Impact Health Policy Weekly

Save the Date Impact Health Policy Partners requests that our clients and friends save the date of Thursday, December 5 for a holiday party! We look forward to coming together at our Washington office to celebrate a great year of working together to positively impact the health and well-being of all Americans

Framing the Week

The House and Senate both return next Monday, September 9. During this Congressional break, we are taking the opportunity to provide in-depth analysis of policies under consideration for a potential lame duck package, which will culminate with the release of the Impact Health Policy Partners Lame Duck memo next week and an Election Preview memo in early October. This week, we focus on Advance Premium Tax Credits and Medicaid program integrity.

Advance Premium Tax Credits

Congress will soon need to consider an extension of the Advanced Premium Tax Credits (APTC), which expire at the end of December 2025. APTCs currently help more than 19 million eligible individuals and families purchase health insurance through the Health Insurance Marketplace. Enhancements to APTCs were first put into place under the American Rescue Plan Act of 2021 (ARPA, P.L. 117-2), and were then extended through 2025 by the Inflation Reduction Act of 2022 (IRA, P.L. 117-169). The intention is to improve the affordability of Marketplace plans and the combination of enhanced APTCs with intentional outreach has led to historic levels of enrollment under the Biden-Harris Administration: more than 21.4 million people enrolled during the 2024 open enrollment period, a 31% increase compared to 2023. If Congress does not extend or make them permanent, almost all marketplace enrollees will face higher premium costs and 3.8 million will become uninsured, per estimates from the Congressional Budget Office (IHPP summary). The Center on Budget and Policy Priorities offers an in depth state-by-state analysis of how premiums will be impacted if APTCs expire.

Congressional Republicans have been <u>very vocal</u> in their opposition to extending enhancements. For Democrats and the Biden-Harris Administration, APTCs are a key element of their efforts to make access to health care and health coverage affordable. While Democrats would prefer to make APTCs permanent, it is more likely that they will be extended during the Lame Duck and the debate over permanency will be punted to later in 2025 when Congress debates the larger tax package.

Medicaid Program Integrity

Earlier this year, the House considered proposals to address improper payments in Medicaid and Medicare as well as policy solutions to improve program integrity. Republicans have been critical of the Center for

Medicare & Medicaid Services (CMS') leadership in managing improper payments, calling for the agency to do more to ensure the accuracy of beneficiary address information as well as prevent fraudsters from using national provider identifiers (NPIs) of deceased providers to submit fraudulent payments. Members of the Energy & Commerce Committee found unanimous bipartisan agreement on five pieces of legislation, advancing all to the House floor during a June markup:

- An amendment in the nature of a substitute (AINS) for H.R. 8084, LIVE Beneficiaries Act
- H.R. 8089, Medicare and Medicaid Fraud Prevention Act of 2024
- An <u>AINS</u> for <u>H.R. 8111</u>, To amend title XIX of the Social Security Act to ensure the reliability of address information provided under the Medicaid program
- An AINS H.R. 8112, To amend title XIX of the Social Security Act to further require certain additional provider screening under the Medicaid program
- An AINS for H.R. 4758, Accelerating Kids' Access to Care Act

Despite the bipartisan nature of the bills advanced in the House, it remains to be seen if they will receive similar bipartisan support in the Senate, which has instead focused on proposals to modernize care delivery in Medicare and Medicaid.

Regulatory Update

The Office of Management and Budget (OMB) is reviewing the following rules:

Medicare

Fraud – The <u>final rule</u> would modify the Medicare Shared Savings Program (Shared Savings Program) regulations to address the impact of significant anomalous billing patterns on performance year (PY) 2023 Accountable Care Organization (ACO) financial reconciliation (no date).

Medicaid

• Drug Rebate Program – The final rule would establishes requirements related to manufacturers' misclassification of covered outpatient drug products under the Medicaid Drug Rebate Program (MDRP). In addition, it finalizes beneficiary protections, as well as MDRP program integrity and administration changes (June 2024).

Private Insurance

ACA Marketplace – The <u>proposed rule</u> would set payment parameters and provisions related to
the risk adjustment programs; cost-sharing parameters; and user fees for issuers offering plans
on Federally-facilitated Exchanges and State-based Exchanges using the Federal platform. It
would also provide additional standards for several other ACA programs (September 2024).

Other Topics

- Mental Health Parity The <u>final rule</u> would clarify plans' and issuers' obligations under the Mental Health Parity and Addiction Equity Act (MHPAEA) and implement new requirements (July 2024).
- **Organ Procurement** The <u>proposed rule</u> would make clarifications and technical modifications to the standards used to evaluate and recertify organ procurement organizations (OPOs) and to the competition and decertification process for organ procurement organizations (March 2025).
- Healthcare System Resiliency and Modernization The <u>proposed rule</u> would revise and update national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers (was set for December 2023).
- Retail Pharmacy Standards The <u>final rule</u> would require pharmacies and vendors to modify the
 currently adopted National Council for Prescription Drug Programs (NCPDP) standards to the
 Telecommunications Standard Implementation Guide Version F6 (F6); Batch Standard
 Implementation Guide version 15; and Batch Standard Subrogation Implementation Guide version
 10 (was set for February 2024).

This Week in Health Policy

Tue. (9/3)

11:00am – HITAC Meeting: HTI-2 Proposed Rule Task Force – The Health Information
Technology Advisory Committee (HITAC) holds a meeting of the HTI-2 Proposed Rule Task
Force to evaluate and provide draft recommendations to the HITAC on the Health Data,
Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health
Interoperability (HTI-2) Proposed Rule. <u>Details</u>.

Wed. (9/4)

- 11:00am HITAC Meeting: HTI-2 Proposed Rule Task Force HITAC holds a meeting of the HTI-2 Proposed Rule Task Force to evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. Details.
- 2:00pm R Street Discussion: Tobacco Smoking Cessation The R Street Institute holds a discussion on the current evidence about reduced-risk nicotine products, their impact on tobacco harm reduction, and how people who use drugs respond to these concepts. Details.

Thurs. (9/5)

- 11:00am HITAC Meeting: HTI-2 Proposed Rule Task Force HITAC holds a meeting of the HTI-2 Proposed Rule Task Force to evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. <u>Details</u>.
- Meeting: MedPAC The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. <u>Details</u>.

Fri. (9/6)

- 8:00am HRSA Meeting: Public Health Future Needs/Equity/Recruitment The Health
 Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on
 Interdisciplinary, Community-Based Linkages for policy and program development and other
 significant matters related to activities authorized under Part D of the Public Health Service Act,
 positioning the public health system to anticipate future needs, reversing the negative trend in
 health care recruitment and retention, and identifying ways to incentivize health equity. Details.
- 1:30pm HHS Meeting: President's Council on Sports, Fitness & Nutrition The Department of Health and Human Services (HHS) holds the annual meeting of the President's Council on Sports, Fitness & Nutrition to share highlights and present awards. Details.

Additional Multi-Day Events

 Sep 4-Sep 6 – HRSA Meeting: Rural Health/Human Services – HRSA holds a meeting of the National Advisory Committee on Rural Health and Human Services to discuss the opioid crisis and its impact on rural families, focusing on prevention efforts but will include related discussions of treatment and recovery and discuss the availability of disability services in rural areas. <u>Details</u>

Featured Analysis

- Impact Chart of PBM Legislation In the Policy Hub Insight Bank here.
- Impact Regulatory Outlook: Spring 2024 Unified Agenda In the Policy Hub Insight Bank here.
- Making Sense of the New Landscape for Health Policy After Recent Supreme Court Decisions

 In the Policy Hub Insight Bank here.
- Impact Mental Health Legislative Update In the Policy Hub Insight Bank here.
- Impact Chart of Key Provisions of Legislative Proposals on Health Care Price Transparency Requirements – In the Policy Hub Insight Bank here.

Congressional Lookback

Thurs. (8/29)

 Sen. Mike Rounds (R-SD) introduced a package of <u>five AI-focused bills</u> for the Senate to consider when it reconvenes in September. <u>Details</u>.

Weds. (8/28)

• The Senate Agriculture, Nutrition, and Forestry Committee Leadership sent a letter to the USDA inquiring about supply chain disruptions and inventory shortages in the Food Distribution Program on Indian Reservations and Commodity Supplemental Food Program. Details.

Regulatory Lookback

Thurs. (8/29)



- **HHS** announced over \$558 million in funding to improve maternal health, reinforcing its commitment to reducing the high maternal mortality rate in the U.S. <u>Details</u>.
- The FDA issued a <u>final rule</u> that will establish a new Federal minimum age of sale for tobacco products. <u>Details</u>.

Tues. (8/27)

• **SAMHSA** <u>announced</u> \$65.7 million in grant awards for substance use prevention services, enhancing the behavioral health workforce and behavioral health care for children and those at risk of becoming unhoused. <u>Details</u>.

Comment & Application Deadlines

- **September 7:** The FDA released <u>draft Q&As</u> to address misinformation about medical devices and prescription drugs. <u>Details</u>.
- September 9: CMS released the CY 2025 MPFS proposed rule. Details.
- September 9: CMS released the CY 2025 OPPS/ASC proposed rule. Details.
- September 20: CMS released a <u>notice of funding opportunity (NOFO)</u> for the Transforming Maternal Health (TMaH) Model. <u>Details</u>.
- September 25: AHRQ issued a <u>Notice of Funding Opportunity (NOFO)</u> aimed at exploring the impact of artificial intelligence (AI) technologies on patient safety. The first application due date is September 25, 2024. The current closing date for applications is May 25, 2027. <u>Details</u>.
- September 26: The FDA issued <u>draft guidance</u> entitled "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies." <u>Details</u>.
- September 30: The CDC is <u>seeking nominations</u> for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). <u>Details</u>.
- February 25: CMMI released an RFA for the Cell and Gene Therapy Access Model. Details.
- **February 25:** CMMI released a <u>NOFO</u> to apply for Cooperative Agreement funding to support states' participation in the Cell and Gene Therapy (CGT) Access Model. <u>Details</u>.