

Wynne Health Group Weekly



FRAMING THE WEEK

The **Republican National Convention** kicks off today, beginning with an in-person roll call to officially nominate President Trump. On Thursday, President Trump will “further illuminate” his second term [“core priorities.”](#) This President’s health care to-do list includes reducing prescription drug prices and ending surprise medical billing, two issues that have alluded both the Trump administration and Congress, as well as other aspirations – prioritizing patients; lowering premiums; covering all pre-existing conditions; and protecting Social Security, Medicare, and veterans.

On Saturday, the President [tweeted](#) that he signed the **avored nations pricing executive order** last week ahead of the 30-day deadline (August 24) given to pharmaceutical companies to reach a deal on an alternative. The executive order is expected to require the Department of Health and Human Services (HHS) to issue a regulation that sets Medicare Part B drug reimbursements to the lowest among the prices of other medically advanced countries.

Meanwhile, Democrats will resume their probe into the operations of the **U.S. Postal Service**, following House passage largely along party lines (257-150) of the Delivering for America Act ([H.R. 8015](#)) on Saturday. Unconvinced by Postmaster General Louis DeJoy’s [assurances](#) that controversial operational changes will be suspended “to avoid even the appearance of any impact on election mail,” House Speaker Nancy Pelosi (D-CA) [interrupted](#) the chamber’s summer recess with the weekend vote. Senate Majority Leader Mitch McConnell (R-KY) [said](#) the Senate would not take up “House Democrats’ piecemeal postal bill,” noting President Trump would not sign the legislation into law. The House is scheduled to reconvene for floor votes on September 14, and the Senate will return on September 8.

The Delivering for America Act would revoke operational changes to the Postal Service – including reduction of office or facility hours, restriction on the use of overtime, and any changes that would have the effect of delaying mail – until the end of the COVID-19 public health emergency or January 31, 2021, whichever is later. It also includes provisions aimed specifically at safeguarding mail-in ballots. An additional \$25 billion would be made available to the Postal Service.

This morning, Postmaster General DeJoy and Chairman of the U.S. Postal Service Board of Governors Robert M. Duncan will [testify](#) before the **House Oversight Committee**. They will be questioned about the impact of operational changes on delivering **prescription medicines** and other essential goods, as well as mail-in voting.

House Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ), Health Subcommittee Chairwoman Anna Eshoo (D-CA), and Oversight and Investigations Subcommittee Chair Diana DeGette (D-CO) are also [investigating](#) the impacts of the operational changes to the Postal Service on the delivery of prescription medicines. They [requested](#) information by September 11, 2020 from CVS Health, Express Scripts, National Association of Chain Drug Stores, Optum Rx, Pharmaceutical Care Management Association, Rite Aid,

and Walgreens on their mail-order delivery services and any complaints received from patients and customers regarding delayed or lost deliveries. House Democrats also asked whether Postmaster General DeJoy's operational changes at the Postal Service should be reversed, potential impacts of these changes if implemented, and any actions they plan to take to mitigate any adverse effects. **Sens. Elizabeth Warren (D-MA) and Bob Casey (D-PA)** are conducting their own [investigation](#) into the Postal Service and mail order prescriptions and have reached out to Cigna and Express Scripts, CVS Health, Walgreens Boots Alliance, UnitedHealth and Optum, and Humana.

Leader McConnell [indicated](#) that House approval of legislation focused only on the Postal Service could create an opportunity for negotiations on a more limited COVID-19 relief package. Senate Republicans are expected to include \$10 billion in assistance to the Postal Service in the **Delivering Immediate Relief to America's Families, Schools and Small Businesses Act**, a scaled-back version of their roughly \$1 trillion coronavirus relief package. The "skinny" plan is expected to:

- Extend the expired federal unemployment benefit at \$300 per week through December 27 (consistent with the President's [memorandum](#));
- Include liability protections for health care providers, businesses, and schools through at least October 1, 2024;
- Provide \$158 billion to the Paycheck Protection Program, allowing only eligible small businesses to obtain a second round of loans from the Paycheck Protection Program (limited to entities with 300 or fewer employees that experienced at least a 35 percent reduction in gross revenue during the first half of 2020 relative to 2019); and
- Provide \$105 billion for schools and universities, \$29 billion for vaccine and drug development and distribution, and \$16 billion for testing and contact tracing.

Speaker Pelosi, however, continues to push for more comprehensive aid. In her latest [Dear Colleague letter \(August 23\)](#), she points to experts' support for Democrats' funding priorities in the Heroes Act, painting a stark contrast with Republicans. Last week, Speaker Pelosi rejected calls from Democrats to vote over the weekend on narrow economic relief measures, such as an extension of the expired weekly \$600 federal unemployment benefit, stating in a [Dear Colleague letter \(August 20\)](#), "we must consider their timing and strategic value. They cannot come at the expense of addressing the priorities of the Heroes Act — particularly support for our heroes in state and local government and education, who are in crisis."

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. (8/24)

- **10:00am – Hearing: U.S. Postal Service** – The House Oversight and Reform Committee convenes a hearing titled, "Protecting the Timely Delivery of Mail, Medicine, and Mail-in Ballots." [Details](#).

Tue. (8/25)

- **3:00pm-3:30pm – CMS Call: COVID-19** – CMS hosts a COVID-19 call for home health and hospice to discuss the agency’s latest COVID-19 guidance. [Details.](#)
- **3:00pm-4:00pm – ACL Webinar: COVID-19** – The Administration for Community Living (ACL) hosts a webinar titled, “Creative Engagement: Successful Approaches to Creatively Engage with Older Adults.” [Details.](#)
- **5:00pm-6:00pm – CMS Call: COVID-19** – CMS hosts a COVID-19 office hours call for hospitals, health systems, and providers to ask questions of agency officials regarding CMS’s temporary actions that empower local hospitals and healthcare systems to: (1) Increase Hospital Capacity – CMS Hospitals Without Walls; (2) Rapidly Expand the Healthcare Workforce; (3) Put Patients Over Paperwork; and (4) Further Promote Telehealth in Medicare. [Details.](#)

Wed. (8/26)

- **12:00pm-3:30pm – NASEM Forum: Mental Health and Substance Use Disorders** – The National Academies of Sciences Engineering Medicine hosts a forum titled, “Caring for People with Mental Health and Substance Use Disorders in Primary Care Settings.” [Details.](#)
- **10:00am-4:00pm – CDC Meeting: Immunizations** – CDC convenes a meeting of the Advisory Committee on Immunization Practices to discuss COVID-19 vaccines, among other topics. [Details.](#)
- **12:15pm-1:15pm – FDA Town Hall: COVID-19** – FDA hosts a virtual Town Hall for clinical laboratories and commercial manufacturers that are developing or have developed diagnostic tests for SARS-CoV-2. [Details.](#)
- **4:30pm-5:00pm – CMS Call: COVID-19** – CMS hosts a COVID-19 call for nursing homes to discuss the agency’s latest COVID-19 guidance. [Details.](#)
- **5:30pm-6:00pm – CMS Call: COVID-19** – CMS hosts a COVID-19 call for dialysis organizations to discuss the agency’s latest COVID-19 guidance. [Details.](#)

Thurs. (8/27)

- **10:00am-1:15pm – SAMHSA Meeting: Mental Health** – SAMHSA convenes a meeting of the Center for Mental Health Services National Advisory Council to discuss SAMHSA response to COVID-19, among other topics. [Details.](#)
- **1:30pm-3:00pm – CMS Listening Session: Opioid Crisis** – CMS hosts a Medicare Learning Network event titled, “Dr. Todd Graham Pain Management Study Listening Session,” to solicit feedback on substance use disorder treatments, technologies, and models that Medicare should cover. [Details.](#)
- **3:00pm-3:30pm – CMS Call: COVID-19** – CMS hosts a COVID-19 call for nurses to discuss the agency’s latest COVID-19 guidance. [Details.](#)

Fri. (8/28)

- **8:30am-12:30pm – FDA Meeting: Drug Development** – FDA hosts a public meeting to provide an opportunity for grantees funded as part of the FDA Standard Core Clinical Outcome Assessments (COAs) and Endpoints Pilot Grant Program to share their development plans for the standard core COA sets and to receive feedback from stakeholders. [Details.](#)

Additional Multi-Day Events

- **August 25-August 26 – HHS Meeting: Health Statistics** – HHS convenes a meeting of the National Committee on Vital and Health Statistics to consider three new operating rules for federal adoption: (1) CAQH CORE Prior Authorization Data Content Rule; (2) CAQH CORE Prior Authorization Infrastructure Rule; and (3) CAQH CORE Connectivity Rule. [Details.](#)
- **August 25-August 28 – FDA Conference: Regulations** – FDA hosts the Regulatory Education for Industry (REI) Annual Conference. [Details.](#)

- **August 26-August 27 – HHS Meeting: Blood and Tissue Safety** – HHS convenes a meeting of the Advisory Committee on Blood and Tissue Safety to discuss the experiences of hospitals and blood centers amid the COVID-19 pandemic, among other topics. [Details](#).

FEATURED WHG ANALYSIS

- **WHG Chart: Biden Campaign vs. Trump Administration Health Care Policies** – In the Policy Hub Insight Bank [here](#).
- **WHG COVID-19 Government Response Catalogue** – Updated 7/31/20 – In the Policy Hub Insight Bank [here](#).
- **Updated WHG Legislative and Regulatory Outlook** – In the Policy Hub Insight Bank [here](#).
- **Chart: Key Federal COVID-19 Funding Opportunities for Providers & Hospitals** – Updated 7/17/20 – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Mon. (8/17)

- **Chairman of the Senate Committee on Agriculture**, Sen. Pat Roberts (R-KS), sent a [letter](#) to USDA Secretary Sonny Perdue urging the Department to continue providing school meal and child nutrition program flexibilities. [Details](#).

REGULATORY LOOKBACK

Thurs. (8/20)

- **HHS [announced](#)** that the FDA will not require premarket review or emergency use authorization (EUA) of laboratory developed tests (LDTs) for COVID-19. [Details](#).
- **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. Comments are due October 19. [Details](#).
- **CMS** recently opened a 30-day federal public comment period on a section 1115 Medicaid demonstration waiver application submitted by the State of Colorado. Comments are due Sept. 12. [Details](#).
- **PTAC** is scheduled to hold a virtual public meeting on Tuesday, September 15, 2020 and Wednesday, September 16, 2020. The Committee will hear from the Preliminary Review Teams (PRTs) and the public on two physician-focused payment model (PFPM) proposals. [Details](#).
- **CMS** is convening a [listening session](#) on August 27 (1:30pm-3:30pm ET) to discuss the Dr. Todd Graham Pain Management Study – a study mandated by the SUPPORT Act aimed at improving access to non-opioid treatment options for acute and chronic pain management in Medicare. [Details](#).
- **HRSA** awarded \$35 million to 50 rural organizations in 33 states in order to increase access to quality health care in rural communities. [Details](#).
- **HHS [announced](#)** that the Defense Production Act is being leveraged for contracts with Becton Dickinson and Quidel Corporation for large volume purchase of diagnostic systems and assays for COVID-19 testing. [Details](#).

Wed. (8/19)

- **HHS, HUD, and the USDA** issued a joint [informational bulletin](#) for state agencies and interested stakeholders regarding existing federal resources and programs that are intended to improve health and housing outcomes in rural America, particularly for older adults and people with disabilities. [Details](#).

- **HRSA** is [proposing](#) to include a hepatitis C screening in an update to the Bright Futures Periodicity Schedule for the Preventive Services Guidelines for Infants, Children, and Adolescents. [Details](#).
- **CMS** [updated](#) the requirements for the 20 percent increase in weighting factor for hospitals treating and discharging Medicare beneficiaries with COVID-19 to include a positive COVID-19 laboratory test. This is effective for admissions occurring on or after September 1, 2020. [Details](#).
- **HHS** [issued](#) an [amendment](#) to increase access to childhood vaccines under the Declaration Under the Public Readiness and Emergency Preparedness (PREP) Act for Medical Countermeasures Against COVID-19. [Details](#).
- **HRSA** recently announced 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. The application deadline is November 16. [Details](#).

Tue. (8/18)

- **CMS** issued an [informational bulletin](#) for states regarding the treatment of third party payers (TPP) in determining the hospital-specific Medicaid disproportionate share hospital (DSH) payment limits for the state plan rate year (SPRY) 2017 DSH audits. [Details](#).
- **FDA** [issued](#) final guidance on the compliance policy for the quantity of bioavailability (BA) and bioequivalence (BE) samples retained under 21 CFR 320.38(c). [Details](#).
- **USPSTF** [issued](#) a final recommendation statement in support of behavioral counseling for all sexually active adolescents and adults who are at increased risk for sexually transmitted infections (STIs). [Details](#).
- **HHS’ Office of Disease Prevention and Health Promotion** [released Healthy People 2030](#), its plan to improve the nation’s health over the next decade. [Details](#).
- **CMS** announced it will resume routine inspections of all providers and suppliers, along with updated enforcement guidance to states regarding these inspections. The agency also released an updated nursing home toolkit intended to support facilities during the COVID-19 pandemic. [Details](#).

Mon. (8/17)

- **HHS** [announced](#) the release of a [report](#) by the Assistant Secretary for Planning and Evaluation (ASPE) that details advances in kidney care since the President’s Executive Order took effect last year. [Details](#).
- **CMS** published a new state health official (SHO) letter that describes how state Medicaid agencies, Medicaid managed care plans (MCOs), Children’s Health Insurance Program (CHIP) agencies, and CHIP managed care entities should implement the May 2020 Interoperability and Patient Access [final rule](#), and to do so in a manner consistent with the 21st Century Cares Act. [Details](#).

COMMENT & APPLICATION DEADLINES

- **Aug 26:** OASH and the HHS Office of Minority Health announced a funding opportunity intended to help build the capacity of state, tribal, and territorial governmental health agencies to test changes to existing public health programs or practices to determine if the modified interventions substantially improve health outcomes for selected health issues. [Details](#).
- **Aug. 28:** 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. [Details](#).

- **Aug. 28:** HHS [announced](#) it would extend the deadline until August 28 for Medicaid, Children's Health Insurance Program (CHIP), and dental providers to apply for the \$15 billion relief announced last month (WHG client [summary](#)). See steps for applying [here](#). [Details](#).
- **Aug. 31:** BARDA is now accepting applications for its 2020 Industry Day Lightning Talks. Applications are due by 12 PM ET on August 31 and BARDA will notify applicants if they have been selected to participate by mid-September. [Details](#).
- **Sept. 1:** HHS [announced](#) a funding opportunity to increase and fast-track the use of health information exchanges (HIEs) and improve linkages between state and local public health agencies. [Details](#).
- **Sept. 4:** CMS is accepting comments on the CY 2021 ESRD prospective payment system and rate update [proposed rule](#) with comment period. [Details](#).
- **Sept. 8:** The FDA [issued](#) a request for public comment on forming the strategic priorities for the Office of Women's Health. [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. 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.](#)