

*Wynne Health Group Weekly*



**FRAMING THE WEEK**

The Senate reconvenes in Washington this week to confirm executive and judicial nominees, while the House remains on recess with plans to return in two weeks. In the meantime, the House Energy and Commerce (E&C) Committee, as well as others, are preparing to hold virtual bipartisan “Committee Forums” in place of traditional in-person hearings to conduct oversight of the federal government’s coronavirus response.

The fight for **state and local government funding** continues to brew, with **Senate Majority Leader Mitch McConnell (R-KY)** [appearing](#) more amenable to provide additional coronavirus relief to states and localities as long as certain liability protections for employers of frontline workers are included. Still, agreeing on an amount remains challenging, as **House Speaker Nancy Pelosi (D-CA)** has signaled state and local governments may need almost \$1 trillion in support – an amount well over the initially appropriated \$150 billion in the Coronavirus Relief Fund. She also floated the idea funding would be allocated in “three tranches” – providing relief at the state, county, and municipal levels.

Speaker Pelosi has also indicated that she wants “**CARES 2**” to include **infrastructure provisions**, addressing their priorities to support community health centers, expand broadband access, and ensure clean water access regardless of ability to pay. The [House Democratic Plan to Connect All Americans to Affordable Broadband Internet](#), which would invest \$80 billion over five years to expand broadband access, as well as the [infrastructure framework](#) unveiled earlier this year will likely serve as a blueprint for forthcoming legislation. While President Trump continues to support the inclusion of infrastructure funding, he stated that he will not support a CARES 2 package unless it includes a payroll tax.

**E&C Committee Chairman Frank Pallone, Jr. (D-NJ)** recently circulated to members key legislative policies that would bolster the **public health response**. They include requiring the Trump administration to develop a comprehensive testing plan as well as a plan to deploy treatments or vaccines when available; requiring health care facilities to publicly report their inventory of medical supplies and personnel capacity; providing federal funding for states and localities to conduct surveillance and contact tracing; and requiring coverage of COVID-19 testing and treatment with no cost-sharing for the insured and uninsured.

These policies will likely be informed by the forthcoming Committee forums, which will feature senior administration officials from the CDC, NIH, FDA, FCC, FTC, DOE and potentially subject matter experts. There may also be an effort to hold a virtual full committee markup to clear out the backlog of bills that have been sitting in the subcommittees. However, it may have to wait on the Hoyer-McCarthy deal to allow proxy voting which appears close, as members are not thrilled to return to Washington given the health risks.

On Wednesday, the **House Appropriations Subcommittee on the Departments of Labor, Health and Human Services, Education, and Related Agencies** will hold an in-person hearing on the federal government’s COVID-19 response. To the chagrin of House Democrats, the White House [blocked Dr.](#)

**Anthony Fauci**, Director of the National Institute of Allergy and Infectious Diseases and a key member of the White House Coronavirus Task Force, from testifying. Instead, **Dr. Tom Frieden**, President and CEO of Resolve to Save Lives and former Director of the CDC, and **Dr. Caitlin Rivers**, Senior Scholar at the Johns Hopkins Center for Health Security, will provide their expertise. Of note, the White House is allowing Dr. Anthony Fauci to testify before the Republican-controlled Senate Health, Education, Labor and Pensions (HELP) Committee on May 12.

On Thursday, the **Senate HELP Committee** will also convene in-person and hear from **Dr. Francis Collins**, Director of the National Institutes of Health (NIH), and **Dr. Gary Disbrow**, Acting Director of the Biomedical Advanced Research and Development Authority (BARDA), about the newly launched [Rapid Accelerate of Diagnostics \(RADx\)](#) initiative. Envisioned by **Senate HELP Committee Chairman Lamar Alexander (R-TN)** and **Senate Appropriations Committee Chairman Roy Blunt (R-MO)**, the “shark-tank” like effort funded in the most recent coronavirus relief package aims to make COVID-19 tests available to all Americans by August 2020. Scientists and inventors will compete for a share of up to \$500 million over all phases of development and have the opportunity to be matched with technical, business, and manufacturing experts to accelerate the development and commercialization of their **COVID-19 testing technologies**.

The newly formed **House Select Committee on the Coronavirus Crisis**, charged with conducting oversight of the federal government’s response to the coronavirus pandemic, may also meet this week. **Majority Whip Jim Clyburn (D-SC)**, the **Chair of the Select Committee**, noted they would focus on “testing, contact tracing, isolation, and the treatment.”

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. (5/4)**

- No events scheduled.

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

- **11:00am-1:15pm – CDC Meeting: Health Statistics** – CDC convenes a meeting of the Board of Scientific Counselors, National Center for Health Statistics to discuss COVID-related mortality data, among other topics. [Details](#).
- **11:00am-2:30pm – PCORI Meeting: COVID-19** – PCORI convenes a meeting of the Board of Governors to discuss activities related to the COVID-19 pandemic, including new funding opportunities and the HERO Registry and trial. [Details](#).
- **11:45am-12:45pm – PCORI Meeting: COVID-19** – PCORI hosts a webinar titled, “Confronting COVID-19: The Changing Role of Telehealth.” [Details](#).
- **3:30pm – ACL Webinar: Alzheimer’s** – ACL hosts a webinar titled, “Update your game plan for supporting LGBT Elders with Alzheimer’s.” [Details](#).

### **Wed. (5/6)**

- **10:00am – Hearing: COVID-19** – The House Appropriations Subcommittee on Departments of Labor, Health and Human Services, Education, and Related Agencies convenes a hearing on the COVID-19 response. [Details.](#)
- **12:15pm-1:15pm – FDA Town Hall: COVID-19** – FDA hosts a virtual town hall titled, “Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests.” [Details.](#)
- **2:00pm-3:00pm – Webinar: COVID-19** – The Brookings Institute hosts a webinar titled, “Telehealth before and after COVID-19.” [Details.](#)
- **3:00pm – ONC Webinar: APIs** – ONC hosts a Q&A webinar on application programming interfaces (APIs). [Details.](#)

#### **Thurs. (5/7)**

- **10:00am – Hearing: COVID-19** – The Senate Health, Education, Labor and Pensions Committee hosts a hearing titled, “Shark Tank: New Tests for COVID-19,” featuring NIH Director Dr. Francis Collins and Acting BARDA Director Dr. Gary Disbrow. [Details.](#)
- **1:00pm-2:30pm – ACL Webinar: Mental Health** – ACL, SAMHSA, Veterans Health Administration, and the National Coalition on Mental Health and Aging host a discussion on ways to prevent social isolation and promote mental health during the COVID-19 pandemic. [Details.](#)

#### **Fri. (5/8)**

- **1:00pm-4:55pm – FDA Meeting: Cellular, Tissue and Gene Therapy** – FDA convenes a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee. [Details.](#)

#### **FEATURED WHG ANALYSIS**

- **WHG COVID-19 Government Response Catalogue** – Last Updated 4/27/20 – 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. (4/30)**

- E&C Chairman Frank Pallone, Jr. and Democratic leaders sent a letter to HHS Secretary Alex Azar, urging the Department to develop a national COVID-19 contact tracing strategy. [Details.](#)

##### **Wed. (4/29)**

- **Sen. Joe Manchin (D-WV) and Shelley Moore Capito (R-WV)** led a bipartisan group of senators in a [letter](#) to HHS and CMS, urging the agencies to increase Medicare payment rates for telephone-based evaluation and management (E/M codes so that they equal Medicare’s established in person visit codes. [Details.](#)
- **Raja Krishnamoorthi (D-IL)**, Chairman of the House Oversight Subcommittee on Economic and Consumer Policy, sent a letter to the FDA, requesting the agency comply with the Subcommittee’s investigation of its policies governing coronavirus serological testing. [Details.](#)

##### **Tue. (4/28)**

- **Sen. Michael Bennet (D-CO)**, a member of the Senate Agriculture Committee, introduced the Food for Families in Crisis Act of 2020 – a proposal that aims to expand access to food assistance through the Supplementary Nutrition Assistance Program (SNAP). [Details](#).

#### Mon. (4/27)

- **Reps. Diana DeGette (D-CO) and Fred Upton (R-MI)** recently [unveiled](#) their bipartisan “Cures 2.0” [concept paper](#), which outlines proposals in the following key areas: public health and pandemic preparedness, caregiver integration, patient engagement in health care decision-making, clinical trials, FDA modernization, and CMS modernization. [Details](#).
- **The House Democrats’ Task Force on Aging and Families** unveiled a set of principles for protecting older Americans amid COVID-19 to guide future relief legislation. [Details](#).
- **E&C Chairman Frank Pallone, Jr.** and Ranking Member Greg Walden introduced the Utilizing Strategic Allied (USA) Telecommunications Act of 2020 – a bipartisan, bicameral bill that would establish a grant program intended to increase access to 5G. [Details](#).
- **CRS** released a brief report on current COVID-19 public health surveillance systems, recent legislative and executive actions to address public health reporting, and policy consideration to help support the nation’s response as well as local-level public health decision-making. [Details](#).

### REGULATORY LOOKBACK

#### Fri. (5/1)

- **EBSA** published [updated COBRA model notices](#) regarding the extension of time frames for group health plans, as well as [Frequently Asked Questions](#) for beneficiaries. [Details](#).
- **AHRQ** [announced](#) a request for nominations for members. The AHRQ advises the Secretary of the Department of Health and Human Services (HHS) and produces evidence to make health care safer, higher quality, more accessible, equitable, and affordable. Nominations are due July 3. [Details](#).
- **SBA** issued two interim final rules to supplement previously posted interim final rules on the Paycheck Protection Program (PPP) with additional guidance regarding disbursements, as well as guidance on the amount of PPP loans that any single corporate group may receive and criteria for non-bank lender participation in the PPP. [Details](#).

#### Thurs. (4/30)

- **CMS** announced a second set of wide-reaching regulatory changes and flexibilities for providers in response to the COVID-19 pandemic. [Details](#).
- **FDA** [established](#) an Emergency Use Authorization (EUA) pathway for COVID-19 antibody tests that have been evaluated in an independent validation study performance at the NIH’s National Cancer Institute (NCI), or by a designated government agency. [Details](#).
- **CDC** [announced](#) it is re-opening 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](#).
- **CDC** released new [resources](#) on COVID-19 contact tracing, including training guidance and resources, preliminary criteria for the evaluation of digital contact tracing tools, and principles of contact tracing. [Details](#).

#### Wed. (4/29)

- **The Department of Treasury** issued an [interim final rule](#) authorizing eligible lenders to use alternative criteria to calculate the maximum loan amount for Paycheck Protection Program (PPP) loans provided to seasonal employers. [Details](#).

- **EBSA and the IRS** released a preview of a [final rule](#) extending certain time frames for group health plans, disability and other employee welfare benefit plans, employee pension benefit plans, and their participants and beneficiaries under the Employee Retirement Income Security Act of 1974 (ERISA) and the Internal Revenue Code of 1986. [Details.](#)
- **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.](#)
- **NICHD announced** updates to the Best Pharmaceuticals for Children Act (BPCA) Program priorities for 2020 through 2021. These priorities include identifying drugs for study in pediatric populations, identifying needs in pediatrics therapeutics, and funding studies in prioritized areas. [Details.](#)

#### **Tue. (4/28)**

- **President Trump** released his “Blueprint for Testing Plans and Rapid Response Programs,” intended to supplement his administration’s “Opening up America Again Guidelines” and support States in establishing robust testing plans. [Details.](#)
- **USPSTF issued** a final recommendation statement for the prevention and cessation of tobacco use in children and adolescents and primary care interventions. The task force recommended primary care interventions to prevent tobacco use, but concluded there was insufficient evidence to recommend cessation interventions. [Details.](#)
- **HRSA** launched the [COVID-19 Uninsured](#) Program Portal, which will provide reimbursement at Medicare levels to providers and facilities for coronavirus-related testing and treatment of the uninsured. [Details.](#)

#### **Mon. (4/27)**

- **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.](#)
- **SBA** updated [Frequently Asked Questions \(FAQs\)](#) as of April 26 for lenders and borrowers regarding the Paycheck Protection Program (PPP). [Details.](#)
- **CDC** published the final CDC Recommendations for Hepatitis C Screening Among Adults – United States, 2020 in the Morbidity and Mortality Weekly Report. [Details.](#)
- **CDC** issued a funding opportunity to provide supplemental funding to current recipients of the Paul Coverdell National Acute Stroke Program. [Details.](#)
- **The Supreme Court** sided with insurers in an 8-1 ruling that the federal government owes insurers over \$12 billion from an Affordable Care Act (ACA) program designed to shield insurers from financial risks. [Details.](#)
- **CMS** announced it is suspending its Advance Payment Program to Medicare Part B suppliers effective immediately. It is furthermore “reevaluating” the payment amounts to be paid through its Part A provider-focused Accelerated Payment Program. [Details.](#)

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

- **May 5:** FDA [issued](#) draft guidance on the inclusion of older adults in cancer clinical trials. The agency notes that older adults are those ages 65 and older, and the guidance emphasizes the particular importance of including adults over the age of 75 in clinical cancer trials. [Details.](#)
- **May 7:** HRSA invites nominations for qualified tribal officials for appointment as voluntary delegate members on the HRSA Tribal Advisory Council (TAC). [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 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](#).
- **Aug. 3:** CDC [announced](#) it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee (HICPAC). [Details](#).