

[This Week in Health Policy](#), [Congressional Lookback](#), [Regulatory Lookback](#), [Comment & Application Deadlines](#)

### *Wynne Health Group Weekly*



#### **FRAMING THE WEEK**

The House and Senate will convene hearings on the COVID-19 pandemic as negotiations on the next **coronavirus relief package** are still not likely to begin until after the 4<sup>th</sup> of July holiday followed by a vote before the August recess. In addition, House Democrats are expected to introduce legislation to strengthen the **Affordable Care Act (ACA)** the week of July 20 with a vote on the House floor likely the following week just before the recess.

Following President Trump's remarks that he told administration officials to "slow the [coronavirus] testing down" in order to keep case numbers low, Senate Democratic Leader Chuck Schumer (D-NY) and Senate Health, Education, Labor and Pensions (HELP) Committee Ranking Member Patty Murray (D-WA) [pointed out](#) that the administration has yet to disburse **nearly \$14 billion in appropriated funding**. This includes more than \$8 billion to expand testing and contract tracing capacity and nearly \$4 billion for public health surveillance and contact tracing. In addition, they noted that "only \$10.8 million, or 0.5% of the \$2 billion" to provide free testing for the uninsured has been obligated.

House Speaker Nancy Pelosi (D-CA) [stated](#) that the House Energy and Commerce (E&C) Committee would question the administration's **coronavirus task force** on "why President Trump wants less testing when experts say much more is needed." Tomorrow's [hearing](#) features 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). The panel last appeared together before the Senate HELP Committee on May 12 to discuss reopening the economy.

Also, on Tuesday, the Senate HELP Committee will continue its discussion on [lessons learned from COVID-19](#) to inform a forthcoming **pandemic preparedness package** championed by Chairman Lamar Alexander (R-TN). Other hearing topics include [racial inequities](#) exacerbated by COVID-19, the dynamic between the [Defense Production Act](#) and small contractors, the role of the [Strategic National Stockpile](#) in a pandemic response, and [telehealth](#) at the VA.

Later this week, Congress is slated to take up legislation aimed at making structural changes to the way police officers do their jobs. The House is scheduled to vote on Democrats' **George Floyd Justice in Policing Act (H.R. 7120)** on Thursday, while the Senate will vote on **Republicans' JUSTICE Act (S. 3985)** as soon as on Wednesday. Speaker Pelosi has said that she "would like to end up in conference" and "try to reconcile the legislation."

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. (6/22)**

- **8:30am-5:00pm – CMS Meeting: Clinical Laboratory Fee Schedule** – CMS hosts a virtual public meeting to receive comments and recommendations on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System codes being considered for Medicare payment under the Clinical Laboratory Fee Schedule (CLFS) for CY 2021. [Details.](#)
- **10:00am – PTAC Meeting: Physician Payment** – CMS convenes a meeting of the Physician-Focused Payment Model Technical Advisory Committee. [Details.](#)
- **12:00pm – Hearing: COVID-19 & Racial Inequities** – The House Education and Labor Committee convenes a hearing titled, “Inequities Exposed: How COVID-19 Widened Racial Inequities in Education, Health, and the Workforce.” [Details.](#)

### **Tue. (6/23)**

- **Primary Elections** – Kentucky and New York hold primary elections.
- **10:00am – Hearing: COVID-19 & Preparedness** – The Senate Health, Education, Labor and Pensions Committee convenes a hearing titled, “COVID-19: Lessons Learned to Prepare for the Next Pandemic.” [Details.](#)
- **11:00am – Hearing: COVID-19 Response** – The House Energy and Commerce Committee convenes a hearing titled, “Oversight of the Trump Administration's Response to the COVID-19 Pandemic.” [Details.](#)
- **11:00am – Hearing: FY 2021 Appropriations** – The House Appropriations Committee a hearing for Member testimony on FY 2021 appropriations. [Details.](#)
- **12:00pm-1:00pm – FDA Webcast: COVID-19 & Respirators** – The FDA hosts a webcast titled, “Respirators for Health Care Personnel Use during COVID-19 Pandemic.” [Details.](#)
- **1:00pm – Hearing: Defense Production Act** – The House Small Business Committee convenes a hearing titled, “An Overview of the Dynamic Between the Defense Production Act and Small Contractors.” [Details.](#)
- **1:00pm – Hearing: COVID-19 & Telehealth** – The House Veterans’ Affairs Subcommittees on Technology Modernization and Health titled, “VA Telehealth During the COVID-19 Pandemic: Expansion and Impact.” [Details.](#)
- **1:00pm-3:00pm – PCORI Meeting: COVID-19 Research** – The Patient-Centered Outcomes Research Institute (PCORI) convenes to discuss research funding for COVID-19 initiatives and suicide prevention among youth. [Details.](#)
- **2:30pm – Hearing: COVID-19 & Inequality** – The House Budget Committee convenes a hearing titled, “Health and Wealth Inequality in America: How COVID-19 Makes Clear the Need for Change.” [Details.](#)

### **Wed. (6/24)**

- **9:00-5:00pm – CDC Meeting: Immunizations** – CDC convenes a meeting of the Advisory Committee on Immunization Practice. [Details.](#)
- **10:00am – Hearing: FCC** – The Senate Commerce, Science, and Transportation Committee convenes a hearing titled, “Oversight of the Federal Communications Commission,” featuring FCC Chairman Ajit Pai and several FCC Commissioners. [Details.](#)

- **10:00am – Hearing: Strategic National Stockpile** – The Senate Homeland Security and Governmental Affairs Committee convenes a hearing titled, “The Role of the Strategic National Stockpile in Pandemic Response.” [Details.](#)
- **12:15pm-1:15pm – FDA Town Hall: COVID-19 Diagnostic Tests** – FDA hosts a virtual town hall titled, “Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests.” [Details.](#)
- **1:00pm – Politico Briefing: COVID-19** – Politico hosts a briefing titled, “The Speed of Science Post-COVID-19,” to discuss what lessons can be learned to accelerate medical research outside of the coronavirus, what can be done to minimize misinformation from flawed or inaccurate scientific studies published during a public health emergency and how can newly developed drugs and vaccines be distributed equitably. [Details.](#)
- **3:00pm – ONC Webinar: Pediatric Care** – The Office of the National Coordination for Health Information Technology (ONC) hosts a Q&A webinar titled, “Health IT for Pediatric Care and Settings.” [Details.](#)

#### **Thurs. (6/25)**

- **12:30pm-4:45pm – HHS Meeting: Coverage** – HHS convenes a meeting of the Advisory Panel on outreach and education to discuss optimal strategies for developing and implementing education and outreach programs for individuals enrolled in, or eligible for, the Health Insurance Marketplace, Medicare, and Medicaid, and CHIP. [Details.](#)
- **2:00pm – Hearing: COVID-19 & Nursing Homes** – The House Ways and Means Subcommittee on Health convenes a hearing titled, “Examining the COVID-19 Nursing Home Crisis.” [Details.](#)
- **2:00pm-3:00pm – CMS Forum: Medicare FFS** – CMS hosts a Special Open Door Forum to discuss a new initiative underway to develop a Medicare Fee for Service (FFS) Documentation Requirement Lookup Service prototype. [Details.](#)

#### **Fri. (6/26)**

- **1:00pm-2:00pm – ACL Webinar: Social Isolation** – The Administration for Community Living (ACL) hosts a webinar titled, “Addressing Social Isolation Through Technology Solutions.” [Details.](#)
- **1:00pm-5:00pm – HHS Meeting: Diabetes** – HHS convenes a meeting of the National Clinical Care Commission, which is charged with the coordination and leveraging of diabetes prevention and treatment programs within HHS. [Details.](#)

#### **Additional Multi-Day Events**

- **June 22-June 25 – AHP Virtual Summit: COVID-19** – The Alliance for Health Policy hosts the Virtual Summit on Health System Recovery from the COVID-19 Pandemic, featuring keynote remarks from Dr. Anthony Fauci (National Institute of Allergy and Infectious Disease) and Brad Smith (CMMI). [Details.](#)

#### **FEATURED WHG ANALYSIS**

- **Chart: Aligned Support on Legislative & Regulatory Changes to Extend COVID-19 Telehealth Flexibilities** – In the Policy Hub Insight Bank [here.](#)
- **WHG COVID-19 Government Response Catalogue** – Updated 6/22/20 – In the Policy Hub Insight Bank [here.](#)
- **Chart: Key Federal COVID-19 Funding Opportunities for Providers & Hospitals** – Updated 5/29/20 – In the Policy Hub Insight Bank [here.](#)

## CONGRESSIONAL LOOKBACK

### Wed. (6/17)

- **The Senate HELP Committee** convened a hearing to discuss which telehealth policy changes made in response to the COVID-19 pandemic ought to be made permanent following the end of the national public health emergency (PHE) period. [Details.](#)
- **The House Energy and Commerce Subcommittee on Health** [convened](#) a hearing to discuss racial and ethnic health disparities during the COVID-19 pandemic, and more broadly, in the health care system. [Details.](#)
- **Sen. Tim Scott (R-SC) and Senate Majority Leader Mitch McConnell (R-KY)**, along with other Republican senators, introduced the Just and Unifying Solutions to Invigorate Communities Everywhere (JUSTICE) Act. Similar to the Executive Order on Safe Policing for Safe Communities, the JUSTICE Act relies on the use of financial incentives to encourage police reforms. [Details.](#)
- **The Trump Administration** submitted its [updated report](#) on COVID-19 demographic data to Congress, as required by the Paycheck Protection Program and Health Care Enhancement Act. [Details.](#)

### Tue. (6/16)

- **Bicameral Democratic Health Committee leaders** sent a letter to HHS Secretary Alex Azar and CMS reiterating their request for a Special Enrollment Period as well as for information detailing actions the Administration would take to ensure access to coverage amid the COVID-19 pandemic. [Details.](#)

### Mon. (6/15)

- **MedPAC** released its June 2020 Report to Congress, outlining a series of policy discussions and recommendations for lawmakers to consider in developing improvements to the Medicare system. [Details.](#)
- **MACPAC** released its June 2020 Report to Congress on potential policy improvements in Medicaid and the Children's Health Insurance Program (CHIP). [Details.](#)

## REGULATORY LOOKBACK

### Thurs. (6/18)

- **CMS** announced that the Inpatient Rehabilitation Facility (IRF) and Long-term Care Hospital (LTCH) Quality Reporting Program (QRP) Provider Preview Reports have been updated and are now available. [Details.](#)
- **SBA** issued an interim final rule to supplement previously posted interim final rules on the Paycheck Protection Program (PPP) with additional guidance on eligibility requirements relating to applicants with past felony convictions. [Details.](#)

### Wed. (6/17)

- **FDA** issued final guidance titled "Patient-Focused Drug Development: Collecting Comprehensive and Representative Input" – the first in a [series of four methodological guidance documents](#) developed to address how to collect and submit information from patients and caregivers for medical product development and regulatory decision making. [Details.](#)
- **EEOC** issued updated [guidance](#) that prohibits employers from requiring workers to take COVID-19 antibody tests, and citing CDC's [interim guidelines](#) that antibody test results "should not be used to make decisions about returning persons to the workplace." [Details.](#)

- CMS released 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.” Comments are due by July 20. [Details](#).

### **Tue. (6/16)**

- **President Trump** issued an [Executive Order on Safe Policing for Safe Communities](#), which focuses on incentivizing (through grants), but not requiring, law enforcement agencies to increase training on de-escalation and other best practices and submit information to a new database that tracks police misconduct. [Details](#).
- **The D.C. Court of Appeals** upheld the previous federal court ruling that vacated the HHS [final rule](#) on requiring drug manufacturers to include list price information in direct to consumer (DTC) advertisements. [Details](#).

### **Mon. (6/15)**

- CDC released an [Overview of Testing for SARS-CoV-2](#) – a compilation of recommendations for COVID-19 testing, including interim testing guidelines for nursing home residents, healthcare personnel, and other critical infrastructure workers. [Details](#).
- FDA [revoked](#) the Emergency Use Authorization (EUA) for hydroxychloroquine sulfate (HCQ) and chloroquine sulfate (CQ) as treatments for COVID-19 due to new evidence that demonstrates that the treatments may not be effective and other serious side effects. [Details](#).
- **The NIH** National Center for Advancing Translational Science (NCATS) [launched](#) the National COVID Cohort Collaborative (N3C), a centralized and secure platform to store and study vast amounts of medical record data from people diagnosed with COVID-19 across the country. [Details](#).
- In a 6-3 opinion, the **U.S. Supreme Court** ruled that employees cannot be fired for being gay or transgender. [Details](#).

### **COMMENT & APPLICATION DEADLINES**

- **June 26:** Senate HELP Committee Chairman Lamar Alexander (R-TN) is requesting comments in response to a [white paper](#), “Preparing for the Next Pandemic” – a starting point for a legislative package to bolster the federal government’s public health infrastructure and capacity. [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 2:** CMS issued a [proposed rule](#) to amend the Department of Health and Human Services’ ACA risk adjustment data validation (HHS-RADV) program. [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 8:** The Office of the Assistant Secretary for Health (OASH) issued a [request for information](#) (RFI) to better understand how stakeholders across the healthcare system have defined “resilience,” including in the use of data, analytic methods, and proven indicators. [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.](#)
- **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. 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.](#)