



Weekly Health Care Checkup: *COVID-19 and Beyond* August 24-28, 2020

IN BRIEF

What Happened This Week: White House officials and House Democrats briefly resumed talks on the next COVID-19 response package this week; however, with both parties still far apart on the bill's overall price tag, it [appears](#) that negotiators are no closer to hammering out a deal than when the discussions came to a standstill earlier this month.

On Tuesday, CMS [announced](#) a number of regulatory changes aimed at keeping nursing home residents and staff safe (including moving from *recommending* to *requiring* nursing homes offer tests to residents when there is an outbreak or residents show symptoms).

On Thursday, HHS [announced](#) the award of a \$760 million contract to Abbott Labs to deploy 150 million rapid diagnostic tests for COVID-19. The test – which received an [Emergency Use Authorization \(EUA\)](#) from the FDA earlier this week – is the first of its kind to deliver results in 15 minutes or less without the use of instrumentation / computer equipment.

CDC also revised their COVID-19 testing [guidelines](#) this week to include a recommendation that individuals who have been in close contact (aka within 6 feet) with a person with COVID-19 but are asymptomatic “do not necessarily need a test” unless they are considered vulnerable or if their health care provider or state or local public health officials recommend that they take a test. A number of public health officials and Congressional Democrats were quick to express their [concern](#) for the Agency's updated recommendation, and several states (including Florida, Texas, Arizona, Illinois, California, New York, New Jersey and Connecticut) have since said they will continue to allow asymptomatic individuals who were exposed to the virus to get tested.

And in other major political news, Republicans formally [nominated](#) Donald Trump to serve as President for a second term during the 2020 GOP Convention this week. In his acceptance [speech](#) last night, Trump warned that the upcoming election “will decide whether we will defend the American way of life, or whether we allow a radical movement to completely dismantle and destroy it.” The President also talked of how he “took on big pharma” during his first four years in office, most recently via a series of [Executive Orders](#) to “massively lower the cost of your prescription drugs and give critically ill patients access to lifesaving cures.”

What to Expect Next Week: While both chambers are still technically in recess next week (through September 8 in the Senate and through September 14 in the House), Treasury Secretary Steve Mnuchin is still expected to [testify](#) (remotely) before the House Select Subcommittee on the Coronavirus Crisis on Tuesday, September 1. Lawmakers are expected to

focus their questioning on providing additional economic relief for individuals and families as well as the implementation of assistance / programs that were already enacted in the previous COVID-19 stimulus bills.

DEEP DIVE

No Deal in Sight After Lawmakers and White House Officials Briefly Resume Talks on the Next COVID-19 Response Package: White House officials and House Democrats briefly resumed talks on the next COVID-19 response package yesterday; however it [appears](#) that negotiators are no closer to hammering out a deal than when the discussions came to a standstill earlier this month. The biggest hang-up continues to be the bill's price tag – the Senate Republican proposal ([the HEALS Act](#)) is in the \$1 trillion range, while House Democrats' [HEROES Act](#) is around \$3.5 trillion. Shortly after yesterday's call with White House officials, House Speaker Nancy Pelosi (D-CA) told [reporters](#) that she offered to drop their topline from \$3.5 to \$2.2 trillion, but stressed that Democrats won't go any lower. "We have to meet the needs of the American people," she said. Given the trillion-dollar difference between them, it remains to be seen when – or if – lawmakers and the White House will be able to come to an agreement in the near future.

In an effort to move the needle on negotiations, Senate Republicans are [reportedly](#) working on another pared down version (in the \$500 million range) of their earlier \$1 trillion HEALS Act proposal, 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.

Further complicating matters is the limited number of legislative working days both chambers have in September when lawmakers return from the August recess. Already, Leader McConnell is planning for the chamber to take up a number of confirmation votes when the Senate returns on September 8. And in order to avoid a government shutdown at the end of the month, both chambers must take up and pass a continuing resolution (CR) to fund the government before the September 30 deadline. On Wednesday, Mark Meadows, the White House Chief of Staff, [predicted](#) that House Speaker Nancy Pelosi (D-CA) might look to the end-of-fiscal-year government funding bill as leverage in the COVID response negotiating process. "It's really been Speaker Pelosi really driving this train as a conductor more so than really anybody," Meadows said. "I think privately she says she wants a deal and publicly she says she wants a deal, but when it comes to dealing with Republicans and the administration, we haven't seen a lot of action." The Speaker's office did not specifically comment on Meadows' suggestion, however a spokesman for Speaker Pelosi said earlier this week that Democrats "welcome the White House back to the negotiating table but they must meet us halfway" in terms of the funding included in the package.

Democratic Lawmakers Introduce Legislation to Reauthorize Elder Justice Act: Earlier this week, a group of Democratic lawmakers introduced a [bill](#) to reauthorize the [Elder Justice Act](#), a 2010 law which authorized several programs and initiatives to better coordinate federal responses to elder abuse, promote elder justice research and innovation, support Adult Protective Services systems, and provide additional protections for residents of long-term care facilities. The Elder Justice Reauthorization Act reauthorizes the Elder Justice Act and funds the bill's provisions with over \$2.2 billion. In a statement, one of the bill's sponsors, House Ways and Means Committee Chairman Richard Neal (D-MA) said the "rampant spread of COVID-19 and the devastation this deadly virus has caused among seniors has highlighted the desperate need to better protect our nation's elderly. The abuse and neglect they experience is unacceptable, and this legislation will improve the federal government's elder justice work by enhancing existing programs and funding research for response methods." A one page summary of the bill can be found [here](#). A section-by-section summary of the bill can be found [here](#).

MEHLMAN CASTAGNETTI
— ROSEN & THOMAS —

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

House Democrats Call on FDA to Ensure “Sound Science” Drives COVID Vaccine Approval Process: In a [letter](#) to FDA Commissioner Stephen Hahn earlier this week, a group of House Energy and Commerce Committee Democrats – including Full Committee Chairman Frank Pallone (NJ), Health Subcommittee Chairwoman Anna Eshoo (CA) and Oversight and Investigations Subcommittee Chair Diana DeGette (CO) – urged the Commissioner to ensure that “sound science and the protection of public health alone” drives the Agency’s COVID-19 vaccine approval process. “We are increasingly concerned by the political pressure that is being exerted by this Administration on FDA,” the letter reads. “This makes it all the more imperative that FDA take the threat to the public’s vaccine confidence into account when conducting the benefit-risk assessment of a potential COVID-19 vaccine.”

CDC Updates COVID-19 Testing Guidelines: A number of public health advocates and Congressional Democrats are expressing [concern](#) for the CDC’s most recent set of COVID-19 testing [guidelines](#), which now state that individuals who have been in close contact (within 6 feet) of a person with a COVID-19 infection for at least 15 minutes but do not have symptoms “do not necessarily need a test” unless they are considered vulnerable or if their health care provider or state or local public health officials recommend that they take a test.

Soon after the updated recommendations were released, a number of public health officials and Congressional Democrats expressed their [concern](#), and several states (including Florida, Texas, Arizona, Illinois, California, New York, New Jersey and Connecticut) have since said they will continue to allow asymptomatic individuals who were exposed to the virus to get tested.

In response to the criticisms, HHS Assistant Secretary for Health Dr. Brett Giroir said the guidelines “received appropriate attention, consultation and input from Task Force experts” before they were released. However, at least one White House Coronavirus Task Force member, Dr. Anthony Fauci, said he was “not part of any discussion or deliberation regarding the new testing recommendations” due to a pre-scheduled surgery. In a recent media interview, Fauci said he was “worried” the interpretation of the recommendations will give people the incorrect assumption that asymptomatic spread is not of great concern. “In fact, it is,” he said.

Trump Administration – in Partnership with Abbott – Announces Plans to Deploy 150 Million Rapid Tests in 2020: On Thursday, HHS [announced](#) the award of a \$760 million contract to Abbott Labs to deploy 150 million rapid, Abbott BinaxNOW COVID-19 Ag Card Point of Care (POC) SARS-CoV-2 diagnostic tests. The test – which received an [Emergency Use Authorization \(EUA\)](#) from the FDA earlier this week – is the first of its kind to deliver test results in 15 minutes or less without the use of instrumentation / computer equipment. The Administration says it intends to distribute these tests to schools and other special needs populations. In a statement, HHS Secretary Alex Azar said the new Abbott test is “another incredibly valuable result of President Trump’s all-of-America approach to constructing our world-leading COVID-19 testing capacity.” He added: “[b]y strategically distributing 150 million of these tests to where they’re needed most, we can track the virus like never before and protect millions of Americans at risk in especially vulnerable situations.”

CMS Announces New Reporting and Testing Requirements for Nursing Homes and Other Providers: On Tuesday, August 25, CMS [announced](#) a number of regulatory changes aimed at keeping nursing home residents and staff safe:

- *Testing Requirements for Nursing Home Residents and Staff:* Going forward, CMS will now require (instead of recommend) nursing homes to offer tests to residents when there is an outbreak or residents show symptoms. CMS says the frequency of staff testing will be based on the degree of community spread (though the Agency says guidance on this will be forthcoming). Labs and nursing homes using point-of-care testing devices will be required to report diagnostic test results as required by the CARES Act.

MEHLMAN CASTAGNETTI
— ROSEN & THOMAS —

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

- **New Requirements for Hospitals to Report Data:** CMS will now also require hospitals and critical access hospitals to report daily data, including, but not limited to elements such as the number of confirmed or suspected COVID-19 positive patients, ICU beds occupied, and availability of essential supplies and equipment such as ventilators and PPE. The Agency says hospitals could face possible termination of Medicare and Medicaid payment if unable to correct reporting deficiencies.
- **New Reporting Requirements for Labs:** The new CMS rule also implements a CARES Act requirement that labs report COVID-19 test results daily to the HHS Secretary. Labs will have a one-time, three-week grace period to begin reporting required test data. CMS will impose a civil monetary penalty in the amount of \$1,000 a day for the first day, and \$500 for each subsequent day for labs that do not comply.
- **Physician and Pharmacist Orders for Tests:** CMS is also updating an earlier policy that covered repeated COVID-19 testing for Medicare beneficiaries without practitioner orders during the Public Health Emergency. The revised policy states that each beneficiary may receive one COVID-19 test without the order of a physician or other health practitioner, but Medicare will require such an order for all further COVID-19 tests. This change helps ensure that beneficiaries receive appropriate medical attention if they need multiple tests. It is also designed to stop fraudsters from performing or billing for unnecessary tests.

In separate but related news, CMS also [launched](#) a new “first of its kind” training program aimed at improving nursing home infection control practices. CMS says the training – which is now available to staff of all Medicare and Medicaid certified nursing homes – was designed specifically with COVID-19 in mind, and incorporates the most recent lessons learned from nursing homes and teaches frontline staff best practices they can implement to address issues related to COVID-19.

And in an effort to further protect nursing home residents and staff, CMS also [announced](#) the release of 1.5 million N95 respirators from the Strategic National Stockpile for distribution to approximately 3,336 nursing home facilities across the country. The Department says the quantity of respirators distributed to each nursing home will be based on the number of medical staff employed at the facility, as reported to CMS’ database. The shipments support only Medicare and Medicaid-approved nursing homes and are in addition to prior shipments of PPE distributed in order to safeguard our most vulnerable populations during the COVID-19 pandemic.

FDA Grants EUA for Convalescent Plasma: Over the weekend, the FDA gave [emergency use authorization \(EUA\)](#) for convalescent plasma to be used as a therapy for hospitalized COVID-19 patients. In his remarks during Sunday’s press conference, FDA Commissioner Stephen Hahn suggested that the blood therapy could save the lives of as many as 35 out of 100 people who otherwise would have died from the virus. This sparked concern from researchers, who claimed that the Commissioner’s claim was misleading. Hahn later [clarified](#), saying the criticism of his remarks were “entirely justified” and added: “[w]hat I should have said better is that the data show a relative risk reduction not an absolute risk reduction.”

A number of Democratic lawmakers also [said](#) they were “increasingly concerned” that the Trump Administration was placing political pressure on the Agency, and added that “any political involvement in a future vaccine or treatment threatens to undermine the credibility of the agency, and public confidence in vaccines and treatments approved for use by FDA.” In response, Hahn [said](#) the decision “was made by FDA career scientists based on data submitted a few weeks ago.”

HHS Extends Deadline for Providers to Apply for Phase 2 General Distribution Funding: Earlier this week, HHS [announced](#) it will extend the deadline for Medicaid, Medicaid managed care, Children’s Health Insurance Program (CHIP), dental providers, and certain Medicare providers to apply for phase 2 general distribution funding to September 13, 2020.

MEHLMAN CASTAGNETTI
— ROSEN & THOMAS —

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

The Provider Relief Funding is coming from the CARES Act and the subsequent Paycheck Protection Program and Health Care Enhancement Act.

HHS' HRSA Announces \$100 Million Award in Support of Health Center Quality Improvement: On Tuesday, HHS' Health Resources and Services Administration (HRSA) [announced](#) it will award \$117 million to over 1,000 health centers nationwide in support of health center quality improvement. In a statement, HHS Secretary Alex Azar said the money will "help ensure that all patients who visit a HRSA-funded health center continue to receive the highest quality of care, including access to COVID-19 testing and treatment." Click [here](#) for the full list of recipients.

FDA Issues Warning About Hand Sanitizers Packaged in Food and Drink Containers: The FDA issued a new [warning](#) to consumers yesterday about alcohol-based hand sanitizers packaged in containers that may appear as food or drinks. In a statement, FDA Commissioner Stephen Hahn said the products "could confuse consumers into accidentally ingesting a potentially deadly product." He added that manufacturers should be "vigilant" about the way their products are packaged and marketed and warned that the Agency will "take appropriate actions as needed to protect the health of Americans."

Noteworthy Guidance Documents: In advance of this year's hurricane season, CDC posted [guidance](#) for those going to a public disaster shelter during the pandemic and also released other [resources](#) for hurricane season preparation. CDC also updated its COVID-19 FAQ [document](#) on the virus...posted updated [information](#) for health departments on the basics of contact tracing...updated a list of [actions](#) for people to take if they have traveled in order to protect those around them from COVID-19...updated their COVID-19 [resources](#) for young adults...updated [information](#) for businesses and workplaces to plan, prepare, and respond to the pandemic...updated [information](#) on employee safety and support, and [considerations](#) for employees to consider when returning to work...updated operation [considerations](#) for schools...and posted special [considerations](#) for mitigating the risks of resumption and sustained operation of schools in low-resource, international settings. FDA also updated its do-not-use [list](#) of hand sanitizers.

OTHER NOTEWORTHY ANNOUNCEMENTS COMING OUT OF WASHINGTON

Republicans Officially Nominate President Trump for Second Term: On Monday, Republicans kicked off the 2020 GOP Convention by formally [nominating](#) Donald Trump to serve as President for a second term. Various Republican lawmakers and Trump loyalists voiced their support for the President throughout the week, as did several members of the President's family. In a [speech](#) from the White House on Tuesday, First Lady Melania Trump expressed her "deepest sympathy" to those who have lost loved ones during the COVID-19 pandemic and added that her husband's Administration "will not stop fighting until there is an effective treatment or vaccine available to everyone."

On Thursday evening, Trump formally accepted his party's nomination in a speech on the south lawn of the White House. In his [remarks](#), the President warned that the upcoming election "will decide whether we will defend the American way of life, or whether we allow a radical movement to completely dismantle and destroy it." The President also talked of how he "took on big pharma" during his first four years in office, most recently via a series of [Executive Orders](#) to "massively lower the cost of your prescription drugs and give critically ill patients access to lifesaving cures."

CMS Delays Release of Physician Self-Referral Final Rule: The Centers for Medicare & Medicaid Services (CMS) [announced](#) this week that it will be delaying the release of a final rule to [amend](#) the Physician Self-Referral Law ("Stark Law") for one year (from August 31, 2020 to August 31, 2021) in an effort to address a number of issues raised by stakeholders during the proposal's comment period. The proposed [changes](#) were part of HHS's Regulatory Sprint to

MEHLMAN CASTAGNETTI
— ROSEN & THOMAS —

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

Coordinated Care and an attempt to provide protection against overutilization and other harms, while giving physicians and other healthcare providers added flexibility to improve the quality of care for their patients.

The release of a separate proposed rule to [amend](#) the Federal Anti-Kickback Statute and Civil Monetary Penalties Law (which was released in tandem with CMS' Stark Law proposal) has not yet been delayed by the Department. That proposed rule would offer flexibility for innovation and improved coordinated care through outcome-based payment arrangements that reward improvements in patient health. The changes also attempt to make it easier for physicians and other health care providers to ensure they are complying with the law by offering specific safe harbors for these arrangements.

UPCOMING COVID / HEALTH-RELATED CONGRESSIONAL HEARINGS

Select Subcommittee on the Coronavirus Crisis Hearing

Topic: Hybrid Hearing with Treasury Secretary Steve Mnuchin

Date / Time: Tuesday, September 1 at 1:00pm

Witnesses: The Honorable Steve Mnuchin, Secretary, Department of the Treasury

ADMINISTRATION ANNOUNCEMENTS

Department of Health and Human Services

- [Trump Administration Announces the Distribution of \\$2.5 Billion to Nursing Homes for COVID-19 Relief Funding](#)
- [Trump Administration Launches National Training Program to Strengthen Nursing Home Infection Control Practices](#)
- [Trump Administration Strengthens COVID-19 Surveillance with New Reporting and Testing Requirements for Nursing Homes, Other Providers](#)
- [Trump Administration to Release 1.5 Million N95 Respirators from the Strategic National Stockpile for Distribution to Nursing Homes](#)
- [Trump Administration Adds Health Plans to June 2020 Plasma Donation Guidance](#)

Centers for Medicare & Medicaid Services

- [CMS Posts Guidance for Implementing New Testing Requirements in Nursing Homes and Labs](#)
- [CMS Releases Additional Frequently Asked Questions on the Treatment of Coronavirus Disease Relief Payments on the Medicare Cost Report](#)
- [CMS Issues Informational Bulletin on Medicaid Reimbursement Strategies to Prevent Spread of COVID-19 in Nursing Facilities](#)

Food and Drug Administration

- [FDA Authorizes First Diagnostic Test Where Results Can Be Read Directly From Testing Card](#)
- [FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers](#)
- [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

- [People With Intellectual and Developmental Disabilities Disproportionately Affected by COVID-19](#)
- [NIH establishes Centers for Research in Emerging Infectious Diseases](#)

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