

Wynne Health Group Weekly



FRAMING THE WEEK

House Speaker Nancy Pelosi (D-CA) is expected to unveil a draft **\$1.2 trillion coronavirus relief package** ahead of a floor vote that could be as soon as this Friday. Speaker Pelosi also indicated that she wants to move soon on a resolution to allow remote voting by proxy in the House. While the package is likely to be viewed as a wish list, it may put pressure on Republicans to come to the negotiating table and pass another bill sooner rather than later, as Senate Majority Leader Mitch McConnell (R-KY) has subscribed to a wait-and-see approach.

Democrats are working to include approximately **\$1 trillion for state and local governments**, with funding allocated in separate tranches to ensure smaller communities receive financial assistance; additional funding for **hospitals and COVID-19 testing**; a 15 percent increase to **SNAP benefits**; **Medicaid funding**; **unemployment assistance**; **enhanced sick leave for workers**; and **direct payments**. Missing from the package are **liability protections for businesses**, a top priority for Leader McConnell (R-KY), and a **payroll tax cut** pushed by President Trump.

Tomorrow, the Senate Judiciary Committee will hold a hearing on liability protection for employers, a “red line” for Republicans and a nonstarter for Democrats. The hearing will likely shed light on the scope of protections Republicans are seeking and whether both parties can reach a compromise, which would increase the likelihood of additional coronavirus relief measures reaching the President’s desk in the near term.

The Senate Health, Education, Labor and Pensions (HELP) Committee will also convene virtually for a hearing focused on **reopening the country** – an interesting topic considering Chairman Lamar Alexander (R-TN) and several of the witnesses are self-quarantining. The panel includes Dr. Anthony Fauci (Director of the National Institute of Allergy and Infectious Diseases at the NIH), Dr. Robert Redfield (CDC Director), Dr. Stephen Hahn (FDA Commissioner), and Dr. Brett Giroir (Assistant Secretary for Health).

Questions at the HELP Committee hearing will likely center around **testing capacity and supply chain issues**, with Democrats [reminding](#) the Trump administration of their statutory obligation to submit to Congress a comprehensive national strategic plan by May 24. The Paycheck Protection Program and Health Care Enhancement Act ([Pub. L. 116-139](#)) requires that the plan address how the HHS Secretary will increase domestic testing capacity, including testing supplies, among other response issues. Of note, President Trump and administration officials are scheduled to hold a press briefing on COVID-19 testing at 4pm ET today.

On Thursday, the House Energy and Commerce Subcommittee on Health will hold a hearing to discuss the removal of **Dr. Rick Bright, former Director of the Biomedical Advanced Research and Development Authority (BARDA)**. He was transferred to the NIH to work on diagnostic testing. Prior to his removal, Dr. Bright had filed a whistleblower complaint raising concerns about the federal government’s response to the coronavirus pandemic, including the handling of supply shortages and the promotion of

hydroxychloroquine as a potential cure. Dr. Bright was invited to testify before the Health Subcommittee, though it is unclear if he will do so.

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. (5/11)

- No events scheduled.

Tue. (5/12)

- **Primary Election** – Nebraska will host in-person Democratic and Republican primary elections.
- **8:30am-5:00pm – HRSA Meeting: Nurse Education** – HRSA convenes a meeting of the National Advisory Council on Nurse Education and Practice. [Details](#).
- **10:00am – Hearing: COVID-19** – The Senate Health, Education, Labor and Pensions (HELP) Committee convenes a hearing titled, “COVID-19: Safely Getting Back to Work and Back to School,” featuring Dr. Anthony Fauci (NIH’s NIAID Director), Dr. Robert Redfield (CDC Director), Admiral Brett Giroir (Assistant Secretary for Health), and Dr. Stephen Hahn (FDA Commissioner). [Details](#).
- **12:00pm-1:00pm – PCORI Meeting: Rare Disease** – PCORI hosts a townhall to provide an overview and information applicants may need to submit a responsive application to the [Limited Competition PCORI Funding Announcement](#): Conducting Rare Disease Research using PCORnet® – Cycle 2 2020 PFA. [Details](#).
- **2:30pm – Hearing: COVID-19** – The Senate Judiciary Committee convenes a hearing titled, “Examining Liability During the COVID-19 Pandemic.” [Details](#).

Wed. (5/13)

- **8:00am-1:00pm – CDC Meeting: Breast Cancer** – CDC convenes a meeting of the Advisory Committee on Breast Cancer in Young Women. [Details](#).
- **9:30am-2:30pm – ONC Meeting: Health IT** – ONC convenes a meeting of the Health Information Technology Advisory Committee. [Details](#).
- **10:00am – Hearing: COVID-19** – The Senate Commerce, Science, and Transportation Committee convenes a hearing titled, “The State of Broadband Amid the COVID-19 Pandemic.” [Details](#).
- **10:30am-12:00pm – ACL Webinar: COVID-19** – The Administration for Community Living (ACL) and other federal agencies host a webinar titled, “Focus on Aging: Federal Partners’ Webinar Series / Supporting Older Adults in Emergencies: Preparedness, Response, and Recovery.” [Details](#).

Thurs. (5/14)

- **10:00am – Hearing: COVID-19** – The House Energy and Commerce Subcommittee on Health convenes a hearing titled, “Protecting Scientific Integrity in the COVID-19 Response.” [Details](#).
- **12:00pm-1:00pm – FDA Webcast: Artificial Intelligence** – FDA hosts a webcast titled, “Artificial Intelligence for Regulatory Science Research.” [Details](#).

Fri. (5/15)

- **3:00pm – CDC Meeting: Healthcare Infection** – CDC convenes a meeting of the Healthcare Infection Control Practices Advisory Committee. Registration deadline is May 14. [Details](#).

FEATURED WHG ANALYSIS

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

Thurs. (5/7)

- **The Senate HELP Committee** convened a [hearing](#) to discuss the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA) initiatives to accelerate access to innovative diagnostic testing technology for COVID-19. [Details](#).

Wed. (5/6)

- **The House Appropriations Subcommittee** on Labor, Health and Human Services, Education, and Related Agencies convened a [hearing](#) to discuss the ongoing U.S. government response to the COVID-19 pandemic. [Details](#).

Tue. (5/5)

- **Sen. Chris Coons (D-DE)** and others introduced the Pandemic Response and Opportunity Through National Service Act, which would fund 750,000 positions in national service programs over a three-year period to help meet the need for as many as 300,000 public health workers. [Details](#).

REGULATORY LOOKBACK

Fri. (5/8)

- **CDC** recently published a [study](#) in *Morbidity and Mortality Weekly* showing a “notable decrease” in provider orders and doses administered for both non-influenza and measles-containing pediatric vaccines following the March 13 emergency declaration. [Details](#).

Thurs. (5/7)

- **CMS** released the 2021 Notice of Benefit and Payment Parameters final rule ([fact sheet](#); [release](#)). [Details](#).
- **CMS** released a new memo that outlines requirements formalized in an interim final rule. These requirements pertain to new COVID-19 reporting requirements for nursing home facilities. [Details](#).
- **The Trump** administration published provider-level data on where the Department of Health and Human Services (HHS) has sent Provider Relief Fund dollars. The dataset is available on the CDC website, [here](#). [Details](#).

- **SBA** issued an [interim final rule](#) to supplement previously posted interim final rules on the Paycheck Protection Program (PPP) with additional guidance on nondiscrimination obligations and additional eligibility requirements for higher education institutions. [Details](#).
- **FDA** [announced](#) final guidance on the development of drugs to treat or prevent cytomegalovirus (CMV) disease in transplantation. [Details](#).

Wed. (5/6)

- **USPSTF** issued a draft recommendation statement and draft evidence review that recommends screening for hepatitis B virus (HBV) infection in adolescents and adults at increased risk for infection. [Details](#).
- **PCORI** [announced](#) a funding opportunity for high-impact, comparative clinical effectiveness research on COVID-19. [Details](#).
- **FDA** [issued](#) final guidance on notifying the Center for Devices and Radiological Health (CDRH) of a permanent discontinuance or interruption in manufacturing a device during the COVID-19 public health emergency (PHE). [Details](#).

Tue. (5/5)

- **DOL** [announced](#) that Dislocated Worker Grant (DWG) funding, made available to states under the CARES Act to temporarily hire workers to respond to COVID-19, can be used for contact tracing. [Details](#).
- **The Departments of Treasury and the Interior** issued a [joint statement](#) regarding the distribution of the Coronavirus Relief Fund (\$8 billion made available in the CARES Act) to Native American tribes. [Details](#).
- **CMS** posted a [new set](#) of COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children’s Health Insurance Program (CHIP) Agencies. [Details](#).

Mon. (5/4)

- **HHS** announced it began processing targeted distributions from the Provider Relief Fund to hospitals in high-impact areas and to rural providers. [Details](#).
- **FDA** [issued](#) an Emergency Use Authorization (EUA) for the investigational antiviral drug remdesivir for the treatment of hospitalized adults and children with COVID-19. [Details](#).
- **CDC** launched the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES) consortium – a network of laboratories that will conduct real-time sequencing of COVID-19. [Details](#).

COMMENT & APPLICATION DEADLINES

- **Rolling:** NIH [announced](#) the launch of Rapid Acceleration of Diagnostics (RADx), a national initiative aimed at speeding innovation, development, and commercialization of COVID-19 diagnostic technologies. This \$1.5 billion stimulus investment complements the NIH’s ongoing Accelerating COVID-19 Therapeutic Interventions and Vaccines public-private partnership. [Details](#).
- **May 13:** GAO is accepting nominations for participation on the Board of Governors of the Patient-Centered Outcomes Research Institute (PCORI). [Details](#).
- **May 15:** SBA is accepting comments on an [interim final rule](#) providing additional guidance regarding the Paycheck Protection Program (PPP) established by the CARES Act. PPP loans are available to apply for until June 30, or until the funds run out. [Details](#).
- **May 18:** USDA is accepting comments on a [proposed rule](#) titled “Employment and Training Opportunities in the Supplemental Nutrition Assistance Program (SNAP).” [Details](#).

- **May 18:** NIH [issued](#) an RFI to assist in the development of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Strategic Plan. The NIDDK’s goal is to develop a broad vision for accelerating research into the causes, prevention, and treatment of diseases and conditions within the Institute’s mission. [Details](#).
- **May 18:** FNS published a [notice](#) reopening the public comment period on a [request for information](#) issued in January on the Special Supplemental Nutrition Program for Women, Infants and Children (WIC Program) National Universal Product Code (NUPC) Database. [Details](#).
- **May 20:** SBA issued an [interim final rule](#) to supplement the first interim final rule on the Paycheck Protection Program (PPP), with additional guidance regarding eligibility for individuals with self-employment income and certain businesses. [Details](#).
- **May 20:** CMS extended the comment period on a [notice of proposed rulemaking](#) (NPRM) that would revise and modernize requirements for Preadmission Screening and Resident Review (PASRR) in Medicaid-certified nursing facilities (NFs). [Details](#).
- **May 28:** SBA issued an [interim final rule](#) to supplement previously posted interim final rules on the Paycheck Protection Program (PPP) with additional guidance regarding promissory notes, authorizations, affiliation, and eligibility. [Details](#).
- **May 31:** CMS released a request for information (RFI) seeking input on ways to improve access, quality, and outcomes for rural maternal and infant health. [Details](#).
- **May 31:** FDA is accepting comments on two proposed amendments regarding the classification of certain hepatitis C virus (HCV) tests. [Details](#).
- **June 1:** CMS is accepting comments on an interim final rule implementing a sweeping array of new provider flexibilities for supporting the health care system’s response to the COVID-19 pandemic. [Details](#).
- **June 1:** CDC and NIOSH issued a [request for information](#) soliciting public comments to inform the scope of the World Trade Center (WTC) Health Program’s research funding cycle for fiscal year (FY) 2021. [Details](#).
- **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 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 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](#).
- **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](#).
- **Aug. 3:** CDC [announced](#) it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee (HICPAC). [Details](#).