

*Wynne Health Group Weekly*



**FRAMING THE WEEK**

With only a few weeks left before the August recess, congressional Democrats and Republicans stand trillions of dollars apart on the **next coronavirus relief package**. The Administration's priority of accelerating the reopening of the country over providing funding for COVID-19 testing is complicating negotiations within the Republican party. This week, Senate Majority Leader Mitch McConnell (R-KY) is expected to unveil Senate Republicans' roughly \$1 trillion coronavirus relief package, a proposal much more narrow in size and scope than the \$3.4 trillion House-approved Heroes Act ([H.R. 6800](#)).

Senate Republicans are seeking \$25 billion for states to support **COVID-19 testing and contact tracing**, but their efforts are meeting resistance from certain White House officials who do not want to allocate additional funding. Senate Democrats are pushing for [\\$30 billion](#) in emergency funding to increase nationwide testing. In a [Dear Colleague letter](#), Senate Minority Leader Chuck Schumer (D-NY) said Democrats would push the administration to more aggressively use the Defense Production Act and to create a national testing and PPE strategy. The Trump administration is also attempting to block \$10 billion in new funding for the Centers for Disease Control and Prevention (CDC). Emergency supplemental funding flowing through the CDC to state, local, and tribal health departments [supports](#) surveillance, contact tracing, testing, guidance development, and other critical public health activities.

Additional **state and local aid** are not expected in Senate Republicans' relief package. Instead, the legislation is expected to include language allowing states and localities more flexibility with the \$150 billion [Coronavirus Relief Fund](#) established under the CARES Act ([P.L. 116-136](#)). Currently, Coronavirus Relief Fund dollars may be used to establish temporary public medical facilities to increase COVID-19 treatment capacity. Fund payments may also support the operations of private hospitals through grants or short-term loans.

The package is largely focused on provisions intended to stimulate the economy. According to a draft summary of the **liability protections** proposal authored by Leader McConnell and Sen. John Cornyn (R-TX), employers would be shielded from lawsuits if they comply with public health guidelines. Hospitals and health care workers would be protected from medical liability claims relating to coronavirus. Employers would only be liable for "gross negligence" and "intentional misconduct." Sen. Cornyn has indicated that employers may choose which guidelines to implement, either federal, state, or local guidelines. Employers would also be immune to COVID-19 related litigation for "injuries arising from workplace coronavirus testing." Democrats have expressed strong opposition to the McConnell-Cornyn proposal and are instead

calling for language requiring that the Occupational Safety and Health Administration (OSHA) issue an Emergency Temporary Standard to protect essential workers.

Other provisions include direct payments to individuals, a workplace credit to help businesses cover the cost of testing and protective equipment, an employee retention tax credit, and changes to the \$600 federal unemployment benefit. Treasury Secretary Mnuchin is also seeking additional funding for the **Paycheck Protection Program**, coupled with new restrictions regarding loan eligibility. President Trump is also demanding a **payroll tax cut**.

Senate Republicans' proposals stand in stark contrast to Senate Democrats' priorities. Last week, Minority Leader Schumer and Senate Democrats announced the [Economic Justice Act](#), a \$350 billion proposal that would make immediate and long-term investments in **communities of color**. Included among the initiatives are \$40 billion to expand and improve access to community-based behavioral, mental, and primary health care providers and services; \$115 billion for infrastructure, including high-speed internet and affordable housing; \$15 billion to incentive non-expansion states to expand Medicaid; and \$15 billion to address maternal mortality. To help offset the cost, the proposal would reprogram \$200 billion of unspent funds from the CARES Act set aside for corporate lending.

In the meantime, the House will consider several other bills this week. They include two bills aimed at increasing access to **affordable child care**: [H.R. 7027](#) would establish a \$50 billion fund to help child care providers safely reopen and [H.R. 7327](#) would provide \$850 million to cover child care costs for essential workers and \$10 billion to improve child care safety, and modify several tax provisions.

The House will also vote on the fiscal year (FY) 2021 National Defense Authorization Act (NDAA) ([H.R. 6395](#)). It includes a provision that would create a **\$1 billion Pandemic Preparedness and Resilience National Security Fund** that includes: \$200 million to purchase goods or services from small businesses in response to the COVID-19 pandemic; \$50 million to produce medical countermeasures against novel threats; and \$750 million to support research and development efforts related to biopreparedness and pandemic preparedness and resilience.

Meanwhile, the Senate will resume consideration of its own version of the NDAA ([S. 4049](#)). The bill contains several provisions to support the **military response to COVID-19 and future pandemics**, including \$44 million for DOD-supported vaccine and biotechnology research and a pilot program on civilian and military partnerships to enhance interoperability and medical surge capability and capacity of the National Disaster Medical System.

In addition, the House will take up its **first appropriations minibuss for FY 2021** ([H.R. 7608](#)). It contains funding for State-Foreign Operations, Agriculture-Rural Development-FDA, Interior-Environment, and Military Construction and Veterans Affairs. The bill [includes](#) language authorizing the FDA to require the recall of unsafe prescription and over-the-counter drugs and overturning the SNAP Able-Bodied Adults Without Dependents (ABAWD) final rule, as well as increased funding for nutrition programs and infrastructure.

Tomorrow, **executives from five pharmaceutical companies** selected as finalists in [Operation Warp Speed](#) – an initiative to accelerate the development, manufacturing, and distribution of **COVID-19 vaccines, therapeutics, and diagnostics** – will testify before the [House Energy and Commerce Subcommittee on Oversight and Investigations](#). The companies include AstraZeneca, Johnson & Johnson, Merck, Pfizer, and Moderna. Interestingly, the witness panel is reminiscent of the Senate Finance Committee hearing last year on prescription drug pricing (at which all companies except for Moderna testified). Questions on vaccine safety, availability, and cost will likely continue to be at the forefront.

Throughout the week, both chambers will convene hearings on a range of COVID-19 related issues – including, **racial health disparities** among seniors in the [Senate Special Committee on Aging](#); **supply chain issues** in the [House Ways and Means Subcommittee on Trade](#); and **reopening public schools** in the [House Education and Labor Subcommittee on Early Childhood, Elementary, and Secondary Education](#). According to the Ed & Labor Committee, the Trump administration blocked CDC Director Dr. Robert Redfield from testifying before the Committee.

Lastly, the [Senate Committee on Commerce, Science, and Transportation](#) will mark-up the bipartisan **Data Mapping to Save Moms’ Lives Act (S. 3152)** on Wednesday. S. 3152 would direct the Federal Communications Commission (FCC) to incorporate certain maternal health outcomes in its [Mapping Broadband Health in America platform](#) (an online platform that allows users to visualize, overlay and analyze broadband and health data at the national, state and county levels). Available health measures include diabetes, obesity, primary care physician access, poor/fair health, preventable hospitalization, and sick days. The FCC would be required to consult with the CDC to determine which maternal health outcomes should be incorporated.

## **THIS WEEK IN HEALTH POLICY**

### **Mon. (7/20)**

- **1:00pm-4:30pm – HHS Meeting: Alzheimer’s Disease** – HHS convenes a meeting of the Advisory Council on Alzheimer’s Research, Care, and Services. [Details](#).
- **3:00pm-4:00pm – ACL Webinar: Caregiving** – The Administration for Community Living (ACL) hosts a webinar titled, “Alone Together: Understanding Social Isolation in Caregiving in the U.S. 2020.” [Details](#).

### **Tue. (7/21)**

- **8:30am-3:30pm – FDA Meeting: Generic Drugs** – FDA convenes a meeting to discuss the reauthorization of the Generic Drug User Fee Amendments (GDUFA) for fiscal years (FYs) 2023 through 2027. [Details](#).
- **9:30am – Hearing: COVID-19 & Racial Health Disparities** – The Senate Special Committee on Aging convenes a hearing titled, “The COVID-19 Pandemic and Seniors: A Look at Racial Health Disparities.” [Details](#).
- **10:00am – Hearing: COVID-19 Vaccine** – The House Energy and Commerce Subcommittee on Oversight and Investigations convenes a hearing titled, “Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine.” [Details](#).
- **1:00pm – Hearing: Nutrition** – The House Agriculture Subcommittee on Oversight and Department Operations convenes a hearing titled, “An Overview of the Farmers to Families Food Box Program.” [Details](#).
- **1:00pm-2:00pm – PCORI Meeting: Health Care Research** – The Patient-Centered Outcomes

Research Institute (PCORI) convenes a meeting of the Board of Governors. [Details](#).

- **2:00pm-4:00pm – CDC Meeting: STDs** – CDC convenes a meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment to discuss COVID-19 response activities and the President’s Initiative on “Ending the HIV Epidemic: A Plan for America.” [Details](#).
- **2:30pm – Hearing: COVID-19 Scams** – The Senate Commerce, Science, and Transportation Subcommittee on Manufacturing, Trade, and Consumer Protections convenes a hearing titled, “Protecting Americans from COVID-19 Scams.” [Details](#).

### Wed. (7/22)

- **8:00am-4:30pm – CMS Meeting: Medicare** – CMS convenes a meeting of the Medicare Evidence Development & Coverage Advisory Committee to discuss home use of noninvasive positive pressure ventilation in patients with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD). [Details](#).
- **10:00am – Executive Session: Maternal Health** – The Senate Commerce, Science, and Transportation Committee will convene an executive session to consider the Data Mapping to Save Moms’ Lives Act (S. 31352), among other legislative measures, and nominations. [Details](#).
- **10:00am-1:00pm – CDC Meeting: Injury Prevention** – CDC convenes a meeting of the Board of Scientific Counselors (BSC), National Center for Injury Prevention and Control (NCIPC) to discuss the CDC Opioid Prescribing Estimates Project, among other topics. [Details](#).
- **1:00pm – Hearing: COVID-19 & SBA** – The House Small Business Committee convenes a hearing titled, “21st Century SBA: An Analysis of SBA’s Technology System” to discuss the Paycheck Protection Program and Economic Injury Disaster Loan Program. [Details](#).
- **1:00pm – Politico Discussion: Housing** – Politico hosts a virtual-deep dive conversation on the role social determinants of health, specifically housing, will have in post-Covid-19 recovery efforts in California. [Details](#).

### Thurs. (7/23)

- **9:00am-2:00pm – Prescription Drug** – FDA hosts a public meeting to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years (FYs) 2023 through 2027. [Details](#).
- **10:15am – Hearing: COVID-19 & Schools** – The House Education and Labor Subcommittee Early Childhood, Elementary, and Secondary Education convenes a hearing titled, “Underfunded & Unprepared: Examining How to Overcome Obstacles to Safely Reopen Public Schools.” [Details](#).
- **2:00pm – Hearing: COVID-19 Supply Chains** – The House Ways and Means Subcommittee on Trade convenes a hearing titled, “Trade, Manufacturing, and Critical Supply Chains: Lessons from COVID-19.” [Details](#).
- **2:00pm – ACL Webinar: Mental Health** – The Administration for Community Living hosts a webinar titled, “Sick and Tired of Being Sick and Tired: People of Color, Disabilities, and Mental Health.” [Details](#).

### Additional Multi-Day Events

- **July 21-July 24 – AHP Summit: Health Care** – The Alliance for Health Policy a summit on the short and long-term impacts of the ongoing COVID-19 pandemic and its potential to significantly transform our health care system. [Details](#).
- **July 22-July 23 – HHS Meeting: Research Protections** – HHS convenes a meeting of the Secretary’s Advisory Committee on Human Research Protections to discuss recommendations on NIH Draft Data Management and Sharing Policy, a review of the Deceased Organ Intervention Research recommendations, and the interpretation of Public Health Surveillance. [Details](#).

- **July 23-July 24** – FDA Workshop: Regulatory Policy – FDA hosts a two-day public workshop titled, “Topical Drug Development - Evolution of Science and Regulatory Policy 2.” [Details](#).

## FEATURED WHG ANALYSIS

- **California Health Care Foundation Blog** – “Washington Begins Horse Trading over Next Phase of COVID-19 Aid,” by Dawn Joyce and Billy Wynne.
- **WHG COVID-19 Government Response Catalogue** – Updated 7/17/20 – In the Policy Hub Insight Bank [here](#).
- **Chart: Key Federal COVID-19 Funding Opportunities for Providers & Hospitals** – Updated 6/26/20 – In the Policy Hub Insight Bank [here](#).
- **Chart: Aligned Support on Legislative & Regulatory Changes to Extend COVID-19 Telehealth Flexibilities** – In the Policy Hub Insight Bank [here](#).

## CONGRESSIONAL LOOKBACK

### Wed. (7/15)

- The House E&C Committee favorably [reported](#) 17 health-related bills by a voice vote. [Details](#).

### Tue. (7/14)

- The House W&M Committee staff released a new [report](#), titled, “Left Out: Barriers to Health Equity for Rural and Underserved Communities” ([press release](#)). [Details](#).
- Two Homeland Security Subcommittees held a [virtual hearing](#) to examine the federal government’s COVID-19 response, with a focus on supply issues. [Details](#).

### Mon. (7/13)

- The House Appropriations Committee [convened](#) a markup of the FY 2021 LHHS appropriations [bill \(report\)](#). [Details](#).

## REGULATORY LOOKBACK

### Fri. (7/17)

- The D.C. Federal Court of Appeals [ruled](#) in favor of CMS, stating the agency has the authority to reduce payments to outpatient clinics for visits at off-campus hospital facilities. [Details](#).
- HUD announced a [NOFA](#) for the [Fair Housing Initiatives Program](#) to support the conduct of fair housing testing in local communities. Applications are due Aug. 17. [Details](#).

### Thurs. (7/16)

- The FCC unanimously [voted](#) to create 988 as the new dialing code for the National Suicide Prevention Lifeline. [Details](#).
- The DOL [released](#) a RFI seeking industry input on paid family and medical leave to care for family members or one’s own health. Comments due Sept. 14. [Details](#).
- The CDC [released](#) provisional drug overdose deaths counts from 2019. [Details](#).
- The U.S. Department of Labor’s Wage and Hour Division [released](#) a RFI soliciting input on the implementation of the Family and Medical Leave Act of 1993. Comments due Sept. 15. [Details](#).
- CMS [updated](#) the Hospital Compare website with refreshed quarterly data from the Hospital IQR; PCHQR; and Hospital OQR Programs. [Details](#).

### Wed. (7/15)

- HUD issued a NOFA for [Choice Neighborhoods Planning Grants](#), which support the development of comprehensive neighborhood revitalization strategies. Applications due Sept. 14. [Details](#).
- USDA and HHS published the [Scientific Report of the 2020 Dietary Guidelines Advisory Committee](#) ([press release](#)). Comments due Aug. 13. [Details](#).
- 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. Comments due Oct. 2. [Details](#).
- HHS [announced](#) that it is launching a new COVID-19 testing initiative to increase and expedite testing for nursing homes located in hotspots. [Details](#).
- The Trump administration sent a [letter](#) to hospitals telling them to stop reporting COVID-19 data through the CDC National Healthcare Safety Network. [Details](#).
- The NIH [announced](#) that an experimental COVID-19 vaccine has generated an immune response in health adults. [Details](#).

#### **Tue. (7/14)**

- FDA [issued](#) final guidance on providing regulatory submissions under section 745A(b) of the Food, Drug, and Cosmetic (FD&C) Act in electronic format. [Details](#).
- AHRQ [announced](#) a request for scientific information to inform their review on Disparities and Barriers for Pediatric Cancer Survivorship Care. Submissions are due Aug. 14. [Details](#).
- HHS [released](#) the May and June COVID-19 Testing Plans from all states, territories, and localities. [Details](#).
- HUD [previewed](#) version of a proposed rule that would permit programs operating as a same-sex or sex-specific facility to prohibit admission of transgender beneficiaries ([press release](#)). [Details](#).
- CMS issued [new guidance](#) to state Medicaid directors extending the compliance timeline for implementation of the [HCBS Settings Rule](#). [Details](#).

#### **Mon. (7/13)**

- SAMHSA issued a [final rule](#) ([press release](#)) addressing the confidentiality of substance use disorder patient records in federal health programs. [Details](#).
- The AHRQ [announced](#) a request for scientific information to inform their review on CPAP Treatment of Obstructive Sleep Apnea in Medicare Eligible Patients. Submissions due Aug. 13. [Details](#).
- HHS [announced](#) an additional \$4 billion in Provider Relief Fund disbursements. [Details](#).

#### **COMMENT & APPLICATION DEADLINES**

- **July 20:** CMS seeks comment on a [proposed rule](#) titled, “Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) Programs and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements.” [Details](#).
- **July 20:** USPSTF issued a [draft recommendation](#) and evidence review that recommends screening for hypertension in adults ages 18 years and older with office blood pressure measurement (OBPM). [Details](#).
- **July 31:** FDA [issued](#) a request for information (RFI) on rare disease clinical trials. [Details](#).
- **Aug. 3:** CDC [announced](#) it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee (HICPAC). [Details](#).
- **Aug. 3:** FDA is accepting comments on 25 new draft PSGs and 24 revised draft product-specific guidances (PSGs). [Details](#).

- **Aug. 3:** The USPSTF issued a [draft recommendation](#) and [evidence review](#) that recommends screening for lung cancer among older adult smokers. [Details](#).
- **Aug. 13:** The AHRQ [announced](#) a request for scientific information to inform their review on CPAP Treatment of Obstructive Sleep Apnea in Medicare Eligible Patients. [Details](#).
- **Aug. 13:** USDA and HHS are accepting comments on the [Scientific Report of the 2020 Dietary Guidelines Advisory Committee](#) ([press release](#)). [Details](#).
- **Aug. 14:** AHRQ [announced](#) a request for scientific information to inform their review on Disparities and Barriers for Pediatric Cancer Survivorship Care. [Details](#).
- **Aug. 14:** HHS and the Department of Treasury issued a [proposed rule](#) to provide greater flexibility for grandfathered group health plans. [Details](#).
- **Aug. 17:** Stakeholder notification of participation in the PDUFA consultation meetings is due.
- **Aug. 17:** Applications for the HUD [NOFA](#) for the [Fair Housing Initiatives Program](#) to support the conduct of fair housing testing in local communities are due. [Details](#).
- **Aug. 20:** FTC is requesting public comment on its Health Breach Notification Rule, which is now subject to the agency's 10-year rule review cycle. [Details](#).
- **Aug. 20:** CMS is accepting comments on the CY 2021 home health prospective payment system and rate update [proposed rule](#) with comment period. [Details](#).
- **Aug. 28:** FDA [issued](#) a request for public comment on the use of codeine for analgesia in children under 12 years of age and the use of cytochrome P450 2D6 (CYP2D6) testing in children under 12 years of age prior to treatment with codeine-containing analgesics. [Details](#).
- **Sept. 4:** CMS is accepting comments on the CY 2021 ESRD prospective payment system and rate update [proposed rule](#) with comment period. [Details](#).
- **Sept. 8:** The FDA [issued](#) a request for public comment on forming the strategic priorities for the Office of Women's Health. [Details](#).
- **Sept. 14:** HUD issued a NOFA for [Choice Neighborhoods Planning Grants](#), which support the development of comprehensive neighborhood revitalization strategies. [Details](#).
- **Sept. 14:** The DOL [released](#) a RFI seeking industry input on paid family and medical leave to care for family members or one's own health. [Details](#).
- **Sept. 15:** The U.S. Department of Labor's Wage and Hour Division [released](#) a RFI soliciting input on the implementation of the Family and Medical Leave Act of 1993. [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. 6:** HRSA [announced](#) a funding opportunity through its Healthy Tomorrows Partnership for Children Program. [Details](#).