

Wynne Health Group Weekly



FRAMING THE WEEK

Congress remains at a stalemate over approving additional COVID-19 aid after Senate Democrats and Republicans blocked each other proposals last Thursday. However, pressure is mounting for Congress to act, as funding for **Paycheck Protection Program (PPP) loans** for small businesses dwindles and the unemployment rate climbs. According to Treasury Secretary Steven Mnuchin, \$90 billion in PPP loan applications have been approved and another \$100 billion are being processed, leaving a balance of about \$160 billion.

Senate Majority Leader Mitch McConnell (R-KY) is [seeking](#) a “clean PPP funding increase” of \$250 billion, while House Speaker Nancy Pelosi (D-CA) and Senate Minority Leader Chuck Schumer (D-NY) are calling for a more expansive [interim emergency coronavirus package](#) – including, \$250 billion in small business assistance (as well as PPP changes), \$100 billion for the **Provider Relief Fund**, \$150 billion for state and local governments via the **Coronavirus Relief Fund**, and a 15 percent increase to the maximum **SNAP benefit**. Democratic leaders are also [demanding](#) additional funding for production and distribution of **national rapid testing and personal protective equipment (PPE)**, as well as public reporting of **demographic information of patients with COVID-19**. Senate Democrats are focused on negotiating with Secretary Mnuchin in hopes that securing President Trump’s endorsement will pressure Senate Republicans to support the more expansive package.

Leader McConnell has [said](#) that he is “in favor of even more funding for hospitals and providers down the line” but “need[s] to see the existing funding begin to work before we can know what additional resources may be needed.”

Last Friday, the Department of Health and Human Services (HHS) [released](#) details on how the **first \$30 billion of the \$100 billion Provider Relief Fund**, created by Coronavirus Aid, Relief, and Economic Security (CARES) Act ([H.R. 748](#)), will be allocated and disseminated. Facilities and providers that received Medicare fee-for-service (FFS) reimbursements in 2019 are eligible for the rapid distribution.

While the Trump administration’s plan for the remaining \$70 billion is not yet available, HHS noted it is working to develop targeted distributions that will focus on: (1) providers in areas particularly impacted by the COVID-19 outbreak; (2) rural providers; (3) providers who deliver services with lower shares of Medicare reimbursement or who predominantly serve the Medicaid population; and (4) providers requesting reimbursement for the treatment of uninsured Americans. HHS reiterated the administration’s position that a portion of the \$100 billion will be used to reimburse health care providers, at Medicare rates, for **COVID-related treatment of the uninsured**. Of note, providers must abstain from **balance billing** any patient for COVID-19 related treatment as a condition of receiving funds from the Provider Relief Fund.

On a related note, Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) and House Energy and Commerce (E&C) Committee Ranking Member Greg Walden

(R-OR) are calling for the next COVID-19 relief package to contain a measure to protect patients from **surprise medical bills**, including bills unrelated to COVID-19. Along with E&C Committee Chairman Frank Pallone, Jr. (D-NJ), they support resolving payment disputes using benchmark payments set at the median contracted rate and allowing independent dispute resolution (i.e., arbitration) for services for which the median contracted rate is greater than \$750 in 2022. Democrats have not yet indicated whether they support including surprise medical billing provisions in a COVID-19 package or prefer to address the issue in an end-of-year package reauthorizing health care extenders, which expire on November 30, 2020.

As for the timing of more comprehensive legislation on COVID-19, floor action remains unclear and complicated. Lawmakers are scheduled to return to Washington next week, but the House Rules Committee is pursuing **alternatives to in-person voting**, such as remote voting or proxy voting – both of which would require a rule change. While the House and Senate are out of session, legislation can only be passed by a voice vote or unanimous consent.

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. (4/13)

- No events scheduled.

Tue. (4/14)

- **3:00pm-4:30pm – FDA Webinar: CLIA Waiver** – FDA hosts a webcast about the Clinical Laboratory Improvement Amendments (CLIA) Final Guidances. [Details](#).

Wed. (4/15)

- **8:30am-4:30pm – ONC Meeting: Health IT** – ONC convenes a meeting of the Health IT Advisory Committee. [Details](#).
- **12:15pm-1:15pm – FDA Town Hall: COVID-19** – FDA hosts a virtual town hall for clinical laboratories and commercial manufacturers to help answer technical questions about the development and validation of diagnostic tests for SARS-CoV-2. [Details](#).

Thurs. (4/16)

- **1:00pm-2:30pm – FDA Webinar: Medical Devices** – FDA hosts a webinar to discuss and answer questions about the 510(k) Third Party Review Program final guidance. [Details](#).
- **2:00pm-3:00pm – CDC Webinar: COVID-19** – CDC hosts a Clinician Outreach and Communication Activity call titled, “Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID-19).” [Details](#).

Fri. (4/17)

- **Democratic Presidential Primary** – Wyoming will hold caucuses via vote-by-mail.

Additional Multi-Day Events

- **April 15-April 16 – FDA Forum: Generic Drugs** – FDA hosts a virtual forum to provide information to help applicants achieve success in the development of generic drug applications, known as Abbreviated New Drug Applications (ANDAs). [Details](#).

FEATURED WHG ANALYSIS

- **WHG Chart: Key Federal COVID-19 Funding Opportunities for Providers & Hospitals** – Last Updated 4/10/20 – In the Policy Hub Insight Bank [here](#).
- **WHG Chart: Key Federal COVID-19 Funding Opportunities for Employers** – In the Policy Hub Insight Bank [here](#).
- **WHG Chart: Key Federal COVID-19 Funding Opportunities for State and Local Government** – In the Policy Hub Insight Bank [here](#).
- **WHG COVID-19 Government Response Catalogue** – Last Updated 4/7/20 – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Thurs. (4/9)

- **The Senate** failed to pass a measure (by unanimous consent) to provide additional COVID-19 relief, as each party rejected the other's proposal. [Details](#).

Wed. (4/8)

- **Sens. Jeanne Shaheen (D-NH) and Bill Cassidy (R-LA)** [led](#) a bipartisan [letter](#) to HHS Secretary Alex Azar and CMS Administrator Seema Verma, calling for more flexibility on interest rates and repayment of Medicare's accelerated advance payments. [Details](#).
- **Senate Finance Chairman and Ranking Member** Chuck Grassley (R-IA) and Ron Wyden (D-OR), House Ways and Means Chairman and Ranking Member Richard Neal (D-MA) and Kevin Brady (R-TX), and Sen. Richard Blumenthal (D-CT) [submitted](#) a [request](#) to the HHS OIG for a review of the use of psychotropic antipsychotic drugs in nursing facilities. [Details](#).
- **Democratic Reps.** Joe Neguse (CO), Ben Ray Lujan (NM), Andy Levin (MI), and Tom Malinowski (NJ) recently [introduced](#) the Coronavirus Community Relief Act ([legislative text](#)), to provide \$250 billion in COVID-19 relief funding to local governments with a population of 500,000 or less. [Details](#).
- **House Oversight and Reform Committee Chairwoman** Carolyn Maloney (D-NY) [released](#) a new [report](#) compiled by HHS (at the request of the Committee) detailing the distribution of personal protective equipment (PPE) and supplies from the Strategic National Stockpile to states (as of April 6, 2020). [Details](#).

Tue. (4/7)

- **Senate Democrats** [unveiled](#) a proposal for a [“Heroes Fund”](#) to provide premium pay to frontline health care workers for potential inclusion in the forthcoming COVID-19 relief package. [Details](#).

Fri. (4/3)

- **MedPAC** convened a virtual session to vote on draft recommendations for inclusion in its forthcoming June 2020 Report to Congress. The event was closed to the public; however, meeting materials and a [full transcript](#) of the discussion are available. [Details](#).

REGULATORY LOOKBACK

Fri. (4/10)

- **HHS** issued a [press release](#) detailing how the first \$30 billion of the \$100 billion Provider Relief Fund created by the CARES Act will be allocated and disseminated. [Details.](#)
- **AHRQ** announced a forecasted funding opportunity focused on the telehealth expansion and the role of primary care during the COVID-19 pandemic. The opportunity is open to broad eligibility. [Details.](#)

Thurs. (4/9)

- **FDA** [issued](#) guidance to provide recommendations to health care providers and investigators on the administration and study of investigational convalescent plasma collected from individuals who have recovered from COVID-19. The guidance also details recommendations for the collection of COVID-19 convalescent plasma collections, including donor eligibility and labeling requirements. [Details.](#)
- **CMS** announced that hospital-specific reports (HSRs), will be available for review no later than Friday, April 10 via QualityNet, for the fiscal year (FY) 2021 Hospital Value-Based Purchasing (VBP) Program. The review and correction period begins Monday, April 13, 2020 and hospitals must submit requests for CMS' consideration by Tuesday, May 12, 2020. [Details.](#)
- **NIH** [announced](#) the launch of a clinical trial for hydroxychloroquine as a potential therapy for COVID-19. The clinical trial will evaluate the safety and effectiveness of hydroxychloroquine for the treatment of adults hospitalized with COVID-19. [Details.](#)
- **The Treasury Department and Federal Reserve**, along with other federal agencies, took several steps to provide economic relief to small and medium-sized businesses, households, and states and local governments affected by the COVID-19 pandemic. [Details.](#)
- **DEA** announced it is adjusting the 2020 aggregate production quotas for certain schedule II controlled substances and the assessment of annual needs for list I chemical ephedrine and pseudoephedrine. [Details.](#)
- **HRSA** awarded 1,387 health centers across the country a collective \$1.32 billion in funding through the CARES Act. A list of award recipients and funding amounts is available [here](#) by state. [Details.](#)
- **FEMA** [issued](#) a temporary final rule to distribute certain scarce personal protective equipment (PPE) for domestic use, so that these materials may not be exported from the U.S. unless exempted or with the explicit approval of FEMA. [Details.](#)

Wed. (4/8)

- **OASH** [announced](#) it is extending the comment period for the public to provide feedback on recommendations for maintaining an adequate national blood supply. Responses are now due on June 21, 2020. [Details.](#)
- **CMS** announced that it is delaying launch and implementation of the Innovation Centers' Emergency Triage, Treat, and Transport (ET3) model to the Fall of 2020. The model was originally slated to begin on May 1, 2020. [Details.](#)
- **FCC** [posted](#) a public inspection version of its Report and Order formally adopting the COVID-19 Telehealth Program. The program will distribute \$200 million in funding (as appropriated by the CARES Act) to providers seeking to establish telehealth systems for treating COVID-19 patients. [Details.](#)

Tue. (4/7)

- **HHS OIG** [released](#) the results of a "pulse survey" conducted with hospital administrators between March 23 and March 27, 2020. The survey was designed to provide decision makers at every level of government with a national snapshot of hospitals' challenges and needs in responding to the COVID-19 pandemic. [Details.](#)

- **ACL** posted a grant opportunity for state governments to apply to receive additional funding for their Aging and Disability Resource Centers' (ADRCs) response to the COVID-19 pandemic through the No Wrong Door System. Applications are due April 15. [Details](#).

Mon. (4/6)

- **CMS** released the final Calendar Year (CY) 2021 Medicare Advantage and Part D Rate Announcement ([fact sheet](#)). [Details](#).
- **CDC** released new [recommendations](#) for individuals to wear cloth face coverings in public settings where other [social distancing measures](#) are difficult to maintain. [Details](#).
- **FNS** recently [launched](#) the "[Meals for Kids](#)" Site Finder – an online tool to help families find meals for children while schools are closed during the COVID-19 pandemic. [Details](#).

Fri. (4/3)

- **SBA** issued an [interim final rule](#) ([press release](#)) providing additional guidance regarding the Paycheck Protection Program (PPP) established by the CARES Act. PPP loans are available to apply for until June 30, or until the funds run out. Interested applicants can apply for a PPP loan [here](#). [Details](#).

COMMENT & APPLICATION DEADLINES

- **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:** 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](#).
- **Apr. 30:** HRSA [issued](#) final eligibility guidelines for the Reimbursement of Travel and Subsistence Expenses Towards Living Organ Donation Program. Comments due April 30. [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 13:** GAO is accepting nominations for participation on the Board of Governors of the Patient-Centered Outcomes Research Institute (PCORI). [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](#).
- **May 31:** CMS released a request for information (RFI) seeking input on ways to improve access, quality, and outcomes for rural maternal and infant health. [Details](#).
- **May 31:** FDA is accepting comments on two proposed amendments regarding the classification of certain hepatitis C virus (HCV) tests. [Details](#).
- **June 1:** CMS is accepting comments on 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](#).
- **June 21:** 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](#).
- **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](#).