This Week in Health Policy, Congressional Lookback, Regulatory Lookback, Comment & Application Deadlines

***Wynne Health Group Weekly***

## FRAMING THE WEEK

Over the weekend, President Biden signed a 30-day extension to funding for surface transportation programs (H.R. 5434) – effectively buying Democrats more time to reach a consensus on the topline number and policies of the Build Back Better Act (budget reconciliation package). **October 31st is the new deadline for the House to pass the Senate-approved bipartisan Infrastructure Investment and Jobs Act (H.R. 3684).** This is a hard deadline, because failing to pass the bipartisan infrastructure package – which includes long-term funding authorization for highways and transit programs – by this date would force the Department of Transportation to furlough thousands of workers (again).

Given that (1) House Speaker Nancy Pelosi (D-CA) can only afford to lose three votes and (2) the "majority" of the 96-member Congressional Progressive Caucus holding firm on its position to "only vote for the small infrastructure bill after the Build Back Better Act passes," **October 31st is also the deadline for the House to pass the budget reconciliation package.** With Sen. Joe Manchin's (D-WV) topline of $1.5 trillion for budget reconciliation, Democrats in the House and Senate are negotiating a trimmed down package – with a possible price tag between $1.5 trillion 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.

## ***MedPAC***

Later this week, the Medicare Payment Advisory Committee (MedPAC) will convene to discuss a wide array of policy issues on payment and delivery reform:

- Approaches for Medicare to address (1) high prices for new "first-in-class" drugs, and (2) high and growing prices for drugs or new products with therapeutic alternatives;
- Proposed projects using new data on Medicare's net prices for prescription drugs. The Consolidated Appropriations Act, 2021 (P.L. 116-260) made the direct and indirect remuneration (DIR) data reported by Part D plan sponsors to the Centers for Medicare and Medicaid Services (CMS) and pricing information for provider-administered drugs under Part B available to MedPAC;
- An update on MedPAC's forthcoming report on beneficiaries' access to care in rural areas. The House Committee on Ways and Means submitted a bipartisan request for the report. The interim report was in the June 2021 report to Congress, and the final report will be in the June 2022 report;
- Policy approaches to implement a "small, more harmonized portfolio" of Medicare's alternative payment models, particularly greater harmonization among spending benchmarks, risk adjustment, allocation of financial risk, and provide participation;
- Ways to improve Medicare Advantage (MA) risk adjustment by limiting the influence of outlier beneficiaries; and
- Alternative Medicare hospital wage index policies.

***Regulatory Update***

The regulatory front appears relatively quiet this week after last week's promulgation of the Surprise Billing Part II interim final rule (details). Of note, a proposed rule to authorize the sale of hearing aids over the counter (OTC) has cleared review by the Office of Management and Budget (OMB). Doing so will allow patients to bypass the need for costly specialist evaluations that the Administration says drives the cost of hearing aids currently to an average cost of $5,000 per pair. As a reminder, the proposed rule is pursuant to President Biden's executive order on promoting competition in the U.S. economy released earlier this summer (WHG summary here). The forthcoming release of this proposed rule will thus mark one of the first major implementation milestones of the EO (another recent developing being the recently released comprehensive plan for drug pricing reform).

## THIS WEEK IN HEALTH POLICY

**Tue. (10/5)**

- **10:00am – Hearing: Violence Against Women** – The Senate Judiciary Committee holds a hearing titled, "Renewing and Strengthening the Violence Against Women Act." Details.
- **10:00am – NIOSH Meeting: Occupational Safety** – The National Institute for Occupational Safety and Health (NIOSH) holds a meeting of the Board of Scientific Counselors to provide advice and guidance to the Director. Details.
- **1:00pm – NQF Meeting: Measure Application** – The National Quality Forum (NQF) holds a meeting of the whole Measure Application Partnership to discuss selection of performance measures. Details.

**Wed. (10/6)**

- **10:00am – FDA Meeting: Medical Devices** – The Food and Drug Administration (FDA) holds a meeting of the Patient Engagement Advisory Committee to discuss medical device recalls. Details.
- **10:00am – HHS Meeting: Antibiotic Resistance** – The Department of Health and Human Services (HHS) holds a meeting of the President's Advisory Council on Combatting Antibiotic-Resistant Bacteria to deliberate and vote on a letter of recommendations. Details.

**Thurs. (10/7)**

- **12:00pm – NCD Meeting: Medicaid Dental** – The National Disability Council (NCD) holds a virtual meeting to give a presentation on the forthcoming Intellectual and Developmental Disabilities Medicaid Dental Reimbursement Project and other program updates. Details.

**Additional Multi-Day Events**

- **October 7-October 8 – MedPAC Meeting** – The Medicare Payment Advisory Commission to discuss Medicare issues and policy questions. 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

**Thurs. (9/30)**

- **The Senate HELP Committee** held a hearing to discuss school reopening during COVID-19 with the Secretaries of HHS and DOE. Details.

## REGULATORY LOOKBACK

**Fri. (10/1)**

- **HHS OIG** released a report showing that a number of high-expenditure Medicare drugs qualified for Orphan Drug Act (ODA) incentives. Details.

**Thurs. (9/30)**

- **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. Comments are due December 6. Details.
- **HHS** issued a final rule to rescind the 2020 final rule that implements the President Trump's executive order on access to affordable life-saving medications. Details.
- **The FDA OMHHE** released a funding opportunity announcement (FOA) to fund innovative research that will strengthen and advance COVID-19 health equity research. Applications are due November 29. Details.
- **The HHS OMH** is seeking nominations for the Center for Indigenous Innovation and Health Equity Tribal Advisory Committee. Nominations are due November 29. Details.

**Wed. (9/29)**

- **CMS** released a report on the disparities in Medicare Advantage associated with dual eligibility or eligibility for a low-income subsidy. Details.
- **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. Comments are due November 29. Details.

**Tues. (9/28)**

- **HHS** awarded almost $1 billion in funding from the American Rescue Plan (ARP) to support the modernization of 1,292 health centers funded by the HRSA Health Center Program. Details.
- **The FDA** issued draft guidance on the electronic submission template for medical device 510(k) submissions. Comments are due November 28. Details.

**Mon. (9/27)**

- **CMS** announced they will provide coverage for COVID-19 booster shots and their administration without cost sharing. Details.

## COMMENT & APPLICATION DEADLINES

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- **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.
- **October 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.
- **November 28:** The FDA issued draft guidance on the electronic submission template for medical device 510(k) submissions. Details.
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- **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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