

Impact Health Policy Weekly

Framing the Week

The House and Senate are both in recess until after Labor Day. 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 and Election Preview memo in September. This week, we are highlighting health care transparency policies under consideration.

Price Transparency

In the divided Congress, members of both parties and chambers have focused on building upon [hospital](#) and [health plan](#) price transparency rules promulgated by the Trump Administration by strengthening transparency and accountability requirements. In December 2023, the House passed the **Lower Costs, More Transparency (LCMT) Act (H.R. 5378)** by a bipartisan vote (320-71). Also, in December 2023, Sens. Mike Braun (R-IN) and Chairman of the Senate Committee on Health, Education, Labor, and Pensions (HELP) Bernie Sanders (I-VT) introduced the **Health Care PRICE Transparency Act 2.0 (S. 3548)** – a bipartisan bill that represents the Senate’s version of the LCMT Act. Though S. 3548 has not been marked up, it continues to garner new cosponsors – 12 total, including four members since June. The continued momentum for price transparency reforms bodes well for the inclusion of a version of these bills in a potential lame duck package.

In this [series of charts](#), we compare the LCMT Act, Health Care PRICE Transparency Act 2.0, and current regulations. Key takeaways:

- **Provider Price Transparency:** Both bills propose to codify key provisions of the Hospital Price Transparency Rule – specifically, requirements for hospitals to post standard charges in machine-readable files and consumer-friendly internet-based price estimator tools. Standard charges are gross charges, discounted cash prices, payer-specific negotiated charges, and de-identified minimum and maximum negotiated charges. In addition, both bills propose changes to address concerns with reporting requirements; increase compliance with the rule; and broaden price transparency to clinical diagnostic laboratories, ambulatory surgical centers, and imaging centers. Regarding monitoring and enforcement, the Health Care PRICE Transparency Act 2.0 proposes a more rigorous approach – requiring a compliance review at least once every year (compared to every three years in the LCMT Act), requiring an attestation from senior officials at hospitals, and prohibiting the HHS Secretary from granting any waivers to penalties. In contrast, the LCMT Act allows the Secretary to waive or reduce penalties for hospitals and ambulatory surgical centers.

- **Health Plan Price Transparency:** Both bills propose to codify key provisions of the Transparency in Coverage Rule – specifically, requirements for group health plans and issuers of group or individual health insurance to disclose pricing information in (1) machine-readable files containing in-network rates for covered items and services and allowed amounts for, and billed charges from, out-of-network providers; and (2) an internet-based price comparison tool (self-service tool) and in paper form, upon request. Both bills propose additional disclosures. Notably, Health Care PRICE Transparency Act 2.0 includes a provision requiring plans and issuers to hold individuals harmless for the balance if the amount ultimately billed or charged to the individual exceeds the cost-sharing amount generated by the self-service tool.

Ownership Transparency

As for ownership transparency, there is bipartisan support for incremental changes that could be included in a potential lame duck health package. LCMT Act includes a provisions requiring a unique national provider identifier (NPI) for hospital-owned outpatient departments when filing a hospital claim under Medicare, which would reveal the specific location where a patient received care. As explained by [experts](#) at Georgetown University’s Center on Health Insurance Reforms, the unique NPI information could facilitate future reforms on site neutrality. They note that the proposal in the LCMT Act does not apply to claims with private insurers. The Senate HELP Committee passed the **Bipartisan Primary Care and Health Workforce Act (S. 2840)**, which would extend the unique NPI requirement to private insurers.

The House Energy and Commerce unanimously passed the **PATIENT Act of 2023 (H.R. 3561)** in May 2023, but it was excluded from the House-passed LCMT Act. The bill includes a provision on mandatory reporting on certain health-related ownership, including private equity companies, with enforcement authority to impose penalties up to \$5 million per violation. House Ways and Means Ranking Member Richard Neal (D-MA) [opposed](#) the LCMT Act for its lack of ownership transparency that would work to address and identify PE control in health care. Whether the proposal could be in play during the lame duck session remains to be seen.

Regulatory Update

The Office of Management and Budget (OMB) completed reviewing a [final rule](#) would prohibit the sale of tobacco products to persons younger than 21 years of age (was set for April 2024). OMB is also reviewing the following rules:

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 [proposed rule](#) 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

- **Organ Procurement** – The [proposed rule](#) 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 [proposed rule](#) 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 [final rule](#) 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

Mon. (8/19)

- **2:00pm – Health Affairs Discussion: Future of Long-Term Care** – Health Affairs holds a discussion on the implications of recent nursing home developments for residents, their families, and the future of long-term care, including nursing home staffing trends. [Details.](#)

Tue. (8/20)

- **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. This meeting of Group 1 will be focusing on: New standardized API for public health data exchange. [Details.](#)

Thurs. (8/22)

- **9:00am – CDC Meeting: Health Care Infection Control Practices** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) to review the progress of on-going workgroups and to vote on the Healthcare Personnel Guideline Cytomegalovirus (CMV) Recommendations and Viral Hemorrhagic Fever Update. [Details.](#)

- **10:00am – 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. This meeting of Group 3 will be focusing on Trusted Exchange Framework and Common Agreement. [Details.](#)
- **1:00pm – 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. This meeting of Group 2 will be focusing on: Select Revised Certification Criteria and New Certification Criteria, including the Real-Time Prescription Benefit Criterion. [Details.](#)
- **1:30pm – NIH Meeting: Drivers of Mental Health Disparities for LGBTQ+ Communities** – The National Institutes of Health (NIH) holds a meeting of the National Institute of Mental Health to present the goals and procedures of the Rural Engagement and Approaches For LGBTQ+ Mental Health (REALM) study, which is developing a longitudinal cohort of diverse LGBTQ+ adults residing in rural and small metropolitan communities across the United States. REALM aims to determine how stigma and discrimination act as drivers of mental health disparities for these communities. [Details.](#)
- **2:00pm – HRSA Meeting: Blood Stem Cell Transplantation** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Council on Blood Stem Cell Transplantation to discuss criteria for defining a high-quality cord blood unit for banking specifications, the unmet needs in blood stem cell transplantation and cellular therapy, updates on transplant outcomes by different donor sources, strategies to improve rates of donation for adult blood stem cell donors and other areas to increase blood stem cell donation and transplantation. [Details.](#)

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.](#)

Regulatory Lookback

Fri. (8/16)

- **NIH [announced](#)** the launch of the Native Collective Research Effort to Enhance Wellness (**[N CREW](#)**) Program with \$268 million in funding to support Native American-led research to address overdose, substance use, and pain. [Details.](#)

Thurs. (8/15)

- **CMS** released the negotiated [Maximum Fair Prices \(MFPs\)](#) for 10 drugs covered under Medicare Part D, which will take effect on January 1, 2026. [Details.](#)

Weds. (8/14)

- **HHS and HRSA** [awarded](#) nearly \$9 million to 18 HRSA-funded health centers to enhance access to cancer screenings and treatment in underserved communities. [Details.](#)
- **CMS** issued a [CMCS Information Bulletin \(CIB\)](#) with requirements and best practices to ensure timely access to family planning services and supplies through Medicaid and CHIP. [Details.](#)

Mon. (8/12)

- **AHRQ** issued a [Notice of Funding Opportunity \(NOFO\)](#) 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. [Details.](#)

Comment & Application Deadlines

- **August 20:** SAMHSA is [seeking](#) applications for the Women’s Behavioral Health Technical Assistance Center (Women’s BH TAC) program for fiscal year 2024. [Details](#)
- **August 26:** CMS issued the CY 2025 home health prospective payment and rate update [proposed rule](#). [Details.](#)
- **August 26:** CMS released its CY 2025 end-stage renal disease (ESRD) prospective payment system (PPS) [proposed rule](#). [Details.](#)
- **September 2:** CMS released an [ICR](#) for the Negotiation Data Elements and Drug Price Negotiations Process for IPAY 2027 of the Medicare Drug Price Negotiation Program. [Details.](#)
- **September 7:** The FDA released [draft Q&As](#) to address misinformation about medical devices and prescription drugs. [Details.](#)
- **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 [notice of funding opportunity \(NOFO\)](#) for the Transforming Maternal Health (TMaH) Model. [Details.](#)
- **September 25:** **AHRQ** issued a [Notice of Funding Opportunity \(NOFO\)](#) 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. [Details.](#)
- **September 26:** The FDA issued [draft guidance](#) entitled “Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.” [Details.](#)
- **September 30:** The CDC is [seeking nominations](#) for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). [Details.](#)

- **February 25:** CMMI released an [RFA](#) for the Cell and Gene Therapy Access Model. [Details](#).