

Wynne Health Group Weekly



FRAMING THE WEEK

Democrats are seeking to draw a stark contrast with Republicans on health care, following the Trump administration's call (in a [brief](#) to the Supreme Court) that the **Affordable Care Act (ACA)** in its entirety "must fall." Today, the **House** is expected to pass the **Patient Protection and Affordable Care Enhancement Act (H.R. 1425)** – a bill to bolster health care coverage, incentivize Medicaid expansion, and lower prescription drug prices through direct government negotiation. H.R. 1425 is not expected to be considered by the Republican-controlled Senate but will, no doubt, be touted by Democrats during the campaign season heading into the November 2020 elections.

This afternoon, the **House Rules Committee** will meet to determine how to structure floor debate over the **Moving Forward Act (H.R. 2)** – a **\$1.5 trillion infrastructure package** that includes measures to modernize the nation's **health care infrastructure** and expand **broadband access**, among other proposals. The House is eyeing on passage before the 4th of July recess, but its viability in the Senate remains unclear. Senate Majority Leader Mitch McConnell (R-KY) has rejected efforts to include infrastructure funding in a coronavirus relief package. The Trump administration, however, is reportedly crafting its own \$1 trillion infrastructure proposal that they aim to include in the next relief package.

The **Senate** will hold a procedural vote this evening to begin debate on the **National Defense Authorization Act for Fiscal Year 2021 (S. 4049)**, which authorizes **\$44 million for vaccine and biotechnology research** supported by the Department of Defense for the COVID-19 response. On Wednesday, the **House Armed Services Committee** will [mark-up](#) its own version of the **National Defense Authorization Act for Fiscal Year 2021 (H.R. 6395)**. It includes a provision that would create a **\$1 billion Pandemic Preparedness and Resilience National Security Fund** – \$200 million to purchase goods or services from small businesses in response to the COVID-19 pandemic; \$50 million to produce medical countermeasures against novel threats; and \$750 million to support research and development efforts related to biopreparedness and pandemic preparedness and resilience.

Tomorrow, the **Senate Health, Education, Labor and Pensions (HELP) Committee** will [question](#) Dr. Anthony Fauci (Director of the National Institute of Allergy and Infectious Diseases), Dr. Robert Redfield (CDC Director), Dr. Stephen Hahn (FDA Commissioner), and Admiral Brett Giroir (Assistant Secretary for Health) on progress toward **reopening the country**. The last time this panel appeared before the Senate HELP Committee on May 12, Dr. Fauci warned that states that prematurely open without the capability to respond effectively may see "spikes that might turn into outbreaks." The recent surge in coronavirus cases in some states have caused governors across the country to pause reopening. Senate HELP Ranking Member Patty Murray (D-WA) will likely again press Admiral Giroir on the administration's national COVID-19 testing strategy, which Democrats have repeatedly called for – especially after the administration has [failed](#) to deliver a plan with clear targets.

In response to the increased need for **mental health and substance use services** amid the COVID-19 pandemic, the **House Energy and Commerce Subcommittee on Health** will convene a [hearing](#) to examine legislation aimed at improving access to these services. This hearing also seeks to address pressure from mental health and behavioral health treatment centers and providers who “have not been included or eligible for sufficient amounts of COVID-19 relief funds” from HHS’ Provider Relief Fund, according to the [E&C Committee memo](#).

Most bills slated for the discussion have bipartisan support, including the **Telemental Health Expansion Act of 2019 (H.R. 5201)**. This bill would permanently include the patient’s home as an eligible originating site for mental health services delivered via telehealth and remove Medicare’s geographic restrictions for these services. The **Greater Mental Health Access Act (H.R. 4428)**, another bipartisan bill, would provide \$6 million in grants from the Prevention and Public Health Fund for outpatient mental health services.

On Thursday, the **Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies** will hear from Dr. Francis Collins (NIH Director), CDC Director Dr. Redfield, and Dr. Gary Disbrow (Acting Director of the Biomedical Advanced Research and Development Authority (BARDA)) on **Operation Warp Speed (OWS)** – an initiative to accelerate the development, manufacturing, and distribution of COVID-19 countermeasures. The hearing will focus on OWS vaccine development. OWS is [aiming](#) to “deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021.” Currently, HHS is narrowing down 14 vaccine candidates to about seven for further testing in early-stage clinical trials.

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. (6/29)

- **1:00pm – Business Meeting: Infrastructure** – The House Rules Committee convenes a meeting to consider a rule to provide a structured amendment process for floor consideration of the Moving Forward Act (H.R. 2). [Details](#).
- **2:00pm-3:00pm – VA Meeting: COVID-19 & Veterans** – VA convenes a meeting of the Advisory Committee on Homeless Veterans to vote on recommendations to the VA Secretary, which will focus primarily on VA’s response to COVID-19. [Details](#).

Tue. (6/30)

- **9:00am-5:00pm – FDA Meeting: Data Strategy** – FDA hosts a meeting to discuss its Technology Modernization Action Plan. [Details](#).
- **9:00am-5:30pm – FDA Webcast: Bioanalysis** – FDA hosts a webinar titled, “Regulatory Education for Industry: Regulated Bioanalysis Workshop: Requirements and Expectations.” [Details](#).
- **10:00am – Hearing: COVID-19 & Reopening** – The Senate Health, Education, Labor and Pensions Committee convenes a hearing titled, “COVID-19: Update on Progress Toward Safely Getting Back to Work and Back to School,” featuring Dr. Anthony Fauci, NIH NIAID Director; Dr. Robert Redfield, CDC Director; Dr. Stephen Hahn, FDA Commissioner; and Assistant Secretary for Health Admiral Brett Giroir. [Details](#).

- **11:00am – Hearing: COVID-19 & Mental Health** – The House Energy and Commerce Subcommittee on Health convenes a legislative hearing titled, “High Anxiety and Stress: Legislation to Improve Mental Health During Crisis.” [Details.](#)

Wed. (7/1)

- **10:00am – Markup: NDAA** – The House Armed Services Committee convenes a markup of H.R. 6395 – National Defense Authorization Act for Fiscal Year 2021, which includes COVID-19-specific provisions. [Details.](#)
- **10:00am – Hearing: Reproductive Health Care** – The House Veterans’ Affairs Subcommittee on Health and Women Veterans Task Force convenes a hearing titled, “Veterans' Access to Reproductive Health Care.” [Details.](#)
- **10:00am – Hearing: Small Business Loan** – The House Small Business Committee convenes a hearing titled, “The Economic Injury Disaster Loan Program: Status Update from the Administration.” [Details.](#)
- **12:00pm – ACT | The App Association Webinar: COVID-19 & Digital Health** – ACT | The App Association’s Connected Health Initiative hosts a webinar titled, “Finding a Path Forward for Digital Health After the COVID-19 Public Health Emergency.” [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.](#)
- **2:30pm – Hearing: COVID-19 & American Indians** – The Senate Committee on Indian Affairs convenes an oversight hearing on “Evaluating the Response and Mitigation to the COVID-19 Pandemic in Native Communities” and legislative hearing to discuss the Coverage for the Urban Indian Health Providers Act (S. 3650). [Details.](#)
- **3:00pm – Hearing: Veterans Health** – The Senate Veterans’ Affairs Committee convenes a hearing titled, “Recruitment, Retention and Building a Resilient Veterans Health Care Workforce.” [Details.](#)

Thurs. (7/2)

- **10:00am – Hearing: COVID-19 Vaccine** – The Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies convenes a hearing titled, “Review of Operation Warp Speed: Researching, Manufacturing, & Distributing a Safe & Effective Coronavirus Vaccine.” [Details.](#)
- **12:30pm – Hearing: COVID-19 & Treasury** – The House Financial Services Committee convenes a legislative hearing titled, “Oversight of the Treasury Department's and Federal Reserve's Pandemic Response.” [Details.](#)

Fri. (7/3)

- Fourth of July Holiday

FEATURED WHG ANALYSIS

- **Chart: Key Federal COVID-19 Funding Opportunities for Providers & Hospitals** – Updated 6/26/20 – 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.](#)
- **WHG COVID-19 Government Response Catalogue** – Updated 6/22/20 – In the Policy Hub Insight Bank [here.](#)

CONGRESSIONAL LOOKBACK

Thurs. (6/25)

- **The Senate Committee on Homeland Security & Governmental Affairs** convened a [hearing](#) to discuss the Role of Strategic National Stockpile in Pandemic Response. [Details](#).
- **E&C Ranking Member Greg Walden (R-OR)** and Communications and Technology Subcommittee Ranking Member Bob Latta (R-OR) unveiled the WIRELESS Leadership Act – a package of 26 bills aimed at streamlining the deployment of broadband infrastructure. [Details](#).
- **The E&C Committee Democratic leaders** released a [report](#) on the Committee’s investigation into short-term, limited duration insurance (STLDI) health care plans and the insurance brokers who sell and sign up people for these plans. [Details](#).

Wed. (6/24)

- **The Senate HELP Committee** convened a hearing to discuss the lessons learned from the current COVID-19 pandemic response to begin preparing for the next pandemic. [Details](#).

Tue. (6/23)

- **The House E&C Committee** [convened](#) a hearing to discuss the government’s response to the COVID-19 pandemic. Trump Administration officials from the NIH, HHS, the FDA, and the CDC testified about their agency’s efforts to support COVID-19 response through guidance and guidelines, the development and distribution of diagnostic tests, therapeutics, and vaccines, and the procurement of PPE. [Details](#).

Mon. (6/22)

- **House Democrats** unveiled updated [legislative text](#) of H.R. 1425, the Patient Protection and Affordable Care Enhancement Act – a bill to bolster coverage rates in the Affordable Care Act (ACA) Exchanges and state Medicaid programs. [Details](#).
- **House Democrats** released the legislative text of the Moving Forward Act (H.R. 2) – a more than \$1.5 trillion infrastructure package that includes measures to modernize the nation’s health care infrastructure and expand broadband access, among other proposals. [Details](#).
- **The House Education and Labor Committee** convened a [hearing](#) to discuss how Congress can address racial inequities exacerbated by COVID-19 in education, health, and the workforce. [Details](#).

REGULATORY LOOKBACK

Fri. (6/26)

- **FDA** [issued](#) final guidance on the review and update of device establishment inspection processes and standards. [Details](#).
- **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. Comments are due by August 28. [Details](#).

Thurs. (6/25)

- **FDA** [updated](#) the consolidated list of guidance documents available on the COVID-19 public health emergency (PHE). The FDA details that the agency will periodically publish a consolidated notice of availability (NOA) of the relevant COVID-19 documents. [Details](#).
- **CMS** issued the CY 2021 home health prospective payment system and rate update [proposed rule](#) with comment period. Comments are due August 20, 2020. [Details](#).

- **CDC** updated and expanded the list of people at risk for getting severely ill from COVID-19 to include those with: Chronic kidney disease; COPD; Obesity; Immunocompromised state from solid organ transplant; Serious heart conditions; Sickle cell disease; and Type 2 diabetes. [Details](#).

Wed. (6/24)

- **FDA** [announced](#) Project Patient Voice, a first of its kind pilot program to communicate patient reported outcomes from cancer clinical trials, initiated by the FDA’s Oncology Center of Excellence. [Details](#).
- **FDA** [issued](#) guidance to answer frequently asked questions (FAQs) on the impact of the COVID-19 public health emergency (PHE) on formal meetings and user fee applications for medical devices. [Details](#).
- **USPSTF** issued a [draft recommendation](#) and evidence review that recommends screening for hypertension in adults ages 18 years and older with office blood pressure measurement (OBPM). [Details](#).
- **U.S. District Judge Carl Nichols**, a Trump appointee, upheld the Trump Administration’s hospital price transparency regulations issued last fall. HHS Secretary Azar hailed the District Court’s ruling, calling it a “victory” for the President’s price transparency agenda. [Details](#).

Tue. (6/23)

- **SBA and the Treasury** [announced](#) that details on PPP borrowers that receive loans above \$150,000 will be made publicly available. Details include business names, addresses, NAICS codes, zip codes, business type, demographic data, non-profit information, jobs supported, and loan amount ranges. [Details](#).

Mon. (6/22)

- **HHS** [updated](#) its Provider Relief Fund frequently asked questions (FAQs) to clarify that recipients are not required to submit a separate quarterly report to HHS or the Pandemic Response Accountability Committee. [Details](#).
- **CMS** released new data detailing the cumulative impact of COVID-19 on Medicare CHIP beneficiaries. [Details](#).

COMMENT & APPLICATION DEADLINES

- **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 20:** CMS seeks comment on 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.” [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](#).

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