

Wynne Health Group Weekly



FRAMING THE WEEK

As negotiations over a **COVID-19 relief package** between House Speaker Nancy Pelosi (D-CA) and Treasury Secretary Steven Mnuchin drag into another week, the outlook for a deal before Election Day appears to be a long-shot given the remaining significant disagreements as well as resistance among Senate Republicans to a bill ranging from \$1.9 trillion to \$2.2 trillion. Senate Majority Leader Mitch McConnell (R-KY) has agreed to consider an agreement if it should come together, but he continues to throw cold water at a pre-election, multi-trillion-dollar deal that would split his caucus just before the election.

Instead, Leader McConnell has been laser-focused on the **Supreme Court**. Today, the Senate is scheduled to vote and confirm the nomination of Judge Amy Coney Barrett to the Supreme Court, solidifying the conservative 6-3 majority. Yesterday, the nomination cleared a procedural hurdle by a rare weekend [51-48 vote](#), with Sens. Lisa Murkowski (R-AK) and Susan Collins (R-ME) joining Democrats.

While Speaker Pelosi and Secretary Mnuchin have inched closer to a deal, including agreeing for the most part on a **national strategy for COVID-19 testing, contact tracing, and surveillance**, substantial differences remain. The amount of federal aid to state and local governments as well as liability protections – a red line for Leader McConnell and a nonstarter for Democrats – are among the major points of contention. Mnuchin's latest offer includes \$300 billion for state and localities, relatively close to the [\\$436 billion](#) proposed in House Democrats' [updated Heroes Act](#). Leader McConnell's failed \$500 billion targeted relief package did not include any state and local aid.

Notably, Speaker Pelosi and Secretary Mnuchin's discussions have broached the ideas of **providing stimulus checks to undocumented immigrants and expanding eligibility for premium tax credits** – which are both strongly opposed by Republicans. The updated Heroes Act would allow individuals who have received (or have been approved to receive) unemployment compensation for any week during the applicable period (date of enactment to 60 days after the last day of the public health emergency) to be eligible for premium tax credits, regardless of their income. For individuals with higher income, tax credits would be determined as if their income was 133 percent of the federal poverty level.

Even if Speaker Pelosi and Treasury Secretary Mnuchin reach a deal, the **logistical challenges** of transforming their agreement into a bill and the timing of a floor vote have also cast doubt on pre-election coronavirus relief. At her [weekly press conference](#) last Thursday, Speaker Pelosi noted, "So, I keep saying, it's just not a question of us agreeing in a room; it's a question of the CBO weighing in with the score, the legislative counsel writes these things, raising their questions and putting it in legislative order. It takes time."

In addition, assuming unified Democratic support, it remains unclear whether the at least 13 Republican senators – needed to overcome the 60-vote filibuster – are willing to back the potential Pelosi-Mnuchin deal. However, Republicans facing tough Senate reelections may cross party lines in the hopes for a

reelection boost. According to polls, up to eight Republican seats are considered toss-ups or leaning Democratic, while only one Democratic seat held by Sen. Doug Jones (D-AL) appears to be in real danger of flipping.

On Friday (October 30), the Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) will discuss **COVID-19 vaccines**. [Agenda items](#) include vaccine allocation, post-licensure safety surveillance protocol and updates from the Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee and COVID-19 vaccine manufacturers. Health and Human Services Secretary Alex Azar remains optimistic that a safe and effective COVID-19 vaccine will be available this year. He recently [said](#), "By the end of January we expect we'd have enough to vaccinate all seniors as well as our health care workers and first responders and by the end of March to early April enough vaccine for all Americans who would want to take a vaccine." The FDA recently gave AstraZeneca and Johnson & Johnson the green light to resume Phase 3 clinical trials after they were halted over safety concerns. Pfizer and Moderna are also in Phase 3 clinical trials.

Lastly, the **Medicaid and CHIP Payment and Access Commission (MACPAC)** [convenes](#) this week (October 29-30) to discuss various issues, including post-pandemic Medicaid eligibility redetermination policies; dually eligible beneficiaries; access to mental health services and treatment; high-cost drugs; and **postpartum coverage**. Of note, the House passed the Helping MOMS Act of 2020 ([H.R. 4996](#)) at the end of September by a voice vote. The bill would allow states to extend Medicaid coverage for new moms through the entire postpartum period and provide a one-year, five percentage point Federal Medical Assistance Percentage (FMAP) enhancement to incentivize extension. There is no Senate companion bill.

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. (10/26)

- **12:30pm-3:30pm – CDC Meeting: Public Health Preparedness** – CDC convenes a meeting of the Board of Scientific Counselors, Center for Preparedness and Response to discuss updates from the CPR Director and Division Directors, CPR Strategic Planning and Science Agenda, and CPR BSC Polio Containment Workgroup (PCWG) Updates. [Details](#).
- **3:00pm-4:00pm – FDA Webinar: Food Safety** – FDA host a webinar to discuss the first 100 days since FDA issued its blueprint for the "New Era of Smarter Food Safety." [Details](#).

Tue. (10/27)

- **9:00am-2:30pm – FDA Meeting: Medical Devices** – FDA hosts a meeting on the reauthorization of the Medical Device User Fee Amendments for fiscal years 2023 through 2027. [Details](#).
- **9:00am-5:00pm – FDA Workshop: Gonorrhea** – FDA hosts a workshop titled, "Development Considerations of Antimicrobial Drugs for the Treatment of Gonorrhea." [Details](#).
- **9:00am-5:30pm – HHS Meeting: Tick-Borne Diseases** – HHS convenes a meeting of the Tick-Borne Disease Working Group to discuss the 2020 report to the HHS Secretary and Congress. [Details](#).
- **9:00am-6:00pm – FDA Meeting: Medical Devices** – FDA convenes a meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee to discuss, make

recommendations, and vote on information regarding the premarket approval application for the Neovasc Reducer System sponsored by Neovasc, Inc. [Details](#).

- **1:30pm-4:30pm – NASEM Meeting: COVID-19** – The National Academies of Sciences, Engineering, and Medicine (NASEM) host a meeting titled, “COVID-19 and the Geography of Vulnerability.” [Details](#).
- **4:00pm-5:00pm – CDC Webinar: COVID-19 Vaccine** – CDC hosts a webinar titled, “COVID-19 Vaccination Implementation Update for Rural Stakeholders.” [Details](#).

Wed. (10/28)

See multi-day events.

Thurs. (10/29)

- **TBD – MACPAC: Day 1** – The Medicaid and CHIP Payment and Access Commission (MACPAC) convenes a virtual public meeting to discuss Medicaid and CHIP payment and policy issues. [Details](#).
- **1:15pm-4:15pm – NIH Meeting: HIV/AIDS** – NIH convenes a meeting of the Office of AIDS Research Advisory Council to discuss updates from the HIV Antiretroviral and Opportunistic Infections Guidelines Working Groups, among other topics. [Details](#).

Fri. (10/30)

- **TBD – MACPAC: Day 2** – MACPAC convenes a virtual public meeting to discuss Medicaid and CHIP payment and policy issues. [Details](#).
- **9:00am-3:00pm – FDA Workshop: Drug Regulation** – FDA hosts a workshop titled, “New Drugs Regulatory Program Modernization: Implementation of the Integrated Assessment of Marketing Applications and Integrated Review Documentation.” [Details](#).
- **9:00am-4:30pm – CDC Meeting: Lead** – CDC convenes a meeting of the Lead Exposure and Prevention Advisory Committee to discuss the 2018 Federal Lead Action Plan; COVID-19 and CDC lead surveillance, lead laboratory methods; U.S. Housing and Urban Development's (HUD) role in lead poisoning prevention; among other topics. [Details](#).
- **1:00pm-5:00pm – NIH Meeting: Diabetes** – NIH convenes a meeting of the Diabetes Mellitus Interagency Coordinating Committee to discuss “Health Literacy and Numeracy: Considerations for Equity Approaches.” [Details](#).

Additional Multi-Day Events

- **October 27-October 28 – CMS Meeting: Payment Codes** – CMS hosts the virtual Healthcare Common Procedure Coding System (HCPCS) public meetings to discuss preliminary coding recommendations for new public requests for revisions to the HCPCS Level II code set Durable Medical Equipment (DME) and Accessories, Orthotics and Prosthetics (O&P), Supplies and for non-drug and non-biological items and services. [Details](#).
- **October 27-October 28 – FDA Meeting: Brand and Generic Drugs** – FDA hosts a meeting titled, “Regulatory Education for Industry: Celebrating 40 Years: An In-Depth Examination of the FDA Orange Book.” [Details](#).
- **October 28-October 29 – CDC Meeting: Immunizations** – CDC convenes a meeting of the Advisory Committee on Immunization Practices to discuss vaccines for COVID-19, seasonal influenza, among other diseases. [Details](#).
- **October 28-October 29 – CDC Meeting: Clinical Labs** – CDC convenes a meeting of the Clinical Laboratory Improvement Advisory Committee to discuss “Clinical Laboratory Medicine in the Age of COVID-19.” [Details](#).

FEATURED WHG ANALYSIS

- **WHG 2020 Election Preview** – In the Policy Hub Insight Bank [here](#).
- **WHG Issue Brief: COVID-19 Vaccine State of Play** – In the Policy Hub Insight Bank [here](#).
- **WHG Summary: The Second General Election Presidential Debate** – In the Policy Hub Insight Bank [here](#).
- **WHG Summary: The Vice Presidential Debate** – In the Policy Hub Insight Bank [here](#).
- **WHG Summary: The First General Election Presidential Debate** – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Thurs. (10/22)

- **The Senate Judiciary Committee** advanced the nomination of Judge Amy Coney Barrett to the Supreme Court by a vote of 12-0. None of the Democratic senators were present to vote. [Details](#).

Wed. (10/21)

- **The Senate** failed to pass a motion to invoke cloture on the GOP targeted COVID-19 relief package championed by Senate Majority Leader Mitch McConnell (R-KY). Leader McConnell lacked the support of 60 members to overcome the procedural hurdle needed to hold a final vote on the package. The cloture measure failed by a 51-44 vote along party lines. [Details](#).

Tue. (10/20)

- **The House Ways & Means Subcommittee on Oversight** [convened](#) a hearing to examine health insurance coverage and the Administration's efforts to undermine the Affordable Care Act (ACA). [Details](#).
- **The Senate** re-released a targeted coronavirus relief package containing approximately \$500 billion in federal aid focused on health care, education, and the economy. [Details](#).

Mon. (10/19)

- **Senate HELP Committee Chair Lamar Alexander (R-TN)** and House Energy & Commerce Ranking Member Greg Walden (R-OR) recently issued a request for input asking stakeholders for suggestions on how to reform the 340B drug discount program. [Details](#).

REGULATORY LOOKBACK

Fri. (10/23)

- **The Department of Justice** [announced](#) the resolution that has been reached related to the criminal and civil investigations regarding opioid manufacturer Purdue Pharma LP (Purdue). The resolution also includes a civil resolution of the civil investigations into individual members of the Sackler family who own Purdue. [Details](#).
- **CDC** announced a funding opportunity for "PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices." The application deadline is January 5, 2021. [Details](#).

Thurs. (10/22)

- **HHS** issued [new guidance](#) under the Public Readiness and Emergency Preparedness Act (PREP Act) that further expands authorization for certain pharmacists (qualified pharmacy technicians and state-authorized pharmacy interns) to order and administer COVID-19 vaccinations, and permits them to administer childhood vaccines and COVID-19 tests. [Details](#).

- **President Donald J. Trump** faced former Vice President and Democratic presidential candidate Joseph R. Biden in the last of two 2020 general election debates. The event was hosted at Belmont University in Nashville, Tennessee. [Details.](#)

Wed. (10/21)

- **FDA [announced](#)** it is conducting a Fit for Use (FFU) pilot program to test the processing and analysis of nonclinical study data provided electronically for the Clinical Data Interchange Standards Consortium (CDISC) for Standard for Exchange of Nonclinical Data (SEND) Implementation Guide (IG): Developmental and Reproductive Toxicology v1.1 (SEND-DART). [Details.](#)
- **HRSA [proposed](#)** establishing an Advisory Committee on Heritable Disorders in Newborns and Children. [Details.](#)
- **CMS [announced](#)** its approval of Nebraska’s Medicaid Section 1115 waiver request for a demonstration called the “Heritage Health Adult.” Starting April 1, 2021, adults covered under the waiver will have the ability to gain added benefits by participating in wellness initiatives and “personal responsibility activities.” [Details.](#)

Tue. (10/20)

- **FDA [issued](#)** draft guidance on annual status report information and other submissions for postmarketing requirements (PMRs) and postmarketing commitments (PMCs). [Details.](#)

Mon. (10/19)

- **HHS and DOD [announced](#)** a partnership with CVS and Walgreens pharmacies to provide and administer COVID-19 vaccines to residents of long-term care facilities (LTCF) with no out-of-pocket costs. [Details.](#)
- **U.S. Court of Appeals for the District of Columbia** ruled in favor of CMS cuts to the 340B hospital program. This decision reverses one previously issued by a lower court in 2019, which said CMS did not act within its legal authority to do make such cuts. [Details.](#)

COMMENT & APPLICATION DEADLINES

- **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.](#)
- **Oct. 30:** 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.](#)
- **Nov. 2:** CMS is collecting comments on a proposed rule to expedite and increase coverage of innovative medical devices. [Details.](#)
- **Nov. 5:** HHS is [soliciting nominations](#) for appointment to the tick-borne disease working group. [Details.](#)
- **Nov. 6:** HHS is accepting applications for 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. [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:** HHS [announced](#) two challenges focused on improving maternal health: the Hypertension Innovator Award Competition and the Reducing Disparities in Breastfeeding Innovation Challenge. [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.](#)
- **Nov. 16:** HRSA announced a funding opportunity titled, “Rural Health Care Services Outreach Program” to support the expansion of health care service delivery in rural areas. [Details.](#)
- **Nov. 18:** CMS announced that it extended the public comment period for the request for information (RFI) titled, “Recommended Measure Set for Medicaid-Funded Home and Community-Based Services.” [Details.](#)
- **Nov. 30:** FDA announced two quality management maturity (QMM) pilot programs: one for domestic drug product manufacturers of prescription and over-the-counter OTC drug products; and one for foreign facilities manufacturing APIs that are used in FDA-regulated prescription and OTC drugs. [Details.](#)
- **Dec. 1:** FDA seeks comment on draft guidance for developing drugs and biologics for adjuvant treatment of renal cell carcinoma and bladder cancer. [Details.](#)
- **Dec. 14:** NIOSH [announced](#) a request for information regarding the use of “elastomeric half-mask respirators” healthcare settings during the COVID-19 pandemic. [Details.](#)
- **Dec. 14:** HHS issued a [proposed rule](#) that would add a Smallpox Countermeasures Injury Table for designated covered smallpox countermeasures. [Details.](#)
- **Dec. 14:** FDA requests nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) and the Medical Devices Advisory Committee (MDAC) device panels in the Center for Devices and Radiological Health. [Details.](#)
- **Dec. 18:** HHS [announced](#) a request for information (RFI) regarding research integrity and the responsible conduct of research. [Details.](#)
- **Jan. 18:** CMS announced that the Community Health Access and Rural Transformation (CHART) [model](#) is open for applications. Letters of intent are due by January 18, 2021. [Details.](#)
- **Jan. 21:** HRSA announced a Notice of Funding Opportunity for the Behavioral Health Workforce Education and Training (BHWET) Program for Professionals for FY 2021. [Details.](#)

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