

Wynne Health Group Weekly



FRAMING THE WEEK

With the Senate back in session, Senate Majority Leader Mitch McConnell (R-KY) announced Republicans will introduce “a new targeted proposal” to provide **coronavirus relief**, [noting](#) that he “will be moving immediately today [September 8] to set up a floor vote as soon as this week.” Lawmakers have only a few weeks in September to address both the government funding deadline and the next round of pandemic relief before members recess at the end of the month to campaign through November.

Treasury Secretary Mnuchin and Speaker Pelosi have announced an informal agreement on a clean **continuing resolution** to provide government funding through December. Details of the package are expected to be released by the end of this week. They have agreed that this continuing resolution will be considered separately from the COVID 4 package, with neither side showing interest in a showdown over whether or not to keep the government open right before the elections. This could push the consideration of surprise medical billing and prescription drug pricing legislation to December at the earliest.

The talks on the COVID 4 package have reached a stalemate as Leader McConnell has released a new \$500 billion interim draft coronavirus financial aid package. This bill is half the size of the original \$1 trillion Senate Republican “skinny” bill, the HEALS Act. This effort is largely a political effort to force Senate Democrats to vote against additional financial aid to help the country during the pandemic. With some changes expected before filing, including additional tax provisions, this new draft contains the following:

- \$300 weekly enhanced unemployment benefits;
- \$29 billion to support vaccine and countermeasure development and distribution;
- \$16 billion for testing and contact tracing;
- \$105 billion for schools and universities;
- \$250 billion in additional funding for the Small Business Administration’s Paycheck Protection Program;
- liability protections for health care providers, businesses, and schools through at least October 1, 2024; and
- a provision converting a prior \$10 billion loan (provided in the CARES Act, [P.L. 116-136](#)) to the U.S. Postal Service into a grant if certain financial conditions are met.

Tomorrow, the Senate Health, Education, Labor and Pensions (HELP) Committee will question NIH Director Dr. Francis Collins and Surgeon General Jerome Adams on **COVID-19 vaccines and public health**. The timing and availability of a safe COVID-19 vaccine has come into focus as President Trump

has touted that a coronavirus vaccine could be approved before the November election. Senate HELP Ranking Member Patty Murray (D-WA) and Senate Minority Leader Chuck Schumer (D-NY) have [pressed](#) senior health officials, arguing that political interference from the Trump Administration has impacted the agencies' work in response to COVID-19.

The House is expected to hold hearings in five subcommittees in September on COVID-19 related issues, including another hearing regarding the progress on a vaccine for COVID-19. The vaccine hearings are expected to have third party interest groups in rather than bringing pharmaceutical manufacturers back to the witness stand.

The House Energy and Commerce (E&C) Committee will consider **38 bills** at a [markup](#) tomorrow. They include measures relating to Medicare and commercial insurance coverage and mental health care access, as well as legislation to stem the opioid crisis. See the [memorandum](#) from E&C Chairman Frank Pallone, Jr. (D-NJ) for the complete lineup.

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. (9/7)

- Labor Day holiday.

Tue. (9/8)

- **6:30pm-7:30pm – CMS Nursing Home COVID-19 Call** – CMS hosts a National Nursing Home COVID-19 call, featuring CMS Administrator Seema Verma, CDC Director Robert Redfield, and Assistant Secretary for Health, Admiral Brett Giroir. [Details](#).

Wed. (9/9)

- **9:30am-2:30pm – ONC Meeting: Health IT** – The Office of the National Coordinator for Health Information Technology convenes a meeting of the Health IT Advisory Committee. [Details](#).
- **9:30am-2:30pm – VA meeting: Veteran Health** – VA convenes a meeting of the Special Medical Advisory Group to discuss the pandemic response, challenges and future health care considerations, precision oncology expansion strategy and geriatrics health care future strategy. [Details](#).
- **10:00am – HELP Hearing: Vaccines** – The Senate Committee on Health, Education, Labor & Pensions (HELP) convenes a hearing titled, “Vaccines: Saving Lives, Ensuring Confidence, and Protecting Public Health. NIH Director Francis Collins and Surgeon General Jerome Adams will testify. [Details](#).
- **11:00am – Markup: Health Care, Mental Health, Drugs** – The House Energy and Commerce Committee convenes a markup of 38 bills, including health care, mental health, and drug measures. [Details](#).
- **12:15pm-1:15pm – FDA Town Hall: COVID-19 Diagnostics** – The FDA hosts a virtual Town Hall for clinical laboratories and commercial manufacturers that are developing or have

developed diagnostic tests for SARS-CoV-2, to help answer technical questions about the development and validation of tests. [Details](#).

- **2:00pm-3:40pm – Brookings Webinar: Health Care Prices** – Brookings hosts a webinar titled, “Are U.S. health care prices too high, too low, or some mix of the two?”, Part 1 of a panel series on health care price regulation honoring Uwe E. Reinhardt (1937-2017). [Details](#).
- **3:30pm – Hearing: Veteran Suicide** – The Senate Veteran Affairs Committee convenes a hearing to examine S. 785: Leading the Way to Comprehensive Mental Health Care and Suicide Prevention for Veterans. [Details](#).

Thurs. (9/10)

- **9:00am-12:30pm – NIH Meeting: Women’s Health** – The NIH Obesity Research Task Force hosts the Obesity and Women’s Health Virtual Symposium. [Details](#).
- **11:00am-12:30pm – FDA Webinar: Medical Devices** – FDA hosts a webinar for device manufacturers and other stakeholders regarding the [Multiple Function Device Products: Policy and Considerations](#) final guidance. [Details](#).
- **12:00pm-1:00pm – FDA Webcast: COVID-19** – The FDA hosts a webcast titled, “Advancing the Science of Real-World Data to Address the COVID-19 Pandemic. [Details](#).”
- **1:00pm-2:00pm – NIHCM Webinar: COVID-19 and Early Childhood** – The National Institute for Health Care Management (NIHCM) Foundation hosts a webinar titled, “Protecting Our Children: COVID-19’s Impact on Early Childhood and ACEs.” [Details](#).

Fri. (9/11)

- **1:00pm-5:30pm – HHS Meeting: Diabetes** – HHS convenes a meeting of the National Clinical Care Commission to discuss recommendations to improve federal programs related to diabetes and its complications. [Details](#).

Additional Multi-Day Events

- **September 8-September 9 – CDC Meeting: Health Statistics** – CDC convenes a meeting of the ICD-10 Coordination and Maintenance (C&M) Committee to discuss ICD-10-CM and ICD-10-PCS topics. [Details](#).
- **September 8-September 9 – FDA Meeting: Medical Devices** – FDA convenes a meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. [Details](#).
- **September 9-September 10 – NIH Meeting: Child Health** – NIH convenes a meeting of the National Advisory Child Health and Human Development Council to discuss administrative matters, Director's Report, Division of Extramural Research Report and, other business. [Details](#).
- **September 9-September 10 – HHS Meeting: Antibiotic-Resistant Bacteria** – HHS convenes a meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria to discuss the COVID-19 mortality rate due to secondary acquired infections, antibiotic stewardship practices during a pandemic, disruptions in the agricultural industry due to COVID-19 and the intersection of AMR and emergency preparedness. [Details](#).
- **September 10-September 11 – FDA Meeting: Drug Safety** – FDA convenes a meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee to discuss the results of required postmarketing studies that evaluated the effect of the reformulation of OXYCONTIN on abuse, misuse, and fatal and non-fatal overdose, associated with OXYCONTIN. [Details](#).

FEATURED WHG ANALYSIS

- **WHG Chart: Biden Campaign vs. Trump Administration Health Care Policies** – In the Policy Hub Insight Bank [here](#).
- **August Edition: COVID-19 Government Response Catalogue** – Updated 8/31/20 – In the Policy Hub Insight Bank [here](#).
- **Updated WHG Legislative and Regulatory Outlook** – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Fri. (9/4)

- **MedPAC** convened virtually for its September public meeting, hosting sessions on the expansion of telehealth in Medicare, and Medicare coverage for vaccines. All WHG session summaries available [here](#).

Thurs. (9/3)

- **MedPAC** convened virtually for its September public meeting, hosting sessions on the impact of the Coronavirus pandemic, the fiscal outlook of Medicare, the skilled nursing facility value-based purchasing program, changes to the Medicare clinical laboratory fee schedule, and private equity and Medicare. All WHG session summaries available [here](#).

Wed. (9/2)

- **CBO** released the Update to the Budget and Economic Outlook for 2020 to 2030 and the Outlook for Major Federal Trust Funds for 2020 to 2030. [Details](#).

REGULATORY LOOKBACK

Fri. (9/4)

- **HHS** [released](#) the Rural Action Plan. This action is pursuant to President Trump's executive order on improving rural health access and telehealth access signed last month. [Details](#).
- **HRSA** [announced](#) it is seeking nominations for 5 members to serve on the Advisory Committee on Heritable Disorders in Newborns and Children for terms up to 4 years. Nominations are due September 22, 2020. [Details](#).

Thurs. (9/3)

- **FEMA** released an [interim policy](#) that clarifies the COVID-19 response work that is eligible for funding through the Public Assistance (PA) program. [Details](#).
- **HHS** [announced](#) it would extend eligibility for the Provider Relief Fund Phase 2 General Distribution allocation to assisted living facilities (ALFs). [Details](#).

Wed. (9/2)

- **FDA** [issued](#) final guidance on the control of nitrosamine impurities in human Drugs. [Details](#).
- **NIH** [awarded](#) \$129.3 million in contracts for scale-up and manufacturing support for new COVID-19 testing technologies as part of the Rapid Acceleration of Diagnostics (RADx) initiative. [Details](#).
- **CMS** released the fiscal year (FY) 2021 inpatient prospective payment system (IPPS) and long-term care hospital prospective payment system (LTCH PPS) [final rule](#), which applies to acute care hospital and LTCH payments beginning Oct. 1, 2020. [Details](#).

Tue. (9/1)

- **FDA** [established](#) a public docket to collect comments on post-marketing pediatric-focused safety reviews of products marketed between September 23, 2019, and September 1, 2020. Comments are due September 22, 2020. [Details.](#)
- **HHS, USDA, and the FCC** [announced](#) they have signed a [Memorandum of Understanding](#) (MOU) to collaborate on the Rural Telehealth Initiative (RTI). [Details.](#)
- **NASEM's** ad hoc Committee on Equitable Allocation for the Novel Coronavirus [released](#) its discussion draft of the preliminary framework for equitable allocation. Comments are due September 4. [Details.](#)
- **CDC** issued an [agency order](#) effectuating a four-month temporary halt in residential evictions in the U.S. [Details.](#)

Mon. (8/31)

- **FDA** [updated](#) the emergency use authorization (EUA) for remdesivir in order to broaden treatment to include all hospitalized adult and pediatric patients with suspected or laboratory confirmed COVID-19. [Details.](#)
- **CMS** issued a proposed rule to expedite and increase coverage of innovative medical devices. Comments are due by November 2, 2020. [Details.](#)
- **FNS** [announced](#) that it would extend several nationwide school meal waivers through the end of the 2020 calendar year, “or until available funding runs out.” [Details.](#)

COMMENT & APPLICATION DEADLINES

- **Sept. 12:** CMS is accepting public comments on a section 1115 Medicaid demonstration waiver application submitted by the State of Colorado. [Details.](#)
- **Sept. 13:** HHS [extended](#) the deadline to apply for Phase 2 General Distribution Funding from the Provider Relief Fund (PRF) to September 13. Steps for applying for the Phase 2 General Distribution for Medicaid, CHIP, dental, and certain Medicare providers can be found [here.](#) [Details.](#)
- **Sept. 14:** HUD issued a NOFA for [Choice Neighborhoods Planning Grants](#), which support the development of comprehensive neighborhood revitalization strategies. [Details.](#)
- **Sept. 14:** The DOL [released](#) a RFI seeking industry input on paid family and medical leave to care for family members or one's own health. [Details.](#)
- **Sept. 15:** The U.S. Department of Labor's Wage and Hour Division [released](#) a RFI soliciting input on the implementation of the Family and Medical Leave Act of 1993. [Details.](#)
- **Sept. 15 and 18:** NIH announced several funding opportunities through its Rapid Acceleration of Diagnostics Radical (RADx-rad) initiative to support the development of novel, non-traditional approaches to identify COVID-19. [Details.](#)
- **Sept. 22:** FDA seeks comment on a proposed rule that would establish annual reporting requirements under the Right to Try Act. [Details.](#)
- **Sept. 27:** ASPE [issued](#) an RFI about education and employment programs serving young people ages 16 to 24 who are unemployed and/or not attending school. [Details.](#)
- **Sept. 29:** CMS [issued](#) an RFI on whether the agency should include exceptions to the requirements for electronic prescription of controlled substances (EPCS) or impose penalties for non-compliance with the requirements. [Details.](#)
- **Sept. 30:** NIH [announced](#) a funding opportunity to identify children at risk for developing Multisystem Inflammatory Syndrome in children (MIS-C), thought to be a severe complication of COVID-19. Applications are due September 30, and letters of intent are due 30 days prior. [Details.](#)

- **Oct. 2:** HHS [released](#) a RFI seeking input from state and local government agencies, local program operators, and the public, on the development of a federal interagency Council on Economic Mobility. [Details](#).
- **Oct. 4:** CMS [issued](#) a proposed rule to create a policy governing the treatment of days associated with beneficiaries enrolled in Medicare Advantage (MA) for the purposes of determining a hospital's Medicare disproportionate patient percentage for discharges on or before October 1, 2013. [Details](#).
- **Oct. 5:** CMS is accepting comments on the CY 2021 hospital outpatient prospective payment system (OPPS) [proposed rule](#) addressing payments to hospital outpatient departments and ambulatory surgery centers (ASCs). [Details](#).
- **Oct. 5:** CMS is accepting comments on the calendar year (CY) 2021 Medicare Physician Fee Schedule (MPFS) [proposed rule](#). [Details](#).
- **Oct. 6:** HRSA [announced](#) a funding opportunity through its Healthy Tomorrows Partnership for Children Program. [Details](#).
- **Oct. 19:** NIH [issued](#) a request for information (RFI) to assist and guide the National Library of Medicine (NLM) Strategic Plan for 2017 to 2027: A Platform for Biomedical Discovery and Data-Powered Health. [Details](#).
- **Oct. 28:** FDA [issued](#) draft guidance on setting endotoxin limits during the development of investigational oncology and biological products. [Details](#).
- **Nov. 7:** FDA [issued](#) draft guidance on drug-drug interaction assessments for therapeutic proteins. [Details](#).
- **Nov. 16:** HRSA is accepting applications for a funding opportunity titled, "Rural Health Network Development Planning Program." The grant supports one year of planning to develop and assist integrated health care networks in becoming operational. [Details](#).