

Wynne Health Group Weekly



FRAMING THE WEEK

The House returns this week with only a few weeks left to come to an agreement on a coronavirus relief package and avert a government shutdown. While the relief package discussions remain stymied with no end in sight, the informal agreement between Speaker Pelosi and the White House on a “clean” **continuing resolution** (CR) continues to move forward without a hitch. Meanwhile, the President was busy over the weekend with an executive order (EO) tying prescription drug and biologic pricing under Medicare Part B and Part D to the “most-favored-nation (MFN) price.”

Treasury Secretary Steven Mnuchin and House Speaker Nancy Pelosi (D-CA) have informally agreed to a “clean” CR that largely maintains the current funding levels and is free of any poison pills. With the November elections right around the corner, the main point of contention is deciding the duration of the continuing resolution. Republicans are pushing for a CR that funds the government through December and Democrats, feeling bullish about the elections, prefer a January expiration date. The CR is expected to reauthorize a slate of expiring **health care extenders, including the following:**

- Health care extenders expiring September 30, 2020
 - Medicare: MACRA technical assistance to small practices and practices in Health Professional Shortage Areas
 - CHIP: 11.5 percentage point increase to E-FMAP
- Health care extenders expiring November 30, 2020
 - Medicare: National Quality Forum, Outreach and Assistance for Low-Income Programs, floor on work geographic practice cost indices
 - Medicaid: Money Follows the Person program, spousal impoverishment protections, certified community behavioral health clinics
 - Public Health: Community health centers (CHCs), teaching health centers, National Health Service Corps, Special Diabetes Program
 - Health Services: Sexual Risk Avoidance Education Program, Personal Responsibility Education Program (PREP), demonstration projects to address health professions workforce needs, Temporary Assistance for Needy Families (TANF)

President Trump signed his EO on “[Lowering Drug Prices by Putting America First](#)” on Sunday in an attempt give his campaign new focus on an old promise to reduce prescription drug prices. The timing and legality of the Department of Health and Human Services’ (HHS) ability to proceed with rulemaking tying **prescription drug and biologic pricing under Medicare Part B and Part D** to the MFN price is another question altogether. This effort widens the Administrations executive order introduced on July 24 at a White House signing ceremony to include Part B and D drugs, directing the HHS Secretary to create demonstration projects requiring Medicare to pay the same lower prices for prescription drugs as those sold in Europe and other developed nations.

On Wednesday (September 16), the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will convene a [hearing](#) to review **coronavirus response efforts**. The witness panel includes Assistant Secretary for Health Admiral Brett Giroir, Assistant Secretary for Preparedness and Response Dr. Bob Kadlec, and CDC Director Dr. Robert Redfield. The discussion may signal whether there is still an appetite among Senate appropriators to try to hash out a deal on a coronavirus relief package before the November elections.

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. (9/14)

- **12:00pm – Hearing: Postal Service** – The House Oversight and Reform Subcommittee on Government Operations convenes a hearing titled, “Postal Update.” [Details](#).

Tue. (9/15)

- **8:00am-11:00am – NIH Meeting: Medical Research** – The NIH convenes a meeting of the National Heart, Lung, and Blood Advisory Council to discuss program policies and issues. [Details](#).
- **9:00am-2:30pm – HHS Meeting: Tick-Borne Diseases** – HHS convenes a meeting of the Tick-Borne Disease Working Group to review the draft 2020 report to the HHS Secretary and Congress that addresses ongoing tick-borne disease research, related federal activities, and gaps in research. [Details](#).
- **10:00am – Hearing: Police Reform** – The House Oversight and Reform Subcommittee on Civil Rights and Civil Liberties titled, “Confronting Violent White Supremacy (Part IV): White Supremacy in Blue—The Infiltration of Local Police Departments.” [Details](#).
- **10:00am-4:30pm – FDA Meeting: Pediatric Drugs** – FDA convenes a meeting of the Pediatric Advisory Committee (PAC) to discuss the pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108-155). [Details](#).
- **12:00pm-1:00pm – FDA Webinar: COVID-19** – FDA hosts a webinar titled, “Gowns and Other Apparel for Use by Health Care Personnel in COVID-19 Pandemic.” [Details](#).
- **12:00pm-4:00pm – VA Meeting: Homelessness** – The VA convenes meeting of the Advisory Committee on Homeless Veterans. [Details](#).
- **12:30pm-1:00pm – Axios Event: Chronic Pain** – Axios hosts a live, virtual event titled, “The State of Chronic Pain: Part 2,” featuring House Energy and Commerce Health Subcommittee Ranking Member Michael Burgess (R-TX), among others. [Details](#).
- **2:00pm-3:00pm – CDC COCA Call: COVID-19** – CDC hosts a Clinician Outreach and Communication Activity (COCA) call titled, “Telehealth & Health Equity: Considerations for Addressing Health Disparities during the COVID-19 Pandemic.” [Details](#).
- **2:00pm-3:00pm – NCQA Webinar: Telehealth** – The National Committee for Quality Assurance hosts a webinar to discuss the Taskforce on Telehealth Policy’s final report. [Details](#).

- **2:00pm-3:00pm – ODF: Rural Health** – CMS hosts an Open Door Forum (ODF) to discuss the CHART Model; Rural Crosswalk: CMS Flexibilities to Fight COVID-19; and Public Health Emergency Rule (CMS-3401-IFC): COVID-19-related flexibilities. [Details.](#)
- **2:30pm-4:00pm – CMS Webinar: Maternal Mortality** – CMS hosts a webinar titled, “Data-Informed Strategies to Address Maternal Mortality and Severe Maternal Morbidity in Medicaid.” [Details.](#)

Wed. (9/16)

- **TBD – FDA Webinar: Medical Cannabis** – FDA hosts a webinar titled, “Cannabis Clinical Research: Drug Master Files (DMFs) & Quality Considerations.” [Details.](#)
- **10:00am – Hearing: COVID-19** – The Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies convenes a hearing to review coronavirus response efforts. [Details.](#)
- **12:15pm-1:15pm – FDA Town Hall: COVID-19** – FDA hosts a town hall titled, “Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests.” [Details.](#)
- **2:00pm – Hearing: COVID-19** – The House Veterans’ Affairs Subcommittee on Oversight and Investigations titled, “Modernizing VA’s Medical Supply Chain: Lessons Learned from the Pandemic.” [Details.](#)
- **2:30pm – Roundtable: Housing** – The Senate Budget Committee convenes a roundtable to examine federal housing assistance programs. [Details.](#)

Thurs. (9/17)

- **10:00am – Hearing: FCC** – The House Energy and Commerce Subcommittee on Communications & Technology convenes a hearing titled, “Trump FCC: Four Years of Lost Opportunities.” [Details.](#)
- **2:00pm-3:00pm – ODF: Hospital Quality** – CMS hosts an ODF to discuss the CY 2021 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule and FY 2021 Hospital Inpatient Prospective Payment System (IPPS) Final Rule. [Details.](#)
- **2:00pm-3:00pm – CDC COCA Call: COVID-19** – CDC hosts a COCA call titled, “Testing and Treatment of 2020-2021 Seasonal Influenza During the COVID-19 Pandemic.” [Details.](#)

Fri. (9/18)

- See multi-day events.

Additional Multi-Day Events

- **September 14-September 15 – NIH Meeting: Human Genome Research** – NIH convenes a meeting of the National Advisory Council for Human Genome Research. [Details.](#)
- **September 14-September 15 – PCORI Meeting: Health Care Research** – The Patient-Centered Outcomes Research Institute (PCORI) convenes a meeting of the Board of Governors to discuss a new cost data provisions, proposed cost data principles for researchers, among other items. [Details.](#)
- **September 14-September 16 – FDA Conference: Drug Manufacturing** – FDA and the Parenteral Drug Association host the PDA/FDA Joint Regulatory Conference titled, “The Future Is Now: Effective Quality Management and Robust Manufacturing.” [Details.](#)
- **September 15-September 16 – HHS Meeting: Payment Models** – HHS convenes a meeting of the Physician-Focused Payment Model Technical Advisory Committee to deliberate on two payment model proposals and discuss using telehealth to optimize health care delivery under physician-focused payment models (PFPMs) and alternative payment models (APMs). [Details.](#)

- **September 17-September 18 – CDC Meeting: Health Statistics** – CDC convenes a meeting of the Board of Scientific Counselors, National Center for Health Statistics to discuss Healthy People 2030, maternal mortality data, among other agenda items. [Details](#).
- **September 17-September 18 – FDA Meeting: Vaccines** – FDA hosts a meeting titled, “Considerations for the Use of Real-World Evidence to Assess the Effectiveness of Preventive Vaccines.” [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

Thurs. (9/10)

- **The House Energy and Commerce Committee** favorably reported 26 health-related bills by a voice vote at a [virtual markup](#) of 38 mostly bipartisan bills. They addressed a range of issues relating to Medicare, coverage, mental and behavioral health, opioid crisis, child health, women’s health, health disparities, and medical research. [Details](#).

Wed. (9/9)

- **Senate HELP Committee** convened a [hearing](#) to examine the Administration’s efforts to develop a COVID-19 vaccine and increase uptake of regularly scheduled vaccines. [Details](#).

Tue. (9/8)

- **Senate Majority Leader Mitch McConnell (R-KY)** unveiled a scaled-back coronavirus relief package containing approximately \$500 billion in federal aid focused on health care, education, and the economy. [Details](#).

REGULATORY LOOKBACK

Fri. (9/11)

- **NIOSH [announced](#)** a request for information regarding the use of “elastomeric half-mask respirators” healthcare settings during the COVID-19 pandemic. Comments are due by October 14, 2020. [Details](#).

Wed. (9/9)

- **HHS [released](#)** a request for information (RFI) to assess whether Clinical Laboratory Improvement Amendments (CLIA)-certified/accredited laboratories are able to provide added COVID-19 testing if additional testing equipment from Thermo Fisher Scientific were made available. Responses are due by September 20, 2020. [Details](#).
- **HHS [released](#)** details about the \$2 billion Provider Relief Fund (PRF) performance-based incentive payments for nursing homes. [Details](#).
- **HHS [announced](#)** it had issued [guidance](#) under the Public Readiness and Emergency Preparedness Act (PREP Act) that expands authorization for certain pharmacists to order and administer COVID-19 vaccinations. [Details](#).

Tue. (9/8)

- **FDA** [updated](#) the consolidated list of guidance documents available regarding the COVID-19 public health emergency (PHE). [Details.](#)
- **HRSA** [awarded](#) more than \$79 million for construction and other capital support to 165 HRSA-funded health centers impacted by disasters in calendar year (CY) 2018 and 2019. [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. 22:** FDA is collecting comments on post-marketing pediatric-focused safety reviews of products marketed between September 23, 2019, and September 1, 2020. [Details.](#)
- **Sept. 22:** 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. [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. 2:** CMS is collecting comments on a proposed rule to expedite and increase coverage of innovative medical devices. [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.](#)