

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

Today, the House is expected to pass the Senate-approved measure increasing the debt ceiling, giving lawmakers until early December to reach a longer-term deal or pass another short-term fix. **December 3** is when the U.S. is projected to hit the debt ceiling and when the continuing resolution funding the federal government for fiscal year 2022 expires.

As for infrastructure, **October 31** is the deadline set by House Speaker Nancy Pelosi (D-CA) for the House to vote on the bipartisan infrastructure package passed by the Senate. Meanwhile, Democrats are negotiating a trimmed down budget reconciliation package – with a possible price tag between \$1.5 trillion (Sen. Joe Manchin’s (D-WV) topline number) and the original \$3.5 trillion. There is less certainty on how exactly the health care priorities – expanding Medicare benefits, address the Medicaid expansion coverage gap, extending premium subsidies, and lowering prescription drug prices – may be scaled back.

In a [Dear Colleague letter](#) sent yesterday, Speaker Pelosi signaled that Democrats may cut entire provisions from the bill rather than shortening their authority. For example, Democrats may cut the expansion of Medicare benefits rather than further delaying their effective date. Pelosi said, “Overwhelmingly, the guidance I am receiving from Members is to do fewer things well so that we can still have a transformative impact on families in the workplace and responsibly address the climate crisis: a Build Back Better agenda for jobs and the planet For The Children!”

COVID-19 Vaccine

Later this week (October 14-15), the Food and Drug Administration’s (FDA) Vaccines and Related Biological Products Advisory Committee will [discuss](#) the **Emergency Use Authorization (EUA) of the Moderna and Johnson & Johnson COVID-19 vaccine booster for adults**. The FDA could make a final decision on the EUA within days of the meeting. The Centers for Disease Control and Prevention (CDC) has scheduled a two-day meeting next week (October 20-21) to [discuss](#) the Moderna and Johnson & Johnson boosters.

Regulatory Update

A number of key rules are now under review at the Office of Management and Budget (OMB). On the Medicare payment front, two key final rules – the [Hospital Outpatient Prospective Payment System \(HOPPS\)](#) and [End Stage Renal Disease Prospective Payment System \(ESRD PPS\)](#) – arrived last week for review. Both final rules may potentially drop later next month. As a reminder, the major provisions of note we may see in these final rules are as follows:

- **HOPPS:** The proposed rule included provisions that would raise fines for hospitals that do not publish their list of standard charges – a requirement pursuant to the Hospital Price Transparency rule. The rule may also include a number of policy and technical changes to the mandatory Radiation Oncology model. Additional details are available [here](#).

- **ESRD:** The proposed rule contained several potential changes to the mandatory ESRD Treatment Choices model, which the Administration is aiming to update to better address health disparities in kidney care. Details are available [here](#).

Beyond Medicare payment updates, an [interim final rule](#) that would address COVID-19 health care staff vaccinations also arrived at OMB last week. The new regulations would be pursuant to President Biden's recently released "Path out of the Pandemic," which included plans for requiring COVID-19 vaccinations for all health care workers at Medicare and Medicaid participating hospitals and other health care settings ([details](#)).

## THIS WEEK IN HEALTH POLICY

### Mon. (10/11)

- **Indigenous Peoples' Day**

### Wed. (10/13)

- **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](#).

### Fri. (10/15)

- **9:00am – NIH Meeting: Patient Safety** – The National Institutes of Health (NIH) holds a meeting of the Clinical Center Research Hospital Board to give updates on patient safety and clinical quality. [Details](#).
- **12:00pm – AHP Briefing: Health Equity** – The Alliance for Health Equity holds a briefing titled, "Equity in Health Data: COVID-19 as a Case Study." [Details](#).

### Additional Multi-Day Events

- **October 13-October 14 – NIH Meeting: Autism Spectrum Disorder** – The NIH holds a meeting of the Interagency Autism Coordinating Committee (IACC) to discuss business, agency updates, and issues related to autism spectrum disorder research and service. [Details](#).
- **October 13-October 14 – FDA Workshop: Opioids** – The Food and Drug Administration (FDA) holds a public workshop titled, "Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Opioid Crisis." [Details](#).
- **October 14-October 15 – FDA Meeting: COVID-19 Vaccine** – FDA convenes a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss the Emergency Use Authorization (EUA) of the Moderna and Johnson & Johnson COVID-19 vaccine booster for adults. [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. (10/8)

- **MedPAC** [convened](#) virtually for Day Two of its October 2021 public meeting and held sessions on Medicare alternative payment models, improving Medicare Advantage's risk adjustment, and the Medicare hospital wage index. All WHG session summaries are available on Policy Hub [here](#).

### Thurs. (10/7)

- **MedPAC** [convened](#) virtually for Day One of its October 2021 public meeting and held sessions on high prices of pharmaceuticals covered under Medicare, data on Medicare's net prices for prescription drugs, and vulnerable beneficiaries' access to care. All WHG session summaries are available on Policy Hub [here](#).

### Tues. (10/5)

- **A group of bipartisan Senators** [sent a letter](#) to the HHS Secretary calling on the Administration to establish an "ambitious goal to prevent Alzheimer's and related dementias and develop a plan to achieve this goal." [Details](#).

## REGULATORY LOOKBACK

### Fri. (10/8)

- **AHRQ** [released](#) a request for supplemental evidence and data submission to inform its review on Telehealth for Women. Submissions are due November 11. [Details](#).
- **CMS** [announced](#) the Star Ratings for [Medicare Advantage](#) (MA) and Part D plans for 2022. [Details](#).

### Thurs. (10/7)

- **CMS** released a new highlight of data on the utilization of Z-codes for social determinants of health. [Details](#).

### Wed. (10/6)

- **HHS** [released](#) a draft of its Strategic Plan for fiscal years (FY) 2022-2026. Comments are due November 7. [Details](#).

### Tues. (10/5)

- **The NIH** [released](#) findings from a study demonstrating how COVID-19 has caused more deaths, directly and indirectly, among Black, American Indian and Alaska Native, and Latino adults compared to white and Asian individuals. [Details](#).

### Mon. (10/4)

- **HHS** issued its [final rule](#) for the Title X Family Planning Program, readopting regulations finalized by the Clinton Administration in 2020 and making several revisions focused on advancing equity. [Details](#).
- **The FDA** [issued](#) a final rule to establish new requirements for the medical device De Novo classification process under the Food, Drug, and Cosmetic (FD&C) Act. [Details](#).

## COMMENT & APPLICATION DEADLINES

- **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:** HHS [released](#) a draft of its Strategic Plan for fiscal years (FY) 2022-2026. Comments are due November 7. [Details.](#)
- **November 7:** The FDA [announced](#) a request for nominations for members to serve on the Tobacco Products Scientific Advisory Committee. [Details.](#)
- **November 11:** AHRQ [released](#) a request for supplemental evidence and data submission to inform its review on Telehealth for Women. Submissions are due November 11. [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.](#)
- **November 28:** The FDA [issued](#) draft guidance on the electronic submission template for medical device 510(k) submissions. [Details.](#)
- **November 29:** The FDA issued draft guidance on [assessing electronic health records \(EHRs\) and medical claims data to support regulatory decision-making](#); [interpreting sameness of gene therapy products under orphan drug regulations](#); and [benefit-risk assessment for new drug and biological products.](#) [Details.](#)
- **November 29:** The HHS OMH is [seeking](#) nominations for the Center for Indigenous Innovation and Health Equity Tribal Advisory Committee. [Details.](#)
- **November 29:** The FDA OMHHE [released](#) a funding opportunity announcement (FOA) to fund innovative research that will strengthen and advance COVID-19 health equity research. [Details.](#)
- **December 6:** HHS, DOL, and Treasury issued an [interim final rule with comment period](#) (IFC) on Part II of its implementation of the No Surprises Act's surprise billing policies. [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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