



Weekly Health Care Checkup September 21-25, 2020

IN BRIEF

What Happened This Week: The late Supreme Court Justice Ruth Bader Ginsburg became the [first](#) woman to lie in state at the US Capitol this week – an honor that seems only fitting given her lifelong devotion to women’s rights / gender equality. Though as mourners continue to pay their respects, her death inevitably sets up a fierce political [battle](#) as the President and Senate Republicans look to move forward with her replacement on the high court (more on that [here](#)).

In other news, Congress appears [poised](#) to avert a government shutdown before the month’s end...the Senate HELP Committee got an [update](#) on the federal response to COVID-19...members of the House Energy and Commerce Subcommittee [debated](#) the impact of the ACA during the ongoing pandemic...and President Trump signed two health-related [executive orders](#) as part of this new “America First Healthcare Plan”.

What to Expect Next Week: President Trump is expected to [announce](#) his nominee to replace the late Justice Ginsburg tomorrow (Saturday, September 26). As it stands now, Senate Majority Leader Mitch McConnell (R-KY) has enough Republican [support](#) to move forward with a confirmation vote on the President’s nominee; however the timing (either before or after the November 3 election) for when all this plays out is still in flux.

The Senate will next convene at 3:00pm on Tuesday, September 29 and will be in session through Friday, October 2. Following Leader remarks on Tuesday, the Senate will resume consideration of H.R.8337 (the Continuing Resolution). At 5:30pm, the Senate will vote on the motion to invoke cloture on the bill.

The House is expected to be in session Tuesday, September 29 through Friday, October 2. At some point during the week, lawmakers will consider several bills under suspension of the rules (list of bills still TBA). It’s also possible – though the situation is still very fluid – that Speaker Nancy Pelosi (D-CA) will move to bring another COVID-19 relief [proposal](#) to the floor for a vote.

***Noteworthy Upcoming Events:** Nemours Children’s Health System and the Duke-Margolis Center for Health Policy are co-hosting an upcoming webinar on Tuesday, September 29 from 2:30 - 4:00 PM ET titled: *Caring for Kids in the COVID-19 Era: Promoting Health Equity and Value*. The event is expected to highlight the roles health systems, payers, and all levels of government can play to address the pandemic’s negative impacts, reduce disparities, and promote health equity for children and their families. In addition, speakers will identify action steps the federal government can take to improve the COVID-19 response for children. Click [here](#) for more information and to register for the event.

DEEP DIVE

Fate of the ACA Uncertain Following Justice Ginsburg's Death: The late Supreme Court Justice Ruth Bader Ginsburg became the [first](#) woman to lie in state at the US Capitol this week – an honor that seems only fitting given her lifelong devotion to women's rights / gender equality, and her historic service on the Court. Though as mourners continue to pay their respects, her death inevitably sets up a fierce political [battle](#) as the President and Senate Republicans look to move forward with her replacement on the high court. If successful, it is almost inevitable that the liberal Ginsburg will be replaced by a much more conservative jurist. At this point, Senate Majority Leader Mitch McConnell (R-KY) has not confirmed when the chamber will move forward with the confirmation vote (either before or after the November 3 elections); however the timing of the vote itself is of particular importance to Democrats who are seeking to uphold President Obama's domestic policy achievement, the Affordable Care Act. In a [case](#) brought by several states represented by Republican Governors and Attorneys General, and joined by the Trump Administration, a lower court held that the entire ACA, including its popular pre-existing condition insurance protections, may be unconstitutional because of changes to the law's "shared responsibility" (i.e., individual mandate) provision. The Court is slated to hear the oral arguments in the case beginning November 10 – seven days *after* the November election – with a decision in the case is expected by June 2021. Supporters of the ACA are concerned that a more conservative Court would be more likely to side with the Trump Administration and Republican states and invalidate the entire law. Stay tuned...

Congress Poised to Avert Government Shutdown Before Month's End: The House voted 359-57 to send a stopgap spending bill ([H.R. 8337](#)) to the Senate for consideration on Tuesday, with the upper chamber expected to follow suit early next week. The measure temporarily funds the government at current levels through December 11 and [extends](#) several health-related programs (originally set to expire November 30). It also holds Medicare Part B monthly premium increases at the 2020 amount (plus 25 percent of the difference between the 2020 amount and the preliminary monthly actuarial rate for 2021) and makes [adjustments](#) to payment requirements under the Medicare Accelerated and Advance Payment Program.

A dustup over Democrats' initial failure to include farmer trade relief payments in the bill nearly derailed bipartisan support for the measure earlier this week; however, negotiators were able to address the situation within a day (the House-passed bill ultimately included the trade relief payments for farmers – sought by President Trump – in exchange for \$8 billion in nutrition assistance – which ended up being four times the amount that House Democrats originally proposed).

Looking ahead, President Trump is expected to sign the bill into law once it makes its way through the Senate (likely next Tuesday, September 29), though given that this bill is only a temporary extension of government funding, expect lawmakers to take up another funding measure upon their return to Washington for the "lame duck" session of Congress.

President Trump Signs Executive Orders as Part of "America First Healthcare Plan": President Trump laid out his "vision" for health care in America while [speaking](#) to a crowd in North Carolina yesterday. As part of this new "America First Healthcare Plan", Trump signed two [executive orders](#). The first order directs the HHS Secretary to work with Congress to address the issue of surprise medical bills by January 1, 2021 (though that appears unlikely given the very few legislative working days remaining and the fact that the four Congressional committees with jurisdiction over the issue have so far failed to reach consensus on the best method for settling billing disputes). If Congress fails to reach an agreement by January, the order directs the HHS Secretary to pursue other actions via the regulatory process, but it does not provide additional details beyond that. The second order seeks to make it the US' "policy" to protect people with pre-existing conditions – a signature element in President Obama's Affordable Care Act, which ironically, could be struck down by the Supreme Court by the end of the year in a [case](#) brought on by the Trump Administration. In the event that

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the law is struck down, it would then be up to Congress to reinstate that protection (an idea which many Republicans support in principle, though lawmakers have so far not been able to coalesce around a single piece of legislation that would allow that to happen).

The President also [suggested](#) in his remarks that a \$200 “discount card” would be soon be sent to Medicare beneficiaries to use on prescription drugs, though he did not provide any further details about how / when this would happen (and it is unclear what authority the President would have to do this without Congressional approval).

Lastly, in line with the President’s health care announcements yesterday, HHS also:

- Issued a [final rule](#) and [guidance](#) allowing a pathway for states to import prescription drugs.
- Solicited private-sector proposals with regard to allowing Americans to get lower-cost FDA-approved [drugs](#) and [insulins](#) from American pharmacies via importation and reimportation.
- Released the 2021 Medicare Advantage and Medicare Part D Premium [landscape](#), which revealed that the average 2021 premiums for Medicare Advantage plans are expected to decline 34.2 percent from 2017, and that Part D premiums will drop 12 percent from 2017, with over 1,600 drug plans offering insulin at no more than \$35 per month.
- Issued [a notice of proposed rulemaking](#) from the HHS’ HRSA to pass on steep discounts at community health centers on insulin and epinephrine to Americans who are uninsured or have high cost-sharing, including the nearly 3 million health center patients with diabetes.

Speaker Pelosi (D-CA) Reportedly Instructs Committee Leaders to Draft Up New COVID Response Proposal, Though its Fate is Uncertain: House Speaker Nancy Pelosi (D-CA) has [reportedly](#) instructed Ways and Means Committee Chairman Richard Neal (D-MA) to draft up a new COVID-19 relief proposal in the \$2.2-2.4 billion range, though given that both parties and the White House are still far apart on the bill’s price tag, it remains unlikely that this latest proposal will make its way to the President’s desk for signature. Stay tuned...

FDA Launches New Digital Health Center of Excellence: The FDA [announced](#) the launch of a new Digital Health Center of Excellence that will reside within the Center for Devices and Radiological Health (CDRH). The Agency says the new Center will focus primarily providing both internal and external stakeholders with technological advice, coordinating and supporting work being done across the FDA, advancing best practices, and reimagining digital health device oversight all with the ultimate goal of empowering digital health stakeholders to advance health care by fostering responsible and high-quality digital health innovation. Bakul Patel (who has previously served as the lead on all of FDA’s regulatory and scientific efforts related to digital health devices since 2010) will serve as the CDRH’s first director.

House Approves Package of E&C Committee-Approved Health Bills: The House voted to approve a number of health-related bills this week, including a [package](#) of ten Energy and Commerce Committee bills tied to suicide prevention, strengthening the Strategic National Stockpile, and maternal health care improvement. In a statement, Committee Chairman Frank Pallone (D-NJ) said the bills “address shortcomings and make strategic improvements throughout our health care system.” He urged the Senate to take up the legislation before year’s end.

Pharma Execs Slated to Testify Before Oversight Committee During Two-Part Hearing on Rx Drug Prices Next Week: A total of five pharma executives are expected to testify before the House Oversight and Reform Committee next week during a two-part [hearing](#) on prescription drug prices. On Wednesday, September 30, lawmakers will hear from Bristol Myers Squibb/Celgene and Teva Pharmaceuticals, followed by executives from Amgen, Mallinckrodt and Novartis AG on Thursday, October 1. Notably absent from the list is AbbVie, which the Committee recently [subpoenaed](#) for

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documents as part of the Committee's ongoing investigation (first launched by the late former Chairman Elijah Cummings) into the pricing practices of 12 drug companies.

Senate HELP Committee Gets Update on Federal Response to COVID-19: Members of the Senate HELP Committee heard from several Trump Administration officials during a [hearing](#) on the federal response to the pandemic yesterday (Wednesday, September 23). As expected, Ranking Member Patty Murray (D-WA) expressed concern about politics interfering with the COVID-19 vaccine approval process. In response, FDA Commissioner Stephen Hahn and other witnesses committed to "fight for the integrity of the agency" and promised to "put the interests of the American people before anything else." A full summary of the discussion can be found [here](#). Yesterday's hearing was likely Chairman Alexander's (R-TN) last health-related Committee hearing before he retires at the end of his term. In his [opening statement](#), he expressed his appreciation for the committee members' ability to work well together despite their differences. "The work of the members of this Committee has reflected my view that it's hard to get here, hard to stay here and while you're here you might as well try to accomplish something good for the country—which we have on numerous occasions," he said.

House Energy and Commerce Subcommittee Examines the ACA's Impact During the Pandemic: On Wednesday, September 23, the House Energy and Commerce Subcommittee on Health held a hearing looking the impact of the Affordable Care Act (ACA) during the COVID-19 pandemic. As expected, the hearing was chock-full of partisan posturing, with Democrats expressing concern that millions more will lose health care coverage during a global pandemic if the Supreme Court [rules](#) all (or parts of) the law invalid later this year. Several Republicans, meanwhile, expressed their support for protections for people with pre-existing conditions regardless of the Supreme Court's ruling. A full summary of the discussion can be found [here](#).

CDC Announces Intent to Distribute \$200 Million to Jurisdictions for Vaccine Preparedness Efforts: Last week, the CDC released a [COVID-19 vaccine distribution plan](#) and separate [interim playbook](#) to help states / jurisdictions assemble and operationalize their COVID-19 vaccine distribution plan. This week, the Agency announced that it will provide \$200 million to jurisdictions to support their vaccine distribution planning and preparedness efforts. In a statement, HHS Secretary Alex Azar said jurisdictions may use the funds to develop and update plans for the eventual distribution and administration of a vaccine, though CDC Director Redfield [told](#) Congress last week that the Agency would likely need an additional \$6 billion in order to adequately distribute the vaccine.

President Suggests White House Has Authority to Veto FDA's Rules for COVID-19 Vaccine EUAs: While speaking to reporters on Wednesday, President Trump suggested that the White House has the authority to veto the FDA's soon-to-be-released guidelines / standards for drug companies seeking for [Emergency Use Approvals \(EUAs\)](#) for COVID-19 vaccines. His comments come just weeks after FDA officials suggested that the standards / data requirements for COVID-19 vaccine EUAs would likely be more rigorous than the typical EUA approval process, with one official describing it as an "EUA plus". In separate, but related news, the House Energy and Commerce Subcommittee on Oversight and Investigations will hold a [hearing](#) next Wednesday, September 30 to examine the "criteria that makers of a COVID-19 vaccine should be required to meet before any potential cure is approved."

FDA Authorizes First Point-of-Care Antibody Test for COVID-19: Earlier this week, the FDA [issued](#) its first Emergency Use Authorization (EUA) for a COVID-19 serology (antibody) point-of-care (POC) test. The Assure COVID-19 IgG/IgM Rapid Test Device was first authorized for emergency use by certain labs in July 2020 to help identify individuals with antibodies to SARS-CoV-2, indicating recent or prior COVID-19 infection. Today, that EUA is [being reissued](#) to authorize the test for POC use using fingerstick blood samples. This authorization means that fingerstick blood samples can now

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be tested in POC settings like doctor's offices, hospitals, urgent care centers and emergency rooms rather than having to be sent to a central lab for testing.

Noteworthy Congressional Inquiries:

- A group of Senate Democrats sent [letters](#) to several health insurers seeking information about their coverage policies for COVID-19 testing.
- A group of House Energy and Commerce Committee Republicans sent [letters](#) to NIH Director Collins and FBI Director Wray requesting information about how their agencies are "working to remove foreign influence from biomedical research."
- A group of House Democratic committee leaders sent a [letter](#) to CMS expressing concern for the Agency's "lack of transparency" in the Accelerated and Advance Payment Programs (AAP).

UPCOMING COVID / HEALTH-RELATED CONGRESSIONAL HEARINGS

House Small Business Committee

Date: Wednesday, September 30

Time: 10:00am

Topic: Full Committee [Hearing](#): How COVID-19 is Impacting Small Businesses Across the Food System

Witnesses:

- Ms. Kimberly Gorton President and CEO Slade Gorton & Co., Inc.
- Mr. Jimmy Wright President Wright's Market
- Mr. Rob Larew President National Farmers Union
- Mr. Collin Castore Owner, Seventh Son Brewing President, Ohio Craft Brewers Association (OCBA)

House Veterans' Affairs Committee

Date: Wednesday, September 30

Time: 10:00am

Topic: Subcommittee on Health [Hearing](#): MISSION Critical: Assessing Community Care Wait Times

Witnesses:

- TBA

House Oversight and Reform Committee

Date: Wednesday, September 30

Time: 10:00am

Topic: Full Committee [Hearing](#): Unsustainable Drug Prices: Testimony from the CEOs (Part I)

Witnesses:

- TBA

House Appropriations Committee

Date: Wednesday, September 30

Time: 1:00pm

Topic: Subcommittee on the Interior, Environment, and Related Agencies [Hearing](#): Indian Country COVID-19 Response and Update

Witnesses:

- Mr. Kevin J. Allis CEO, National Congress of American Indians

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- Ms. Stacy A. Bohlen CEO, National Indian Health Board
- Ms. Francys Crevier CEO, National Council of Urban Indian Health

House Veterans Committee

Date: Wednesday, September 30

Time: 2:30pm

Topic: Subcommittee on Technology Modernization for Agencies [Hearing](#): Examining VA's Ongoing Efforts in the Electronic Health Record Modernization Program

Witnesses:

- TBA

House Oversight and Reform Committee

Date: Thursday, October 1

Time: 10:00am

Topic: Full Committee [Hearing](#): Unsustainable Drug Prices: Testimony from the CEOs (Part II)

Witnesses:

- TBA

House Oversight and Reform Committee

Date: Thursday, October 1

Time: 10:00am

Topic: Full Committee [Hearing](#): Unsustainable Drug Prices: Testimony from the CEOs (Part II)

Witnesses:

- TBA

House Select Coronavirus Crisis Subcommittee

Date: Friday, October 2

Time: 9:00am

Topic: Subcommittee [Hearing](#): Hybrid Hearing With Secretary Of Health And Human Services Alex M. Azar II

Witness:

- Secretary of Health and Human Services Alex Azar

ADMINISTRATION ANNOUNCEMENTS

Department of Health and Human Services

- [Administration Announces \\$200 Million from CDC to Jurisdictions for COVID-19 Vaccine Preparedness](#)

Centers for Medicare & Medicaid Services

- [Trump Administration Announces Historically Low Medicare Advantage Premiums and New Payment Model to Make Insulin Affordable Again for Seniors](#)
- [CMS Announces Transformative New Model of Care for Medicare Beneficiaries with Chronic Kidney Disease](#)
- [CMS Announces New Federal Funding for 33 States to Support Transitioning Individuals from Nursing Homes to the Community](#)
- [CMS Issues Urgent Call to Action Following Drastic Decline in Care for Children in Medicaid and Children's Health Insurance Program Due to COVID-19 Pandemic](#)
- [CMS to Expand Successful Ambulance Program Integrity Payment Model Nationwide](#)

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- [CMS Announces Innovative Payment Model to Improve Care, Lower Costs for Cancer Patients](#)
- [CMS Seeks Feedback on Performance of Medicaid Funded Home and Community-Based Services](#)

Food and Drug Administration

- [FDA Takes Actions to Help Lower U.S. Prescription Drug Prices](#)
- [FDA Authorizes First Point-of-Care Antibody Test for COVID-19](#)
- [FDA Requiring Labeling Changes for Benzodiazepines](#)
- [FDA Launches the Digital Health Center of Excellence](#)
- [FDA Clarifies Types of Evidence Relevant to Determining the “Intended Use” of FDA-Regulated Products](#)
- [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 Discover Genetic and Immunologic Underpinnings of Some Cases of Severe COVID-19](#)
- [Fourth Large-Scale COVID-19 Vaccine Trial Begins in the United States](#)
- [NIH Expands Clinical Trials to Test Convalescent Plasma Against COVID-19](#)
- [Negative Pressure Wound Therapy Does Not Cut Infection Risk in Obese Women After Cesarean Delivery](#)
- [NIH Study Details Self-Reported Experiences With Post-Exertional Malaise in ME/CFS](#)

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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