



Weekly Health Care Checkup

October 19-23, 2020

IN BRIEF

What Happened This Week: On Tuesday, the House Ways and Means Subcommittee on Oversight held a [hearing](#) to examine ACA enrollment under the Trump Administration. As expected, the discussion during the hearing was quite partisan, with Democrats accusing the Trump Administration of “sabotaging” the ACA through cuts to advertising and outreach and Republicans alternatively blasting Democrats’ claims that Republicans do not support pre-existing condition protections.

On Wednesday, Senate Majority Leader Mitch McConnell (R-KY) moved forward with a procedural vote on a “targeted” \$500 billion proposal, though – as expected – Senate Democrats [blocked](#) the legislation from moving forward, arguing that the bill did not go far enough to address the nation’s pandemic response ([negotiations](#) between the White House and House Speaker Nancy Pelosi (D-CA) on the long-stalled, larger COVID-19 stimulus package failed to make any headway this week).

On Thursday, Senate Judiciary Committee Republicans [voted](#) to advance Judge Amy Coney Barrett’s nomination to the Supreme Court. That same day, the FDA’s Vaccines and Related Biological Products Advisory Committee convened a virtual public [meeting](#) to discuss the development of a COVID-19 vaccine. And later that evening, President Trump and Democratic Presidential hopeful Joe Biden squared off in the third and final 2020 [debate](#). Both candidates sparred over a range of topics throughout the event, including COVID-19 and health care.

And in other non-COVID news, it appears that the Trump Administration is backtracking on its original [plan](#) to distribute \$200 drug “discount cards” to Medicare beneficiaries ahead of the November election after several Congressional Democrats expressed [concern](#) that the effort was politically motivated.

What to Expect Next Week: Leader McConnell is expected to move forward with a final [vote](#) on Judge Amy Coney Barrett’s nomination to the Supreme Court on Monday, October 26. It is expected that Senate Republicans – who hold a 53-47 majority in the Senate – will have the votes to confirm Barrett as only two Senate Republicans (Collins (ME) and Murkowski (AK)) have indicated that they will not vote to confirm Judge Barrett prior to the elections.

At this point, it is highly unlikely – if not impossible – for Congress to vote on a larger COVID-19 stimulus package *before* the November elections. Speaker Pelosi did [say](#) yesterday that negotiators were “just about there” on the overall framework for a deal; however she was quick to emphasize that even if a deal were struck, writing the legislation would take several days (in other words, no votes are likely to occur ahead of the November 3rd elections).

DEEP DIVE

Senate Judiciary Committee Republicans Advance Judge Barrett's US Supreme Court Nomination, Full Senate Vote Set for Early Next Week: The Senate Judiciary Committee [voted](#) yesterday (Thursday, October 22) to advance Judge Amy Coney Barrett's nomination to the Supreme Court. As expected, Committee Democrats boycotted the vote – citing concerns about how Barrett might rule in upcoming cases related to the Affordable Care Act and abortion – though the Committee's Republicans (with a 12-10 majority) were still able to approve her nomination despite their absence. Looking ahead, Senate Majority Leader Mitch McConnell (R-KY) is expected to tee up a procedural vote to move forward with Barrett's nomination today (Friday, October 23). A [final vote](#) on her confirmation will likely take place on Monday, October 26.

Trump and Biden Square Off in Final Presidential Debate of 2020 Election: President Trump and Democratic Presidential hopeful Joe Biden squared off in the final 2020 [debate](#) last night (Thursday, October 22). Both candidates sparred over a range of topics throughout the event, including COVID-19 and health care. At one point, President Trump said he'd like to "terminate" the Affordable Care Act and replace it with a "brand-new, beautiful health care" plan (though he did not provide specifics as to what he would replace it with). When asked about the pending Supreme Court case against the ACA (of which the Trump Administration is part of), Trump said he would seek to ensure protections for preexisting conditions if the ACA were struck down. In response, Biden suggested that the President will "never come up with a plan," adding: "I guess we're going to get the pre-existing condition plan the same time we get the infrastructure plan that we waited for in '17, '18, '19, '20."

Senate Democrats Block McConnell's "Targeted" COVID-19 Response Legislation From Moving Forward; Bipartisan Deal on Larger Stimulus Package Unlikely Before November Elections: On Wednesday, Senate Majority Leader Mitch McConnell moved forward with a procedural vote on a "targeted" \$500 billion proposal, though – as expected – Senate Democrats [blocked](#) the legislation from moving forward, arguing that the bill did not go far enough to address the nation's pandemic response. In his [remarks](#) on the Senate floor just prior to the vote, McConnell acknowledged that the latest proposal was not "perfect," but suggested that the bill would "move us past Speaker Pelosi's all-or-nothing obstruction and deliver huge support, right now, for the most pressing needs of our nation." In [response](#), Senate Democratic Leader Chuck Schumer (D-NY) blasted the GOP proposal as a "political stunt."

Meanwhile, negotiations between House Speaker Nancy Pelosi (D-CA) and White House officials on a larger stimulus package failed to make any headway this week – despite Pelosi's self-imposed Tuesday deadline for a deal. At this point, it is highly unlikely – if not impossible – for Congress to vote on a larger COVID-19 stimulus package *before* the November elections. Speaker Pelosi did [say](#) yesterday that negotiators were "just about there" on the overall framework for a deal; however she was quick to emphasize that even if a deal were struck, writing the legislation would take several days (in other words, no votes are likely to occur ahead of the November 3rd elections). Looking even further ahead, White House Chief of Staff Mark Meadows seemingly threw cold water on the idea that a deal would come together during the lame duck session of Congress post-elections in his [comments](#) to reporters late Wednesday evening; however the situation is still very fluid (as it has been for several months now).

FDA's Vaccines and Related Biological Products Advisory Committee Convenes to Discuss COVID-19 Vaccine Development: On Thursday, members of the FDA's Vaccines and Related Biological Products Advisory Committee convened a virtual public [meeting](#) to discuss the development of a COVID-19 vaccine(s). Various infectious disease experts, physicians, and scientists discussed a number of issues during the day-long meeting, including the lack of diversity in current vaccine trials, vaccine hesitancy, emergency-use authorizations (EUAs), and the status of the ongoing clinical trials being conducted by six different drug manufacturers (Pfizer, Moderna, AstraZeneca, Janssen, Novavax, and GSK). In order to

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increase diversity in clinical trials, committee members noted that the trials in which the NIH is participating include requirements for enrolling patients with specific risk factors to ensure diversity in clinical trials. There was also discussion about pregnant women and children being largely underrepresented in the current clinical trials (a concern which was magnified by the revelation that only one company, Pfizer, has enrolled children in its trials). FDA officials also said they were aware of the public's skepticism regarding the safety and efficacy of the coronavirus vaccination and acknowledged the importance of helping the public gain trust and confidence in it. Officials noted that they have attempted to address said hesitations by emphasizing that EUA requirements will closely mirror standard licensure requirements. Additionally, FDA officials made it clear that clinical trials must continue, even after EUAs have been granted.

In separate, but related news, a group of organizations representing the pharmaceutical supply and payment chain [released](#) a set of guiding principles yesterday for the "safe efficacious development, distribution, and allocation of vaccine(s) to achieve mass immunization against COVID-19." The groups say the principles "represent the commitment of the private sector to the efficient, well-coordinated distribution, allocation, and mass immunization against COVID-19 as a necessary countermeasure to the current pandemic."

White House Backs Away From Plan to Distribute Medicare Drug "Discount" Cards Ahead of November Election: It appears that the Trump Administration is backtracking on its original [plan](#) to distribute \$200 drug "discount cards" to Medicare beneficiaries ahead of the November election after several Congressional Democrats expressed [concern](#) that the effort was politically motivated. Instead, White House Chief of Staff Mark Meadows [said](#) Wednesday that the Administration is now looking at "November or December" as their targeted deadline for card distribution. The latest development comes after press [reports](#) indicated that HHS General Counsel Robert Charrow warned (via an internal memo) that the President's proposed new plan could violate federal election laws.

CMS to Delay Implementation of Radiation Oncology Model Until July 2021: On Wednesday, CMS [said](#) it will delay implementation of its new [Radiation Oncology Model](#) until July 1, 2021 (instead of January 1, 2021) after a number of medical groups – including the American Society for Radiation Oncology – expressed concern that mandatory participation in the model would be "untenable" for practices already facing staff shortages and other challenges as a result of the COVID-19 pandemic. In [response](#), ASTRO said they were "thankful" for the delay, though they added that they remain "seriously concerned" about the "excessive payment cuts" in the model. "ASTRO is committed to a successful alternative payment model for radiation oncology, and we look forward to working with CMS during the delay period to ensure that the concerns of ASTRO and its more than 10,000 members, as well as cancer patients, members of Congress and other radiation oncology stakeholders are addressed," the group said. If implemented, participating hospital outpatient departments could see a 4.7 percent cut; participating group practices could see cuts as much as 6 percent.

Bipartisan Group of Lawmakers Urge House Leaders to Address CMS's Proposed Cuts to Specialists in 2021 PFS: A bipartisan group of over 200 House lawmakers sent [letter](#) to Speaker Nancy Pelosi (D-CA) and Republican Leader Kevin McCarthy (R-CA) this week urging them to consider legislation to address the "excessively steep cuts" to specialists in CMS's [proposed](#) cuts in the 2021 physician fee schedule. In order to safeguard beneficiaries' access to care during this pandemic, we as Congress should examine possible bipartisan solutions to address excessively steep cuts. We encourage you to incorporate the resulting policy changes in any upcoming legislation moving through the House," the letter reads.

CMS Administrator Touts Administration's Efforts to Lower Drug Prices in Response to Recent Op-Ed: In response to a recent [op-ed](#) claiming that the Trump Administration's efforts to lower drug prices were merely "campaign rhetoric," CMS Administrator Seema Verma [suggested](#) that the author's argument "falls flat" and added that it "unaccountably disparages" the Administration's [Part D Senior Savings Model](#). Alternatively, Verma said the model "will give the 1.3

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million diabetic seniors enrolled in Medicare's prescription drug benefit access to insulin for no more than \$35 for a month's supply — and often a lot less."

Ways and Means Subcommittee Members Trade Jobs During Hearing on ACA Enrollment: The House Ways and Means Subcommittee on Oversight held a hearing on Tuesday to examine the status of Affordable Care Act enrollment under the Trump Administration. As expected, the discussion during the hearing was quite partisan, with Democrats accusing the Trump Administration of "sabotaging" the ACA through cuts to advertising and outreach and Republicans alternatively blasting Democrats' claims that Republicans do not support pre-existing condition protections. A full summary of the hearing can be found [here](#). The ACA's open enrollment period for the 2021 plan year begins Sunday, November 1 and will run through Tuesday, December 15. On Monday, the Trump Administration [announced](#) that the average premium for a benchmark plan under the ACA will drop two percent next year. The Administration also said it expects premiums to drop for the third year in a row, though deductibles are expected to increase for individuals who do not qualify for subsidies.

FDA Approves First Treatment for COVID-19: On Thursday, the FDA [approved](#) the antiviral drug Veklury (Remdesivir) for use in adult and pediatric patients (older than 12 years) for the [treatment](#) of COVID-19 requiring hospitalization. The Agency notes, however, that the drug should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. In a statement, FDA Commissioner Stephen Hahn said the drug approval was "supported by data from multiple clinical trials that the agency has rigorously assessed and represents an important scientific milestone in the COVID-19 pandemic."

HHS Expands Relief Fund Eligibility and Updates Reporting Requirements: HHS announced yesterday that it would be expanding the pool of eligible Provider Relief Fund (PRF) Phase 3 [applicants](#) to include providers across a broad category of practices. The Department says these providers and all Phase 3 applicants will have until 11:59PM EST on November 6, 2020 to submit their applications for payment consideration. Once validated, these providers will receive a baseline payment of approximately 2% of annual revenue from patient care plus an add-on payment that considers changes in operating revenues and expenses from patient care, including expenses incurred related to coronavirus. All payment recipients will be required to attest to receiving the Phase 3 General Distribution payment and accept the associated Terms and Conditions.

Handful of States Reportedly in Talks to Conduct Independent COVID-19 Vaccine Reviews: A handful of states — including New York, California, Michigan, West Virginia, and Washington DC — are [reportedly](#) in talks to conduct independent COVID-19 vaccine reviews in an effort to address vaccine hesitancy, though at this point, it is unclear whether the states would move to block the vaccine from being administered or simply issue their findings in a report if the review revealed any potential public safety concerns.

In separate, but related news, HHS Secretary Alex Azar said earlier this week that the Department would not be distributing any additional funding to states for vaccine planning, suggesting that they already have "plenty of resources to manage the vaccine distribution program." Secretary Azar's comments come after CDC Director Redfield's recently [suggested](#) that \$6 billion would be needed to distribute the vaccine.

GAO to Investigate Potential Political Influence at CDC and FDA: The nonpartisan GAO [announced](#) it will conduct an investigation into whether the FDA or the CDC were subjected to political influence by the Trump Administration during the COVID-19 pandemic. The announcement comes after Democratic Senators Elizabeth Warren (MA), Patty Murray (WA), and Gary Peters (MI) sent a [letter](#) to the GAO requesting that the Agency conduct the review. "The Trump Administration has reportedly pressured the CDC and FDA throughout the COVID-19 pandemic, repeatedly applying

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political pressure and imposing orders on career scientists that undermine the agencies' credibility and independence," the lawmakers wrote. The Senators also introduced [legislation](#) (the Science and Transparency Over Politics (STOP) Act) earlier this year that would require a newly-formed task force to conduct an investigation into political interference with decisions made by scientific agencies of HHS in connection with the pandemic response.

In separate, but related news, recent media [reports](#) have indicated that HHS Secretary Alex Azar is dissatisfied with FDA Commissioner Stephen Hahn's handling of the COVID-19 vaccine approval process and, as a result, is seeking to have the Commissioner replaced. Secretary Azar has since denied these recent rumblings.

HHS Issues Guidance Expanding Access to Vaccines, COVID-19 Tests: HHS issued [guidance](#) this week (using its authority under the PREP Act) to [authorize](#) authorizing qualified pharmacy technicians and state-authorized pharmacy interns to administer childhood vaccines, COVID-19 vaccines (when made available), and COVID-19 tests (all subject to several requirements). The Department's guidance states that the pharmacy intern must be authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs, but this authorization need not take the form of a license from, or registration with, the state board of pharmacy.

CDC Updates Guidance Defining COVID-19 Exposure After Correctional Facility Employees With Multiple Brief Exposures to Persons with COVID-19 Led to Transmission: The CDC updated [guidance](#) this week clarifying the amount of time it would take for an individual to be considered a close contact exposed to a person with COVID-19. The updated guidance now defines a close contact as someone who has spent a "cumulative total of 15 minutes or more, in a 24-hour period within six feet of an infected person" (note that previous guidance defined a close contact as someone who spent at least 15 *consecutive* minutes within 6 feet of a confirmed case). The guidance was updated after a Correctional Facility in Vermont [discovered](#) that multiple, short and non-consecutive exposures to persons confirmed to have COVID-19 led to transmission.

Other Noteworthy Updates to COVID-19 Guidance:

- CDC updated general [FAQs](#) related to COVID-19.
- CDC updated [considerations for who should get tested](#) for COVID-19.
- CDC updated [guidance](#) on the appropriate use of testing for SARS-CoV-2 in light of additional testing capacity.
- CDC updated their COVID-19 testing [overview](#) with information on viral and antibody tests.
- CMS updated its [Toolkit](#) on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes.
- CDC updated [strategies](#) for protecting K-12 school staff from COVID-19.
- CDC updated [guidance](#) to K-12 schools on COVID-19 symptom screening as part of a school reopening process.
- CDC updated [guidance](#) to help universities protect students, faculty, and staff from COVID-19 infections and slow the spread.
- CDC updated [information](#) on contact tracing to slow the spread of COVID-19.
- CDC updated the contact tracing communication [toolkit](#) for health departments.
- CDC updated [guidance](#) on the definitions and management of contacts of people with COVID-19 and community-related exposures.

UPCOMING COVID / HEALTH-RELATED CONGRESSIONAL HEARINGS

N/A

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ADMINISTRATION ANNOUNCEMENTS

Centers for Medicare & Medicaid Services

- [CMS Approves Nebraska Medicaid Demonstration to Provide Pathway to Enhanced Benefits for Eligible Adults](#)
- [Premiums for HealthCare.gov Plans Are Lower for Third Consecutive Year](#)

Food and Drug Administration

- [Advisory Committees Give FDA Critical Advice and the Public a Voice](#)
- [FDA Approves First Treatment for COVID-19](#)
- [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

- [Scientists Use Gene Therapy and a Novel Light-Sensing Protein to Restore Vision in Mice](#)
- [NIH Study Tests a Comprehensive Model Intervention to Reduce Opioid Overdose Deaths in Hard-Hit Communities](#)

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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