

*Wynne Health Group Weekly*



**FRAMING THE WEEK**

House Speaker Nancy Pelosi (D-CA) and Treasury Secretary Mnuchin are expected to continue negotiations on a **coronavirus relief package** this week. A deal before the election remains uncertain despite some concessions from both Democrats and Republicans over the last week. **President Donald Trump's COVID-19 prognosis** continues to be a mystery, as the President, his medical team, and Chief of Staff Mark Meadows have issued incomplete, confusing, and contradictory statements.

Meanwhile, Senate Republicans are [charging ahead](#) with the **Senate Judiciary Committee Supreme Court nomination hearing** for Judge Amy Coney Barrett on October 12, despite Judiciary Committee members Sens. Mike Lee (R-UT) and Thom Tillis (R-NC) testing positive for COVID-19. Senate Democratic Leader Chuck Schumer (D-NY) and Senate Judiciary Committee Ranking Member Dianne Feinstein (D-CA) are [calling on](#) Senate Majority Leader Mitch McConnell (R-KY) to delay the nomination process, citing safety concerns over an in-person hearing. They also insist that a “virtual confirmation hearing for a lifetime appointment to the federal bench is not an acceptable substitute.”

House Democrats and the Trump administration have moved closer on the overall price tag of the **coronavirus relief package** – \$2.2 trillion and \$1.62 trillion, respectively – and some major relief provisions. For example, Treasury Secretary Steven Mnuchin's latest offer includes \$50 billion for the **Provider Relief Fund** and \$75 billion for testing and contracting – both in line with Democrats' updated Heroes Act.

However, they still have “significant disagreement in key areas,” according to Speaker Pelosi. In a [Dear Colleague letter](#), Speaker Pelosi outlined their five priorities: (1) unemployment insurance; (2) funding for schools, states, and localities; (3) child tax credit and earned income tax credit; (4) the use of testing and contact tracing funds; and (5) appropriations. Speaker Pelosi pointed out that House Democrats have reduced their updated Heroes Act by \$144 billion, but the White House wants \$44 billion more in cuts. As for aid to states and localities, Treasury Secretary Mnuchin offered \$250 billion but House Democrats are pushing for \$436 billion – nearly half the amount they proposed in the original Heroes Act.

Speaker Pelosi suggested that the President's COVID-19 diagnosis “changes the dynamic” and may help get a deal across the finish line. On Saturday (October 3), President Trump, in a [tweet](#), called on both parties to “work together and get it done.” Still, House [passage](#) of the updated Heroes Act last Thursday (October 1), by a 214-207 vote, provides Democrats, especially moderate Democrats facing tough races, with some political cover on the campaign trail in case a deal is not reached.

On Wednesday (October 7), Vice President Mike Pence and Sen. Kamala Harris (D-CA) go head-to-head in the **first vice presidential debate**, which takes on greater significance considering the President's hospitalization. Debate moderator, Susan Page of USA Today, has not yet announced the specific debate topics, but they will likely include a range of health care issues discussed at the presidential debate, such as

the Affordable Care Act, the Trump administration's health care plan, and the coronavirus pandemic. There will be nine topics and approximately 10 minutes to discuss each topic.

To support the COVID-19 response, the Wynne Health Group is making its coverage of related legislative and regulatory updates publicly available. We encourage you to share our COVID-19-related summaries available [here](#).

An overview of health policy events of interest in the coming week is posted to [Policy Hub](#) and included below for your convenience.

## **THIS WEEK IN HEALTH POLICY**

### **Mon. (10/5)**

- **2:30pm-4:00pm – PCORI Webinar: Health Care Research** – The Patient-Centered Outcomes Research Institute (PCORI) hosts a webinar titled, “Considering the Full Range of Outcomes in PCORI Research – Patients, Caregivers and Consumers.” [Details](#).

### **Tue. (10/6)**

- **12:30pm-5:00pm – FDA Meeting: Drug Development** – FDA convenes a meeting titled, “Patient-Focused Drug Development for Stimulant Use Disorder.” [Details](#).

### **Wed. (10/7)**

- **12:15pm-1:15pm – FDA Town Hall: COVID-19** – FDA hosts a virtual town hall titled, “Coronavirus (COVID-19) Test Development and Validation.” [Details](#).
- **2:00pm-3:20pm – Brookings Discussion: Health Care Prices** – The Brookings Institute convenes a discussion titled, “Lessons from international experience in determining health care prices.” [Details](#).
- **9:00pm-10:30pm – Vice Presidential Debate** – USA Today hosts the first vice presidential debate between Democratic vice presidential nominee Kamala Harris and Vice President in Salt Lake City, UT.

### **Thurs. (10/8)**

- **8:00am-5:00pm – FDA Meeting: New Drug Application** – FDA convenes a joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee convenes a meeting to discuss new drug application (NDA) 211179, for amphetamine sulfate immediate-release oral capsules, submitted by Arbor Pharmaceuticals, LLC, for the proposed indication of treatment of attention deficit hyperactivity disorder. [Details](#).
- **9:00am-5:00pm – FDA Webcast: Drug Registration** – FDA hosts webcast titled, “Regulatory Education for Industry: Drug Registration and Listing Workshop.” [Details](#).
- **10:00am-4:00pm – FDA Workshop: Liver Disease** – FDA hosts a workshop titled, “Assessing Changes in Pharmacokinetics of Drugs in Liver Disease.” [Details](#).
- **12:00pm-1:00pm – FDA Webcast: Topical Generics** – FDA hosts a webcast titled, “Bioequivalence of Complex Topical Generics: In Vitro and In Vivo.” [Details](#).
- **2:00pm-3:00pm – CDC Call: Flu in Children** – CDC hosts a Clinician Outreach and Communication Activity (COCA) call titled, “Recommendations for Influenza Prevention and Treatment in Children: An Update for Pediatric Providers.” [Details](#).

### **Fri. (10/9)**

- **8:00am-5:00pm – FDA Meeting: New Drug Application** – FDA convenes a meeting of Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk

Management Advisory Committee to discuss new drug application (NDA) 213378, olanzapine/samidorphan oral tablets, submitted by Alkermes, Inc., for the proposed indications of schizophrenia and bipolar I disorder. [Details](#).

### **Additional Multi-Day Events**

- **October 5-October 7 – VA Meeting: Veteran Health** – The VA convenes a meeting of the Veterans’ Rural Health Advisory Committee to discuss rural health care access, among other topics. [Details](#).

### **FEATURED WHG ANALYSIS**

- **WHG Summary: The First General Election Presidential Debate** – In the Policy Hub Insight Bank [here](#).
- **September Edition: COVID-19 Government Response Catalogue** – Updated 9/30/20 – In the Policy Hub Insight Bank [here](#).
- **Commonwealth Fund Blog: “Investing in Providers During the Pandemic: How Have Federal Dollars Been Distributed?”** By Lovisa Gustafsson & Josh LaRosa
- **Updated WHG Legislative and Regulatory Outlook** – In the Policy Hub Insight Bank [here](#).

### **CONGRESSIONAL LOOKBACK**

#### **Fri. (10/2)**

- **MedPAC** convened for Day Two of its virtual September public meeting, including sessions on the evolution of Medicare’s advanced alternative payment models (A-APMs) and vertical integration in Medicare payment policy. All WHG session summaries are available [here](#).
- **The House Select Subcommittee on the Coronavirus Crisis** [convened](#) a hearing with HHS Secretary Alex Azar to examine the Administration’s political interference in the COVID-19 pandemic response. [Details](#).

#### **Thurs. (10/1)**

- **President Trump** signed [H.R. 8337](#), a bipartisan continuing resolution (CR) to extend federal government funding through December 11, 2020, averting a government shutdown. [Details](#).
- **MedPAC** convened for Day One of its virtual September public meeting, including sessions on the skilled nursing facility value-based purchasing program; hospice payment policy; equity in the Medicare Advantage benchmark policy; and Indirect Medical Education (IME). All WHG session summaries are available [here](#).

#### **Wed. (9/30)**

- **The E&C Subcommittee on Oversight and Investigations** convened a [hearing](#) to examine the safety and effectiveness of, access to, and the public’s trust in prospective COVID-19 vaccines. [Details](#).
- **The Senate** passed, by roll call vote (84-10), [H.R. 8337](#), a bipartisan continuing resolution (CR) to extend federal government funding through December 11, 2020. [Details](#).

#### **Tue. (9/29)**

- **House Democrats** released an updated version of the Heroes Act – a \$2.2 trillion package to provide additional coronavirus relief. The updated bill is a marker that stakes out House Democrats’ starting position in renewed negotiations with Treasury Secretary Steven Mnuchin. [Details](#).

- **The House** passed a number of health-related measures by a voice vote that address maternal health, rare pediatric disease, school-based health, and mental and behavioral health. Considering that the Senate is largely preoccupied with the Supreme Court confirmation process, the chamber is unlikely to take up these bills in the near term. [Details](#).

#### **Mon. (9/28)**

- **Senators Chuck Grassley (R-IA), Michael Bennet (D-CO)**, Rob Portman (R-OH), Sherrod Brown (D-OH), Josh Hawley (R-MO), and Patty Murray (D-WA) recently introduced the Accelerating Kids' Access to Care Act ([S. 4717](#)) in the Senate. [Details](#).

### **REGULATORY LOOKBACK**

#### **Fri. (10/2)**

- **HHS [announced](#)** a Phase 3 General Distribution of \$20 billion from the Provider Relief Fund (PRF). The funds will be open to previously ineligible providers (e.g., those who began practicing in 2020) and will permit those who have already received funds through previous distributions to apply for additional funding that reflects financial losses and changes in operating expenses due to the pandemic. Providers can begin applying for funds on Monday, Oct. 5 and will have through Nov. 6, 2020 to apply. [Details](#).

#### **Thurs. (10/1)**

- **HRSA** announced a funding opportunity titled, “Rural Health Care Services Outreach Program” to support the expansion of health care service delivery in rural areas. Applications are due November 16. [Details](#).
- **HRSA** is seeking public comment on proposed methodological changes to how it designates geographic areas eligible for its rural health grants. Comments are due by October 23. [Details](#).
- **FDA** issued draft guidance for developing drugs and biologics for adjuvant treatment of renal cell carcinoma and bladder cancer. Comments are due December 1. [Details](#).

#### **Wed. (9/30)**

- **NIH [awarded](#)** \$239 million to improve COVID-19 testing for underserved and vulnerable populations, as part of the Rapid Acceleration of Diagnostics (RADx) Initiative Underserved Populations (RADx-UP). [Details](#).
- **NIH [announced](#)** that initial Phase 1 trial results from the Moderna vaccine candidate demonstrate that the vaccine is well-tolerated and generates a strong immune response in older adults. [Details](#).
- **FDA [issued](#)** draft guidance on physiologically based pharmacokinetic (PBPK) analyses in biopharmaceutics applications for oral drug product development. [Details](#).
- **OASH [announced](#)** it is establishing a Medicaid Reentry Stakeholder Group as required by the Medicaid Reentry Act, and is seeking non-federal nominations – due on October 23. [Details](#).
- **CMS** updated the Medicaid & CHIP External Quality Review (EQR) tables and figures with new data for the 2018-2019 reporting cycle. [Details](#).
- **CMS** posted a Medicaid and CHIP Enrollment Trend Snapshot revealing that from February 2020 – the month before the President declared the PHE – to June 2020, national Medicaid and CHIP enrollment increased by over 4 million, or almost 5.7 percent. [Details](#).

#### **Tue. (9/29)**

- **President Donald J. Trump** faced former Vice President and Democratic presidential candidate Joseph R. Biden in the first of three 2020 general election debates. [Details](#).

- **FDA** [issued draft guidance](#) on E14 and S7B Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic, developed with the support of the International Council for Harmonisation (ICH). [Details](#).
- **CMS** released the FY 2019 Medicaid & CHIP Child Core and Adult Core Data Sets. The annual release provides information on 23 frequently reported child quality measures and 25 frequently reported adult quality measures voluntarily reported by state Medicaid programs. [Details](#).

### **Mon. (9/28)**

- **HHS** released long-awaited reporting requirements for funds obtained via the Provider Relief Fund (PRF). The [newly released requirements](#) contain significant changes from the guidance HHS previously released in July. [Details](#).
- **FDA** released two final guidance documents on blood glucose test systems. The first guidance focuses on self-monitoring blood glucose test systems for over-the-counter use, while the second guidance is on blood glucose monitoring systems for prescription point-of-care use. [Details](#).
- **FDA** issued final and draft guidance on abbreviated new drug applications (ANDAs). The agency released [final guidance](#) on amendments and requests for final approval to tentatively approved ANDAs and [draft guidance](#) on failure to respond to ANDA complete response letter (CRL). [Details](#).
- **FDA** [issued](#) final guidance on assessing COVID-19 related symptoms in outpatient adults and adolescent subjects in clinical trials of drugs and biological products for COVID-19 prevention or treatment. [Details](#).
- **CDC** released a [report](#) that found that the incidence of COVID-19 cases in children aged 12-17 years nearly doubled the incidence of COVID-19 cases in children aged 5-11 years. School-aged children with at least one underlying medical condition were more likely to experience severe outcomes related to COVID-19. [Details](#).

### **COMMENT & APPLICATION DEADLINES**

- **Sept. 29:** CMS [issued](#) an RFI on whether the agency should include exceptions to the requirements for electronic prescription of controlled substances (EPCS) or impose penalties for non-compliance with the requirements. [Details](#).
- **Sept. 30:** NIH [announced](#) a funding opportunity to identify children at risk for developing Multisystem Inflammatory Syndrome in children (MIS-C), thought to be a severe complication of COVID-19. Applications are due September 30, and letters of intent are due 30 days prior. [Details](#).
- **Oct. 1:** HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health (OASH) issued a [request for information \(RFI\)](#) on its draft Sexually Transmitted Infections National Strategic Plan 2021-2025 (STI Plan). [Details](#).
- **Oct. 2:** HHS [released](#) a RFI seeking input from state and local government agencies, local program operators, and the public, on the development of a federal interagency Council on Economic Mobility. [Details](#).
- **Oct. 4:** CMS [issued](#) a proposed rule to create a policy governing the treatment of days associated with beneficiaries enrolled in Medicare Advantage (MA) for the purposes of determining a hospital's Medicare disproportionate patient percentage for discharges on or before October 1, 2013. [Details](#).
- **Oct. 5:** CMS is accepting comments on the CY 2021 hospital outpatient prospective payment system (OPPS) [proposed rule](#) addressing payments to hospital outpatient departments and ambulatory surgery centers (ASCs). [Details](#).
- **Oct. 5:** CMS is accepting comments on the calendar year (CY) 2021 Medicare Physician Fee Schedule (MPFS) [proposed rule](#). [Details](#).

- **Oct. 6:** HRSA [announced](#) a funding opportunity through its Healthy Tomorrows Partnership for Children Program. [Details.](#)
- **Oct. 9:** PTAC requests input from the public on information that could help inform its review of the use of telehealth to optimize health care delivery under physician-focused payment models (PFPMs) and alternative payment models (APMs). [Details.](#)
- **Oct. 14:** NIOSH [announced](#) a request for information regarding the use of “elastomeric half-mask respirators” healthcare settings during the COVID-19 pandemic. [Details.](#)
- **Oct. 19:** NIH [issued](#) a request for information (RFI) to assist and guide the National Library of Medicine (NLM) Strategic Plan for 2017 to 2027: A Platform for Biomedical Discovery and Data-Powered Health. [Details.](#)
- **Oct. 23:** FDA seeks comment on a proposed rule to amend the agency’s medical product “intended use” regulations. [Details.](#)
- **Oct. 28:** HHS issued a proposed rule to implement President Trump’s Executive Order to require that entities receiving funding under section 330(e) of the Public Health Service Act, and who participate in the 340B Drug Pricing Program, to establish programs for offering insulin and injectable epinephrine to low-income patients at the price the health center purchased these drugs through the 340B program. [Details.](#)
- **Oct. 28:** FDA [issued](#) draft guidance on setting endotoxin limits during the development of investigational oncology and biological products. [Details.](#)
- **Nov. 2:** CMS is collecting comments on a proposed rule to expedite and increase coverage of innovative medical devices. [Details.](#)
- **Nov. 7:** FDA [issued](#) draft guidance on drug-drug interaction assessments for therapeutic proteins. [Details.](#)
- **Nov. 13:** CMS is accepting comments on [Part I of its Advance Notice](#) of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part D Payment Policies for Calendar Year (CY) 2022. [Details.](#)
- **Nov. 16:** HRSA is accepting applications for a funding opportunity titled, “Rural Health Network Development Planning Program.” The grant supports one year of planning to develop and assist integrated health care networks in becoming operational. [Details.](#)