [Reinstate Unemployment Benefits](#): The CARES Act’s unemployment benefits expired July 31. The President’s Executive Order allows state governors to set up a program to provide an extra \$400 per week in unemployment benefits (retroactive to the first week of August when the \$600 / week CARES Act payments expired); 25 percent of that payment would be provided by the states.
4. [Extend Federal Student Loan Payment Suspension](#): Under the CARES Act, federal student loan payments were set to resume October 1, 2020. The President’s Executive Order extends the payment suspension through January 1, 2021.

As expected, Democratic lawmakers – and a handful of Republicans – [questioned](#) the legality and effectiveness of the President’s Orders; however, it is unclear when – or if – lawmakers will be able to reach a deal on the next package as both parties are seemingly still far apart on some of the major details in the bill. At this point, the major [sticking points](#) continue to be: the bill’s price tag ([Senate Republicans’ HEALS Act](#) proposal is in the \$1 trillion range, while [House Democrats’ HEROES Act](#) is upwards of \$3 trillion) and funding for state and local governments (no new funding for state and local governments was included in the GOP proposal, though House Democrats’ HEROES Act calls for upwards of \$1 trillion in state and local aid).

Looking ahead, both chambers are expected to be in recess for the next few weeks (through September 8 in the Senate and through September 14 in the House), although party leaders in both chambers have told their members to be on standby for votes in the event that an agreement on the next COVID response package is reached. In his remarks on the Senate floor yesterday, Senate Majority Leader Mitch McConnell (R-KY) said he is “still hoping” lawmakers will be able to hammer out a deal “in the coming weeks”.

Energy and Commerce Committee Launch Investigation into Business Practices of Health and Dental Insurance Companies During Pandemic: Last week, House Energy and Commerce Committee Chairman Frank Pallone (D-NJ) [announced](#) that the Committee would be launching an investigation into the business practices of health and dental insurance companies during the pandemic. This week, Pallone – along with Health Subcommittee Chairwoman Anna G. Eshoo (D-CA) and Oversight and Investigations Subcommittee Chair Diana DeGette (D-CO) – sent oversight [letters](#) to nine health and dental insurance companies requesting information about their policies and practices during the COVID-19 pandemic. More specifically, the lawmakers said their primary concerns are with regard to reports of companies failing

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to comply with the consumer protection provisions in two previously enacted COVID response bills (the Families First Act and the CARES Act), which they say, has resulted in barriers to free COVID testing.

House Coronavirus Subcommittee Seeks Information on Operation Warp Speed: The Chairman of the House Oversight Select Committee on the Coronavirus Crisis Jim Clyburn (D-SC) sent [letters](#) to HHS Secretary Alex Azar, Operation Warp Speed Chief Advisor Dr. Moncef Slaoui, and David Harris, President and Chief Executive Officer of Advanced Decision Vectors, requesting information and documents on potential conflicts of interest in the Administration's vaccine and therapeutic development initiative, [Operation Warp Speed](#). The lawmaker also requested information on the Trump Administration's process for selecting vaccine candidates for investment through the initiative. "I am concerned that the selection of candidate vaccines for Operation Warp Speed lacked transparency and excluded many vaccine experts," Clyburn wrote, adding that he was "also concerned that Dr. Slaoui's financial interests in companies receiving federal funding—which he has referred to as 'my retirement'—raise serious ethical issues and could undermine public confidence in this process."

House E&C Committee Leaders Express Concern About Pandemic's Effect on Overdoses: In a joint [letter](#) sent earlier this week to HHS Secretary Alex Azar, House Energy and Commerce Committee Chairman Frank Pallone (D-NJ) and Ranking Member Greg Walden (R-OR) expressed concern that the pandemic has "exacerbated the ongoing substance use disorder and overdose crisis" and urged the Secretary to provide them with a briefing on "what more the federal government needs to do to address this growing crisis."

In separate, but related news, the CDC [released](#) a Morbidity and Mortality Weekly Report (MMWR) on Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic (from June 24-30, 2020), which revealed that while adults in the US reported "considerably elevated" adverse mental health conditions associated with COVID-19, younger adults, racial/ethnic minorities, essential workers, and unpaid adult caregivers reported having experienced "disproportionately worse" mental health outcomes, increased substance use, and elevated suicidal ideation. In a [blog post](#) this week, NIH Director Francis Collins discussed the wide range of negative impacts the pandemic is having on people affected by a variety of health conditions, including those struggling with substance use disorders.

And on the heels of this most recent mental health report, the CDC also recently [released](#) provisional data showing that deaths involving synthetic opioids, cocaine, and psychostimulants with abuse potential (including methamphetamine) continue to rise when compared to the previous year (6.6 percent increase in provisional drug overdose mortality for the 12 months ending in January 2020) compared to an increase of 4.8 percent and 3.0 percent for the 12 months ending in December 2019 and November 2019, respectively).

President Trump Holds Briefing on Reopening the Nation's Schools: On Wednesday, President Trump held a [briefing](#) to discuss safely reopening the nation's schools. In his remarks, Trump suggested that the concept of having children attend school every other day "seems a little ridiculous" and later added that virtual learning is "not as good as being [at school]". Click [here](#) for the Administration's newly released fact sheet on reopening. In separate, but related news, House Energy and Commerce Committee Chairman Frank Pallone (D-NJ) and leaders of the Committee's Oversight and Health Subcommittees sent a [letter](#) to CDC Director Robert Redfield calling for a new briefing on the "concerning" impacts of the pandemic on the nation's youth.

HHS Secretary Azar Visits Taiwan to Discuss Pandemic Response Efforts: Earlier this week, HHS Secretary Alex Azar met with Taiwan's President and various health officials to praise the country's response to the pandemic. In his [remarks](#), Secretary Azar said the country "applied the best science and public health methods to confronting COVID-19" while doing so with an "open and democratic spirit". In contrast, Azar commented that China "has had the chance to warn the

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world and work with the world on battling the virus...but they chose not to, and the costs of that choice mount higher every day."

HHS Announces New Investment in Diagnostic Labs to Expand COVID Testing Capacity: Yesterday, HHS [announced](#) a combined investment in two commercial diagnostic laboratories to expand capacity to conduct up to 4 million additional COVID-19 tests per month. The investments – totaling \$6.5 million – were awarded to Aegis Sciences Corporation and Sonic Healthcare USA. Both will provide laboratory equipment supplied by Beckman Coulter Life Sciences and Thermo Fisher Scientific and increased staffing and infrastructure in an effort to allow the US to perform an additional 1 million tests each week by early October. "We are committed to leveraging every possible opportunity to expand the nation's SARS-CoV-2 testing capacity over the next several months," said Assistant Secretary for Health ADM Brett Giroir, M.D. "For this opportunity, we were able to match available instrumentation and reagents with commercial labs that were ready to immediately expand their services. We are honored to work with these labs and life sciences tools companies to ensure increased access to testing as may be needed this fall."

HHS Announces Allocation of CARES Act Provider Relief Funding for Nursing Homes: Late last week, HHS [announced](#) its intent to distribute \$5 billion in CARES Act funding to nursing homes nationwide. Approximately \$2.5 billion will be distributed in mid-August to support increased testing, staffing, and PPE needs (according to HHS, funding will also be available for those establishing COVID isolation facilities). The remaining funding – which will be distributed throughout the fall – will instead be linked to nursing home performance (performance will be based on the nursing home's ability to minimize COVID spread and COVID-related fatalities among its residents).

HHS Announces Funding Opportunity for Health Information Exchanges: On Wednesday, HHS [announced](#) that the Office of the National Coordinator for Health Information Technology (ONC) will use \$2.5 million in CARES Act funding to award up to five cooperative agreements under the Strengthening the Technical Advancement and Readiness of Public Health Agencies via Health Information Exchange (STAR HIE) Program. According to the Department, the new funding opportunity is aimed at expanding and accelerating innovative uses of electronic health information via health information exchanges in support of state and local public health agencies. Applications are due September 1, 2020; the anticipated award date is September 31, 2020. More information can be found on the Notice of Funding Opportunity posting [here](#).

HRSA Unveils COVID-19 Testing Dashboard for FQHCs: HHS' Health Resources and Services Administration (HRSA) recently unveiled a new [dashboard](#) which provides a high-level view of the following: national counts for patients tested at Federally Qualified Health Centers (FQHCs) for COVID-19; percentage of patients that have tested positive for COVID-19 by state; and percentage of patients that have tested positive for COVID-19 by race and ethnicity.

FDA Posts FAQs on Importing Medical Devices During COVID-19 Pandemic: The FDA unveiled a new [webpage](#) this week with FAQs on Importing Medical Devices During the COVID-19 Pandemic. The FAQ page provides information on importing devices that have been issued Emergency Use Authorizations (EUAs) and devices for which an enforcement-discretion policy has been published in a guidance document. Information on importing respirators, face masks, and personal protective equipment (PPE), donating medical devices, importing other medical devices, monitoring import status, and identifying contacts for import questions is also included.

FDA Posts FAQs on Registration and Listing Medical Devices During COVID-19 Pandemic: The FDA also unveiled a new [webpage](#) with FAQs on Registration and Listing of Medical Devices During the COVID-19 Pandemic. The FAQ page provides information for medical device establishments about procedures and requirements concerning the registration of facilities and the listing of devices during the COVID-19 pandemic.

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Noteworthy Guidance / Updates from the CDC: Click [here](#) for updated guidance for businesses and workplaces to plan, prepare, and respond to the pandemic. Click [here](#) for information on staying safe and slowing the spread of COVID-19 while scheduling services or repairs inside the home. Click [here](#) for an FDA consumer update on staying safe and slowing the spread of the virus (unsurprisingly, the steps include: washing your hands often; using a mask when around others; avoiding crowds; and practicing social distancing). And in case you've been experiencing seasonal allergies this time of year, click [here](#) for updated CDC information on allergies vs. COVID-19.

OTHER NOTEWORTHY HEALTH-RELATED ANNOUNCEMENTS COMING OUT OF WASHINGTON

Democratic Presidential Candidate Joe Biden Chooses California Senator Kamala Harris as Running Mate: On Tuesday, presumptive Democratic Presidential candidate Joe Biden [declared](#) Kamala Harris as his running mate in the 2020 election. Harris – who is currently the junior US Senator from California – previously served as San Francisco District Attorney and as the state's Attorney General. Biden and Harris appeared at an event together – albeit socially distanced – on Wednesday for the first time since the news was made public. In his remarks, Biden said he had “no doubt that I picked the right person to join me.” Harris later said she was “incredibly honored” and “ready to get to work.” Harris is the first African American and the third woman to be candidate for Vice President. She previously ran for the Democratic presidential nomination herself, but [ended](#) her campaign in December 2019.

On health care, Harris does support Medicare for All, although her plan would allow individuals the option of maintaining employer-sponsored coverage or purchasing Medicare Advantage plans from private insurers (though she says insurers would be subject to “strict requirements to ensure it lowers costs and expands services”). Under this new system, employers would secure insurance coverage for their employees by either paying into Medicare for All or Medicare Advantage. In terms of pay-fors, Harris has proposed taxing households earning more than \$100,000 (the threshold for households in “high-cost areas” would be raised); and imposing taxes financial transactions.

On issues related to drug pricing, Harris supports allowing Medicare to negotiate for drug prices and also supports allowing HHS to set prices for drugs that are cheaper in economically comparable countries or US prices increase faster than inflation (though she has not been clear about whether this policy would apply to Medicare Part D, Part B or both).

Trump Administration Announces New Community Health Access and Rural Transformation (CHART) Model: On Tuesday, CMS [announced](#) a new Community Health Access and Rural Transformation (CHART) Model aimed at improving access to high quality care while reducing costs. Under the new model, CMS will provide funding for rural communities to build systems of care through a Community Transformation Track and will enable providers to participate in value-based payment models through an Accountable Care Organizations (ACO) Transformation Track.

Under the Community Transformation Track, CMS says it will select up to 15 lead organizations who will be responsible for working with model participants and driving health care delivery system redesign. These leads and their community partners will receive upfront cooperative agreement funding, financial flexibilities through a predictable capitated payment amount for participant hospitals in a community, and operational and regulatory flexibilities.

Under the ACO Transformation Track, CMS says it will select up to 20 rural-focused ACOs to receive advanced payments as part of joining the Medicare Shared Savings Program. The Agency says it expects these advanced payments to help CHART ACOs engage in value-based payment efforts that will improve outcomes and quality of care for rural beneficiaries. CHART ACOs will be offered payments comprised of two components:

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1. A CHART ACO will be able to receive a one-time upfront payment equal to a minimum of \$200,000 plus \$36 per beneficiary to participate in the 5-year agreement period in the Shared Savings Program.
2. A CHART ACO will be able to receive a prospective per beneficiary per month (PBPM) payment equal to a minimum of \$8 for up to 24 months.

The Notice of Funding Opportunity for the Community Transformation Track is expected to be released in September. The Request for Application for the ACO Transformation Track is expected to be available in early 2021. More information on the new model can be found [here](#).

UPCOMING COVID / HEALTH-RELATED CONGRESSIONAL HEARINGS

N/A

ADMINISTRATION ANNOUNCEMENTS

Department of Health and Human Services

- [Assistant Secretary for Health Admiral Brett Giroir Statement on COVID-19 Point-of-Care Testing Effort in Miami](#)
- [HHS Invests in Diagnostic Labs to Expand COVID-19 Testing Capacity in the United States](#)
- [HHS Announces Investments for HIEs to Strengthen their Ability to Support State and Local Public Health Agencies](#)
- [Trump Administration Collaborates with Moderna to Produce 100 Million Doses of COVID-19 Investigational Vaccine](#)
- [Voluntary National Guidelines for Respite Care Agencies, Providers, Family Caregivers, and Respite Care Recipients](#)
- [Secretary Azar Highlights the Importance of Open, Transparent Global Health Leadership During Visit to Taiwan](#)
- [Secretary Azar Press Conference Remarks with Taiwan Health Minister Chen](#)
- [Secretary Azar Statement on Meeting with Taiwan President Tsai](#)
- [HHS Secretary Azar Signs Joint Statement with Taiwan Minister of Health and Welfare](#)
- [HHS Secretary Azar Meets with President Tsai of Taiwan and Praises Taiwan's Transparent COVID-19 Response](#)
- [HHS Releases July - December COVID-19 State Testing Plans](#)

Centers for Medicare & Medicaid Services

- [Trump Administration Announces Initiative to Transform Rural Health](#)
- [CMS Proposes Updates to Coverage Policy for Artificial Hearts and Ventricular Assist Devices \(VADs\)](#)

National Institutes of Health

- [Clinical Trials of Monoclonal Antibodies to Prevent COVID-19 Now Enrolling](#)

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.](#)

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QUICK LINKS

- [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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