



Weekly Health Care Checkup: *COVID-19 and Beyond* August 17-21, 2020

IN BRIEF

What Happened This Week: In an effort to move the needle on COVID-19 relief package negotiations, and in response to House Democrats' announcement of a Saturday vote on a postal service funding [bill](#), Senate Republicans [unveiled](#) a considerably pared down version of the [HEALS Act](#) (their counter proposal to the House Democrats' [HEROES Act](#)). However, House Democratic leaders [rejected](#) the proposal, despite calls from over 100 members of the Democratic party to ditch the "all or nothing" approach in favor of a smaller package to address the CARES Act's now-expired unemployment benefits. As a result, negotiations on the path forward for the next package are expected to continue...

In other major political news, Democrats formally [nominated](#) Joe Biden as their candidate for President in the 2020 election. Various Democratic political heavyweights appeared – albeit virtually – throughout the week to voice their support for Biden.

What to Expect Next Week: Both the House and Senate 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 House Speaker Nancy Pelosi (D-CA) has called for a vote tomorrow (Saturday, August 22) on a Democrat-backed [bill](#) to assist the US Postal Service ahead of the November elections.

And although it is technically recess, the House Oversight and Reform Committee will hear from Postmaster General Louis DeJoy during a [hearing](#) titled: *Protecting the Timely Delivery of Mail, Medicine, and Mail-in Ballots* (DeJoy also [testified](#) before the Senate Homeland Security Committee earlier today).

The GOP convention is [scheduled](#) to take place next week (August 24-27). Most events will be virtual given the ongoing pandemic. President Trump is expected to formally accept his party's nomination in a [speech](#) on the south lawn of the White House next Thursday, August 27.

DEEP DIVE

Negotiations Continue on the Next COVID-19 Relief Package: Both the House and Senate 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 negotiations on the next COVID-19 relief package are still ongoing and party leaders in both chambers have told their members to be on standby for votes in the event that an agreement is reached.

In an effort to move the needle on negotiations, and in response to House Democrats' announcement of a Saturday vote on a postal service funding [bill](#), Senate Republicans [unveiled](#) a considerably pared down version of the [HEALS Act](#) (their counter proposal to the House Democrats' [HEROES Act](#)). However, House Democratic leaders rejected the idea of a piecemeal approach to the next COVID package, despite calls from over 100 members of the Democratic party to ditch the "all or nothing" approach in favor of a smaller package to address the CARES Act's now-expired unemployment benefits. "I don't think strategically it's where we should go right now, because the Republicans would like to pass something like that and say forget about it," House Speaker Nancy Pelosi (D-CA) [said](#) during a media interview yesterday. "Forget about state and local [government funding], forget about our investments in stopping the virus, forget about other initiatives that feed the food insecure children in our country, vote by mail initiatives and the rest."

Democratic Senators Urge HHS to Standardize Reporting of COVID Cases on College Campuses: A group of Democratic Senators (including Elizabeth Warren (MA), Chris Murphy (CT), and Tina Smith (MN)) sent a [letter](#) to HHS Secretary Alex Azar and CDC Director Robert Redfield earlier this week, urging them to issue "detailed guidance" for colleges and universities on the reporting of COVID-19 cases. The lawmakers also asked about the Department's plans to study outbreaks in congregate settings (such as colleges, etc.) in order to better understand the effectiveness of different mitigation strategies.

HHS Says Process for Hospital Reporting Data "Has Not and Is Not Changing": A Trump Administration spokesperson confirmed that the Department's process for hospital reporting data "has not and is not changing" after a recent news [report](#) suggested that the CDC was reversing its decision to require hospitals to report data to a new [HHS Protect System](#). Instead, the spokesperson said the Department is transitioning away from the current method of requiring hospitals to manually collect / manually enter data to an automated process.

In separate, but related news, House Energy and Commerce Committee Chairman Frank Pallone (D-NJ), Health Subcommittee Chairwoman Anna Eshoo (D-CA), and Oversight Subcommittee Chairwoman Diana DeGette (D-CO) sent a [letter](#) to the GAO this week asking the non-partisan agency to review the Trump Administration's recent decision to the move to the [HHS Protect System](#), which they argue "sidelined the nation's top public health officials" and "led to unnecessary confusion."

FDA Rescinds Guidance on Premarket Review of Laboratory Developed Tests: In a [notice](#) posted earlier this week, the FDA announced it will be rescinding all guidance / related issuances on premarket review of lab developed tests (LDT). The Agency explained that while companies seeking approval or clearance of, or an emergency use authorization for an LDT may *voluntarily* submit a premarket approval application, premarket notification or an EUA request, they are not required to do so. However, those companies who choose to use LDTs in their laboratories *without* FDA premarket review or authorization may do so with the understanding that they would not be eligible for PREP Act coverage absent approval, clearance or authorization and would remain subject to regulation by CMS.

Soon after the notice was published, House Energy and Commerce Committee Chairman Frank Pallone (D-NJ) issued a [statement](#) calling the Administration's decision "deeply concerning: and added: "given the importance of testing for our ability to control the spread of COVID-19 and the Administration's past blunders with serological tests, I do not believe that now is the time to reduce oversight of COVID-19 tests." The Chairman requested a briefing from the HHS Secretary on the matter.

Trump Administration Leverages DPA to Expedite Shipments of COVID-19 Instruments and Antigen Tests to Nursing Homes: On Thursday, HHS [announced](#) that it has invoked the Defense Production Act (DPA) to expedite

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shipments of COVID-19 instruments and rapid point-of-care antigen tests to nursing homes. To do so, the Department applied priority rated orders for contracts with Becton Dickinson and Quidel Corporation through September, which HHS says will fulfill a large-volume purchase of diagnostic systems and assays for COVID-19 testing and will expedite shipments of these systems and assays to every nursing home certified by CMS with a Clinical Laboratory Improvement Amendment Certificate of Waiver.

CDC Study Finds American Indians are More Likely to Test Positive for COVID-19 Than Non-Hispanic White Americans: A new CDC report revealed that American Indians and Alaska Natives are 3.5 times more likely to receive a positive COVID-19 test result than non-Hispanic white persons; however, the Agency also noted that the limited data makes it difficult to accurately quantify the disparity in COVID-19 incidence, severity, and outcomes among AI/AN persons compared with those among other racial/ethnic groups. In separate, but related news, the latest [data](#) from the CDC's COVID Data Tracker shows that Hispanic and Non-White individuals account for 60 percent of the COVID-19 cases, despite only accounting for 40 percent of the US population.

CDC and the Ad Council Launch New Campaign to Encourage Black Americans to Wear Masks: The CDC Foundation, together with the Ad Council launched a national [campaign](#) this week called "You Will See Me" in an effort to inspire and empower Black Americans to wear face masks. The campaign PSAs will feature actors, athletes, comedians, musicians, and families.

Noteworthy New / Updated Guidance Documents: CDC updated its [resources](#) for conducting contact tracing. CDC posted a COVID-19 prevention messaging [toolkit](#) for airlines to use with travelers / employees. The CDC created another COVID-19 messaging [toolkit](#) for relevant state / local / government partners to use with those who live, work, and travel along the US-Mexico border. CDC updated [information](#) about setting up community isolation centers for COVID-19 patients who may not be able to isolate at home, but are also not sick enough to be hospitalized. The FDA recently released an [FAQ document](#) in an effort to answer consumer questions about UV lights to disinfect homes / personal items. The FDA released an [FAQ document](#) with information regarding inspections for facilities that manufacture pharmaceutical products and sites involved in the conduct of clinical, analytical and nonclinical studies.

OTHER NOTEWORTHY HEALTH-RELATED ANNOUNCEMENTS COMING OUT OF WASHINGTON

Democrats Officially Nominate Joe Biden as Presidential Candidate: On Tuesday, Democrats formally [nominated](#) Joe Biden as their candidate for President in the 2020 election. Throughout the week, various Democratic political heavyweights appeared – albeit virtually – to voice their support for Biden. On Wednesday evening, Biden's running mate, Senator Kamala Harris (CA), [urged](#) Americans to "elect a president who will bring something different, something better, and do the important work...who will bring all of us together to achieve the future we collectively want." In his own acceptance [speech](#) Thursday evening, Biden said President Trump has "cloaked America in darkness for much too long" and added that – if elected – he would be an "ally of the light not of the darkness."

Much like the Democratic convention, the GOP convention is expected to take place almost entirely virtually next week (August 24-27). President Trump is expected to formally accept his party's nomination in a [speech](#) on the south lawn of the White House next Thursday, August 27.

Supreme Court to Hear Trump Administration's ACA Challenge *After* November Election: The Supreme Court will hear the Trump Administration's challenge to the Affordable Care Act (ACA) on November 10 – a few days *after* the November elections. In a [briefing](#) filed earlier this summer, the Trump Administration's Justice Department claimed that

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because the individual mandate and the guaranteed-issue and community-rating provisions were invalidated, the remainder of the ACA "cannot survive."

UPCOMING COVID / HEALTH-RELATED CONGRESSIONAL HEARINGS

N/A

ADMINISTRATION ANNOUNCEMENTS

Department of Health and Human Services

- [Trump Administration Uses Defense Production Act to Aid Our Most Vulnerable](#)
- [OCR Resolves Complaint with Utah After it Revised Crisis Standards of Care to Protect Against Age and Disability Discrimination](#)
- [Statement on FDA EUA for LumiraDx UK Ltd.'s - LumiraDx SARS-CoV-2 Antigen Test](#)
- [CDC Data Show Disproportionate COVID-19 Impact in American Indian/Alaska Native Populations](#)
- [HHS Expands Access to Childhood Vaccines During COVID-19 Pandemic](#)
- [EngAGED Webinar on Creative Engagement Activities for Older Adults During COVID-19](#)

Centers for Medicare & Medicaid Services

- [CMS Administrator Seema Verma Hosts Roundtable in Dallas on COVID-19](#)
- [Trump Administration Issues Joint Informational Bulletin Intended to Improve Health and Housing Outcomes for Older Adults and People with a Disability in Rural America](#)
- [CMS Announces Resumption of Routine Inspections of All Provider and Suppliers, Issues Updated Enforcement Guidance to States, and Posts Toolkit to Assist Nursing Homes](#)

Food and Drug Administration

- [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.](#)

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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