



Weekly Health Care Checkup: *COVID-19 and Beyond* August 31 – September 4, 2020

IN BRIEF

What Happened This Week: With bipartisan negotiations on the next COVID-19 response package at a standstill, Senate Republicans [continued](#) to hone in on a pared down version of their HEALS Act proposal this week, though it is [unclear](#) at this point whether Senate GOP Leaders will be able to secure enough support for the new “skinny” proposal when lawmakers return from the August recess next week.

On Monday, AstraZeneca [announced](#) it will begin phase three clinical trials of its COVID-19 vaccine, making it the third drug manufacturer to move to “late stage” human trials (following Moderna and Pfizer/BioNTec earlier this summer). In separate, but related news, a committee formed by the National Academies of Sciences, Engineering, and Medicine released a [discussion draft](#) – as part of a study commissioned by NIH and CDC – earlier this week with a preliminary framework for equitable allocation of the vaccine.

And in other health-related news, CMS [issued](#) its annual Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) final rule for fiscal year (FY) 2021 ([CMS-1735-F](#)) on Wednesday. Beginning next year, CMS says payments for inpatient hospital services will increase by \$3.5 billion (or 2.7 percent) – an increase from the 1.6 percent payment increase that the Agency first proposed earlier this spring.

What to Expect Next Week: The Senate is expected to reconvene in Washington on Tuesday, September 8 at 3:00pm. Upon their return, lawmakers are expected to resume consideration of Brett Ludwig to be US District Judge for the Eastern District of Wisconsin. The chamber will then move to vote on the motion to invoke cloture Ludwig’s nomination at 5:30pm.

It’s also [possible](#) that Senate Majority Leader Mitch McConnell (R-KY) will unveil a pared down version of the earlier COVID response package (the HEALS Act) next week, although it is unclear at this point whether GOP Leadership will be able to secure enough votes from Democrats and members of their own party for passage. Stay tuned...

On the Senate hearings front, NIH Director Francis Collins and US Surgeon General Jerome Adams are expected to testify before the Senate HELP Committee on Wednesday during a [hearing](#) on vaccines and public health. The following week, HELP Committee members will get an update on the federal response to the COVID-19 pandemic during a [hearing](#) on Wednesday, September 23 at 10am. Click [here](#) to view the full schedule of upcoming COVID and other health-related hearings in the Senate.

The House will still be in recess through September 14, although several hearings are still slated for next week, including an Energy and Commerce COVID-related hearing and a separate markup to consider various pieces of legislation (the details for both events have not yet been formally announced). Click [here](#) to view the full schedule of upcoming COVID and other health-related hearings in the House.

When the House returns the week of September 14, members are expected to consider the following pieces of legislation on the floor:

- [H.R. 2639](#) – Strength in Diversity Act
- [H.R. 2574](#) – Equity and Inclusion Enforcement Act
- [H.R. 2694](#) – Pregnant Workers’ Fairness Act
- [H. Res. 908](#) – Condemning All Forms of Anti-Asian Sentiment as Related to COVID-19

The following week (September 21), House members are expected to take up the following:

- [H.R. 3884](#) – Marijuana Opportunity Reinvestment and Expungement Act
- [H.R. 7856](#) – FY21 Intelligence Reauthorization Act
- [Energy Innovation / Clean Energy Package](#) (E&C/SST)

To close out September, members in both chambers are expected to turn their attention to legislation (a continuing resolution) to fund the government beyond the end of the current fiscal year (September 30) and legislation to address other expiring items, such as flood insurance and surface transportation.

DEEP DIVE

With Bipartisan Negotiations on the Next COVID-19 Response Package at a Standstill Again, Senate Republicans Turn Their Attention to Pared Down Version of Their Earlier HEALS Act Proposal: During a House Select Subcommittee on the Coronavirus Crisis [hearing](#) on Tuesday, Treasury Secretary Steve Mnuchin told lawmakers that both he and the President are supportive of Congress taking up and passing an additional COVID response package and stressed that White House officials are “prepared to sit down with the speaker at any time to negotiate.” The Secretary then called House Speaker Nancy Pelosi (D-CA) shortly after the hearing in an effort to jumpstart negotiations; however it [appears](#) that that conversation yielded little headway. At this point, the bill’s price tag continues to be the biggest hang-up (the Senate Republican proposal ([the HEALS Act](#)) is in the \$1 trillion range, while House Democrats’ [HEROES Act](#) is around \$3.5 trillion). Both Mnuchin and Pelosi did, however, [agree](#) to not use the looming end-of-fiscal-year government funding bill as leverage in the COVID response negotiating process.

Separately, Senate Republicans are [reportedly](#) working on another pared down version (in the \$500 million range) of their earlier \$1 trillion HEALS Act proposal in an effort to move the needle on negotiations, though given the opposition of at least 20 GOP Senators to take up any additional COVID funding legislation, Leader McConnell (R-KY) would need to secure bipartisan support for the GOP-drafted package – an [unlikely](#) scenario given the upcoming elections.

Senate Democratic Leaders Say They Need “Immediate Answers” From CDC and FDA With Regard to Potential Political Interference: On Wednesday, Senate Democratic Leader Chuck Schumer (D-NY) and Senate HELP Committee Ranking Member Patty Murray (D-WA) issued a [statement](#) saying they need more “immediate answers” from the CDC and FDA with regard to how the agencies are responding to the COVID-19 pandemic without political interference. “After

MEHLMAN CASTAGNETTI
— ROSEN & THOMAS —

1341 G Street NW
Washington, DC 20005
www.mehlmancastagnetti.com
202-585-0258

so many examples of political interference at FDA and CDC over the past few weeks, we shouldn't let several more weeks pass before we get answers," the Senators wrote.

House W&M Chairman Neal (D-MA) Urges Medical Societies to "Push Racial Health Equity Forward": House Ways and Means Committee Chairman Richard Neal (D-MA) sent [letters](#) to several medical societies this week calling on the groups to partner with the Committee to address racial inequities. "COVID-19 has illuminated and exacerbated longstanding racial inequities in our health care system that we must correct," Chairman Neal said. "As clinicians, health equity scholars, and medical professional societies continue to work toward eliminating racial health inequities, the consequences to health and the perpetuation of unequal outcomes make this work more urgent than ever. We must redouble our efforts. I look forward to the leadership of professional societies, who have been strong partners of government, to push this racial health equity agenda forward."

AstraZeneca Becomes Third Manufacturer to Begin Phase III Clinical Trials of COVID-19 Vaccine, NASEM Releases Discussion Draft for Vaccine Allocation: On Monday, AstraZeneca [announced](#) it will begin phase three clinical trials of its COVID-19 vaccine, making it the third drug manufacturer to move to "late stage" human trials (following Moderna and Pfizer/BioNTec earlier this summer). During a press briefing late last week, HHS Deputy Chief of Staff for Policy Paul Mango, said the Department feels it is "absolutely on track – if not a little bit ahead" to meet the [Operation Warp Speed](#) objective of having a safe and effective vaccine approved by the end of the year. "There are no guarantees in science, but what Operation Warp Speed does is maximize the probability of having at least one acceptable vaccine in large quantities before the end of the year," Mango said.

In separate, but related news, a committee formed by the National Academies of Sciences, Engineering, and Medicine released a [discussion draft](#) – as part of a study commissioned by NIH and CDC – earlier this week with a preliminary framework for equitable allocation of the vaccine. The group hosted an [open online session](#) to hear from a variety of stakeholders nationwide on Wednesday. During the session, committee members said they took into account a number of factors, including racial/ethnic and other health disparities, as well as groups at higher risk from COVID-19 due to health status, occupation, or living conditions. They also emphasized that public input, especially communities highly impacted by COVID-19, will be "essential to produce a final report that is objective, balanced, and inclusive."

FDA Schedules Vaccines and Related Biological Products Advisory Committee Meeting: The FDA [announced](#) that the Vaccines and Related Biological Products Advisory Committee will hold a [public meeting](#) on October 22 from 10am-5pm to discuss the general matter of the development, authorization, and/or licensure of vaccines indicated to prevent COVID-19. In a statement, FDA Commissioner Stephen Hahn said the Committee members – comprised of outside scientific and public health experts from around the country – "will help ensure clear public understanding regarding clinical development of these vaccines indicated to prevent COVID-19 and the data needed to facilitate their authorization or licensure." He added that it is "critical for people to see FDA's expectations for data to support safety and effectiveness."

HRSA Announces Assisted Living Facilities May Now Apply for Provider Relief Fund Phase 2 General Distribution Allocation: On Tuesday, HHS' Health Resources and Services Administration (HRSA) [announced](#) that assisted living facilities may now apply for funding under the Provider Relief Fund phase 2 "general distribution" allocation. Eligible ALFs will receive 2 percent of their annual revenue from patient care. Facilities applying for the current Phase 2 General Distribution funding will have until September 13, 2020 to begin their application by entering their Tax Identification Number for validation.

MEHLMAN CASTAGNETTI
— ROSEN & THOMAS —

1341 G Street NW
Washington, DC 20005
www.mehlmancastagnetti.com
202-585-0258

HHS Announces Allocation of Cloth Face Masks to Schools: The Department [announced](#) this week that it would allocate up to 125 million cloth face masks to schools nationwide (with an emphasis on students who are low-income and on schools providing in-person instruction). Click [here](#) to view the full list of the mask distribution by state.

CDC Temporarily Halts Evictions Through End of Year: In line with the President's recent [Executive Order](#), the CDC [announced](#) this week that it will be using its authority to halt evictions through the end of the year. Under the CDC Order, American renters who meet certain conditions cannot be evicted if they have affirmatively exhausted their best efforts to pay rent, seek Government rental assistance, and are likely to become homeless due to eviction.

CDC Releases MMWR on Incidence of COVID-19 Infections Among Frontline Healthcare Personnel: Earlier this week, the CDC [released](#) an Morbidity and Mortality Weekly Report (MMWR) on seroprevalence of SARS-CoV-2 among frontline health care personnel in a multistate hospital network between April and June 2020. The data revealed that among 3,248 personnel observed, 6 percent had antibody evidence of previous COVID-19 infection; 29 percent of personnel with COVID-19 antibodies were asymptomatic in the preceding months, and 69 percent had not previously received a diagnosis of COVID-19 infection. The report also noted that the prevalence of COVID-19 antibodies was lower among personnel who reported always wearing a face covering while caring for patients (6 percent), compared with those who did not (9 percent).

Noteworthy Guidance Documents and Other Agency Updates:

- CDC updated its [FAQs](#) document on COVID-19.
- CDC updated [information](#) on contact tracing.
- CDC updated its COVID-19 contact tracing communications [toolkit](#) for health departments.
- CDC updated [standard operating procedures](#) for healthcare facilities in non-US settings.
- CDC updated [information](#) for businesses and workplaces to plan, prepare, and respond to the pandemic.
- CDC updated [information](#) on worker safety and support.
- CDC updated [information](#) for children and teens going back to school.
- CDC updated [information](#) metrics for sharing among international and national stakeholders.
- CDC updated their interim [guidance](#) for Rapid Antigen Testing for SARS-CoV-2.
- CDC released [information](#) with considerations for use of antigen testing in nursing homes.
- CDC updated [information](#) on eCR Now: COVID-19 Electronic Case Reporting.
- CDC updated their interim infection prevention and control [guidance](#) for dental settings during the pandemic.
- CDC updated [information](#) on community mitigation (non-us settings).
- CMS released [FAQs](#) on point of care antigen testing and [FAQs](#) CLIA and University Laboratory Testing.
- ACL released a resource [guide](#) for kinship families and grandfamilies.
- ASPR released [information](#) on discharge planning and care coordination during the pandemic.
- FEMA issued a new interim [policy](#) clarifying eligible work under the Public Assistance Program (applicable to eligible applicants only and is exclusive to emergency and major disaster declarations for the COVID-19 pandemic; policy applies to work performed on or after September 15, 2020).

OTHER NOTEWORTHY ANNOUNCEMENTS COMING OUT OF WASHINGTON

CMS Finalizes Annual Medicare Hospital IPPS and LTCH Rule for FY 2021: CMS [issued](#) its annual Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) final rule for fiscal year (FY) 2021 ([CMS-1735-F](#)) earlier this week. Beginning next year, CMS says payments for inpatient hospital services will increase by \$3.5 billion (or 2.7 percent) – an increase from the 1.6 percent payment increase that the Agency first proposed earlier

MEHLMAN CASTAGNETTI
— ROSEN & THOMAS —

1341 G Street NW
Washington, DC 20005
www.mehlmancastagnetti.com
202-585-0258

this spring. In addition to this payment increase, the final rule also includes a new technology add-on payment pathway for certain antimicrobial products and a new Medicare Severity-Diagnosis Related Group (MS-DRG) specifically for cases involving CAR T-cell therapies. The final rule is effective October 1, 2020.

UPCOMING COVID / HEALTH-RELATED CONGRESSIONAL HEARINGS

Wednesday, September 9

10:00am

Senate Health, Education, Labor and Pensions Committee [Hearing](#): Vaccines: Saving Lives, Ensuring Confidence, and Protecting Public Health

11:00am

House Science, Space, and Technology Subcommittee on Research and Technology [Hearing](#): The Impact of the COVID-19 Crisis on University Research

11:00am

House Transportation and Infrastructure Subcommittee on Railroads, Pipelines, and Hazardous Materials [Hearing](#): Amtrak's Response to COVID-19

1:00pm

House Select Subcommittee on the Coronavirus Crisis [Hearing](#): Ensuring a Free, Fair, and Safe Election During the Coronavirus Pandemic

3:30pm

Senate Veterans' Affairs Committee [Hearing](#): S.785: Leading the Way to Comprehensive Mental Health Care and Suicide Prevention for Veterans

Thursday, September 10

10:05am

House Committee on Veterans' Affairs [Hearing](#): H.R. 7541; H.R. 7504; H.R. 7784; H.R. 7879; H.R. 7747; H.R. 7888; H.R. 7964; H.R. 3450; H.R. 3788; H.R. 3826; H.R. 6092; H.R. 7469; H.R. 8005; H.R. 8033; H.R. 8084; H.R. 8068; H.R. 8149; H.R. 8148; H.R. 8108; H.R. 8144; H.R. 8145; H.R. 8130; H.R. 8107; H.R. 8147; Discussion Draft - ANS for Veterans' ACCESS Act; Discussion Draft – Veterans Comprehensive Prevention, Access to Care, and Treatment Act of 2020; Discussion Draft - Ensuring Veterans' Smooth Transition Act; Discussion Draft - VA Research Technology Act; Discussion Draft - VA High Altitude and Suicide Research Act; Discussion Draft - VA Expanded Care Hours Act, and Discussion Draft - Veterans Burn Pits Exposure Recognition Act of 2020

11:00am

House Foreign Affairs Subcommittee on Europe, Eurasia, Energy and the Environment [Hearing](#): Protecting Democracy During COVID-19 in Europe and Eurasia and the Democratic Awakening in Belarus

2:00pm

House Natural Resources Subcommittee on Indigenous Peoples of the United States [Hearing](#): Examining the Bureau of Indian Education's School Reopening Guidance During the COVID-19 Pandemic

MEHLMAN CASTAGNETTI
— ROSEN & THOMAS —

1341 G Street NW
Washington, DC 20005
www.mehlmancastagnetti.com
202-585-0258

Friday, September 11

1:30pm

House Science, Space, and Technology Subcommittee on Energy [Hearing](#): Biological research at the Department of Energy: Leveraging DOE's unique capabilities to respond to the COVID-19 pandemic

** It's possible that the House Energy and Commerce Committee will hold a COVID-related hearing at some point next week and a separate markup to consider various pieces of legislation, although the details for both events have not yet been formally announced.*

**Looking further ahead to Wednesday, September 23 at 10am, members of the Senate HELP Committee will get an [update](#) on the federal response to the COVID-19 pandemic.*

ADMINISTRATION ANNOUNCEMENTS

Department of Health and Human Services

- [Trump Administration Announces \\$2 Billion Provider Relief Fund Nursing Home Incentive Payment Plans](#)
- [HHS Release Rural Action Plan](#)
- [FAQs—Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#)
- [Trump Administration Announces Provider Relief Fund Application for Assisted Living Facilities](#)
- [Federal Communications Commission, U.S. Department of Health and Human Services, and U.S. Department of Agriculture Team Up for Rural Health Initiative](#)
- [Import Screening Pilot Unleashes the Power of Data and Leverages Artificial Intelligence](#)
- [HHS Extends Coverage For COVID-19 Screening Tests at Congregate Facilities During the Pandemic](#)
- [New Research Shows Promise of Telehealth in Treating Opioid Use Disorder](#)

Centers for Medicare & Medicaid Services

- [Fiscal Year \(FY\) 2021 Medicare Hospital Inpatient Prospective Payment System \(IPPS\) and Long Term Acute Care Hospital \(LTCH\) Final Rule \(CMS-1735-F\)](#)
- [CMS Care Compare Empowers Patients When Making Important Health Care Decisions](#)
- [CMS Advancing Seniors' Access to Cutting-edge Therapies and Technology in Medicare Hospital Rule](#)
- [CMS Administrator Announces Proposal to Spur Innovation for America's Seniors, Participates in Roundtable Discussion Among Health Industry Leaders in Minneapolis](#)
- [CMS Acts to Spur Innovation for America's Seniors](#)
- [CMS Issues 2020 Federally-Facilitated Exchange Navigator Awards](#)

Food and Drug Administration

- [FDA Updates Investigational COVID-19 Convalescent Plasma Guidance](#)
- [Click here for the full list of all new FDA updates.](#)

Guidance Documents from the Centers for Disease Control and Prevention

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

MEHLMAN CASTAGNETTI
— ROSEN & THOMAS —

1341 G Street NW
Washington, DC 20005
www.mehlmancastagnetti.com
202-585-0258

National Institutes of Health

- [NIH Continues to Boost National COVID-19 Testing Capacity](#)
- [NIH-Supported Study to Track Prevalence and Impact of SARS-CoV-2 Among Pregnant Women in Low- and Middle-Income Countries](#)
- [Phase 3 Clinical Testing in the US of AstraZeneca COVID-19 Vaccine Candidate Begins](#)
- [People With Intellectual and Developmental Disabilities Disproportionately Affected by COVID-19](#)

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](#)

MEHLMAN CASTAGNETTI
— ROSEN & THOMAS —

1341 G Street NW
Washington, DC 20005
www.mehlmancastagnetti.com
202-585-0258