

Impact Health Policy Weekly

Framing the Week

The House and Senate are both in recess until after Labor Day. During this break, we are continuing to take the opportunity to dive a bit deeper into issues of interest. This week, we are looking at current legislation focused on pharmacy benefit manager (PBM) and prescription drugs. The House has incorporated their PBM provisions into broader health-related transparency packages, while the Senate has crafted larger PBM-specific packages aimed at several PBM practices.

Six committees of jurisdiction have taken up and advanced PBM-related legislation out of committee. Impact Health Policy provides a chart [here](#) of all PBM legislation considered in the 118th Congress. Below we describe the major legislative vehicles for PBM reform by Committee:

- **Senate Finance Committee (SFC)** – The [Modernizing and Ensuring PBM Accountability \(MEPA\) Act \(summary\)](#) features provisions to limit PBM reimbursement to a bona fide service fee; increase transparency requirements; establish standardized pharmacy performance measures; and prohibit spread pricing in Medicaid.
- **Senate Health, Education, Labor, and Pensions (HELP) Committee** – [S. 1339](#), the Pharmacy Benefit Manager Reform Act ([summary](#)) includes provisions related to PBM transparency, prohibiting spread pricing, and 100 percent rebate pass-through to insurers.
- **House Energy and Commerce (E&C) Committee** – [H.R. 3561](#), the Promoting Access to Treatments and Increasing Extremely Needed Transparency (PATIENT) Act ([summary](#)) establishes PBM transparency requirements, prohibits spread pricing in Medicaid, and address cost sharing for highly rebated drugs.

The bill is also inclusive of transparency requirements for hospitals and insurers; aligns payment rates for drug administration and hospital outpatient departments, provides increased funding for community health centers, the special diabetes program, and the Teaching Graduate Medical Education Program, and cancels \$16 billion in cuts to Disproportionate Share Hospital (DSH) payments.

- **House Ways and Means (W&M) Committee** – [H.R. 4822](#), the Health Care Price Transparency Act of 2023 ([summary](#)) features PBM transparency requirements and limiting Part D cost sharing to the net price of Part D drugs. The bill also features hospital insurer transparency provisions, as well as proposals to address the use of prior authorization in [Medicare Advantage](#).

- **House Education and Workforce Committee** – The Committee has advanced [H.R. 4507](#), the Transparency in Coverage Act, [H.R. 4508](#), the Hidden Fee Disclosure Act, and [the DATA Act \(summaries\)](#), which address PBM transparency requirements, PBMs use of gag clauses, and PBM and third-party administrator compensation to plan fiduciaries. The Transparency in Coverage Act also codifies the Hospital Transparency in Coverage final rule.

What's Next? With a short amount of time to finalize appropriations bills and must-pass reauthorizations by the end of the fiscal year, other health-related legislation, such as PBM reform, hospital and insurer transparency, and site-neutral proposals may be included in an end-of-year package. With the House and Senate taking different approaches to PBM reform, the two chambers will need to come to agreement on which provisions among transparency, prohibiting spread pricing, and addressing rebates and PBM reimbursement will make it into the final package.

Regulatory Update:

No new rules have cleared review at the Office of Management and Budget (OMB). OMB is reviewing the following rules:

- **Minimum staffing standards for long-term care facilities** – [Proposed rule](#) would address staffing requirements at long-term care facilities, including nursing homes. Industry pushback has delayed the release of the rule, initially intended for June. Stakeholders are meeting with OMB in early September, meaning we are unlikely to see the proposal until the fall.
- **Medicaid and CHIP Enrollment and Eligibility** – [Final rules](#) intended to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP and the Basic Health Program. The first final rule expected in September 2023 will remove barriers and facilitate enrollment of new applicants, particularly those dually eligible for Medicare and Medicaid. The second final rule expected in February 2024 will implement changes to align enrollment and renewal requirements for most individuals in Medicaid and promote maintenance of coverage.
- **Mandatory Medicaid and CHIP Core Set Reporting** – [Final rule](#) would establish requirements for mandatory reporting of the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP, the behavioral health measures on Adult Health Care Quality Measures for Medicaid, and the Core Set of Health Care Quality Measures for Medicaid Health Home Programs. The final rule is expected in August 2023.
- **Food and Drug Administration (FDA) Regulation of Laboratory-Developed Tests (LDTs)** – [Proposed rule](#) would make explicit that LDTs are devices under the Federal Food, Drug, and Cosmetic Act and subject to FDA regulation.

This Week in Health Policy

Mon. (8/21)

- **2:00pm – CMS Meeting: MCP RFA Office Hours** – The Centers for Medicare and Medicaid Services (CMS) holds office hours to discuss questions related to the Making Care Primary (MCP) Request for Applications (RFA). Questions can be submitted in advance via registration or sent to MCP@cms.hhs.gov. [Details.](#)

Tue. (8/22)

- **10:00am – FDA Meeting: Tobacco Products’ Strategic Plan** – The Food and Drug Administration (FDA) holds a meeting to obtain feedback on the proposed strategic goals that are being used to develop FDA’s Center for Tobacco Products’ (CTP) comprehensive Strategic Plan. [Details.](#)
- **3:00pm – Urban Institute Discussion: Correctional Workforce Rewards** – The Urban Institute holds a discussion on rewards and sanctions in the correctional environment and how research and lessons from on-the-ground implementation can be used to promote a healthy and productive workplace. [Details.](#)

Wed. (8/23)

- **10:30am – HITAC Meeting: Pharmacy Interoperability** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Pharmacy Interoperability and Emerging Therapeutics Task Force to discuss program updates. [Details.](#)
- **12:00pm – CMS Meeting: Medicaid and CHIP Renewals** – The Centers for Medicare and Medicaid Services (CMS) holds a Medicaid and Children’s Health Insurance Program (CHIP) webinar on engaging faith and community organizations, including best practices and updates on CMS’ work related to the renewals. [Details.](#)

Thurs. (8/24)

- **1:00pm – BPC Discussion: Housing Support** – The Bipartisan Policy Center holds a discussion on research highlighting the role of neighborhoods in childhood development and the implications for federal housing policy and the potential for targeted housing support to expand access to opportunity for low-income families. [Details.](#)
- **2:00pm – Health Innovation Alliance Discussion: Information Blocking** – The Health Innovation Alliance holds a discussion with the National Coordinator for Health Information Technology focused on the information blocking regulations from the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) final rules and how these rules will impact laboratories, pharmacies, community health centers and others. [Details.](#)

Additional Multi-Day Events

- **August 22-August 23 – NIST Meeting: Internet of Things** – The National Institute of Standards and Technology holds a meeting of the Internet of Things Advisory Board to discuss public safety and health care among other topics, including policies or multi-stakeholder activities that promote or are related to the privacy of individuals who use or are affected by the Internet of Things (IoT). [Details.](#)

Featured Analysis

- **Impact Regulatory Outlook: 2023 Unified Agenda** – In the Policy Hub Insight Bank [here.](#)
- **Impact Updated Chart: PBM Legislation Under Consideration** – In the Policy Hub Insight Bank [here.](#)

- **Impact Tracker of COVID-19 PHE Flexibilities** – In the Policy Hub Insight Bank [here](#)
- **Impact Health Policy Guide to the 118th Congress** – In the Policy Hub Insight Bank [here](#).
- **Impact Roundup of Surprise Billing and Transparency Updates**– In the Policy Hub Insight Bank [here](#).

Regulatory Lookback

Fri. (8/18)

- **CISA, ONCD, OMB, and DARPA** announced an [RFI](#) to gather input from the open source software community and cybersecurity experts. Comments are due October 9. [Details](#).

Weds. (8/16)

- **ASPE** released a comprehensive [report](#) outlining the impact of the IRA on prescription drug costs for the more than 65 million Americans enrolled in the Medicare program. [Details](#).
- **The DOJ** released an updated [Language Access Plan](#) aimed at providing equal access to its programs, activities, and services for individuals regardless of their language proficiency. [Details](#).

Tues. (8/15)

- **The EEOC** issued an [NPRM](#) to implement the Pregnant Workers Fairness Act. Comments are due October 10. [Details](#).

Mon. (8/14)

- **CMMI** released a [Request for Application](#) detailing payment, care delivery, quality, and other policies for the Making Care Primary (MCP) Model. Applications are due November 30. [Details](#).

Comment & Application Deadlines

- **August 23:** The FDA issued [draft guidance](#) entitled: “Psychedelic Drugs: Considerations for Clinical Investigations. [Details](#).
- **August 25:** CMS released the CY 2024 ESRD PPS [proposed rule](#). [Details](#).
- **August 26:** CMS released a [notice with comment](#) to establish the TCET pathway. [Details](#).
- **August 28:** The FDA [issued](#) an RFI to assess whether in-home disposal products can mitigate the risk of nonmedical use or overdose of opioid analgesics. Submissions are due August 28. [Details](#).
- **September 5:** CMS issued a [proposed rule](#) that describes the agency’s proposed actions to remedy the payment for 340B drugs for calendar years (CYs) 2018 through 2022. [Details](#).
- **September 5:** The CFPB and HHS issued an [RFI](#) on high-cost specialty financial products used to pay for health care. [Details](#).
- **September 6:** The FDA [issued](#) a proposed rule to establish tobacco product manufacturing practice (TPMP) requirements. [Details](#).
- **September 11:** HHS released a [proposed rule](#) to ensure short-term, limited duration insurance (STLDI) and fixed indemnity benefits coverage do not undermine consumer protections and requirements under the ACA. [Details](#).
- **September 11:** CMS released the CY 2024 MPFS [proposed rule](#). [Details](#).

- **September 11:** CMS released the CY 2024 OPPS [proposed rule](#). [Details](#).
- **September 29:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [Details](#).
- **October 6:** CISA and FEMA are collaborating to [provide](#) \$374.9 million in grants to enhance cybersecurity for state and local governments, responding to increasing threats to critical infrastructure and public safety. [Details](#)
- **October 10:** The EEOC issued an [NPRM](#) to implement the Pregnant Workers Fairness Act. [Details](#).
- **November 17:** The FDA [issued](#) a proposed rule to amend its prescription drug labeling regulations to require the inclusion Patient Medication Information (PMI). [Details](#).
- **November 30:** CMMI released a [Request for Application](#) detailing payment, care delivery, quality, and other policies for the Making Care Primary (MCP) Model. [Details](#).