



Weekly Health Care Checkup: *COVID-19 and Beyond* September 7-11, 2020

IN BRIEF

What Happened This Week: The Senate returned from August recess this week and hit the ground running on a number of items, beginning with [consideration](#) of a Trump district court nominee on Tuesday. That same day, Senate Republican Leaders unveiled a new “targeted” [version](#) of their earlier HEALS Act [proposal](#), though Democrats (who continue to maintain that they will [not support](#) a bill with a price tag lower than \$2.2 trillion) were quick to label the bill a [non-starter](#) and effectively [blocked](#) the bill from moving forward during a vote on Thursday.

Shifting gears to some of the more noteworthy Senate hearings this week, NIH Director Francis Collins and US Surgeon General Jerome Adams testified before the [Senate HELP Committee](#) on Wednesday during a hearing on vaccines and public health. Throughout the hearing, several Democrats expressed concern about the possibility of political meddling in the COVID-19 vaccine review and approval process, though both witnesses assured lawmakers that science will be the “only measure” by which a vaccine is approved (in separate, but related news, FDA officials [confirmed](#) this week that they will soon release guidelines / standards for drug companies seeking [Emergency Use Approvals \(EUAs\)](#) for COVID-19 vaccines – more on that [here](#)).

The House is not expected to officially return to Washington until Monday, September 14; however, several committees still convened for hearings and markups remotely this week. On Wednesday, the [House Science, Space, and Technology Subcommittee on Research and Technology](#) heard from representatives at Carnegie Mellon, Oakland University, the University of Illinois, and Purdue University during a hearing about how the pandemic is impacting university operations and research. That same day, Amtrak President and CEO William Flynn told members of the [House Transportation and Infrastructure Subcommittee Railroads, Pipelines, and Hazardous Materials](#) that the passenger railroad now anticipates needing up to \$4.9 billion in funding to operate and invest in its network, support its partners, and address various Congressional concerns, such as avoiding employee furloughs and maintaining daily long distance service. The [House Energy and Commerce Committee](#) also approved a slew of bills during a markup this week – including 2 COVID-related measures. And later today (Friday, September 11), the [House Science, Space, and Technology Subcommittee on Energy](#) will examine ways in which the Department of Energy’s capabilities can be leveraged to respond to the pandemic.

What to Expect Next Week: The Senate is scheduled to be in session Monday, September 14 – Friday, September 18. The chamber will kick off the week again with [votes](#) on additional Trump district court nominees.

The House will [reconvene](#) after a monthlong August recess on Monday, September 14 (though votes are postponed until 6:30pm). Expect lawmakers to take up the following pieces of [legislation](#) when they return:

- [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

With hopes of another COVID response package coming to fruition before the November election now dashed, expect both chambers to turn the bulk of their attention to funding 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.

Click [here](#) to view the full schedule of upcoming COVID and other health-related hearings in the House and Senate next week.

DEEP DIVE

GOP’s New “Targeted” COVID-19 Relief Package Fails to Advance in the Senate Without the Needed Support From Democrats: Senate Republican Leaders moved forward with a vote on their latest “targeted” COVID-19 relief [package](#) yesterday; however, without the needed support from Democrats – who labeled the bill a [non-starter](#) earlier this week – the proposal failed to get the 60 votes needed to advance.

The roughly \$500-700 million package was initially introduced with the intent of moving the needle on stalled COVID response negotiations between Congressional Republicans, Democrats, and the White House, though the main sticking point between both parties continues to be the bill’s price tag as Democrats continue to maintain they will [not support](#) a package lower than \$2.2 trillion. Although about half the cost of Republican’s initial [HEALS Act](#) proposal, the updated GOP bill still included: liability protections for schools / businesses; a second round of loans under the CARES Act’s Paycheck Protection Program to support for small businesses; \$16 billion in funding for COVID-19 testing; \$31 billion for COVID-19 therapeutics / vaccines; \$105 billion to support schools; a modified \$10 billion loan turned grant for the US Postal Service; and a modified unemployment benefit.

With both sides seemingly deadlocked, it is unclear whether lawmakers will be able to negotiate a bipartisan deal on the next COVID response package before the November elections given the dwindling number of legislative working days remaining and the growing number of must-do items piling up (such as funding the government beyond the September 30 deadline).

Senate HELP Committee Conducts Hearing on Vaccines and Public Health: The Senate Health, Education, Labor, and Pensions (HELP) Committee held a hearing Wednesday, September 9 to explore the progress made thus far on a COVID-19 vaccine, remind parents about the importance of childhood vaccinations, and encourage as many Americans as possible to get the flu vaccine this fall. Witnesses included NIH Director Francis Collins and US Surgeon General Jerome Adams.

In her opening statement, Ranking Member Patty Murray (R-WA) expressed concern that the CDC and FDA’s efforts to approve and distribute a safe and effective COVID-19 vaccine would be “undermined by political meddling.” In response, NIH Director Collins explained that if / when any of the current six vaccine candidates make it through their rigorous clinical trials, they will then be subjected to a thorough review by an independent group of experts (the [Data and Safety](#)

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[Monitoring Board](#)) before the FDA even has a chance to review the vaccine. He also pointed out that the nine pharma companies working on COVID vaccines recently [committed](#) to “stand with science” and not put forward a vaccine until it had been thoroughly vetted for safety and efficacy. “I’m hoping this quells some of the concerns out there about safety and efficacy,” he said. When asked about whether he thought a vaccine would be approved before the November elections, Dr. Collins said it’s too soon for anyone to make that prediction. “Certainly, to try to predict whether it happens on a particular week before or after a particular date in early November is well beyond anything that any scientist right now could tell you and be confident they know what they are saying.”

A full summary of the discussion can be found [here](#). Looking ahead, members of the Senate HELP Committee will get an [update](#) on the federal response to the COVID-19 pandemic during a hearing on Wednesday, September 23.

FDA to Soon Release Guidelines / Standards for COVID Vaccine EUAs: FDA officials [confirmed](#) this week that they will soon release guidelines / standards for drug companies seeking [Emergency Use Approvals \(EUAs\)](#) for COVID-19 vaccines. During a typical EUA approval process, companies are only required to provide data showing that their product may be effective. However, officials suggested this week that the EUA standards / data requirements for COVID vaccines will be more like an “EUA plus” and more closely mirror what is typically required for a full drug approval.

FDA Updates its COVID-19 Response At-A-Glance Summary: The FDA recently [updated](#) its COVID-19 response “at-a-glance” summary. The document offers up-to-date facts, figures, and timeline of the Agency’s response efforts thus far.

CMS Administrator Verma Hosts COVID-19 Roundtable in Florida: CMS Administrator Seema Verma hosted a [roundtable](#) with health care providers in Tampa Florida this week to discuss how the COVID-19 pandemic is affecting long term care residents and vulnerable populations in the area. During the event, several participants highlighted the ways in which telehealth has allowed providers to be more flexible with care delivery and many said it has contributed to a more “resilient” health care system during the pandemic.

CMS to Approve Amendment to Texas’ Section 1115 Demonstration: Earlier this week, CMS announced it will approve an amendment to the [Texas Section 1115](#) demonstration that enables the state to extend its Medicaid state plan 30-day spell of illness limitation for an additional 30-day period with the ultimate goal of helping COVID-19 patients with cost of care and length of hospital stay requirements.

CDC Updates COVID Testing Data Tracker: The CDC recently updated its [COVID-19 Testing Data Tracker](#) to include information on correctional facilities, NIH Vulnerability Index data, and upgraded testing information.

CDC Issues Interim Guidance for COVID-19 Rapid Antigen Testing: CDC updated [guidance](#) on how to best interpret COVID-19 rapid antigen test results in an effort to help health care providers make the most effective use of antigen tests in different situations.

Other Noteworthy Updates to Agency Guidance Documents:

- CDC updated [information](#) on how restaurants and bars can protect communities during COVID-19.
- CDC updated a [toolkit](#) for school administrators on cleaning, disinfecting, and hand hygiene in schools.
- CDC updated [guidance](#) aimed at enhancing frontline public health capacity.
- CDC updated additional [tools and resources](#) for non-US healthcare settings.
- CDC updated a guidance [document](#) on mitigating COVID-19 transmission in markets in low-resource settings.
- CDC updated [information](#) on shared and congregate housing.

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- CDC updated [information](#) on travel during the COVID-19 pandemic.
- CMS updated its [toolkit](#) on state actions to mitigate COVID-19 prevalence in nursing homes.

OTHER NOTEWORTHY ANNOUNCEMENTS COMING OUT OF WASHINGTON

House Energy and Commerce Committee Approves Over 25 Health-Related Bills During Virtual Markup; Democratic Leaders Reportedly Eyeing Floor Votes on the Measures in the Coming Weeks: On Wednesday, September 9, the House Energy and Commerce Committee approved over 25 health-related bills during a virtual [markup](#). Several of the measures were introduced with bipartisan support, including one bill ([H.R. 4439](#)) that would provide a long-term extension of the pediatric priority review voucher program (which expires this month), and another bill ([H.R. 2564](#)) that would help seniors avoid late enrollment penalties in Medicare. Other legislation that was approved with bipartisan support would expand access to mental health services and combat the opioid epidemic. During the markup, Committee Chairman Frank Pallone (D-NJ) said House Democratic Leaders will aim to bring the legislation to the floor for a vote in the next few weeks, though he did not specify when. "The idea would be to try to move all of these to the floor," he said, adding: "I'm not saying that's necessarily going to happen but that's what we're going to try to do." A full summary of the markup can be found [here](#).

GOP Lawmakers Introduce Legislation Aimed at Lowering Drug Costs for Seniors: Earlier this week, Senators Pat Toomey (R-PA) and Mike Crapo (R-ID) introduced a bill ([S. 3013](#), the Encouraging Innovative Benefit Design to Lower Costs for Seniors Act) aimed at lowering prescription drug costs for seniors by:

- Requiring CMS to increase the maximum number of plan options under Medicare Part D from three to at least four plans in each region; and
- Allowing Medicare Part D sponsors to offer two additional plans provided that at least one of them passes on rebates to the consumer.

In a statement, Senator Toomey said the current [restrictions](#) on the number of plan options under Medicare Part D "limits insurers from providing seniors with plans that best fit their needs." He added that the bill would address this problem by "encouraging insurers to develop and offer a greater variety of prescription drug plans to seniors." Click [here](#) for a one-pager on the bill.

Congressional Democrats Issue Report on CMS Administrator's Use of Taxpayer Dollars: A group of Democratic Congressional Committee Leaders capped off a yearlong investigation into CMS Administrator Seema Verma's use of taxpayer dollars with a [report](#) this week claiming that Verma and her top aides "abused the federal contracting process to stock CMS with handpicked Republican consultants who billed the government hourly rates of up to \$380." The lawmakers go on to claim that Verma's consultants charged CMS nearly \$6 million for work that included "boosting her public profile and personal brand, serving as her preferred communications advisors, arranging private meetings for her with media personalities and other high-profile individuals, and routinely traveling with her to events across the country." Verma has not yet publicly commented on the findings, although an HHS spokesperson called the report a "reckless drive-by election year hit job."

UPCOMING COVID / HEALTH-RELATED CONGRESSIONAL HEARINGS

House Committee on Financial Services

Topic: Full Committee [Hearing](#): Prioritizing Fannie's and Freddie's Capital over America's Homeowners and Renters? A Review of the Federal Housing Finance Agency's Response to the COVID-19 Pandemic

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Date: Wednesday, September 16

Time: 12:00pm

Witnesses: TBA

House Committee on Veterans' Affairs

Topic: Subcommittee on Oversight and Investigations [Hearing](#): Modernizing VA's Medical Supply Chain: Lessons Learned from the Pandemic

Date: Wednesday, September 16

Time: 2:00pm

Witnesses: TBA

House Committee on Financial Services

Topic: Subcommittee on Investor Protection, Entrepreneurship and Capital Markets [Hearing](#): Insider Trading and Stock Option Grants: An Examination of Corporate Integrity in the Covid-19 Pandemic

Date: Thursday, September 17

Time: 12:00pm

Witnesses: TBA

ADMINISTRATION ANNOUNCEMENTS

Department of Health and Human Services

- [Harnessing Technology to Address Loneliness and Social Isolation](#)
- [RIC Panel Discussion: Engaging Members in Plan Governance During COVID-19](#)
- [Engaged Social Isolation Virtual Summit](#)
- [Federal Government Adjusts COVID-19 Entry Strategy for International Air Passengers](#)
- [Trump Administration Takes Action to Expand Access to COVID-19 Vaccines](#)
- [New Resource: Discharge Planning During the COVID-19 Pandemic](#)

Centers for Medicare & Medicaid Services

- [CMS Administrator Hosts Roundtable in Tampa on COVID-19](#)

Food and Drug Administration

- [Advancing the Science of Real-World Data to Address the COVID-19 Pandemic](#)
- [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.](#)

National Institutes of Health

- [NIH ACTIV Initiative Launches Adaptive Clinical Trials of Blood-Clotting Treatments for COVID-19](#)
- [Probiotic Skin Therapy Improves Eczema in Children, NIH Study Suggests](#)
- [Study Shows Decline in Awareness, Treatment and Control of High Blood Pressure](#)
- [Miglustat Improves Swallowing in Children and Adolescents With Niemann-Pick Type C1 Disease](#)

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- [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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