

Wynne Health Group Weekly



FRAMING THE WEEK

A remarkably busy week lies ahead, and the stakes are high – possible government shutdown on Friday, potential debt default in October, and 2022 midterm elections.

- **Government funding for fiscal year (FY) 2022 and the debt ceiling** – Today, the Senate will vote on a procedural motion to move to a floor vote of the House-passed continuing resolution ([H.R. 5305](#)). The continuing resolution would extend FY 2021 funding levels through December 3, 2021 and suspend the debt limit through December 16, 2022. This procedural vote is expected to fail, since Republicans are lockstep in their opposition to helping Democrats address the looming debt crisis. Still, a government shutdown amid the twin crises of the COVID-19 pandemic and the economic recession seems unlikely. Senate Minority Leader Mitch McConnell (R-KY) has [said](#) “Senate Republicans would support a clean continuing resolution that includes appropriate disaster relief and targeted Afghan assistance. We will not support legislation that raises the debt limit.” We could see the Senate pass a clean continuing resolution to avert the government shutdown and deal with the debt limit at a later time.
- **Traditional Infrastructure** – Today, the House will begin debate on the Infrastructure Investment and Jobs Act ([H.R. 3684](#)) – the bipartisan traditional infrastructure package passed by the Senate in August. The floor vote is scheduled for Thursday, September 30 – the expiration date of surface transportation authorization, which funds federal highway and public transportation programs (Fixing America’s Surface Transportation Act ([FAST Act](#); [P.L. 114-94](#))). With a razor-thin majority, House Speaker Nancy Pelosi (D-CA) can only lose three votes and needs progressives’ votes, whose support depends on reaching an agreement on the price tag and components of the budget reconciliation package.
- **Budget Reconciliation** – Over the weekend, the House Budget Committee [advanced](#) the \$3.5 trillion Build Back Better Act. The [legislation](#) is composed of the legislative recommendations submitted by all 13 committees of jurisdiction. It includes provisions allowing Medicare drug price negotiation; expanding Medicare coverage to include dental, hearing, and vision benefits; closing the Medicaid expansion coverage gap; and making permanent the enhancements to ACA premium tax credits. The package that ultimately passes the House and Senate appears likely to have a smaller price tag, given concerns raised by moderates, though it is unclear how exactly the multi-trillion package will be scaled down.

COVID-19

On Thursday, the Senate Health, Education, Labor and Pensions Committee will [question](#) Health and Human Services Secretary Xavier Becerra and Education Secretary Miguel Cardona about reopening schools during COVID-19. On the vaccine front, Pfizer/BioNTech has reported it plans to seek authorization

of its COVID-19 vaccination for children under 12 in the coming days. Pfizer says it will submit its data on children ages 5-11 to the Food and Drug Administration (FDA), who will then review the data to determine whether the vaccine is safe for children. The Centers for Disease Control and Prevention (CDC) Director Dr. Rochelle Walensky stated the full review process could occur “in the order of weeks.” Earlier this month, the FDA outlined how it will ensure the safety and efficacy of the vaccine for children [here](#).

Regulatory Update

The October 1 deadline for the release of a [second interim final rule](#) on surprise medical billing (i.e., Surprise Billing Part II) continues to draw near. This rule will establish the specifics for the independent dispute resolution (IDR) process (i.e., arbitration) and the patient-provider dispute resolution process (for uninsured individuals to appeal a bill charged that is substantially greater than the good faith estimate). The rule, however, has not yet appeared at the Office of Management and Budget (OMB), meaning the White House has not received the rule for final approval. Given the impending due date, we may see the rule appear at OMB in the coming days before its release expected by the end of the month.

In addition, a final rule to rescind the Trump Administration’s “penny pricing” rule has just [cleared](#) OMB for review. We may see the final rule released in the *Federal Register* imminently. In brief, the Trump-era rule would require entities participating in the 340B Drug Pricing Program to offer insulin and injectable epinephrine to patients with low-incomes at the price at which the health center purchased the drugs through the 340B program. Additional details are available [here](#).

THIS WEEK IN HEALTH POLICY

Mon. (9/27)

- **9:30am – ASPE Meeting: SDOH and Payment Models** – The Office of the Assistant Secretary for Planning and Evaluation holds a meeting of the Physician-Focused Payment Model Technical Advisory Committee to discuss efforts to address social determinants of health (SDOH) and equity in Alternative Payment Models (APMs) and physician-focused payment models. [Details](#).
- **1:00pm – NIH Meeting: Grant Applications** – The National Institutes of Health (NIH) holds a meeting of the Center for Scientific Review to provide advice to the Director on matters related to planning, execution, conduct, support, review, evaluation, and referral of grant applications. [Details](#).

Tue. (9/28)

- **9:00am – FDA Meeting: PDUFA** – The Food and Drug Administration (FDA) holds a meeting to discuss recommended updates for the reauthorization of the Prescription Drug User Fee Act (PDUFA) for FY 2023 through FY 2027. [Details](#).
- **10:15am – Hearing: COVID-19** – The House Education & Labor Civil Rights and Human Services Subcommittee and Health, Employment, Labor, and Pensions Subcommittee hold a joint hearing titled, “How to Save a Life: Successful Models for Protecting Communities from COVID-19.” [Details](#).
- **12:00pm – AHP Briefing: COVID-19** – The Alliance for Health Policy (AHP) holds a virtual briefing titled, “Lessons Learned from COVID-19 and Other Emergencies.” [Details](#).
- **1:00pm – NIHCM Webinar: AI and Health Equity** – The National Institute for Health Care Management (NIHCM) holds a webinar titled, “Who Gets Health Care and Why: AI, Race and Health Equity.” [Details](#).

Wed. (9/29)

- **10:00am – Hearing: Abortion** – The Senate Judiciary Committee holds a hearing titled, “Texas’s Unconstitutional Abortion Ban and the Role of the Shadow Docket.” [Details](#).
- **10:15am – Hearing: Return to School** – The House Education & Labor Subcommittee on Early Childhood, Elementary, and Secondary Education holds a hearing titled, “Back to School: Highlighting Best Practices for Safely Reopening Schools.” [Details](#).

- **12:00pm – NIH Meeting: Cancer Research** – The NIH National Cancer Institute Council of Research Advocates holds a meeting to discuss program updates. [Details](#).

Thurs. (9/30)

- **8:00am – VA Meeting: Electronic Health Records** – The Department of Veterans Affairs (VA) holds a meeting of the Special Medical Advisory Group to discuss electronic health record modernization, health equity, and workforce strength and resiliency. [Details](#)
- **8:30am – FDA Meeting: Vaccine Research** – The FDA holds a meeting of the Vaccines and Related Biological Products Advisory Committee to provide an overview of research programs and make recommendations on the selections of strains to be included in the influenza virus vaccines for the 2021 to 2022 southern hemisphere season. [Details](#).
- **9:00am – BPC Discussion: Rural Housing** – The Bipartisan Policy Center (BPC) holds a virtual discussion titled, “Meeting Rural American’s Housing Needs: A Conversation with Sens. Smith and Rounds.” [Details](#).
- **10:00am – Hearing: Abortion** – The House Committee on Oversight and Reform holds a hearing titled, “A State of Crisis: Examining the Urgent Need to Protect and Expand Abortion Rights and Access.” [Details](#).
- **10:00am – Hearing: School Reopening** – The Senate Health, Education, Labor & Pensions Committee holds a hearing titled, “School Reopening During COVID-19: Supporting Students, Educators, and Families.” [Details](#).
- **2:00pm – HHS Meeting: COVID-19 and Equity** – The Department of Health and Human Services (HHS) Office of Minority Health holds a meeting of the COVID-19 Health Equity Task Force to present and vote on final recommendations for mitigating inequities caused or exacerbated by COVID-19. [Details](#).

FEATURED WHG ANALYSIS

- **WHG Side-by-Side of Medicaid Expansion Gap Bills** – In the Policy Hub Insight Bank [here](#).
- **WHG Side-by-Side of Health Technology Assessment Models** – In the Policy Hub Insight Bank [here](#).
- **WHG Updated 2021 Legislative and Regulatory Outlook** – In the Policy Hub Insight Bank [here](#).
- **WHG Chart Key Federal Public Option Bills in the 117th Congress; Side-by-Side Comparison** – In the Policy Hub Insight Bank [here](#).
- **WHG Overview of Recent Development on Federal Telehealth Policy** – In the Policy Hub Insight Bank [here](#).
- **WHG Chart of the Major Drug Pricing Proposals in the 117th Congress** – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Fri. (9/24)

- **MACPAC convened** virtually for Day Two of its September 2021 public meeting and held sessions on monitoring access to care, health information technology (IT) adoption among behavioral health providers, and vaccines for adult Medicaid beneficiaries. All WHG session summaries are available on Policy Hub [here](#).

Thurs. (9/23)

- **MACPAC convened** virtually for Day One of its September 2021 public meeting and held sessions on the primary care and specialty care workforces and rates of churn due to state eligibility processes. All WHG session summaries are available on Policy Hub [here](#).
- **The House O&R Committee released** a new report on the impact of prohibiting drug price negotiations on taxpayer dollars. [Details](#).

Wed. (9/22)

- **The House E&C Subcommittee on Oversight and Investigations** held a [hearing](#) to discuss the impacts of the COVID-19 pandemic on children. [Details](#).
- **SFC Chairman Wyden and Ranking Member Crapo** [released](#) an RFI seeking input from stakeholders on legislative proposals to improve access to mental health and SUD services. Responses are due November 1. [Details](#).

Mon. (9/20)

- **House E&C leadership** [wrote](#) to HHS Secretary Xavier Becerra in support of the administration's [proposal](#) to increase penalties for hospitals failing to comply with recent hospital price transparency requirements. [Details](#).

REGULATORY LOOKBACK

Fri. (9/24)

- **The USDA** [announced](#) that it will establish an Equity Commission to identify USDA programs, policies, systems, and practices that contribute to barriers to access, systemic discrimination, or exacerbate racial, economic, health, and social disparities. [Details](#).
- **NIOSH** [released](#) an RFI on evidence-based workplace and occupational safety and health interventions to prevent stress, support stress reduction, and foster positive mental health within the health workforce. Submissions are due November 26 [Details](#).

Thurs. (9/23)

- **SAMHSA** [announced](#) it is hosting a meeting of its Interdepartmental Serious Mental Illness Coordinating Committee. [Details](#).
- **HHS OIG** [released](#) a report finding that 79 percent of opioid treatment program (OTP) services provided through Medicaid in Colorado did not meet federal and state requirements. [Details](#).

Wed. (9/22)

- **HHS ONC** [announced](#) it is awarding \$73 million in cooperative agreements for public health IT workforce development. [Details](#).
- **The FDA** [announced](#) the availability of a list of artificial intelligence and machine learning (AI/ML)-enabled devices legally marketed in the United States. [Details](#).
- **HHS OIG** [released](#) a report examining whether MA inappropriately leveraged chart reviews and health risk assessments (HRAs) to maximize risk-adjusted payments. [Details](#).
- **CMS** [announced](#) that it has launched a new [Medicare.gov](#) tool to compare vaccination rates of staff and residents across nursing homes. [Details](#).

Tues. (9/21)

- **CMS** [announced](#) it is seeking nominations for a TEP related to the development and maintenance of vaccination-related items and measures for the IRF, LTCH, SNF and HH settings. Nominations are due October 11. [Details](#).
- **The HHS OWH** [announced](#) an opportunity for organizations to become a Self-Measured Blood Pressure (SMBP) Partner. Applications will be accepted beginning on October 1. [Details](#).

Mon. (9/20)

- **CMS** [awarded](#) \$15 million in grants from the American Rescue Plan to State Medicaid agencies to support planning efforts to expand community-based mobile crisis intervention services. [Details](#).

COMMENT & APPLICATION DEADLINES

- **September 21:** HRSA [announced](#) a funding opportunity for the teaching Health Center Graduate Medical Education (THCGME) New and Expanded Residency Program. [Details](#).

- **September 25:** The FDA [announced](#) a request for nominees to serve as voting or nonvoting consumer representatives on several agency advisory committees. [Details](#)
- **September 28:** CMS [issued](#) a proposed rule that would authorize states to make payment to third parties, to facilitate easier access to employee benefits. [Details](#).
- **October 5:** PCORI [announced](#) funding opportunities with special areas of emphasis that include telehealth for chronic disease management and addressing racism and bias in healthcare systems and care delivery. [Details](#).
- **October 9:** CMS [issued](#) a proposed rule with rescind the Most Favored Nation (MFN) Model interim final rule. [Details](#).
- **October 11:** The Department of Agriculture RHS [announced](#) available grant funding for the establishment of the Emergency Rural Health Care Grant Program. [Details](#).
- CMS [announced](#) it is seeking nominations for a TEP related to the development and maintenance of vaccination-related items and measures for the IRF, LTCH, SNF and HH settings. [Details](#).
- **December 11:** The FDA [issued](#) a request for comments on issues related to the post-approval regulation of PANDAs. [Details](#).
- **October 13:** HRSA [seeks](#) public comment on proposed updates to the Periodicity Schedule for HRSA's Bright Futures Program. [Details](#).
- **October 15:** CMS [issued](#) a proposed rule to repeal the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" [final rule](#). [Details](#).
- **October 18:** The CDC [seeks comments](#) on two contraception guidance documents, which provide evidence-based recommendations to assist health care providers when counseling patients on contraceptive choice and use. [Details](#).
- **October 18:** HHS released a [notice of proposed rulemaking](#) (NPRM) that implements reporting requirements and enforcement provisions of Title I (No Surprises Act) and Title II (Transparency) of Division BB of the Consolidated Appropriations Act, 2021 (CAA). [Details](#).
- **October 22:** The U.S. Citizenship and Immigration Services [announced](#) that it is seeking written comments and related materials regarding public charge inadmissibility. [Details](#).
- **November 1:** SFC Chairman Wyden and Ranking Member Crapo [released](#) an RFI seeking input from stakeholders on legislative proposals to improve access to mental health and SUD services. [Details](#).
- **November 7:** The FDA [announced](#) a request for nominations for members to serve on the Tobacco Products Scientific Advisory Committee. [Details](#).
- **November 26:** NIOSH [released](#) an RFI on evidence-based workplace and occupational safety and health interventions to prevent stress, support stress reduction, and foster positive mental health within the health workforce. [Details](#).
- **December 7:** The FDA announced the launch of the [Novel Excipient Review Pilot Program](#) as a new pathway for manufacturers to obtain agency review of certain novel excipients. [Details](#).

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