

Wynne Health Group Weekly



FRAMING THE WEEK

Democrats appear to be getting close to a compromise on **prescription drug pricing reforms** – including versions of Medicare drug price negotiation, Part D redesign, inflation rebates that are more moderate than originally proposed in [H.R. 3](#) ([WHG summary](#) of the most pertinent drug pricing proposal provisions in the 117th Congress). We could see the House vote on the **Build Back Better Act** ([H.R. 5376](#); [WHG summary](#)), followed by the Senate-approved bipartisan [Infrastructure Investment and Jobs Act](#), as soon as this week.

Still, passage of the **Further Surface Transportation Extension Act of 2021** ([H.R. 5763](#)) bought Democrats more time to reach a deal on the budget reconciliation package. December 3 is the new expiration date for surface transportation programs at the Department of Transportation. However, Democrats are eager to deliver President Biden a much-needed legislative win. An [NBC News poll](#) released yesterday finds **42 percent of Americans approve of President Joe Biden's job performance**, down from 53 percent in April when the Biden Administration was able to tout the then newly enacted American Rescue Plan Act of 2021 ([P.L. 117-7](#)).

Additionally, lawmakers will soon need to refocus their attention on **fiscal year (FY) 2022 spending bills**. The continuing resolution ([P.L. 117-43](#)) expires December 3. House and Senate Appropriations Committee leaders are meeting this week to discuss spending levels for FY 2022. In addition, Congress must deal with the **debt limit** by early December.

COVID-19

Tomorrow, the CDC's Advisory Committee on Immunization Practices (ACIP) will [vote](#) on whether the newly [FDA-authorized Pfizer COVID-19 vaccine](#) should be recommend for all children 5 to 11 years or only certain subgroups of children. The vaccine could be available to the public within a few days of CDC making a formal recommendation after the ACIP vote. The Biden Administration is partnering with pediatricians' offices and other primary cates, children's hospital systems, pharmacies, school and community-based clinics, and community health centers and rural health clinics to ensure convenient and equitable access to children, according to its [operational plan](#).

The Office of Management and Budget (OMB) has concluded review of regulations requiring **COVID-19 vaccinations among health care workers and large employers**. We could see both regulations this afternoon.

- Centers for Medicare and Medicaid Services (CMS) [interim final rule with comment period](#) would require Medicare and Medicaid facilities – including nursing homes, hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies, among others – to mandate COVID-19 vaccines among workers.
- Occupational Safety and Health Administration (OSHA) [emergency temporary standard](#) (ETS) would require large employers (with 100+ employees) to mandate COVID-19 vaccinations or weekly testing.

Medicare Payment Rules

Last week, CMS released the final rule for its calendar year (CY) 2022 end stage renal disease (ESRD) prospective payment system (PPS) (full summary [here](#)). This week, we may see the remaining final rules for the CY Medicare payment updates – the Medicare Physician Fee Schedule, the Hospital Outpatient PPS, and the Home Health PPS – which have all cleared review by the OMB. A brief overview of what we may see included in these final rules follows.

- **Medicare Physician Fee Schedule (MPFS):** CMS may finalize a number of provisions related to telehealth expansion under its current regulatory authorities. Specifically, CMS may make changes that increase beneficiary access to audio-only services for certain conditions, and may extend the timeframe by which CMS will retain temporarily added telehealth services to continue collecting data and study their impact on beneficiary outcomes. Other changes will likely include continued implementation of its MIPS Value Pathways program, as well as continued implementation of certain SUPPORT Act provisions around requirements for the electronic prescribing of controlled substances.
- **Hospital Outpatient PPS (HOPPS):** CMS may finalize its proposals to increase fines for hospitals that do not publish their list of standard charges (as required by the Hospital Price Transparency final rule). The proposed rule also included a number of changes to the CMS Radiation Oncology model, which we may see finalized in the forthcoming rule as well.
- **Home Health PPS:** CMS may finalize its proposal to expand the Home Health Value Based Purchasing model to all 50 states, as well as provisions that would make permanent certain COVID-19 waivers related to home health aide supervision and the use of telecommunications for unplanned occurrences.

Nutrition

Tomorrow, a Senate Agriculture Subcommittee will [hear](#) from policy experts about “The State of Nutrition in America 2021.” During the COVID-19 pandemic, a slew of nutrition-related flexibilities has been used by the Biden Administration and Congress to strengthen food security within schools, the Supplemental Nutrition Assistance Program (SNAP), the Special Nutrition Program for Women, Infants and Children (WIC), among other programs. Additionally, the Build Back Better Act includes several provisions to further increase access to nutrition benefits in schools as well as \$140 million to support nutrition programs for Older Americans.

THIS WEEK IN HEALTH POLICY

Mon. (11/1)

- **8:45am – NIH Meeting: Deafness** – The National Institutes of Health (NIH) National Institute on Deafness and Other Communication Disorders holds a meeting of the Board of Scientific Counselors to provide program updates. [Details.](#)
- **2:00pm – NQF Meeting: Hospitals** – The National Quality Forum (NQF) holds a meeting of the Measure Application Partnership Hospital Workgroup to discuss measures for hospitals. [Details.](#)

Tue. (11/2)

- **9:00am – FDA Meeting: Biosimilar User Fee Act** – The Food and Drug Administration (FDA) holds a meeting to discuss proposed recommendations for the reauthorization of the Biosimilar User Fee Act for fiscal years 2023 through 2027. [Details.](#)
- **10:00am – Hearing: Nutrition** – The Senate Committee on Agriculture, Nutrition & Forestry Subcommittee on Food and Nutrition, Specialty Crops, Organics, and Research holds a hearing titled, “The State of Nutrition in America 2021.” [Details.](#)

- **10:00am – DOS Meeting: AIDS and COVID-19** – The Department of State (DOS) President’s Emergency Plan for AIDS Relief (PEPFAR) holds a meeting of the Scientific Advisory Board to discuss the impact of COVID-19 on people living with HIV infection and other updates. [Details](#).
- **10:00am – Hearing: VA Electronic Health Records** – The House Veterans Affairs Committee Technology Modernization Subcommittee holds a hearing titled, “Next Steps: Examining Plans for the Continuation of the Department of Veterans Affairs Electronic Health Record Modernization Program.” [Details](#).
- **12:30pm – CDC Meeting: COVID-19 and Polio** – The Centers for Disease Control and Prevention (CDC) Board of Scientific Counselors holds a meeting of the Center for Preparedness and Response to provide updates on COVID-19 and Polio programs. [Details](#).

Wed. (11/3)

- **10:00am – FCC Meeting: Equity** – The Federal Communications Council (FCC) holds a meeting of the Communications Equity and Diversity Council to provide recommendations on advancing equity across the technology sector. [Details](#).

Thurs. (11/4)

- **9:30am – FDA Meeting: Blood Products** – The FDA holds a meeting of the Blood Products Advisory Committee to provide updates from research programs. [Details](#).
- **10:00am – FDA Meeting: Psychopharmacological Drugs** – The FDA holds a meeting of the Psychopharmacologic Drugs Advisory Committee to provide recommendations on regulatory issues. [Details](#).
- **12:00pm – VA Meeting: Homelessness** – The Department of Veterans Affairs (VA) holds a meeting of the Committee on Homeless Veterans to hear briefings from federal agencies regarding services for homeless veterans. [Details](#).
- **2:00pm – NQF Meeting: Post-Acute/Long Term Care** – NQF holds a meeting of the Measure Application Partnership Post-Acute Care/Long-Term Care Workgroup to provide input on measures for post-acute care and long-term care providers. [Details](#).

Fri. (11/5)

- **2:30pm – NQF Meeting: Clinicians** – NQF holds a meeting of the Measure Application Partnership Clinician Workgroup to discuss measures related to clinicians. [Details](#).

Additional Multi-Day Events

- **November 2-November 5 – 12:30pm – HRSA Meeting: Migrant Health** – The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Council on Migrant Health to discuss updates. [Details](#).
- **November 2-November 3 – 10:00am – CDC Meeting: Immunizations** – The CDC holds a meeting of the Advisory Committee on Immunization Practices to discuss the adult immunization schedule, Ebola vaccine, hepatitis vaccines, Orthopoxviruses vaccine and COVID vaccines. [Details](#).
- **November 2-November 3 – 10:00am – HRSA Meeting: Primary Care and Dentistry Training** – The HRSA Advisory Committee on Training in Primary Care Medicine and Dentistry holds a meeting to finalize the annual Report to Congress. [Details](#).

FEATURED WHG ANALYSIS

- **WHG Issue Brief on Health Equity Implications of Potential Telehealth Reform Under Medicare** – In the Policy Hub Insight Bank [here](#).
- **WHG Side-by-Side of Live Drug Pricing Proposals Under Consideration for Reconciliation** – In the Policy Hub Insight Bank [here](#).
- **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](#).

CONGRESSIONAL LOOKBACK

Fri. (10/29)

- **MACPAC convened** virtually for Day Two of its October 2021 public meeting and held sessions on integrating care for dually eligible beneficiaries; behavioral health priorities; and the workforce for home- and community-based services. All WHG session summaries are available on Policy Hub [here](#).

Thurs. (10/28)

- **The House Rules Committee** released [updated legislative text](#) of the Build Back Better Act (H.R. 5376), reflecting the \$1.75 trillion [framework](#) unveiled by President Biden. [Details](#).
- **The White House** released a formal [framework](#) ([press release](#)) for the envisioned “Build Back Better Act,” the roadmap for a forthcoming [budget](#) reconciliation package. [Details](#).
- **MACPAC convened** virtually for Day One of its October 2021 public meeting and held sessions on data issues in monitoring access to care for Medicaid beneficiaries; vaccines for adults enrolled in Medicaid; and an analysis of disproportionate share hospital allotments. All WHG session summaries are available on Policy Hub [here](#).

Tues. (10/26)

- **The House E&C Subcommittee on Health** held a [hearing](#) to discuss seven bills related to the health care workforce. [Details](#).

REGULATORY LOOKBACK

Fri. (10/29)

- **CMS released** its calendar year (CY) 2022 end-stage renal disease (ESRD) prospective payment system (PPS) final rule. [Details](#).
- **CMS released** its monthly update of data that provides a snapshot of the impact of COVID-19 on the Medicare population. [Details](#).
- **ASPE announced** the release of a new report examining health insurance coverage rates in 2020-2021. [Details](#).

Thurs. (10/28)

- **HHS issued a proposed rule** to withdraw or repeal the “Securing Updated and Necessary Statutory Evaluations Timely” SUNSET final rule. Comments are due December 28. [Details](#).

Wed. (10/27)

- **HHS announced** it is making available up to \$256 million in grant funding to support equitable, affordable, and high-quality access to family planning services through the Title X family planning program. Applications are due January 11. [Details](#).
- **SAMHSA released** data from the 2020 National Survey on Drug Use and Health detailing the percentage of Americans experiencing substance use and mental health issues. [Details](#).
- **CMS announced** a request for comments on two draft measures. Comments are due November 26. [Details](#).
- **HRSA announced** a request for comments on two updated draft recommendations in the [Women’s Preventive Services Guidelines](#). Comments are due November 27. [Details](#).

Tues. (10/26)

- **PCORI formally adopted** five National Priorities for Health to inform PCORI’s long-term [vision](#) for research funding. [Details](#).

Mon. (10/25)

- **The USDA [announced](#)** \$1.15 billion in grant funding for rural broadband access. Applications are due February 22. [Details](#).

COMMENT & APPLICATION DEADLINES

- **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. [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. [Details](#).
- **November 12:** AHRQ released a request for information (RFI) on [telehealth during COVID-19](#). [Details](#).
- **November 19:** HHS [announced](#) that it is proposing to repeal two final rules from the Trump Administration era, including the HHS Good Guidance Practices and the HHS Transparency and Fairness in Civil Administrative Enforcement Actions. [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 26:** CMS [announced](#) a request for comments on two draft measures. [Details](#).
- **November 27:** HRSA [announced](#) a request for comments on two updated draft recommendations in the [Women's Preventive Services Guidelines](#). Comments are due November 27. [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](#).
- **December 13:** AHRQ released a request for information (RFI) on [climate change](#). [Details](#).
- **January 11:** HHS [announced](#) it is making available up to \$256 million in grant funding to support equitable, affordable, and high-quality access to family planning services through the Title X family planning program. [Details](#).
- **December 28:** HHS issued a [proposed rule](#) to withdraw or repeal the "Securing Updated and Necessary Statutory Evaluations Timely" SUNSET final rule. [Details](#).
- **January 18:** The FDA issued a [proposed rule](#) and [draft guidance](#) to improve access to hearing aids through the establishment of an over-the-counter (OTC) hearing aid category. [Details](#).
- **January 21:** The FDA [issued](#) draft guidance on data standards for drug and biological product submissions containing real-world data (RWD). [Details](#).
- **February 22:** The USDA [announced](#) \$1.15 billion in grant funding for rural broadband access. [Details](#).

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