



## Weekly Health Care Checkup October 26-30, 2020

### IN BRIEF

**What Happened This Week:** On Monday, Judge Amy Coney Barrett was [confirmed](#) (52-48) by the Senate to the US Supreme Court. As expected, Democrats – including 2020 Presidential hopeful Joe Biden – were quick to express concern for Barrett’s confirmation as her seat on the high court essentially secures a 6-3 conservative majority for the foreseeable future. More on that [here](#).

No major news on the path forward for the next COVID-19 stimulus package. With all hopes of reaching a deal before the November 3<sup>rd</sup> elections now dashed, it remains to be seen whether negotiators and the White House will be able to reach a deal during the “lame duck” session of Congress. On Tuesday, President Trump [suggested](#) that “we’ll get the best stimulus package you’ve ever seen” after the election, though he did not elaborate. Separately, House Republicans released a [summary](#) of a new, targeted COVID-19 response package earlier today. While it is unlikely that this GOP-backed proposal will move through the House as currently drafted given the Democratic majority, the bill is reportedly being introduced with the intention of moving the needle on negotiations between Democrats, Republicans, and the White House on a larger COVID-19 package post-November elections.

HHS issued a number of regulatory announcements this week. On Tuesday, CMS released a [proposed rule](#) to change coverage and payment policies for Medicare Durable Medical Equipment (DME), Prosthetics, Orthotic Devices, and Supplies (DMEPOS). On Thursday, the Agency finalized its price transparency [rule](#), which will require private health plans to disclose prices up front to consumers. That same day, HHS’s Office of the National Coordinator for Health IT (ONC) [extended](#) the compliance dates and timeframes for information blocking and health IT certification requirements set forth in the 21<sup>st</sup> Century Cures Act [final rule](#). CMS also [released](#) a plan this week to remove regulatory barriers and ensure consistent coverage and payment for the administration of an eventual vaccine for Medicare beneficiaries.

Earlier today, the FDA also [released](#) a [list](#) of 223 essential medicine products, including 96 device medical countermeasures. The list, which was required under an August 6 [executive order](#), identifies crucial medicines and other medically-necessary equipment that should be available “at all times” in the event of infectious disease outbreaks or any chemical, biological, radiological, or nuclear threats.

**What to Expect Next Week:** Election day is Tuesday, November 3. [Voters](#) will head to the polls (if they have not already done so via early voting in many states) to either elect a new president (former Vice President Joe Biden and his running mate Kamala Harris) or incumbent president Donald Trump and his running mate, current Vice President Mike Pence. Voters will also elect representatives from all 435 Congressional districts across each of the 50 states. 35 Senate seats are also up for grabs (12 Democratic seats and 23 Republican). 11 gubernatorial elections will also take place on Tuesday. Stay tuned...

## **DEEP DIVE**

**Senate Confirms Judge Amy Coney Barrett to the US Supreme Court:** Judge Amy Coney Barrett was [confirmed](#) (52-48) by the Senate to the US Supreme Court on Monday, October 26. Every Republican Senator voted in favor of Barrett's nomination with the exception of Susan Collins (though Collins – who is facing a tight reelection race – said her opposition was based on the nomination vote being so close to the election and not on Barrett's qualifications). A ceremony was held on the South Lawn of the White House Monday evening, in which Barrett gave a brief speech stating that she would keep her personal beliefs from interfering with her judicial decisions. Justice Clarence Thomas administered the judicial oath to Barrett during the ceremony, and Chief Justice John Roberts administered her second oath in a private ceremony on Tuesday. Given that her confirmation essentially secures a 6-3 conservative majority on the high court, Democrats were quick to express their concern for Barrett's confirmation. Shortly after the Senate vote on Monday evening, Presidential hopeful Joe Biden released a [statement](#) suggesting that the "rushed and unprecedented confirmation of Amy Coney Barrett as Associate Justice to the Supreme Court, in the middle of an ongoing election, should be a stark reminder to every American that your vote matters."

**CMS Finalizes Price Transparency Rule:** On Thursday, October 29, the Trump Administration finalized its price transparency [rule](#), which will require private health plans to disclose prices up front to consumers. Under the rule, each health plan must now provide consumers with an online tool where they can view negotiated rates between their physicians and insurers. Additionally, the online resource must include out-of-pocket cost estimates for procedures, prescription drugs, common services, and durable medical equipment (DME). HHS says the rule, which was first proposed nearly a year ago in November 2019, will be phased in over a four-year period. Beginning in 2022, health insurers will be required to provide access to data files that can be used by technology companies to build apps allowing patients to view prices across the health care market. In 2023, insurers must provide their beneficiaries with cost-sharing information on 500 specific services, as well as items such as DME. Finally, in 2024, insurers will be required to share all cost-sharing information with respect for their services. The Administration says the rule is part of a broader goal to increase market competition and give more decision-making power to consumers. Though given that this rule was finalized less than a week before the general election, it is unclear where it will stand if President Trump is not elected for another term.

**HHS ONC Releases Interim Final Rule that Extends Deadlines for Information Blocking and Health IT Certification Requirements in the 21st Century Cures Act:** On Thursday, October 29, HHS's Office of the National Coordinator for Health IT (ONC) [extended](#) the compliance dates and timeframes for information blocking and health IT certification requirements set forth in the 21<sup>st</sup> Century Cures Act [Final Rule](#). The Department says the extension will allow for stakeholders to better focus their attention on immediate concerns related to the ongoing COVID-19 pandemic. However, the national coordinator for health IT, Dr. Don Rucker, made it clear that ONC would not be removing the requirements, noting that this extension only serves to "...provid[e] additional time to allow everyone in the health care ecosystem to focus on COVID-19 response." The original compliance date was set for November 2, 2020, but the interim rule extends the deadline to April 5, 2021.

**CMS Issues Proposed Rule to Update Medicare Coverage, Payment, and Coding for New Technologies:** CMS issued a [proposed rule](#) on Tuesday, October 27 that would change coverage and payment policies for Medicare Durable Medical Equipment (DME), Prosthetics, Orthotic Devices, and Supplies (DMEPOS). If finalized, the rule would expand Medicare coverage and payment for continuous glucose monitors, expand the classification of external infusion pumps under DME (which would make home infusion of drugs more accessible for beneficiaries), reduce administrative burdens, and ensure higher payment amounts to suppliers for DMEPOS items and services in rural and non-contagious areas. The Agency says it hopes that these changes will "provide more choices for beneficiaries with diabetes, while streamlining the process for innovators in getting their technologies approved for coverage, payment, and coding by Medicare."

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**CMS Announces Plans to Cover (Eventual) COVID-19 Vaccine for Medicare Beneficiaries:** On Wednesday, October 28, CMS [released](#) a plan to remove regulatory barriers and ensure consistent coverage and payment for the administration of an eventual vaccine for Medicare beneficiaries. The Agency says the toolkits – which were sent to providers, states and insurers – were designed to increase the number of providers that can administer the vaccine, ensure adequate reimbursement for administering the vaccine in Medicare, while making it clear to private insurers and Medicaid programs their responsibility to cover the vaccine at no charge to beneficiaries. CMS also said it will take action to increase reimbursement for any new COVID-19 treatments that are approved or authorized by the FDA.

**FDA Releases List of Crucial Medicines for Public Health Emergencies:** On Friday, October 30, the FDA [released](#) a [list](#) of 223 essential medicine products, including 96 device medical countermeasures. The list, which was required under an August 6 [executive order](#), identifies crucial medicines and other medically-necessary equipment that should be available “at all times” in the event of infectious disease outbreaks or any chemical, biological, radiological, or nuclear threats. To attain this goal, the executive order calls for increased domestic production of these items and decreased reliance on foreign producers. The FDA worked alongside federal partners to create the list, focusing their attention on medicines for acute care facilities treating patients with severe illnesses or injuries. Due to the swift and unpredictable nature of the COVID-19 pandemic, the FDA determined that this list was necessary to ensure better preparedness for future public health emergencies.

**COVID-19 Stimulus Negotiations Remain at Standstill:** On Monday, October 26, House Speaker Nancy Pelosi (D-CA) [spoke](#) with Treasury Secretary Steve Mnuchin to further negotiate a second COVID stimulus package. The two spoke by phone for almost an hour, but according to Pelosi’s spokesman Drew Hammill, they could not agree on “[health language](#)” regarding COVID testing and contact tracing. This latest setback marks the third month of back and forth on a stimulus bill that has not come to fruition due to partisan disagreements. President Trump [acknowledged](#) Tuesday that an agreement on a second coronavirus relief package would not happen until after the election, though he [promised](#) that “... after the election, we’ll get the best stimulus package you’ve ever seen.” Separately, House Republicans released a [summary](#) of a new, targeted COVID-19 response package earlier today. While it is unlikely that this GOP-backed proposal will move through the House as currently drafted given the Democratic majority, the bill is reportedly being introduced with the intention of moving the needle on negotiations between Democrats, Republicans, and the White House on a larger COVID-19 package post-November elections.

**Halted AstraZeneca and Johnson & Johnson COVID-19 Vaccine Trials Resume:** AstraZeneca and Johnson & Johnson both have been cleared to resume their COVID-19 vaccine clinical trials. Both companies recently had to pause their clinical trials due to safety concerns. Two participants in AstraZeneca’s UK-based trial had suffered [neurological problems](#), and a Johnson & Johnson participant [reportedly](#) had a stroke. However, investigators found that the unexplained illnesses in both trials were not connected to the vaccines. On Friday, October 23, AstraZeneca released a [statement](#), declaring that the FDA had authorized the company to continue with clinical trials in the US. This decision was made following the FDA’s review of safety data from global trials. The FDA concluded that it is safe to continue with the trials. Johnson & Johnson also released a [statement](#) on October 23, stating that they were also given the green light by the FDA to continue with its coronavirus vaccine trial. An independent data safety monitoring board reviewed the safety data of the Johnson & Johnson trial and recommended that the trial resume.

**Bipartisan Group of Lawmakers Express Concern About Lack of Coverage for COVID-19 Testing:** In a [letter](#) sent October 23, a bipartisan group of 54 House lawmakers called on HHS Secretary Alex Azar, seeking a clarification of tri-agency [guidance](#) released earlier this year on June 23. The lawmakers, led by, Reps. David McKinley (R-WV) and Bill Pascrell (D-NJ), stated in their letter that the guidance has been widely misinterpreted due to confusion over coverage

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requirements for COVID-19 testing. They stated that this misunderstanding has led to "...an increase of coverage denials from health plans for COVID-19 testing, particularly for asymptomatic individuals." The lawmakers urged Secretary Azar for HHS to issue a clarification of the guidance to ensure individuals can receive COVID testing without cost-sharing, even when they are asymptomatic.

**Senate Health Committee Chairman Lamar Alexander Urges Governors of New York and California to Not Interfere with COVID-19 Vaccine:** In a [statement](#) on Saturday, October 24, Senate HELP Committee Chairman Lamar Alexander (R-TN) requested that New York Governor Andrew Cuomo (D) and California Governor Gavin Newsom (D) stop "second guessing" FDA scientists' decisions on the safety and efficacy of coronavirus vaccines. Both governors have declared that they would set up their own individual COVID-19 vaccine review panels within their respective states. The Chairman said that these efforts would undermine the FDA's "gold standard of safety and efficacy," which could "...delay approval, discourage Americans from taking the vaccine, and cost lives."

## **UPCOMING COVID / HEALTH-RELATED CONGRESSIONAL HEARINGS**

N/A

## **ADMINISTRATION ANNOUNCEMENTS**

### **Department of Health and Human Services**

- [Trump Administration Distributes Incentive Payments to Nursing Homes Curbing COVID-19 Deaths and Infections](#)
- [HHS, DOD Collaborate on Plans to Purchase of Lilly Investigational Therapeutic to Treat COVID-19](#)
- [ACL/CMS Webinar 11/12: HCBS Innovation During COVID--Medicaid HCBS Payers & Providers](#)

### **Centers for Medicare & Medicaid Services**

- [CMS Advances Seven Finalists in Artificial Intelligence Health Outcomes Challenge](#)
- [CMS Completes Historic Price Transparency Initiative](#)
- [Price Transparency Press Call Remarks by Administrator Seema Verma](#)
- [CMS Refunds Withheld Funds Designated for the Fire Department of the City of New York](#)
- [Trump Administration Acts to Ensure Coverage of Life-Saving COVID-19 Vaccines & Therapeutics](#)
- [New CMS Proposals Streamline Medicare Coverage, Payment, and Coding for Innovative New Technologies and Provide Beneficiaries with Diabetes Access to More Therapy Choices](#)
- [Preview 2021 Plans and Prices on HealthCare.gov Ahead of the Upcoming Federal Health Insurance Exchange Open Enrollment Period](#)

### **Food and Drug Administration**

- [Dr. Hahn's Opening Remarks at the MDUFA Public Meeting](#)
- [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 Scientists Discover Key Pathway in Lysosomes that Coronaviruses Use to Exit Cells](#)

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- [Scientists Use Clues in the Human Genome to Discover New Inflammatory Syndrome](#)
- [Postpartum Depression May Persist Three Years After Giving Birth](#)

## **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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