

Wynne Health Group Weekly



FRAMING THE WEEK

While initially speeding out of the gate with a large “Phase 4” recovery bill focused on infrastructure and other Democratic priorities, House Speaker Nancy Pelosi (D-CA) released a [Dear Colleague](#) over the weekend acknowledging that a bipartisan effort is needed to create a “**CARES 2**” package that will build off the last emergency relief measure – **CARES Act (H.R. 748)**. With public health officials indicating that we’ve just begun to see the beginning stages of this pandemic and unemployment claims soaring, the focus will remain squarely on the crisis.

Speaker Pelosi is calling for the “CARES 2” package to provide more relief – in the form of additional funding and resources for **hospitals and community health centers; states and localities; and small businesses**; and more generous **unemployment benefits** and additional **direct payments for individuals**. Regarding timing, floor action on a “CARES 2” package is not likely until later this month, as Congress is not expected to convene in Washington before April 20. Though Senate Majority Leader Mitch McConnell (R-KY) has embraced more of a wait-and-see approach on additional legislation, he noted the chamber would reconvene “if circumstances require the Senate to return for a vote sooner than April 20.”

In the meantime, lawmakers, including those in the newly formed House Select Committee on the Coronavirus Crisis, will continue with “forward looking” oversight of the Trump administration’s response to COVID-19 that will not focus on the Administration’s initial response to the ongoing public health crisis. Rather, the oversight will focus on the quick implementation of the three relief packages; the **Strategic National Stockpile**; and the cost of **COVID-19 treatment**, particularly for the uninsured.

The Centers for Medicare and Medicaid Services (CMS) may soon release detailed guidance on how providers and hospitals can use part of the \$100 billion federal aid package, appropriated in the CARES Act, to specifically cover **COVID-19 care for the uninsured**, following the administration’s [announcement](#) last Friday. “As a condition of receiving funds under this program, providers will be forbidden from balancing billing the uninsured for the cost of their care. Providers will be reimbursed at Medicare rates,” said HHS Secretary Alex Azar.

In addition, CMS is slated to publish the **final Rate Announcement for Medicare Advantage and Part D** today (WHG summaries of [Part I](#) and [Part II](#) of the Advance Notice).

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. (4/6)

- **12:00pm-12:30pm – AHP Webinar: COVID-19** – The Alliance for Health Policy (AHP), The Commonwealth Fund, and the National Institute for Health Care Management Foundation convene a webinar titled, “Advancing Prevention and Treatment: A Conversation with Dr. Mark McClellan” (former FDA Commissioner). [Details](#).

Tue. (4/7)

- **10:00am-4:00pm – HRSA Meeting: Organ Transplantation** – HRSA convenes a meeting of the Advisory Committee on Organ Transplantation. [Details](#).
- **11:45am-12:45pm – PCORI Webinar: COVID-19** – PCORI hosts a webinar titled, “Confronting COVID-19: Finding Hospital Capacity and Improving Patient Flow.” [Details](#).
- **2:00pm-3:30pm – MLN: Interoperability** – CMS hosts a Medicare Learning Network (MLN) to discuss the Interoperability and Patient Access final rule. [Details](#).

Wed. (4/8)

- **12:15pm-1:15pm – FDA Town Hall: COVID-19** – FDA hosts a virtual town hall titled, “Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests.” [Details](#).
- **3:00pm – ONC Webinar: Information Blocking** – ONC hosts a webinar for a Q&A with ONC leadership on information blocking. [Details](#).

Thurs. (4/9)

- No events scheduled.

Fri. (4/10)

- No events scheduled.

FEATURED WHG ANALYSIS

- **WHG Chart: Key Federal COVID-19 Funding Opportunities** – Providers & Hospitals – In the Policy Hub Insight Bank [here](#).
- **WHG COVID-19 Government Response Catalogue** – Last Updated 3/31/20 – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Thurs. (4/2)

- **MACPAC** met virtually for its April 2020 public meeting. WHG session summaries regarding dual eligible beneficiaries, the Medicare Shared Savings Program, maternity care in Medicaid, and Medicaid’s response to COVID-19, and Medicaid financing during economic crises, are available on Policy Hub [here](#).
- **House Speaker Nancy Pelosi** (D-CA) [announced](#) the formation of the House Select Committee on the Coronavirus Crisis – a select bipartisan oversight panel that will be chaired by Majority Whip Jim Clyburn (D-SC). The Select Committee will be charged with overseeing the implementation of appropriated funds made available through COVID-19 response legislation. [Details](#).
- **House O&R Committee Chairwoman** Carolyn Maloney (D-NY) sent a letter to Pharmaceutical Research and Manufacturers of America (PhRMA) requesting its member drug companies to commit to setting affordable list prices for medications, including vaccines, that may be used to prevent or treat COVID-19. [Details](#).

Wed. (4/1)

- **Fourteen House Committee Chairs** sent a [letter](#) to OMB Acting Director Russell Vought requesting an immediate extension of public comment periods, hearings and meetings due to the ongoing COVID-19 pandemic. They asked OMB to direct agencies to extend public comment periods, including those that closed between March 13 to present, by at least 45 days beyond the end of the declared national emergency. [Details](#).

REGULATORY LOOKBACK

Fri. (4/3)

- **CMS** released new guidance to state and local governments and long-term care facilities (i.e., nursing homes) to aid in limiting the spread of COVID-19. The guidance contains five new recommendations. [Details](#).
- **FEMA** published a [fact sheet](#) outlining the requirements private non-profit (PNP) organizations must meet in order to be eligible to apply for funding through the [Public Assistance \(PA\) Program](#). [Details](#).

Thurs. (4/2)

- **SAMHSA** announced a funding opportunity for emergency grants to address mental and substance use disorders during COVID-19. Eligibility is limited to states, territories, and tribes and SAMHSA anticipates awarding a total of \$110 million to 60 recipients. Applications due April 10. [Details](#).
- **HHS** [announced](#) that it has developed “crisis standards of care strategies” to optimize ventilator use in the face of unprecedented demand on hospital and ICU resources. [Details](#).
- **CDC** recently released [contingency and crisis capacity strategies](#) about decontamination and reuse of filtering facepiece respirators (FFRs). [Details](#).
- **ACL** is forecasting a grant opportunity for state governments to receive additional funding for their Aging and Disability Resource Centers (ADRC) in response to the COVID-19 pandemic through the No Wrong Door System. [Details](#).
- **DOJ and HHS** [announced](#) the DOJ’s COVID-19 Hoarding and Price Gouging Task Force has acquired hoarded personal protective equipment (PPE), including 192,000 N95 masks, 598,000 medical grade gloves, and 130,000 surgical masks. [Details](#).
- **FDA** [issued](#) guidance to address the urgent need for blood during the COVID-19 pandemic revising previous recommendations regarding blood donor eligibility in order to expand access to critically needed bloody supply. [Details](#).
- **CMS** announced it has extended the deadline for its request for information (RFI) on improving rural maternal and infant health to May 31. Full details on what is contained in the RFI is included [here](#). [Details](#).
- **GAO** recently announced it is accepting nominations for participation on the Board of Governors of the Patient-Centered Outcomes Research Institute (PCORI), due May 13. [Details](#).

Wed. (4/1)

- **CDC** released a [Morbidity and Mortality Weekly Report \(MMWR\)](#) titled, “Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019 – United States, February 12-March 28, 2020.” [Details](#).
- **FDA** issued two proposed amendments regarding the classification of certain hepatitis C virus (HCV) tests. Comments are due May 31. [Details](#).

- **ACL** announced two related funding opportunities to strengthen aging services for minority populations – the Minority Aging Technical Assistance & Resource Center (TARC) program and the Coordinating Center for the Minority Aging TARC program. [Details](#).
- **ACL** announced a funding opportunity to support testing and documentation of innovative practices that enhance the quality, effectiveness, and other proven outcomes of nutrition service programs (NSP) within the aging services network. Applications due May 26. [Details](#).
- **FCC** announced a new plan dedicating \$200 million to support health care facilities standing up telehealth programs in response to the COVID-19 pandemic. The funding comes from CARES Act appropriations made to the FCC. [Details](#).

Tue. (3/31)

- **CMS** issued an interim final rule implementing a sweeping array of new provider flexibilities for supporting the health care system’s response to the COVID-19 pandemic ([press release](#)). The changes leverage many of the avenues available to the agency in affecting policy, importantly including blanket 1135 waiver authority and the agency’s interim final rulemaking ability. [Details](#).
- **HRSA** [issued](#) final eligibility guidelines for the Reimbursement of Travel and Subsistence Expenses Towards Living Organ Donation Program. Comments due April 30. [Details](#).
- **FDA** [announced](#) the Coronavirus Treatment Acceleration Program (CTAP), a new program intended to expedite the development of safe and effective life-saving treatments. [Details](#).

Mon. (3/30)

- **FDA** [issued](#) Emergency Use Authorization (EUA) to allow chloroquine phosphate and hydroxychloroquine phosphate products to be distributed and used for patients with COVID-19. [Details](#).
- **FDA** [issued](#) two Emergency Use Authorizations (EUAs) to increase the supply of ventilators and respirators during the COVID-19 outbreak. [Details](#).
- **Vice President Pence** sent a [letter](#) to [hospitals](#) asking them to report data about both COVID-19 testing and hospital capacity on a daily basis. The administration intends to use the data to help better understand disease patterns and develop policies for [prevention](#) and control of COVID-19. [Details](#).
- **SAMHSA** announced a funding opportunity for fiscal year (FY) 2020 State Opioid Response (SOR) [grants](#), totaling \$1.42 billion. Applications are due May 19. [Details](#).
- **CDC** announced a funding opportunity for the “BOLD Public Health Centers of Excellence to Address Alzheimer’s Disease and Related Dementias.” Applications are due by May 26, 2020. [Details](#).
- **OCR** [issued](#) a [bulletin](#) reminding providers that discrimination based on race, color, national origin, disability, age, sex and religion are prohibited in HHS-funded programs, including in the provision of health care services during COVID-19. [Details](#).
- **ASPR** [announced](#) it will support vaccines in development by Janssen as well as Moderna and the National Institute of Allergy and Infectious Diseases (NIAID). [Details](#).
- **CMS** announced it is expanding advanced and accelerated payments for providers and suppliers to support response efforts to the COVID-19 outbreak ([fact sheet](#)). [Details](#).

Fri. (3/27)

- **CMS** released set of [FAQs](#) designed to give state Medicaid programs implementation guidance on the 6.2 percent increase in the Federal Medical Assistance Percentage (FMAP) for each state and territory, which was made possible under Section 6008 of the Families First Coronavirus Response Act. [Details](#).

- **FNS** announced various regulatory waivers to ease operation and ensure beneficiary access in the SNAP, WIC, and school-based Child Nutrition Programs. [Details](#).

COMMENT & APPLICATION DEADLINES

- **Apr. 9:** FDA issued final guidance on providing regulatory submissions in electronic format and a [request for comments](#) on the draft Electronic Common Technical Document (eCTD) v4.0 Technical Conformance Guide. [Details](#).
- **Apr. 12:** CMS released a request for information (RFI) seeking input on ways to improve access, quality, and outcomes for rural maternal and infant health. [Details](#).
- **Apr. 14:** OMB released a solicitation for comments on questions posed by the Interagency Technical Working Group on Evaluating Alternative Measures of Poverty regarding the development of additional measures for poverty, beyond the current Official Poverty Measure (OPM) and Supplemental Poverty Measure (SPM). [Details](#).
- **Apr. 15:** FDA [issued](#) a request for information (RFI) related to the use of vaping products that are associated with lung injuries, to gather information from the public that could help identify and evaluate additional steps the agency could take to address the recent surge in lung injuries associated with e-cigarettes and vaping. [Details](#).
- **Apr. 18:** CMS released a proposed rule that establishes Civil Monetary Penalties (CMPs) for group and non-group health plans that do not fulfill their Medicare Secondary Payer reporting obligations. [Details](#).
- **Apr. 20:** CMS published a [notice of proposed rulemaking](#) (NPRM) that would revise and modernize requirements for Preadmission Screening and Resident Review (PASRR) in Medicaid-certified nursing facilities (NFs). [Details](#).
- **Apr. 22:** USDA issued two new proposed rules that will roll back certain Obama-era requirements in the National School Lunch Program (NSLP), the School Breakfast Program (SBP) and the Summer Food Service Program (SFSP). [Details](#).
- **Apr. 23:** OASH within HHS seeks public comment regarding Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act, addressing recommendations for maintaining an adequate national blood supply. [Details](#).
- **Apr. 23:** AHRQ [issued](#) a request for information to inform their review on platelet-rich plasma (PRP) for wound care in the Medicare population. [Details](#).
- **Apr. 24:** CMS released a proposed rule that would extend the CMMI's Comprehensive Care for Joint Replacement (CJR) model for an additional three-years. [Details](#).
- **Apr. 24:** FDA [issued](#) a proposed amendment to reclassify HIV diagnostic and supplemental tests into class II (special controls), subject to premarket notification. [Details](#).
- **Apr. 24:** CMS seeks applications for its Medicare Advantage Value-Based Insurance Design (MA VBID) by 11:59 pm ET on Friday, April 24, 2020. [Details](#).
- **May 5:** FDA [issued](#) draft guidance on the inclusion of older adults in cancer clinical trials. The agency notes that older adults are those ages 65 and older, and the guidance emphasizes the particular importance of including adults over the age of 75 in clinical cancer trials. [Details](#).
- **May 7:** HRSA invites nominations for qualified tribal officials for appointment as voluntary delegate members on the HRSA Tribal Advisory Council (TAC). [Details](#).
- **May 18:** USDA is accepting comments on a [proposed rule](#) titled "Employment and Training Opportunities in the Supplemental Nutrition Assistance Program (SNAP)." [Details](#).
- **May 18:** NIH [issued](#) an RFI to assist in the development of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Strategic Plan. The NIDDK's goal is to develop a broad vision for accelerating research into the causes, prevention, and treatment of diseases and conditions within the Institute's mission. [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](#).
- **Aug. 3:** CDC [announced](#) it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee (HICPAC). [Details](#).