

Wynne Health Group Weekly



FRAMING THE WEEK

Democratic leaders are beginning to float proposals for a fifth **COVID-19 relief package** that could rival the \$2 trillion CARES Act ([Pub. L. 116-136](#)). However, Senate Majority Leader Mitch McConnell (R-KY) indicated another package would likely not be considered until members return to Washington next week at the earliest. Leader McConnell has also expressed serious concerns over the national debt and suggested states declare bankruptcy (currently not allowed under current law) instead of receiving federal aid, setting up a political battle that could further delay legislative action.

Meanwhile, President Trump has already [tweeted](#) his wish list for the next legislative package – including “fiscal relief to **state/local governments** for lost revenues from COVID-19,” “**infrastructure investments** for bridges, tunnels, broadband” and “**payroll tax cuts**.”

When asked last Friday how much funding is needed in the next bill for state and local governments, House Speaker Nancy Pelosi (D-CA) called for a level comparable to the amount given to small businesses, which would be close to \$700 billion. A bipartisan bill [unveiled](#) by Sens. Bob Menendez (D-NJ) and Bill Cassidy (R-LA), which would create a \$500 billion fund to provide relief to states and localities, may be a viable option, especially since it aligns with a recent request made by the [National Governors Association](#). The legislation would also expand eligibility to include counties and towns with populations of 50,000 or greater and allow funds to be used for lost revenues. The \$150 billion Coronavirus Relief Fund, made available in the CARES Act, is limited to jurisdictions with at least 500,000 people and may only be used to cover new costs of responding to the pandemic.

Senate Minority Leader Chuck Schumer (D-NY) also said Democrats would continue to push for other priorities, including federal assistance for people having trouble paying **rent; hazard pay** for essential workers, and a 15 percent increase in **Supplemental Nutrition Assistance Program (SNAP) benefits**.

Today, health care providers can begin registering for the [Health Resources and Service Administration \(HRSA\)’s program](#) in order to seek **reimbursement for COVID-19 related testing and treatment for uninsured patients** furnished on or after February 4, 2020. Providers will be reimbursed at Medicare rates, subject to available funding. Regarding next steps, providers can begin submitting claims electronically on May 6 and expect to receive reimbursements in mid-May.

In addition, \$10 billion allocated for **rural health clinics and hospitals** and \$400 million to **Indian Health Service facilities** may be distributed as soon as this week. Funding will be allocated based on operating expenses. HHS [noted](#) that certain providers, including **skilled nursing facilities, dentists, and providers that solely take Medicaid**, will receive further, separate funding. The administration did not provide further insight into how much these providers should expect or what factors will be considered when determining the additional amounts.

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. (4/27)

- **8:00am-4:00pm – HRSA Meeting: Stem Cell Transplantation** – HRSA convenes a meeting of the Advisory Council on Blood Stem Cell Transplantation. [Details](#).
- **9:00am-12:30pm – HHS Meeting: Tick-Borne Disease** – HHS convenes a meeting of the Tick-Borne Disease Working Group to review chapters being developed for the 2020 report to Congress on federal tick-borne activities and research. [Details](#).
- **11:00am-5:00pm – CMS Webinar: QHP** – CMS hosts the Qualified Health Plan (QHP) Issuer Conference. [Details](#).

Tue. (4/28)

- **Democratic Presidential Primary** – Ohio will hold primaries via vote-by-mail.
- **11:45am-12:45pm – PCORI Webinar: COVID-19** – The Patient-Centered Outcomes Research Institute hosts a webinar titled, “Confronting COVID-19: Finding Hospital Capacity and Improving Patient Flow.” [Details](#).

Wed. (4/29)

- **9:00am-4:30pm – CDC Meeting: Lead Exposure** – CDC convenes a meeting of the Lead Exposure and Prevention Advisory Committee. [Details](#).
- **11:00am-3:00pm – VA Meeting: Genomic Medicine** – VA convenes a meeting of the Genomic Medicine Program Advisory Committee to discuss various VA research programs, including the Million Veteran Program (MVP). [Details](#).
- **11:00am-4:45pm – CMS Webinar: QHP** – CMS hosts the QHP Issuer Conference. [Details](#).
- **12:00pm-5:00pm – HRSA Meeting: Graduate Medical Education** – HRSA convenes a meeting of the Council on Graduate Medical Education. [Details](#).
- **1:00pm-2:00pm – FDA Webinar: Drug Safety** – FDA hosts a webinar to provide an overview of the PADE Compliance Program, as well as discuss inspection findings and trends from PADE inspections completed in Fiscal Year 2019. [Details](#).

Thurs. (4/30)

- **12:00pm-1:30pm – ACL Webinar: COVID-19** – The Administration for Community Living (ACL) hosts a webinar titled, “Supporting Family Caregivers of Older Adults through Times of Stress and Isolation.” [Details](#).
- **12:30pm-3:50pm – CDC Meeting: Injury Prevention** – CDC convenes a meeting of the Board of Scientific Counselors, National Center for Injury Prevention and Control to discuss an update on the CDC Opioid Prescribing Estimates Project, the Management of Acute and Chronic Pain: Opportunities for Stakeholder Engagement, among other topics. [Details](#).
- **1:00pm-4:00pm – CMS Webinar: Healthcare Fraud** – CMS’ Healthcare Fraud Prevention Partnership hosts a virtual information sharing session. [Details](#).

Fri. (5/1)

- **10:00am – HRSA Meeting: Community-Based Linkages** – HRSA convenes a meeting of the Advisory Committee on Interdisciplinary, Community-Based Linkages. [Details.](#)

FEATURED WHG ANALYSIS

- **WHG COVID-19 Government Response Catalogue** – Last Updated 4/27/20 – In the Policy Hub Insight Bank [here.](#)
- **WHG Chart: Key Federal COVID-19 Funding Opportunities for Providers & Hospitals** – Last Updated 4/24/20 – In the Policy Hub Insight Bank [here.](#)
- **WHG Chart: Key Federal COVID-19 Funding Opportunities for Employers** – Last Updated 4/24/20 – In the Policy Hub Insight Bank [here.](#)
- **WHG Chart: Key Federal COVID-19 Funding Opportunities for State and Local Government** – Last Updated 4/24/20 – In the Policy Hub Insight Bank [here.](#)

CONGRESSIONAL LOOKBACK

Thurs. (4/23)

- **The House** passed the Senate-approved Paycheck Protection Program and Health Care Enhancement Act ([H.R. 266](#)) – a \$484 billion relief package to provide additional coronavirus relief to small business, health care providers, and hospitals, as well as provide funding to expand COVID-19 testing capacity. [Details.](#)

Tue. (4/21)

- **The Senate** passed by unanimous consent a \$484 billion interim package to provide additional coronavirus relief to small businesses, health care providers, and [hospitals](#), as well as provide funding to expand COVID-19 testing. [Details.](#)
- **CRS** published a brief report on the effect of the COVID-19 pandemic on organ donation and transplantation. [Details.](#)
- **CRS** published a [snapshot](#) of the domestic public health response to COVID-19, as of April 16, 2020, including actions taken by the White House; HHS, CDC, FDA, and FEMA; and Congress. [Details.](#)

Mon. (4/20)

- **Sens. Bob Menendez and Bill Cassidy** [announced](#) they will introduce bipartisan legislation to establish the State and Municipal Aid for Recovery and Transition (SMART) Fund – a \$500 billion fund to provide COVID-19 relief to state and local governments – when the Senate reconvenes. [Details.](#)
- **E&C Committee Chairman Frank Pallone** [sent](#) a [letter](#) to Coronavirus Task Force Coordinator Dr. Deborah Birx, requesting information on the Trump administration’s plans to expand testing and prepare for the easing of social distance guidelines. [Details.](#)
- **E&C Chairman Frank Pallone** and other Committee leaders [sent](#) a [letter](#) to HHS Secretary Alex Azar and FEMA Administrator Peter Gaynor, demanding detailed information on the acquisition and distribution of COVID-19 medical supplies. [Details.](#)
- **Senate Finance Committee Ranking Member Ron Wyden** [released](#) a [letter](#) from the Department of Labor (DOL) clarifying guidance regarding the Pandemic Unemployment Assistance (PUA) Program. [Details.](#)

REGULATORY LOOKBACK

Fri. (4/24)

- **HHS announced** it is extending the deadline for hospitals to submit data that will inform how \$10 billion is distributed to areas highly impacted by COVID-19. The new deadline is Saturday, April 25 by 3PM ET. [Details](#).
- **CDC** issued a supplemental funding opportunity titled, “Tribal Public Health Capacity-Building and Quality Improvement Umbrella Cooperative Agreement” (CDC-RFA-OT18-18030301SUPP20). [Details](#).

Thurs. (4/23)

- **SBA and the Treasury** released [Frequently Asked Questions \(FAQs\)](#) regarding Paycheck Protection Program (PPP) loans. [Details](#).
- **CMS** recently announced two sets of guidance documents affecting individual and group market health plan issuers, Medicare Advantage (MA) sponsors, and Medicare Part D sponsors. [Details](#).
- **CMS** announced new [guidance](#) that will allow independent freestanding emergency departments (IFEDs) to provide care to Medicare and Medicaid beneficiaries during the COVID-19 public health emergency. [Details](#).
- **CDC announced** it will [award](#) \$631 million in supplemental funding to 64 jurisdictions to support the COVID-19 response through the existing Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) cooperative agreement. [Details](#).

Wed. (4/22)

- **HHS announced** its plan for allocating and disseminating the remaining \$70B of the \$100B appropriated to the Provider Relief Fund under the CARES Act. [Details](#).
- **The Medicare Trustees** released their annual report outlining the future solvency of the Medicare program. Of note, the following projections do not account for the potential effects of the COVID-19 pandemic, as the Trustees believe it would not be possible to adjust their estimates accurately at this time. [Details](#).
- **CMS** issued a memorandum to all eligible qualified health plan (QHP) issuers announcing reporting flexibilities for the Quality Rating System (QRS), the QHP Enrollee Experience Survey, and Quality Improvement Strategy Programs (QIS). [Details](#).
- **HHS Office of the Secretary** sent a letter to administrators requesting that all [hospitals](#) report certain data elements by April 23, 2020. [Details](#).

Tue. (4/21)

- **CMS and ONC** officially published the final rules on interoperability, information blocking, and the ONC Health IT Certification Program in the Federal Register. Both rules are effective on June 30, 2020. [Details](#).
- **FDA issued** draft guidance on technical considerations for demonstrating reliability of emergency-use injectors. This guidance is intended to provide considerations for emergency-use injectors marketed with emergency-use products under a biologics license application (BLA), new drug application (NDA), or abbreviated new drug application (ANDA). [Details](#).
- **NIH** announced the first [treatment guidelines for COVID-19 patients](#), intended for healthcare providers. [Details](#).
- **FDA** issued final guidance on nonbinding feedback after certain FDA inspections of device establishments that identifies a standardized method for communicating and submitting requests for nonbinding feedback and describes how the agency responds to the requests. [Details](#).
- **HHS** announced \$955 million in grants from ACL to help communities meet the needs of older adults and people with disabilities as they work to minimize the spread of COVID-19. The grants, authorized through the Coronavirus Aid, Relief and Economic Security (CARES) Act, increase funding for ACL’s programs by 40 percent. [Details](#).

Mon. (4/20)

- CMS [issued](#) recommendations to re-open healthcare systems in communities that have low incidence of COVID-19 and are in Phase 1 of the Guidelines for Opening Up America Again. This guidance updates previous recommendations on limiting non-essential surgeries and medical procedures during the COVID-19 pandemic. [Details](#).

Fri. (4/17)

- CMS released an [article](#) providing guidance on implementing several provisions of the Coronavirus Aid, Relief, and Economic Security (CARES) Act related to Inpatient Prospective Payment System (IPPS) hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs). [Details](#).
- USDA's **Rural Development Service** announced the opening of a second application window for funding under the Distance Learning and Telemedicine (DLT) grant program with new funding from the CARES Act. Applications from rural applicants are due July 13. [Details](#).
- USDA's **Food and Nutrition Service** published a [notice](#) reopening the public comment period on a [request for information](#) issued in January on the Special Supplemental Nutrition Program for Women, Infants and Children (WIC Program) National Universal Product Code (NUPC) Database. [Details](#).
- CMS published [notice](#) to extend the comment period on a [notice of proposed rulemaking](#) (NPRM) that would revise requirements for Preadmission Screening and Resident Review (PASRR) by Medicaid-certified nursing facilities (NFs). [Details](#).

COMMENT & APPLICATION DEADLINES

- **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 15:** 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 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 20:** 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. [Details](#).
- **May 20:** CMS extended the comment period on 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](#).

- **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 1:** 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](#).
- **June 9:** CMS is accepting comments on 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](#).
- **June 15:** CMS requests comment on the fiscal year (FY) 2021 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule ([fact sheet](#)). [Details](#).
- **June 16:** 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](#).
- **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](#).