



Weekly Health Care Checkup: *COVID-19 and Beyond* August 3-7, 2020

IN BRIEF

What Happened This Week: Despite several meetings throughout the week, Congressional leaders and the White House say they are still [far apart](#) on some of the major details in the next COVID-19 response package, leaving the path to passage uncertain.

The President signed two COVID-related Executive Orders this week. The first was an [Executive Order on Improving Rural Health and Telehealth Access](#), which – among other things – called on the HHS Secretary to issue a proposed rule extending the additional telehealth services offered to Medicare beneficiaries beyond the duration of the COVID-19 Public Health Emergency. The second was an [Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States](#), which – broadly speaking – would require the US government to purchase “essential” medicines and medical supplies domestically rather than from overseas.

And in case you missed it, Mehlman Castagnetti hosted a briefing on Wednesday with COVID-19 expert, Dr. Michael Osterholm, a professor of public health and director of the Center for Infectious Disease Research and Policy at the University of Minnesota. Click [here](#) to view the Zoom video recording.

What to Expect Next Week: Leaders in both chambers have delayed the start of the traditionally month-long August recess to allow for more time to negotiate the details of the next COVID package. While it is unclear when – or if – lawmakers and the White House will be able to reach a deal, the President did [suggest](#) this week that his Administration was looking into whether he could issue a series of Executive Orders to: 1) postpone federal payroll tax collection, 2) reinstitute an expired eviction moratorium (which expired July 24), and 3) reinstate the CARES Act’s unemployment benefits (which expired July 31). Stay tuned to see if those plans formalize / pan out...

DEEP DIVE

Negotiations on Next COVID Response Package Continue as Both Parties Still “Far Apart” on Major Issues in the Bill: The path to passage for the next COVID-19 response package continues to face an uphill battle heading into the weekend as both parties and the White House say they are still [far apart](#) on some of the major details in the bill. “The differences are still significant,” White House Chief of Staff Mark Meadows said yesterday. Separately, Senate Democratic Leader Chuck Schumer (D-NY) called yesterday’s progress “disappointing” and House Speaker Nancy Pelosi (D-CA) said the situation was “most unfortunate”.

At this point, the major [sticking points](#) continue to be: 1) 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); 2) liability protections for schools and businesses (House Democrats do not favor the liability protection language in the Senate GOP's proposal); and 3) 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, it is unclear when – or if – lawmakers and the White House will be able to reach a deal, although the President [suggested](#) this week that his Administration is looking into whether he could issue a series of Executive Orders to: 1) postpone federal payroll tax collection, 2) reinstitute an expired eviction moratorium (which expired July 24), and 3) reinstate the CARES Act's unemployment benefits (which expired July 31).

Trump Signs Executive Order Requiring US Government to Buy "Essential" Drugs and Medical Supplies From American Companies: On Thursday, President Trump signed an [Executive Order](#) requiring the US government to purchase "essential" medicines and medical supplies domestically rather than from overseas. "We cannot rely on China and other nations across the globe that could one day deny us products in a time of need...We just can't do it," the President said.

The EO does not specifically list which drugs / medical supplies would be subject to the "Buy American" EO. Instead, it instructs the FDA Commissioner to consult with relevant government agencies to develop the list of medicines, medical countermeasures, and critical inputs that are "essential for public health" in the US. The Administration says the EO would *not* apply in situations where: 1) the application would be inconsistent with the public interest; 2) the drugs / supplies are not produced in the US "in sufficient and reasonably available commercial quantities and of a satisfactory quality"; or 3) the application would cause the cost of the procurement to increase by more than 25 percent (while speaking to reporters yesterday, White House Trade Advisor Peter Navarro [said](#) these waivers are considered "standard" in all "Buy American" Executive Orders).

Unsurprisingly, a number of pharmaceutical manufacturers were quick to express concern for the President's latest policy announcement. In a statement yesterday, PhRMA President and CEO Stephen Ubl warned the EO "could disrupt the global pharmaceutical supply chain, jeopardizing our ability to respond to the current crisis and potentially leading to major long-term supply chain disruptions, including shortages." Instead, Ubl called on the Administration to implement policies that "enable more domestic manufacturing without putting the stability of pharmaceutical supply chains at risk."

Energy and Commerce Committee to Investigate Business Practices Health and Dental Insurance Companies During Pandemic: On Thursday, 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. While he did not specifically say which companies would be part of the investigation, he did say that the Committee would be sending oversight letters to a "series" of companies seeking answers to a "variety" of questions. "I want to know if they're in compliance with existing statute requiring COVID-19 testing be free of consumer cost-sharing for all patients and how they intend to use their profits to help the American people during this time of crisis," Chairman Pallone said.

House Democratic Committee Leaders Renew Calls for Trump Administration to Develop National COVID-19 Response Strategy: On Thursday, a number of House Democratic committee leaders – including Select Subcommittee on the Coronavirus Crisis Chairman Jim Clyburn (D-SC), Energy and Commerce Committee Chairman Frank Pallone (D-NJ), Ways and Means Committee Chairman Richard Neal (D-MA), Financial Services Committee Chairwoman Maxine

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Waters (D-CA), Oversight and Reform Committee Chairwoman Carolyn Maloney (D-NY), Education and Labor Committee Chairman Bobby Scott (D-VA), and Small Business Committee Chairwoman Nydia Velazquez (D-CA) – released a joint oversight [analysis](#) of the Trump Administration’s response to the coronavirus pandemic. In the report, the lawmakers suggest that the President “failed to produce an adequate national testing strategy, failed to develop a plan to safely reopen schools, failed to coordinate a 50-state strategy to respond to the pandemic and failed to use the full power of the Defense Production Act to produce and coordinate the distribution of personal protective equipment (PPE) and critical supplies for our frontline heroes.” They added it is “far past time for the White House to correct its failures and finally provide the federal leadership and clear, comprehensive national strategy we need to fight this pandemic.”

In separate, but related news, Energy and Commerce Committee Chairman Frank Pallone (D-NJ) and Oversight Subcommittee Chairwoman Diana DeGette (D-CO) sent a [letter](#) to the White House Coronavirus Task Force and HHS Secretary Alex Azar this week calling on the Administration to finalize and release a national COVID-19 vaccine plan. “Alarming, in the absence of a comprehensive plan, the Administration appears to be making decisions without the critical input of public health partners or consideration for the existing infrastructure the nation has long relied upon for the allocation, distribution, and tracking of vaccines,” the lawmakers wrote.

Ways and Means Committee Chairman Urges CMS to Make Nursing Data “More Reliable and Comprehensive”: House Ways and Means Committee Chairman Richard Neal (D-MA) sent a [letter](#) to CMS Administrator Seema Verma earlier this week expressing concern for the quality of nursing home data being collected. In the letter, Chairman Neal wrote that despite the Agency’s [requirement](#) for long term care facilities to report COVID-19 data, “reports of insufficient and unreliable nursing home data persist, most notably nursing home COVID-19 staff fatality data.” He added that the issues of unreliable and insufficient data “go beyond lapses in staff data, as the Nursing Home COVID-19 Public File contains large amounts of insufficient, unreliable, and missing data.”

Democratic Senators Introduce Legislation Aimed at Increasing Diversity on CARES Oversight Commission: Earlier this week, Senators Chris Van Hollen (D-MD), Kamala Harris (D-CA), Robert Menendez (D-NJ), and Cory Booker (D-NJ) introduced the [CARES Congressional Oversight Commission Diversity Act](#) aimed at ensuring that the communities who have been hit hardest by the pandemic are represented on the Congressional Oversight Commission. “We know Black, Latinx, Pacific Islander, and Native American communities have been hit hardest by both the health and financial impacts of the coronavirus, and it is essential that these communities have a seat at the table in guiding and overseeing the federal response to the pandemic,” said Senator Van Hollen. “We’ll be pushing Senate leadership to include this crucial provision in the next relief package.”

Ways and Means Committee Task Force Conducts Roundtable on the Role of Telehealth During COVID-19 and Beyond: On Thursday, members of the House Ways and Means Committee’s Rural and Underserved Communities Health Task Force conducted a roundtable on the [Role of Telehealth During COVID-19 and Beyond](#). Participants included:

- Tearsanee Carlisle Davis, DNP, FNP-BC, FAANP – Director of Clinical and Advanced Practice Operations at the University of Mississippi Medical Center’s Center for Telehealth and Assistant Professor at UMMC School of Nursing
- Ateev Mehrotra, MD, MPH - Associate Professor of Health Care Policy, Department of Health Care Policy, Harvard Medical School; Associate Professor of Medicine and Hospitalist, Beth Israel Deaconess Medical Center
- Keris Myrick, MBA – Chief of Peer and Allied Health Professions for the Los Angeles County Department of Mental Health

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- Jason Tibbels, MD – Chief Quality Officer, Teladoc Health; President, The Institute of Patient Safety and Quality of Virtual Care

During the event, members and panelists discussed the pros and cons to making current telehealth flexibilities (during the COVID-19 Public Health Emergency) permanent, the shift more towards value-based payments (including the use of alternative payment models), and the need for infrastructure upgrades in certain areas of the country – particularly for patients in rural areas without access to broadband. Many also stressed that any new policies going forward should ensure that racial minorities and those people in rural areas are able to access telehealth services. The event was the first of several roundtables for the Task Force to discuss their top four policy areas of focus: 1) Addressing direct social determinants of health; 2) Enacting payment system reforms; 3) Strengthening technology and infrastructure; and 4) Reinforcing our workforce.

NIH-Moderna Investigational COVID-19 Vaccine Shows Promise in Mouse Studies: Scientists at the NIH's NIAID and biotechnology company Moderna, along with collaborators from the University of North Carolina at Chapel Hill, Vanderbilt University Medical Center in Nashville, and the University of Texas at Austin [conducted](#) preclinical research on the investigational vaccine, mRNA-1273, and found that it protected mice from infection with COVID-19.

New CMS Policy Allows Insurance Issuers to Offer Temporary Premium Reductions: On Monday, CMS [announced](#) a new temporary policy allowing health insurance issuers to offer temporary premium reductions for individuals with 2020 coverage in the individual and small group markets. In a statement, CMS Administrator Seema Verma called this latest action “just the latest in a series of flexibilities CMS has extended to health insurers to help them support their enrollees during this unprecedented time.”

NIH Begins Clinical Trial to Test Antibody Treatment in Hospitalized COVID-19 Patients: NIH is currently [accepting](#) volunteers who were hospitalized with COVID-19 (at select hospitals around the world) to participate in a Phase 3 randomized, controlled trial (known as ACTIV-3) to test multiple different kinds of monoclonal antibody treatments (lab-produced molecules engineered to serve as substitute antibodies that can restore, enhance or mimic the immune system's attack on disease cells). This latest study is one of four from the NIH's [Accelerating COVID-19 Therapeutic Interventions and Vaccines \(ACTIV\) Program](#). In a statement, NIH's NIAID Director Anthony Fauci explained that “studying the impact of this investigational therapeutic on multiple patient populations at the same time is critical to determining whether it can help COVID-19 patients with differing levels of disease severity. These concurrent trials have the potential to yield significant and comprehensive clinical data.” On Monday, NIH Director Dr. Francis Collins and Dr. Fauci participated in a Facebook [conversation](#) to discuss the launch.

NIH Director on Drug Repurposing for Treatment of COVID-19: On Monday, August 4, NIH Director Francis Collins released a [blog post](#) exploring the practice of “drug repurposing” to help treat COVID-19 patients in the absence of a targeted anti-viral therapy. In the post, Dr. Collins suggests that “there may be quite a few existing drugs and/or experimental drugs fairly far along in the development pipeline that have potential to be repurposed for treating COVID-19,” adding that some of them might also work well in combination with Remdesivir, or perhaps other drugs, as treatment “cocktails,” including drugs used to successfully treat HIV and hepatitis C. In separate, but related news, NIH also recently [announced](#) that it has begun a randomized, controlled clinical trial to evaluate the safety and efficacy of a treatment regimen consisting of the antiviral Remdesivir *plus* the immunomodulator interferon beta-1a in patients with COVID-19.

FDA Calling on Recovered COVID Patients to Donate Plasma: The FDA is out with a new PSA [campaign](#) seeking to increase donations of convalescent plasma by the end of August in the “whole-of-America” fight against COVID-19. Convalescent plasma (the liquid part of blood that is collected from patients who have recovered from COVID-19) is

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currently being investigated for the treatment of COVID-19 because there is no approved treatment for and there is some information that suggests it might help some patients recover.

Noteworthy Agency Guidance Updates: CDC updated its general [FAQs](#) on a number of COVID-19 topics. The FDA recently issued updated warning [information](#) on hand sanitizer that consumers should not use due to various issues with the products; CDC posted additional warning [information](#) about serious adverse health events, including death, associated with ingesting alcohol-based hand sanitizers containing methanol. CDC posted more [information](#) to help rural communities deal with challenges during the pandemic. CDC updated its [guidance](#) for businesses and workplaces to plan, prepare, and respond to COVID-19. The Agency also updated its [guidance](#) on worker and safety, and updated [information](#) on things to consider before returning to work. If you have tested positive for COVID-19, CDC also posted updated [information](#) on when you may end social isolation. CMS updated [FAQs](#) on COVID-19 testing at skilled nursing facilities and nursing homes.

OTHER NOTEWORTHY HEALTH-RELATED ANNOUNCEMENTS COMING OUT OF WASHINGTON

Trump Administration Issues Executive Order on Rural Health and Telehealth Access, CMS Follows With Telehealth Expansion Proposals: On Monday, August 3, President Trump signed an Executive Order on [Improving Rural Health and Telehealth Access](#), which – among other things – called on the HHS Secretary to issue a proposed rule extending the additional telehealth services offered to Medicare beneficiaries beyond the duration of the COVID-19 Public Health Emergency (PHE). Soon after the EO was released, CMS [issued proposals](#) (via its annual [Medicare Physician Fee Schedule Proposed Rule](#)) to make certain telehealth and workforce flexibilities provided during the COVID-19 PHE permanent, including "home visits for the evaluation and management of a patient (in the case where the law allows telehealth services in the patient's home), and certain types of visits for patients with cognitive impairments." In addition, the Agency is seeking public input on other services to permanently add to the telehealth list beyond the PHE and is also proposing to temporarily extend payment for other telehealth services such as emergency department visits, for a specific time period, through the calendar year in which the PHE ends. In a statement, CMS Administrator Seema Verma suggested that "telemedicine can never fully replace in-person care, but it can complement and enhance in-person care by furnishing one more powerful clinical tool to increase access and choices for America's seniors." The Agency is accepting comments on the proposed rule through October 5, 2020.

CMS Finalizes Several Annual Medicare Payment Rules: The Center for Medicare & Medicaid Services (CMS) finalized several annual Medicare payment rules (as required by statute) earlier this month, all of which are summarized below.

- **FY 21 Payment Rates for SNFs:** On July 31, 2020, CMS [issued](#) its annual final rule ([CMS-1737-F](#)) for Fiscal Year (FY) 2021 updating the Medicare payment rates and the value-based purchasing program for skilled nursing facilities (SNFs). Within the final rule, CMS projects that aggregate Medicare program payments to SNFs will increase by 2.2 percent in FY 2021 over FY 2020. The rule also applies a five percent cap on wage index decreases from FY 2020 to FY 2021, makes changes to the International Classification of Diseases, Version 10 (ICD-10) code mappings (in response to stakeholder feedback), and includes other "minor" administrative changes related to the SNF Value-Based Purchasing (VBP) Program.
- **FY 21 Hospice Payment Rate Update:** On July 31, 2020, CMS [issued](#) its annual final rule ([CMS-1733-F](#)) updating fiscal year (FY) 2021 Medicare payment rates and the wage index for hospices. Within the final rule, CMS updates the hospice payment rates and cap amount for FY 2021 and applies a five percent cap on wage index decreases from FY 2020 to FY 2021. In addition, the Agency also provided examples on its website of the hospice election statement and the hospice election statement addendum to reflect the changes finalized in the FY 2020 hospice final rule (as of October 1, 2020).

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- **FY 21 Payment and Policy Changes for Inpatient Psychiatric Facilities:** On July 31, 2020, CMS [issued](#) a final rule ([CMS-1731-F](#)) updating Medicare payment policies and rates for the IPF Prospective Payment System (PPS) for Fiscal Year (FY) 2021. Within the final rule, the Agency finalized a 2.2 percent payment rate update for FY 2021 and also finalized its proposal to adopt revised Office of Management and Budget (OMB) statistical area delineations resulting in wage index values being more representative of the actual costs of labor in a given area.
- **FY 21 Payment Policies and Rates for Facilities Under the Inpatient Rehabilitation Facility PPS:** On August 4, 2020, CMS [issued](#) a final rule ([CMS-1729-F](#)) updating Medicare payment policies and rates for facilities under the Inpatient Rehabilitation Facility (IRF) Prospective Payment System (PPS) for Fiscal Year (FY) 2021. For FY 2021, CMS is updating the IRF PPS payment rates by 2.4 percent (reflecting a 2.4 percent IRF market basket reduced by a 0.0 percentage point multifactor productivity adjustment). CMS says an additional 0.4 percent increase to aggregate payments due to updating the outlier threshold to maintain estimated outlier payments at 3.0 percent of total payments results in an overall update of 2.8 percent (or \$260 million) for FY 2021, relative to payments in FY 2020. Lastly, the Agency said it will also apply a five percent cap on wage index decreases from FY 2020 to FY 2021.

Appeals Court Sides With Trump Administration in Case Against Public Charge Rule: The US Court of Appeals for the Second Circuit [sided](#) with the Trump Administration earlier this week in a case brought by immigrant rights group, CASA de Maryland, against the Administration's [public charge rule](#). In the 2-1 ruling, the Court said the Administration's rule – which updated the Department of Homeland Security's policy for determining whether any noncitizens applying for admission or adjustment are inadmissible because they are likely to become a public charge – was "unquestionably lawful". The rule has been the subject of a number of lawsuits since it was finalized last August.

UPCOMING COVID / HEALTH-RELATED CONGRESSIONAL HEARINGS

N/A

ADMINISTRATION ANNOUNCEMENTS

Department of Health and Human Services

- [HHS, DOD Collaborate with Johnson & Johnson to Produce Millions of COVID-19 Investigational Vaccine Doses](#)
- [Innovative Solutions to Address Social Isolation in Older Adults During the COVID-19 Pandemic](#)
- [Tribal and Urban Indian Organization Leader Message on COVID-19](#)
- [Investing in Advanced Manufacturing to Support Public Health Preparedness](#)

Centers for Medicare & Medicaid Services

- [CMS Approves New Hampshire's State Relief and Empowerment Waiver](#)
- [CMS Announces a Temporary Policy for Premium Reductions](#)
- [Trump Administration Proposes to Expand Telehealth Benefits Permanently for Medicare Beneficiaries Beyond the COVID-19 Public Health Emergency and Advances Access to Care in Rural Areas](#)

National Institutes of Health

- [NIH Clinical Trial Testing Remdesivir Plus Interferon Beta-1a for COVID-19 Treatment Begins](#)
- [NIH Harnesses AI for COVID-19 Diagnosis, Treatment, and Monitoring](#)
- [NIH-Moderna Investigational COVID-19 Vaccine Shows Promise in Mouse Studies](#)
- [NIH Clinical Trial to Test Antibodies and Other Experimental Therapeutics for Mild and Moderate COVID-19](#)

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- [NIH Launches Clinical Trial to Test Antibody Treatment in Hospitalized COVID-19 Patients](#)

Food and Drug Administration

- [FDA Commissioner: No matter What, Only a Safe, Effective Vaccine Will Get Our Approval](#)
- [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

- [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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