

*Wynne Health Group Weekly*



**FRAMING THE WEEK**

Congress remains at an impasse on the **next coronavirus relief package**, as Majority Leader Mitch McConnell (R-KY) said a decision on whether to proceed on the “fourth and final bill” will likely be made “in about a month.” He added that Senate Republicans would take the lead on the bill, which would be “narrowly crafted,” pouring cold water on House Democrats’ desire for quick passage of the provisions found in the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act ([H.R. 6800](#)).

Still, Senate Minority Leader Chuck Schumer (D-NY) said he would continue to urge Republicans to negotiate and push for Senate passage of the **House-approved Paycheck Protection Program Flexibility Act of 2020** ([H.R. 7010](#)), which received overwhelming bipartisan support (417-1) last week. H.R. 7010 would ease some restrictions by extending the time small businesses have to use the loans from eight weeks to 24 weeks; extending the rehiring deadline from June 30 to December 30; and reducing the loan amount employers have to spend on payroll in order for it to be forgiven from 75 percent to 60 percent. According to the [Small Business Administration](#), a total of \$511 billion in loans have been approved as of May 23, leaving about \$148 billion in Paycheck Protection Program funding.

As Congress considers making available **additional relief dollars to states**, the House Energy and Commerce Subcommittee on Oversight and Investigations will host a hearing with **Governors Jared Polis (D-CO), Gretchen Whitmer (D-MI), and Asa Hutchinson (R-AR)**, focusing on the challenges faced by states in facing the pandemic and specifically looking into efforts to increase testing capacity. The House-approved HEROES Act would replenish the [Coronavirus Relief Fund](#), providing distinct funding streams to states (\$500 billion) and local governments (\$375 billion).

Looking forward, the House does not plan to return for floor votes until June 30, unless House Democrats reach a deal with Senate Republicans on coronavirus legislation sooner. In the meantime, the House plans to hold hearings and markups on must-pass legislation, including **appropriation bills for FY 2021** and **legislation to bolster the Affordable Care Act (ACA)**, with floor votes slated for the end of June and early July, [according](#) to the House Majority Leader Steny Hoyer (D-MD).

Major legislative packages already introduced in the House, including the HEROES Act and the Take Responsibility for Workers and Families Act ([H.R. 6379](#)), as well as Senate Democrats’ [white paper](#) on **expanding health care coverage and affordability**, may provide some clues as to the types of legislation House Democrats will consider this summer with respect to the ACA. Provisions in the white paper include establishing special enrollment periods; restructuring the sliding scale for premium assistance for individuals enrolled in a qualified health plan offered on the ACA exchange; providing additional funding to support outreach, education, and ACA enrollment assistance; and overturning the Trump administration’s proposed expanding short-term plans and relaxing guardrails for Section 1332 waivers.

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. (6/1)**

- **11:00am-12:00pm – NQF Webinar: Population Health** – The National Quality Forum hosts a webinar titled, “The Future of Population Health: Addressing Challenges & Advancing Opportunities.” [Details](#).
- **1:00pm-3:00pm – NQF Webinar: Long-Term Services & Supports** – NQF convenes a meeting of the Person Centered Planning and Practice Standing Committee to discuss long-term services and supports. [Details](#).

### **Tue. (6/2)**

- **Presential Primaries** – The District of Columbia and the following states will hold primary elections: DE, IN, MD, MT, NM, PA, RI, and SD.
- **10:00am – Hearing: COVID-19 & Incarceration** – The Senate Judiciary Committee convenes a hearing titled, “Examining Best Practices for Incarceration and Detention During COVID-19.” [Details](#).
- **11:30am – Hearing: COVID-19 & States** – The House Energy and Commerce Subcommittee on Oversight and Investigations convenes a hearing titled, “On the Front Lines: How Governors are Battling the COVID-19 Pandemic.” [Details](#).
- **2:00pm-3:00pm – NQF: Artificial Intelligence** – NQF hosts a webinar titled, “The Role of Healthcare Quality in Artificial Intelligence.” [Details](#).
- **2:00pm-3:30pm – Brookings Webinar: COVID-19 & Reopening** – Brookings hosts a webinar titled, “A roadmap for reopening America: How to save lives and livelihoods.” [Details](#).
- **2:30pm – Hearing: COVID-19 & FDA** – The Senate Finance Committee convenes a hearing titled, “COVID-19 and Beyond: Oversight of the FDA’s Foreign Drug Manufacturing Inspection Process.” [Details](#).
- **3:00pm-4:00pm – FDA Webcast: Cell Therapies** – FDA hosts a webcast titled, “Streamlining Genetic Safety Analysis for Ex Vivo Genome Edited Cell Therapies.” [Details](#).

### **Wed. (6/3)**

- **10:00am – Hearing: COVID-19 & Small Business** – The Senate Small Business and Entrepreneurship Committee convenes a hearing titled, “Perspectives from Main Street: COVID-19’s Impact on Small Business.” [Details](#).
- **1:00pm – Hearing: COVID-19 & Economy** – The House Budget Committee convenes a hearing titled, “Addressing the Economic Impacts of COVID-19: Views from Two Former CBO Directors.” [Details](#).
- **11:00am – Hearing: COVID-19 & Voting** – The House Judiciary Committee convenes a hearing titled, “Protecting the Right to Vote During the COVID-19 Pandemic.” [Details](#).
- **12:15pm-1:15pm – FDA Town Hall** – FDA hosts a virtual town hall for clinical laboratories and commercial manufacturers that are developing or have developed diagnostic tests for SARS-CoV-2. [Details](#).

- **2:00pm – Forum: COVID-19 & VA** – The House Veterans’ Affairs Subcommittee on Health convenes a forum titled, “Mission Readiness: VA’s Preparedness for Natural Disasters During a Pandemic.” [Details.](#)
- **2:00pm-3:00pm – CDC Webinar: COVID-19 & Dentists** – CDC hosts a Clinical Outreach and Communication Activity (COCA) call titled, “Guidance for Dental Settings During the COVID-19 Response.” [Details.](#)
- **2:00pm-3:00pm – Brookings Webinar: Privacy Legislation** – Brookings hosts a webinar titled, “What will it take to bridge gaps in federal privacy legislation?” [Details.](#)
- **2:30pm – Hearing: OMB** – The Senate Budget Committee convenes a nomination hearing on Russell Vought to be Director of Office of Management and Budget (OMB). [Details.](#)
- **3:00pm – Hearing: COVID-19 & VA** – The Senate Veterans’ Affairs Committee convenes a hearing titled, “Fiscal Year 2021 Budget and 2022 Advance Appropriations Requests, and Fiscal Year 2020 Enacted CARES Act Supplemental Appropriations for the Department of Veterans Affairs.” [Details.](#)

#### Thurs. (6/4)

- **10:00am – Hearing: COVID-19 & School** – The Senate Health, Education, Labor and Pensions Committee convenes a hearing titled, “COVID-19: Going Back to College Safely.” [Details.](#)
- **10:00am-11:00am – BPC Discussion: Telehealth** – The Bipartisan Policy Center (BPC) hosts a discussion titled, “Telehealth and COVID-19 in Rural Areas.” [Details.](#)
- **1:00pm-3:00pm – CDC Meeting: Infection Control** – CDC convenes a meeting of the Healthcare Infection Control Practices Advisory Committee to discuss COVID-19, program updates among other topics. [Details.](#)

#### Fri. (6/5)

- See multi-day events.

#### Additional Multi-Day Events

- **June 1-June 2 – PACHA Meeting: COVID-19 & HIV** – The Presidential Advisory Council on HIV/AIDS (PACHA) convenes virtually to discuss COVID-19’s impact on the HIV response and the Ending the HIV Epidemic Initiative. [Details.](#)
- **June 1-June 2 – CMS Meeting: HCPCS** – CMS convenes virtual Healthcare Common Procedure Coding System (HCPCS) to discuss preliminary coding recommendations for new public requests for revisions to the HCPCS Level II code set for Durable Medical Equipment (DME) and Accessories, Orthotics and Prosthetics (O&P), Supplies and other non-drug and non-biological items. [Details.](#)
- **June 2-June 3 – AHRQ Meeting: Health IT** – AHRQ convenes a meeting of the Healthcare Information Technology Research Subcommittee. [Details.](#)
- **June 4-June 5 – FDA Meeting: ICH** – FDA convenes a two-day web conference to learn more about stakeholder experiences with the International Council for Harmonisation (ICH) Good Clinical Practice guideline (ICH E6). [Details.](#)
- **June 4-June 5 – PCORI Meeting: Patient Engagement** – PCORI convenes a meeting of the Advisory Panel on Patient Engagement. [Details.](#)
- **June 4-June 5 – PCORI Meeting: Clinical Effectiveness** – PCORI convenes a meeting of the Advisory Panel on Clinical Effectiveness and Decision Science. [Details.](#)

#### **FEATURED WHG ANALYSIS**

- **Chart: Key Federal COVID-19 Funding Opportunities for Providers & Hospitals** – Updated 5/29/20 – In the Policy Hub Insight Bank [here](#).
- **Chart: Compilation of Federal COVID-19 Telehealth Flexibilities** – In the Policy Hub Insight Bank [here](#).
- **WHG COVID-19 Government Response Catalogue** – Updated 5/22/20 – In the Policy Hub Insight Bank [here](#).
- **Chart: Key Federal COVID-19 Funding Opportunities for Employers** – Last Updated 4/24/20 – In the Policy Hub Insight Bank [here](#).
- **Chart: Key Federal COVID-19 Funding Opportunities for State and Local Government** – Last Updated 4/24/20 – In the Policy Hub Insight Bank [here](#).

## CONGRESSIONAL LOOKBACK

### Fri. (5/29)

- **Sen. Elizabeth Warren (D-MA)**, along with Sens. Tim Kaine (D-VA), Bernie Sanders (I-VT), Tammy Baldwin (D-WI), Bob Casey (D-PA), and Tammy Duckworth (D-IL) [sent a letter](#) to the Department of Labor’s Office of Inspector General requesting an audit of OSHA’s handling of inspections and citations during the COVID-19 pandemic, as well as its decision not to issue an ETS. [Details](#).

### Thurs. (5/28)

- **The House Ways and Means Committee** convened its first ever virtual hearing to discuss the disproportionate impact of COVID-19 on communities of color. [Details](#).
- **The House** passed the TRUTH Act ([H.R. 6782](#)) (269-147) and the Paycheck Protection Program Flexibility Act of 2020 ([H.R. 7010](#)) (417-1). [Details](#).
- **The House Education and Labor Subcommittee** on Workforce Protections convened a [hearing](#) to examine the federal government’s actions to protect workers from COVID-19. [Details](#).

### Wed. (5/27)

- **Reps. Diana DeGette (D-CO) and Larry Bucshon (R-IN)** [introduced](#) bipartisan legislation intended to expand coronavirus testing capacity and accessibility. [Details](#).

### Tue. (5/26)

- **The House Oversight and Reform Committee** [convened](#) a briefing with the HHS Principal Deputy Inspector General (IG) Christi Grimm to examine the Administration’s COVID-19 response. Ms. Grimm spoke about the HHS OIG’s fourteen ongoing projects focused on COVID-19 that examine testing, the Strategic National Stockpile (SNS), and the distribution of Provider Relief Funds, among other topics. [Details](#).

## REGULATORY LOOKBACK

### Fri. (5/29)

- **SBA** issued an interim final rule to supplement previously posted interim final rules on the Paycheck Protection Program (PPP) with additional guidance on loan forgiveness and loan review procedures and related borrower and lender responsibilities. [Details](#).
- **FDA** [issued](#) several documents related to the publication of the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). [Details](#).
- **FDA** [issued](#) a request for information (RFI) on rare disease clinical trials ([press release](#)). Submissions are due July 31. [Details](#).

- CMS issued a [proposed rule](#) to amend the Department of Health and Human Services' ACA risk adjustment data validation (HHS-RADV) program. [Details](#).

#### **Thurs. (5/28)**

- FDA [issued](#) guidance on the effect of the COVID-19 public health emergency (PHE) on formal meetings and user fee applications in order to provide answers to frequently asked questions (FAQs). [Details](#).
- CMS [released](#) a fact sheet for state and local governments seeking CMS payment for care in hospital alternate care sites (ASCs) during the public health emergency. [Details](#).

#### **Wed. (5/27)**

- HHS OIG [released](#) its strategic plan for oversight of COVID-19 response and recovery. [Details](#).
- NIH [released](#) its strategic plan to accelerate nutrition research over the next 10 years, which focuses on precision nutrition and calls for a multidisciplinary approach through expanded collaboration across NIH Institutes and Centers to accelerate nutrition science. [Details](#).

#### **Tue. (5/26)**

- HHS [announced](#) a 45-day deadline extension for providers to accept the Terms and Conditions for receiving payments from the Provider Relief Fund. Providers are now granted 90 days from the date they receive a payment to accept the Terms and Conditions, or return the funds. [Details](#).
- HHS submitted its [COVID-19 Strategic Testing Plan](#) to Congress, as required by the Paycheck Protection Program and Health Care Enhancement Act. [Details](#).
- NIH announced that peer-reviewed data demonstrates that remdesivir improves the recovery time for patients with COVID-19, especially among those with severe cases. [Details](#).
- CMS announced that over 1,750 Medicare Advantage and Part D plans have applied to participate in the Part D Senior Savings Model. [Details](#).

### **COMMENT & APPLICATION DEADLINES**

- **June 9:** CMS is accepting comments on proposed rules for fiscal year (FY) 2021 Medicare payment across three different payment streams: Skilled nursing facilities (SNF); the Hospice wage index and payment rate update; and Inpatient psychiatric facilities (IPF). [Details](#).
- **June 15:** CMS requests comment on the fiscal year (FY) 2021 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule ([fact sheet](#)). [Details](#).
- **June 16:** CDC issued a [request for comment](#) soliciting input on and experiences with pain and pain management to inform the agency's assessment of the need for updating or expanding the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain. [Details](#).
- **June 17:** USDA extended the comment period on the proposed rule titled, "Employment and Training Opportunities in the Supplemental Nutrition Assistance Program (SNAP)." [Details](#).
- **June 21:** OASH within HHS seeks public comment regarding Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act, addressing recommendations for maintaining an adequate national blood supply. [Details](#).
- **June 21:** FDA seeks comments on draft guidance on technical considerations for demonstrating reliability of emergency-use injectors. [Details](#).
- **June 27:** ASPR [announced](#) the establishment of the National Advisory Committee on Children and Disasters (NACCD) and a request for nominations for members. [Details](#).
- **June 30:** NIH issued two requests for letters of interest (LOIs): 1) LOIs for National Cancer Institute (NCI) Molecular Analysis for Therapy Choice (MATCH); and 2) LOIs for pediatric-focused NCI-MATCH. LOIs are due June 30. [Details](#).

- **June 30:** CDC re-opened the public comment period for the proposed update of the 2006 “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.” [Details](#).
- **June 30:** The White House Office of National Drug Control Policy (ONDCP) issued an [Advance Notice of Proposed Rulemaking](#), soliciting comments on proposed criteria for designating emerging drug threats. [Details](#).
- **July 3:** AHRQ [announced](#) a request for nominations for members. AHRQ advises the Secretary of HHS and produces evidence to make health care safer, higher quality, more accessible, equitable, and affordable. [Details](#).
- **July 7:** CMS is accepting comments on an interim final rule with comment period (IFC) containing a second set of wide-reaching regulatory changes and flexibilities for providers in response to the COVID-19 pandemic. [Details](#).
- **July 10:** CMS is accepting comments on the FY 2021 inpatient prospective payment system (IPPS) and long-term care hospital prospective payment system (LTCH PPS) proposed rule. [Details](#).
- **July 14:** CDC [issued](#) a request for information regarding personnel and the retention of next generation sequencing (NGS) data in clinical and public health laboratories. [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. 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](#).