

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

With Congress in recess this week, we recap lawmakers' jam-packed to-do list for this month:

- **Budget Reconciliation (September 15)** – Committees are drafting and marking up legislative language in response to the reconciliation instructions in the fiscal year (FY) 2022 budget resolution ([S.Con.Res. 14](#)), with a soft deadline of September 15. The \$3.5 trillion package is chock full of major health care reforms – such as addressing the Medicaid expansion coverage gap; extending the temporary to Affordable Care Act (ACA) premium subsidies; expanding Medicare to include dental, vision, and hearing benefits; lowering prescription drug prices; among others detailed in Democrats' [framework agreement](#).
- **Bipartisan Infrastructure Package (September 27)** – House Speaker Nancy Pelosi (D-CA) has set September 27 as the deadline for the House to vote on the nearly \$1 trillion bipartisan infrastructure package passed by the Senate. The House is expected to pass the package.
- **FY 2022 Appropriations (September 30)** – The House has made some progress on passing FY 2022 appropriations bills – e.g., a seven-bill minibus ([H.R. 4502](#)) including funds for the Departments of Health and Human Services (HHS). However, the Senate only began marking up appropriations bills last month. The lack of significant progress, as well as attention focused on the budget reconciliation package, increases the odds that Congress will pursue a continuing resolution ahead of the September 30 deadline to avoid a government shutdown.
- **Debt Limit (October 1)** – The Treasury Department has begun taking “[extraordinary measures](#)” to prevent the United States from defaulting on its obligations. Treasury Secretary Janet Yellen has [warned](#) Congress that the federal government could exhaust these measures as soon as October 1.

Regulatory Update

While no major regulations have recently cleared or are pending review at the Office of Management and Budget (OMB), the most recently updated Unified Agenda targeted a variety of potential regulatory developments for September 2021. Notably among these include:

- The potential release of the [proposed rule](#) for calendar year (CY) 2023 of the Medicare Advantage (MA) and Part D programs.
- A potential [proposed rule](#) for an “Alternative Payment Model for Medicare.”
- Potential issuance of a [final rule](#) to address unlawful discrimination on the basis of disability in certain HHS-funded health and human services programs.
- Potential issuance of [final regulations](#) regarding the employer shared responsibility provisions to HRAs and other account-based group health plans.

Beyond these rules, the statutory deadline for the release of the [second interim final rule](#) on surprise medical billing (i.e., Surprise Billing Part II) is October 1. It is likely we will see rulemaking activity on this front by the end of this month as the Administration prepares to meet the fast-approaching deadline.

## **THIS WEEK IN HEALTH POLICY**

### **Mon. (9/6)**

- **Labor Day**

### **Wed. (9/8)**

- **9:30am – Hearing: Aging** – The Senate Special Committee on Aging convenes a hearing titled, “Living Your Best Life Now: Enjoying Your Golden Years with Physical and Mental Vitality.” [Details.](#)
- **1:00pm – NCCC Meeting: Diabetes** – The National Clinical Care Commission (NCCC) holds a meeting on improvements to federal programs related to diabetes and its complications. [Details.](#)

### **Thurs. (9/9)**

- **9:30am – ONC Meeting: Health IT** – The Office of National Coordinator for Human Information Technology (ONC) holds a meeting of the Health IT Advisory Committee to discuss issues of interoperability, privacy and security, and patient access. [Details.](#)
- **9:30am – NIH Meeting: General Medicine** – The National Institutes of Health (NIH) Institute of General Medical Sciences holds a meeting of the National Advisory General Medical Sciences Council to hear the Director’s report and discuss program policies and issues. [Details.](#)
- **10:30am – Politico Discussion: Health Care** – Politico holds a panel discussion titled, “Health Care Innovators: The Return to In-Person Work.” [Details.](#)
- **12:00pm – NIH Meeting: Child Health** – The NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development holds a meeting to hear the Director’s report and discuss program updates. [Details.](#)
- **12:15pm – NIH Meeting: Alcohol Abuse** – The NIH National Institute on Alcohol Abuse and Alcoholism holds a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism to hear program updates. [Details.](#)
- **1:00pm – NIH Meeting: Neurological Disorders and Stroke** – The NIH National Institute of Neurological Disorders and Stroke holds a meeting of the National Advisory Council on Neurological Disorders and Stroke to hear the Director’s Report and discuss program updates. [Details.](#)

### **Fri. (9/10)**

- **10:00am – NIH Meeting: Integrative Health** – The NIH National Center for Complementary and Integrative Health holds a meeting of the National Advisory Council for Complementary and Integrative Health to hear the Director’s Report and discuss program updates. [Details.](#)
- **11:00am – NIH Meeting: Minority Health** – The NIH National Institute on Minority Health and Health Disparities holds a meeting of the National Advisory Council on Minority Health and Health Disparities to hear the Director’s report discuss program updates. [Details.](#)

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

- **September 8-September 9 – NQF Meeting: Quality Measures** – The National Quality Forum convenes a meeting of the Measure Applications Partnership (MAP) Coordinating Committee to provide feedback on measures selected for review that are currently in use in federal health programs. [Details.](#)
- **September 9-September 10 – NIH Meeting: Diabetes and Kidney Disease** – The NIH National Diabetes and Digestive and Kidney Diseases Advisory Council holds a meeting to present the Director’s report and other scientific presentations. [Details.](#)

- **September 9-September 10 – HHS Meeting: Health Statistics** – The Department of Health and Human Services (HHS) National Committee on Vital and Health Statistics holds a meeting to receive program updates and discuss current health data policy topics. [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 117<sup>th</sup> 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 117<sup>th</sup> Congress** – In the Policy Hub Insight Bank [here](#).

#### CONGRESSIONAL LOOKBACK

##### Fri. (9/3)

- **MedPAC convened** virtually for Day Two of its September 2021 public meeting and held sessions on designing a post-acute care value incentive program and the impact of the Bipartisan Budget Act on the home health PPS. All WHG session summaries are available on Policy Hub [here](#).

##### Thurs. (9/2)

- **MedPAC convened** virtually for Day One of its September 2021 public meeting and held sessions on the effects of COVID-19 on Medicare payment adequacy and the Part D low-income subsidy. All WHG session summaries are available on Policy Hub [here](#).

#### REGULATORY LOOKBACK

##### Thurs. (9/2)

- **HHS OIG** released a new [report](#) that details some of the complex conditions that Medicare beneficiaries with COVID-19 are experiencing. [Details](#).

##### Wed. (9/1)

- **HHS delegated** the Food and Drug Administration (FDA) Commissioner the authority to once again independently issue agency regulations. [Details](#).

##### Tues. (8/31)

- **The FDA updated** its guidance on conducting clinical trials for medical products during the COVID-19 [public health](#) emergency. [Details](#)
- **HHS awarded** \$10.7 million in American Rescue Plan funds to expand access to pediatric mental health care through telehealth. [Details](#).
- **CMS issued** guidance on COVID-19 testing and vaccine expenditures through two State Health Official letters. [Details](#).
- **Medicare Trustees** released their long-anticipated 2021 [report](#) on the status of the Hospital Insurance (HI) and Supplemental Medicare Insurance (SMI) trust funds. [Details](#).

##### Mon. (8/30)

- **The CBO released** an updated report on the impact of drug price negotiations on new drug development. [Details](#).

- **The U.S. Citizenship and Immigration Services** [announced](#) that it is seeking written comments and related materials regarding public charge inadmissibility. Comments are due October 22. [Details.](#)

#### COMMENT & APPLICATION DEADLINES

- **September 13:** CMS [released](#) its calendar year (CY) 2022 Medicare Physician Fee Schedule (MPFS) proposed rule. [Details.](#)
- **September 15:** The NIH Office of Research on Women's Health [requests](#) comments to inform planning of the Women's Health Consensus Conference. [Details.](#)
- **September 17:** The CDC [announced](#) it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee. [Details.](#)
- **September 17:** CMS [released](#) the CY 2022 Hospital Outpatient Prospective Payment System and ASC Payment System Proposed Rule. [Details.](#)
- **September 19:** HRSA [seeks comments](#) on draft updates to the [Women's Preventive Services Guidelines.](#) [Details.](#)
- **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 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.](#)
- **December 11:** The FDA [issued](#) a request for comments on issues related to the post-approval regulation of PANDAs. [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 22:** The U.S. Citizenship and Immigration Services [announced](#) that it is seeking written comments and related materials regarding public charge inadmissibility. [Details.](#)

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