

*Wynne Health Group Weekly*



**FRAMING THE WEEK**

Congressional leaders and the Trump administration are closing in on an approximately **\$470 billion interim package** to provide additional **COVID-19 relief to small businesses, health care providers, and hospitals**. Congress is likely to vote on a package this week. House Republicans have indicated they will demand a recorded vote, requiring a majority of the chamber to return to Capitol Hill.

Specifically, the package adds \$310 billion to the [Paycheck Protection Program \(PPP\)](#) and \$60 billion to the [Economic Injury Disaster Loan \(EIDL\) Program](#) – both programs overseen by the Small Business Administration (SBA) that have run out of funding. Democrats managed to carve out \$60 billion of the new PPP funding for community-based lenders to ensure loans for minority and underserved areas. The agreement would also include additional health provider relief, though less than what Democrats had demanded – \$75 billion (instead of \$100 billion) for the **Provider Relief Fund** and \$25 billion (instead of \$30 billion) for **COVID-19 testing**.

Senate Majority Leader Mitch McConnell (R-KY) said the interim package would not include the additional \$150 billion for coronavirus relief for **state and local governments**, nor the 15 percent **SNAP benefit increase** sought by Democrats.

Lawmakers may include bipartisan policy fixes in this new package that would affect implementation of the CARES Act ([116-36](#)). First, the new package may include a provision creating an exception to allow **government-owned hospitals** – which includes a large chunk of **rural hospitals** and **rural health clinics** – to participate in the **Paycheck Protection Program**. The package may also include language waiving or reducing the 10.25 percent rate for **Medicare’s accelerated and advance payments**.

On the regulatory front, CMS is expected to soon release an additional array of **waiver flexibilities** to aid the COVID-19 response. A new interim final rule – the same rulemaking vehicle CMS used in its [first set](#) of waivers – [arrived](#) at OMB for review on April 14<sup>th</sup>. The rule would effectuate “additional policy and regulatory revisions” for providers responding to the COVID-19 pandemic, and could include specific flexibilities around **telehealth, providers’ scopes of practice, and reporting requirements**.

Such changes will add to the growing pool of temporary flexibilities that CMS is reportedly considering extending beyond the emergency period. While no details are yet confirmed, CMS Administrator Seema Verma remarked last week that the agency is eyeing the telehealth flexibilities in particular as potential changes to maintain after the pandemic’s conclusion.

As for the dispersal of the **Provider Relief Fund**, HHS Secretary Alex Azar informed lawmakers last week that HHS needs up to a week-and-a-half to finalize formulas and timelines for the next tranche of funding, despite Administrator Verma hinting that funding would be distributed by the end of last week. The second wave of funding will likely be aimed at more specific provider groups in need of additional support.

Last week, Senate Finance Democrats [urged](#) HHS to consider the following factors for future distribution of funds: (1) providers excluded by the methodology applied to the first tranche of funds (i.e., facilities and providers did not receive Medicare fee-for-service reimbursements in 2019), such as Medicaid-dependent safety net providers, and those with variable payer mix, including Medicare Advantage; (2) impact of lost revenues as a result of a moratorium on elective care; (3) burden on community-based organizations providing essential care to help keep patients at home; and (4) severity of the outbreak in a geographic area.

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. (4/20)**

- **10:00am-2:00pm – HRSA Meeting: Nurse Education** – HRSA convenes a meeting of the National Advisory Council on Nurse Education and Practice to discuss the nurse faculty shortage. [Details.](#)

### **Tue. (4/21)**

- **9:00am-5:00pm – NIH Meeting: Women’s Health** – NIH convenes a meeting of the Advisory Committee on Research on Women’s Health. [Details.](#)
- **10:00am-12:00pm – BPC Webinar: COVID-19** – The Bipartisan Policy Center (BPC) hosts a webinar titled, “COVID-19 Exposes Threat to America’s Broken Rural Health Care System: BPC Task Force Policy Recommendations,” featuring Sens. Chuck Grassley (R-IA) and Bill Cassidy (R-LA), Rep. Xochitl Torres Small (D-NM). [Details.](#)
- **11:45am-12:45pm – PCORI Webinar: COVID-19** – The Patient-Centered Outcomes Research Institute (PCORI) hosts a webinar titled, “Confronting COVID-19: Finding Hospital Capacity and Improving Patient Flow.” [Details.](#)
- **2:00pm-3:00pm – Brookings Webinar: COVID-19** – The Brookings Institute hosts a webinar titled, “Webinar: Public health surveillance, AI bias, and risks to privacy in the fight against COVID-19.” [Details.](#)
- **2:00pm-3:30pm – ACL Webinar: Alzheimer’s** – The Administration for Community Living (ACL) and other organizations host a webinar titled, “The Power of Partnership: Working together to support dementia caregivers and reach diverse communities.” [Details.](#)
- **2:00pm-3:30pm – ACL Webinar: Nutrition** – ACL hosts a webinar on innovative nutrition projects. [Details.](#)

### **Wed. (4/22)**

- **2:00pm-3:30pm – BPC Webinar: COVID-19** – BPC hosts a webinar on how AI is being used on the front lines of health to fight COVID-19. [Details.](#)

### **Thurs. (4/23)**

- **9:00am-5:00pm – NIH Meeting: Medical Research** – NIH convenes a meeting of the National Library of Medicine Board of Scientific Counselors. [Details.](#)
- **3:00pm-5:00pm – ACL/CMS Webinar: COVID-19** – ACL and CMS host a webinar titled, “Promising Practices Training Series: Ensuring Continuity of HCBS During the COVID-19 Pandemic.” [Details.](#)

#### **Fri. (4/24)**

- **12:00pm-1:00pm – ACL Webinar: Limb Loss** – ACL hosts a webinar about the new Amputee Coalition Support App. [Details](#).
- **1:30pm-3:00pm – FDA Webinar: Drug-Drug Interaction** – FDA hosts a webinar to discuss updates on FDA’s drug-drug interaction final guidances. [Details](#).

#### **Additional Multi-Day Events**

- **April 20-April 21** – FDA Workshop: Medical Product Surveillance – FDA hosts a public workshop to discuss the Sentinel Initiative, an active medical product surveillance system. [Details](#).

#### **FEATURED WHG ANALYSIS**

- **WHG COVID-19 Government Response Catalogue** – Last Updated 4/17/20 – In the Policy Hub Insight Bank [here](#).
- **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](#).

#### **CONGRESSIONAL LOOKBACK**

##### **Thurs. (4/16)**

- **Senate Finance Ranking Member Ron Wyden (D-OR)** and 11 other Democratic colleagues sent a [letter](#) to HHS Secretary Alex Azar, urging the Department to prioritize transparency, equity, and urgency when distributing the remaining \$70 billion in the Provider Relief Fund. [Details](#).

##### **Wed. (4/15)**

- **Senate HELP Committee Ranking Member Patty Murray (D-WA)** released a white paper titled, “A Roadmap to Reopening by Ensuring a Speedy and Ubiquitous Lab Testing System (RESULTS).” [Details](#).

##### **Tue. (4/14)**

- **E&C Chairman Pallone** and Oversight & Investigations Subcommittee Chair DeGette sent a letter urging HHS Secretary Alex Azar to ensure the work of the HHS Office of Inspector General (OIG) remains independent and to cooperate with all OIG evaluations, audits, and investigations. [Details](#).

##### **Mon. (4/13)**

- **Democratic health leaders** [sent a letter](#) to HHS Secretary Azar, Treasury Secretary Mnuchin, and Labor Secretary Scalia, urging the Administration to establish a new Special Enrollment Period (SEP) and increase awareness of the existing SEP for individuals who lose their employer-based health coverage. [Details](#).

#### **REGULATORY LOOKBACK**

##### **Fri. (4/17)**

- **NIH** [announced](#) a public-private partnership to accelerate the development of COVID-19 vaccine and treatment options. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership aims to develop an international strategy for a coordinated research response to COVID-19. [Details](#).
- **SBA** issued an [interim final rule](#) to supplement the first interim final rule on the Paycheck Protection Program (PPP), with additional guidance regarding eligibility for individuals with self-employment income and certain businesses. Comments are due May 20. [Details](#).

#### **Thurs. (4/16)**

- **President Trump** unveiled [“Guidelines for Opening Up America Again”](#) – guidance for states to reopen their economies in phases. [Details](#).
- **CMS** released the fiscal year (FY) 2021 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule ([fact sheet](#)). [Details](#).
- **CDC** issued a [request for comment](#) soliciting input on and experiences with pain and pain management to inform the agency’s assessment of the need for updating or expanding the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain. [Details](#).
- **The Treasury** [announced](#) that information about the Coronavirus Relief Fund for states, tribal governments, and eligible local governments, including information about what applicants need to do to access funds, as well as how funding amounts will be determined. [Details](#).

#### **Wed. (4/15)**

- **CDC and NIOSH** issued a [request for information](#) soliciting public comments to inform the scope of the World Trade Center (WTC) Health Program’s research funding cycle for fiscal year (FY) 2021. [Details](#).
- **CMS** announced it is nearly doubling Medicare payment for lab tests that use “high-throughput technologies” for rapidly detecting COVID-19 cases to \$100. [Details](#).

#### **Tue. (4/14)**

- **CDC** issued a funding opportunity to provide approximately \$46.7 million in supplemental funding to support activities aimed at strengthening the nation’s public health infrastructure; ensuring a competent, current, and connected public health system; and improving the delivery of essential services through capacity-building assistance. [Details](#).
- **DHS and FEMA** announced a funding opportunity for state, local, and tribal emergency management agencies – the FY 2020 Emergency Management Performance Grant Program COVID-19 Supplemental. [Details](#).

#### **Mon. (4/13)**

- **CMS** released proposed rules for fiscal year (FY) 2021 Medicare payment across three different payment streams: Skilled nursing facilities (SNF); the Hospice wage index and payment rate update; and Inpatient psychiatric facilities (IPF). [Details](#).
- **FCC** formally opened the application period for its COVID-19 telehealth program. Applications will be accepted on a rolling basis. [Details](#).
- **CMS** announced that MA organizations and other organizations that submit diagnoses for risk adjustment will now be able to submit telehealth diagnoses for risk adjustment, in response to the COVID-19 pandemic. [Details](#).
- **CMS** [announced](#) it is removing the non-invasive ventilators (NIV) product category from Round 2021 of the DMEPOS program, in response to the COVID-19 pandemic. [Details](#).
- **FDA** [issued](#) an Emergency Use Authorization (EUA) to decontaminate N95 and N95-equivalent respirators for reuse by health care workers in hospital settings. [Details](#).

- **Secretary Azar** sent a letter to hospital administrators detailing FAQs about the hospital, hospital laboratory, and acute care facility data reporting requested by Vice President Pence on March 29, 2020. [Details.](#)
- **HUD** Fair Housing Initiatives Program (FHIP) issued [funding opportunities](#) for three of its initiatives. The application deadline for each initiative is May 11, 2020. [Details.](#)
- **FDA** [issued](#) product specific guidance for [chloroquine phosphate](#) and [hydroxychloroquine phosphate](#) that provide recommendations on the design of bioequivalence studies to support abbreviated new drug applications. [Details.](#)
- **EBSA** released [FAQs](#) regarding implementation of the Families First Coronavirus Response Act, the CARES Act and other health coverage issues related to COVID-19. [Details.](#)
- **CMS, DOL, and the Treasury** released FAQs regarding the implementation of the Families First Coronavirus Response Act (FFCRA), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, and other health coverage issues related to COVID-19. [Details.](#)
- **FDA** [issued](#) final guidance on developing and labeling in vitro companion diagnostic devices for a specific group of oncology devices. [Details.](#)
- **CMS** released a comprehensive set of frequently asked questions (FAQ)s outlining the increased federal funding opportunities for Medicaid and CHIP, including information on how recent COVID-19-related congressional action has modified funding for these programs. [Details.](#)

## COMMENT & APPLICATION DEADLINES

- **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 6:** SBA is accepting comments on an [interim final rule](#) 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. [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](#).