

Wynne Health Group Weekly



FRAMING THE WEEK

After days of negotiating with the Trump administration, Senate Majority Leader Mitch McConnell (R-KY) is expected to unveil **Republicans' coronavirus relief package** later today, finally kicking off negotiations with Democrats. The \$600 federal unemployment benefit expiring at the end of the week is putting pressure on the White House and Congress to act fast, with Treasury Secretary Steven Mnuchin and White House Chief of Staff Mark Meadows even floating the idea for piecemeal legislation. House Speaker Nancy Pelosi (D-CA) has quickly rejected that approach indicating that the House would remain in session until a deal is reached.

According to a draft agreement circulated last week, the relief package is expected to appropriate \$303 billion in emergency supplemental funding. This includes \$25 billion for the Provider Relief Fund; \$25 billion for testing; \$26 billion for vaccine research and distribution; \$4.5 billion for mental health, suicide prevention, and overdose response programs; and \$7.6 billion for community health centers.

The package is also expected to include several health care policy provisions, such as extending **telehealth reimbursement flexibilities** through the end of 2021 and pushing back the repayment date for **Medicare advance payments** from this August to January 2021. In addition, the legislation is expected to contain **liability protections for employers** and a number of measures to stimulate the economy, including another round of direct payments and additional funding for the Paycheck Protection Program.

Later this week, the House will consider its [second appropriations minibus for FY 2021 \(H.R. 7617\)](#) – a compilation of seven spending bills, including Labor-HHS-Education, Defense, Commerce-Justice-Science, Energy and Water Development, Financial Service and General Government, Homeland Security, and Transportation-Housing and Urban Development. The **Labor-HHS-Education bill** includes \$9 billion in emergency supplemental funding for the Centers for Disease Control and Prevention to support the federal government's coronavirus response. Another \$9 billion would be made available to support other public health and response activities, particularly at the state and local levels.

The Senate Finance Committee will convene a two-part hearing to examine ways to protect the **U.S. medical supply chain** amid the COVID-19 pandemic. Committee members will hear from senior officials from the Department of Homeland Security, U.S. Customs and Border Protection, and U.S. Immigration, Customs, and Enforcement on [Tuesday](#), followed by senior executives specializing in supply chain and logistics at large health care systems (Vizient and UC Health) as well as the President of the International Safety Equipment Association on [Thursday](#).

On Wednesday, the **House Energy and Commerce (E&C) Subcommittee on Health** will convene a legislative hearing to discuss five bipartisan bills that would **reauthorize various public health programs**. At the last E&C markup, Chairman Frank Pallone, Jr. (D-NJ) indicated that the next full Committee markup will likely not be until September.

- **School-Based Health Centers Reauthorization Act of 2019 (H.R. 2075)** would reauthorize funding that expired in 2014 for [school-based health centers](#), which provide a full range of age-appropriate health care services such as mental health care, through FY 2024.
- **Early Act Reauthorization of 2019 (H.R. 4078)** would reauthorize and increase funding through FY 2024 for the CDC to develop initiatives to increase knowledge of breast health and breast cancer among women, particularly among those under the age of 40 and those who face increased risks for developing breast cancer.
- **Creating Hope Reauthorization Act (H.R. 4439)** would permanently reauthorize the [rare pediatric disease priority review voucher program](#) at the Food and Drug Administration (FDA).
- **TRANSPLANT Act of 2019 (H.R. 4764)** would reauthorize funding for the [C.W. Bill Young Cell Transplantation Program](#), which helps patients who need a bone marrow transplant or umbilical cord transplant, and the [National Cord Blood Inventory](#), which coordinates the collection and storage of new cord blood units.
- **United States Anti-Doping Agency Reauthorization Act of 2019 (H.R. 5373)** would reauthorize funding for the U.S. Anti-Doping Agency through FY 2027 to promote clean and healthy sporting among young athletes, leading up to the 2028 Olympics in Los Angeles.

On Friday, the **House Select Subcommittee on the Coronavirus Crisis** will [question](#) Dr. Anthony Fauci, the nation's top infectious disease expert, Admiral Brett Giroir, who leads the federal testing response, and CDC Director Dr. Robert Redfield on whether a **national plan** is needed to contain the coronavirus pandemic. Since late June, the Trump administration has refused to comply with Chairman James Clyburn's (D-SC) [requests](#) for documents showing the demand and supply for testing, contact tracing, and other countermeasures; the causes of the recent explosion in cases; and the Administration's effort to – in the President's words – “slow the testing down.”

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. (7/27)

- **10:00am – FCC Meeting: Hospital Robocalls** – The Federal Communications Commission (FCC) convenes a meeting of the FCC's Hospital Robocall Protection Group to discuss best practices concerning (1) how voice service providers can better combat unlawful robocalls made

to hospitals; (2) how hospitals can better protect themselves from such calls, including by using unlawful robocall mitigation techniques; and (3) how the Federal Government and State governments can help combat such calls. [Details](#).

- **10:30am-12:00pm – BPC Webinar: Dual Eligibles** – The Bipartisan Policy Center (BPC) hosts a webinar titled, “A Pathway to Full Integration of Care for Medicare-Medicaid Beneficiaries.” [Details](#).
- **3:00pm – HRSA Webcast: Provider Relief Fund** – CMS hosts a webcast titled, “Getting started with the Provider Relief Fund for Medicaid, CHIP, and dental providers.” [Details](#).

Tue. (7/28)

- **10:00am – Hearing: COVID-19 Financial Relief** – The Senate Homeland Security and Governmental Affairs Committee convenes a hearing titled, “Oversight of COVID-19 Financial Relief Packages.” [Details](#).
- **10:15am – Hearing: COVID-19 Supply Chain** – The Senate Finance Committee convenes a hearing titled, “Part 1: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic.” [Details](#).
- **11:00am – Hearing: Environmental Health** – The House Energy and Commerce Subcommittee on Environmental and Climate Change convenes a hearing titled, “There's Something in the Water: Reforming Our Nation's Drinking Water Standards.” [Details](#).
- **2:00pm-3:00pm – World Congress Webinar: COVID-19 & Primary Care** – The World Congress hosts a webinar titled, “The Future of Primary Care: How Providers Can Adapt to Changing Patient Demands, Gain Flexibility, and Develop Economic Stability.” [Details](#).
- **2:00pm-3:00pm – CDC Meeting: Diabetes** – The CDC hosts a Clinician Outreach and Communication Activity (COCA) Call titled, “Coronavirus Disease 2019 (COVID-19) and Diabetes: The Importance of Prevention, Management, and Support.” [Details](#).

Wed. (7/29)

- **10:00am – Hearing: Public Health Programs** – The House Energy and Commerce Subcommittee on Health convenes a hearing titled, “Improving Access to Care: Legislation to Reauthorize Key Public Health Programs.” [Details](#).
- **11:00am – FCC Meeting: Broadband** – FCC convenes a meeting of the Broadband Deployment Advisory Committee to discuss reports from the Increasing Broadband Investment in Low-Income Communities, Broadband Infrastructure Deployment Job Skills and Training Opportunities, and Disaster Response and Recovery working groups. [Details](#).
- **3:00pm – Hearing: VA Telehealth** – The Senate Veterans’ Affairs Committee convenes a hearing titled, “VA Telehealth During and Beyond COVID-19: Challenges and Opportunities in Rural America.” [Details](#).

Thurs. (7/30)

- **9:30am – Hearing: COVID-19 Supply Chain** – The Senate Finance Committee convenes a hearing titled, “Part 2: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic.” [Details](#).
- **12:00pm-5:00pm – HRSA Meeting: Rural Health** – HRSA convenes a meeting of the Secretary’s National Advisory Committee on Rural Health and Human Services to discuss the development of a vision statement that emphasizes rural community transformation, sustainable services, and resiliency. [Details](#).

Fri. (7/31)

- **9:00am – Hearing: COVID-19** – The House Select Subcommittee on the Coronavirus Crisis convenes a hearing titled, “The Urgent Need For A National Plan To Contain The Coronavirus,” featuring National Institute of Allergy and Infectious Diseases Director Dr. Anthony Fauci, CDC Director Dr. Robert Redfield, and Assistant Secretary for HHS Admiral Brett Giroir. [Details.](#)

Additional Multi-Day Events

- **July 17-July 31 - NAIC Meeting: Health Insurance** – The National Association of Insurance Commissioners convenes its summer 2020 national meetings in a virtual format. [Details.](#)
- **July 29-July 30 – CMS Meeting: Laboratory Tests** – CMS convenes a meeting of the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests to discuss the FY 2021 Clinical Laboratory Fee Schedule. [Details.](#)

FEATURED WHG ANALYSIS

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

CONGRESSIONAL LOOKBACK

Wed. (7/22)

- **Sens. Roger Wicker (R-MS) and Tina Smith (D-MN)** [introduced](#) the PPP Access for Rural Hospitals Act (S. 4217), which would waive the Small Business Administration (SBA) affiliation rules for non-profit critical access hospitals and hospitals located in rural areas. [Details.](#)
- **The Senate Special Committee on Aging** [convened](#) a hearing yesterday to discuss the COVID-19 pandemic and its effect on seniors. [Details.](#)

Tue. (7/21)

- **The E&C Subcommittee on Oversight and Investigations** [convened](#) a hearing to examine the COVID-19 vaccine development process. [Details.](#)
- **Reps. Katie Porter (D-CA) and Raja Krishnamoorthi (D-IL)** sent a [letter](#) to HHS and the Biomedical Advanced Research Development Authority (BARDA) regarding “the lack of investment” in clinical trials and research on preventive COVID-19 immune globulin (COVID-IG) injections. [Details.](#)

Mon. (7/20)

- **Senate HELP Chairman Lamar Alexander (R-TN)** introduced the Preparing for the Next Pandemic Act – a bill aimed at bolstering the nation’s capacity to respond to the COVID-19 pandemic and future public health crises. [Details.](#)

REGULATORY LOOKBACK

Fri. (7/24)

- **President Trump** signed four Executive Orders (EOs) addressing importation ([here](#)), 340B “penny pricing” for insulin and Epi-Pens at federally qualified health centers (FQHCs) ([here](#)), drug rebates ([here](#)), and favored-nation international pricing. [Details](#).

Thurs. (7/23)

- **NIH** announced that the Rapid Acceleration of Diagnostics (RADx) program has outlined a framework to manufacture 6 million diagnostic tests per day by the end of 2020 with support from the Office of the Assistant Secretary for Health, the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense. [Details](#).
- **HHS** and the Department of Defense (DoD) [announced](#) an agreement with Pfizer for large-scale production and delivery of 100 million doses of a COVID-19 vaccine after the vaccine’s successful manufacture and approval. [Details](#).
- **FDA** [issued](#) a proposed rule that would establish annual reporting requirements under the Right to Try Act. Comments are due September 22. [Details](#).
- **HHS OCR** issued [guidance](#) for recipients of federal financial assistance about civil rights protections prohibiting discrimination on the basis of race, color, and national origin during the COVID-19 pandemic. The bulletin focused on recipients’ compliance with Title VI of the Civil Rights Act of 1964 (Title VI). [Details](#).
- **HHS Secretary Alex Azar** [signed](#) a [renewal](#) of his determination that the novel coronavirus (COVID-19) pandemic constitutes a nationwide public health emergency (PHE). This newest declaration will be effective through October 23, 2020, unless the Sec. Azar determines that the PHE has ceased to exist prior to that date. [Details](#).

Wed. (7/22)

- **FDA** [published](#) a list of class II devices exempt from premarket notification (510(k)) requirements, subject to certain limitations. [Details](#).
- **FDA** published findings that reveal people with cancer who contracted COVID-19 face an increased rate of hospitalization and a 16-fold increased mortality risk. [Details](#).

Tue. (7/21)

- **HHS** restored public access to COVID-19 data that hospitals report to the federal government. The data is now available on [HHS Protect](#), a data and analytics platform that “integrates data across federal, state, and local governments and the healthcare industry” and which supports the HHS Coronavirus Data Hub. [Details](#).
- **CDC** [announced](#) an opportunity for stakeholders to provide input on pain management, including the benefits and harms of opioid use. Persons interested in participating in these conversations should email InjuryCenterEngage@cdc.gov by August 21, 2020. [Details](#).
- **President Trump** issued a [memorandum](#) clarifying that undocumented immigrants will not be counted in the 2020 census for the purpose of dividing seats in Congress among the states. [Details](#).
- **CMS** announced it is seeking nominations for a Technical Expert Panel (TEP) to support development of cost measures for use in the CMS Innovation Center’s Kidney Care Choices (KCC) Model. Nominations are due August 7, 2020. [Details](#).
- **HHS OCR** announced two resolutions to protect religious rights within health care settings during the COVID-19 pandemic. The [first](#) is related to religious visitation, and the [second](#) involves religious accommodation related to the use of personal protective equipment (PPE). [Details](#).

COMMENT & APPLICATION DEADLINES

- **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](#). [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.](#)