# Highmark's Weekly Capitol Hill Report

**Issues for the week ending July 19, 2024**

## Federal Issues

Regulatory

### CMS Issues Final Part Two Guidance on the Medicare Prescription Payment Plan

CMS released the final part two guidance and related fact sheet for the Medicare Prescription Payment Plan (MPPP) that was established by section 11202 of the Inflation Reduction Act (P.L. 117-169).

According to the fact sheet, the final part two guidance is primarily focused "on Part D enrollee education, outreach, and communications related to the Medicare Prescription Payment Plan," building upon what was included in the final part one guidance. In addition to the guidance, CMS has published six model documents "to support Part D sponsors in meeting their education, outreach, and communications requirements," which are available on the CMS website.

**Why this matters:** The guidance includes a summary of significant comments that CMS received in response to the draft part two guidance, as well as the agency's response

## In this Issue:

to those significant comments. The final guidance also summarizes key changes and updates made from the draft part two guidance as well as clarifications which include:

- The final guidance does not require Part D sponsors to send an MPPP election request form with the membership ID card mailing. Instead, Part D sponsors may choose to either send an election request form with the membership ID card mailing or separately in a different mailing sent out within the same timeframe as the membership ID card mailing.

- The final guidance does not specifically require targeted outreach during the plan year based on prior authorization or other utilization management edits in place for a drug with out-of-pocket costs at or above the pharmacy point of sale (POS) notification threshold. The final guidance still requires Part D sponsors to put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit during the plan year. CMS states that Part D sponsors must develop their own strategies for ongoing outreach during the plan year to enrollees who are likely to benefit from the program.

- The final guidance includes modified requirements for the re-adjudication of prescription drug claims for new MPPP participants. The final guidance states that only the prescription that triggered the likely to benefit notification must be reversed and reprocessed, so the date of service on the claim falls within the enrollee's dates of participation in the MPPP. If the enrollee has other prescriptions with earlier dates of service that have not yet been paid for and picked up, the pharmacy is only

## Industry Trends

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- **HHS Announces Social Worker Licensure Compact to Address Workforce Shortages**

required to reverse and reprocess those claims at the request of the participant.

- CMS states that it "does not intend to conduct any audits of plan sponsors' Medicare Prescription Payment Plan programs in CY 2025 and will engage with plan sponsors throughout the first year of the program to identify educational opportunities and potential compliance issues, with the goal of supporting all plan sponsors in offering compliant programs."

**Go Deeper:** Read the fact sheet here

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## AHIP Comments on CMMI Model Focused on Expanding Access to Organ Transplant

AHIP submitted a comment on a proposed rule from the Centers for Medicare & Medicaid Services (CMS) implementing the Increasing Organ Transplant Access (IOTA) Model under the CMS Innovation Center (CMMI).

**Why this matters:** The model would complement the recent launch of the Health Resources & Services Administration's Organ Procurement and Transplantation Network (OPTN) Modernization Initiative. If finalized, IOTA will evaluate whether using performance-based payments for transplant hospitals increases the number of kidney transplants to patients with end-stage renal disease (ESRD).

**Highlights of the comment letter include:**

- Supporting CMS's proposal not to include Medicare Advantage (MA) enrollees when calculating provider bonuses under this model as this could cause confusion with value-based care programs already implemented by plans. Instead AHIP encouraged CMMI to seek alignment with MA plans by providing sufficient time, details, and technical assistance to voluntarily integrate the model into their value-based programs.

- Encouraging the Innovation Center to evaluate AHIP, the AMA, and NAACOS' Future of Value playbook for IOTA and other models to facilitate multi-payer alignment.

- Recommending CMS ensure quality measures used in the program be feasibly reported and suggesting the agency explore ways to leverage technology to reduce reporting burden.

- Recommending CMS explore ways to make a more person-centered performance measure set and consider ways to foster coordination with community-based organizations equipped to address social needs and downstream providers that can assist with managing post-acute care to better position transplant hospitals and their patients for success.

**Go Deeper:** Read our comments here.

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## CMS Releases FAQ on PrEP NCD

CMS recently published a frequently asked questions (FAQ) document to prepare pharmacies and other stakeholders for an upcoming national coverage determination (NCD) under Part B for preexposure prophylaxis (PrEP) to prevent HIV.

**Why this matters:** The document lays out coding and other implementation details the agency says pharmacies need to have in place to avoid disrupting patient access when the NCD comes out. CMS added that the final version of the NCD is expected to be similar to the proposed version published in July 2023. If finalized, the drugs will be immediately covered under Part B instead of Part D.

**Go Deeper:** Review the FAQ here. Read more about the proposed NCD here.

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## CMS Issues Guidance Implementing Medicaid Provider Directory Requirements

The Centers for Medicare & Medicaid Services (CMS) recently released a State Health Official (SHO) letter to provide guidance on Medicaid and CHIP provider directory requirements.

**The Bottom Line:** No new requirements for managed care organizations. The SHO explains that current Medicaid and CHIP managed care regulations already address most of the requirements enacted by the Consolidated Appropriations Act, 2023 (CAA 2023).

**Additional SHO Highlights:**

- A new provider directory requirement from the CAA 2023 that provider directories be searchable in electronic form and include whether the provider offers covered services via telehealth. These requirements were incorporated into the May 2024 Managed Care final rule.

A reminder for states of the availability of enhanced FFP for Medicaid FFS provider directory development and operations, and details non-compliance policies.

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### CMS Issues Updated Guidance on 2025 Agent/Broker Compensation Rates & Training and Testing Guidelines

On July 18, the Centers for Medicare & Medicaid Services (CMS) issued memorandum to provide updated MA and Part D guidance on contract year 2025 agent/broker compensation rates and training and testing guidelines. CMS indicates that it has updated the calendar year 2025 fair market value (FMV) amounts previously published in its June 28, 2024 memo in light of the preliminary injunction issued by the U.S. District Court for the Northern District of Texas on July 3, 2024.

CMS further states that "the regulatory language within 42 C.F.R. § 422.2274(a), (c), (d), (e) and § 423.2274(a), (c), (d), (e) that was effective prior to the issuance of the 2025 Final Rule will be in effect for Contract Year 2025 while the stay is ordered." Additionally, CMS provides guidance to plans on compensation rate submissions for 2025 and notes that the agency "will not pursue compliance actions against plans for failing to submit data by July 26, as long as plans make a good faith effort to submit the requisite data to CMS in HPMS in a timely manner."

CMS has also updated portions of the CY 2025 agent/broker training and testing guidelines in light

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## State Issues

### Pennsylvania

Legislative

### PBM Legislation Summary

The Senate and House recently passed an amended version of HB 1993, legislation that imposes requirements and prohibitions on PBMs. The legislation was subsequently delivered to Governor Josh Shapiro, who signed the legislation last week as Act 77 of 2024. New definitions contained within the Act will take effect on Wednesday, October 15 with the remainder taking effect on Friday, November 14.

AHIP and other stakeholders previously submitted letters opposing both the House and Senate versions of the bill, outlining concerns with numerous provisions, including a prohibition on spread pricing, requirements concerning preferred networks, and any willing pharmacy requirements. AHIP also pushed for the inclusion of language specifically exempting self-insured ERISA plans.

**Why this matters:** Importantly, the final bill does not include a prohibition on spread pricing and does include clear ERISA preemption language. Notable provisions included in the as-passed version include the following:

***Section 1. Applicability***

- Applies the act to contracts between pharmacies, PBMs, and health insurers or health benefit plans, but does not apply to self-insured health benefit plans subject to ERISA, except for provisions in Chapter 5.

***Section 6. PBM Operational Requirements***

- Prohibits a PBM as part of a contract agreement from:
  - Reimbursing pharmacies or pharmacists less than it reimburses its own affiliated pharmacies for the same services,
  - Reimbursing qualified health centers or covered entities less than similar non-participating entities,
  - Authorizing the PBM to unilaterally alter contract terms, and
  - Designating a prescription drug as specialty drugs unless it meets specific criteria.

- Requires a PBM to pass through at least 95% of any prescription drug manufacturer rebate to the health benefit plan if the plan delegates rebate negotiation to the PBM.

- Prohibits health plans, insurers, or PBMs from:
  - Requiring exclusive use of mail-order pharmacies or PBM affiliates.
  - Prohibiting or limiting the choice of in-network pharmacies or pharmacists if they meet contract terms.
  - Mandating the use of PBM-affiliated retail pharmacies.
  - Transferring prescriptions without the individual's request.
  - Using financial incentives to benefit PBM-affiliated retail pharmacies exclusively.
  - Auto-enrolling individuals in mail-order services, except under specific conditions.

- Allows PBMs, health plans, or insurers to:
  - Require the use of an approved specialty pharmacy within the PBM's network.
  - Auto-enroll individuals in mail-order services for maintenance medication after the first 90 days and allow them to opt out at any time.

- Prohibits health benefit plans, insurers, or PBMs from collecting from members any difference between what the member pays to the pharmacy and the cost-sharing amount defined in the member's benefit plan.

- Establishes network adequacy requirements for PBMs.

***Section 7. PBM Transparency Report***

- Requires each registered PBM to submit a transparency report to the department containing data from the prior calendar year for each health insurer client in the Commonwealth.

- Requires the report to aggregate the amount of:
  - All rebates received from pharmaceutical manufacturers for all health insurer clients and for each health insurer client.
  - Administrative fees received from all manufacturers for all health insurer clients and for each health insurer client.
  - Rebates received from all pharmaceutical manufacturers and not passed through to health insurer clients.

    - The highest, lowest, and mean aggregate retained rebate percentage for all health insurer clients and for each health insurer client.
    - For PBMs controlling or affiliated with a pharmacy, a description of any differences in reimbursement or charges between affiliated and nonaffiliated pharmacies.

- Requires the department to publish the PBM transparency report on its public website.

- Allows the department to direct PBMs to include additional categories for aggregated data.

- Establishes confidentiality standards for the transparency report.

***Section 10. Compliance and Penalties***

- The department may order a PBM, a health insurer, and a PBM's affiliates to produce records, books, or other information as necessary to ensure compliance with the act.

- Permits the department, at the PBM's expense, to retain expert(s) to conduct an analysis of PBM business practices, including:
    - The impact of steering and spread pricing on the cost of prescription drugs to consumers.
    - The impact to consumers and pharmacies of requiring insurers to reimburse pharmacies using NADAC and a minimum $10.49 dispensing fee.

- Requires the department to establish a process for pharmacies to refer the designation of a prescription drug as a specialty drug if it fails to meet the criteria under section 103.

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## Pennsylvania Legislative Update

On Monday, July 15 Governor Shapiro signed Senate Bill 1092, Senator DiSanto's Insurance Rebate and Inducement prohibition into law at Act 62 of 2024, as well as Houe Bill 1664, Representative Scott's Virtual Credit Card legislation into law as Act 58 of 2024. Senate Bill 1092 will take effect on Sunday, January 11, 2026, with House Bill 1664 taking effect on Saturday, September 13th.

**Pharmacy Transparency:**
Representative Cutler has filed House Co-Sponsorship Memo 3485 which would require insurers to pass any prescription drug rebates they receive directly onto members of an insurance plan. Staff are working with Representative Cutler to obtain more information on the forthcoming legislation.

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Regulatory

## Updates to the PA DOH Infection Control Plan Approval Process

The Bureau of Epidemiology has rolled out new improvements to the infection control review and approval process, effective immediately. The improvements outlined largely reflect the concerns expressed by hospitals and ambulatory surgery facilities.

**Background:** During 2022, the Pennsylvania Department of Health's Bureau of Epidemiology rolled out a new process for reviewing and approving infection control plans for hospitals and ambulatory surgery facilities. Soon after the process was unveiled, hospitals reported challenges getting infection control plans approved, prolonged timelines for screening and approval, strains on infection control resource personnel, and variations in the review process.

The Hospital & Healthsystem Association of Pennsylvania (HAP) began discussions with DOH later that year in an attempt to strike a balance between improving the standard of infection control plans and engaging in a revision process so lengthy that it offered diminishing return.

**Under the new process:**

- Infection control plans will no longer be subject to the screening process.
- Facilities will no longer be required to submit policies as part of the infection control plan.
- DOH will be drastically reducing the number of re-submissions with the goal of incorporating all comments and revisions in one round.
- DOH will be using a file collection platform to streamline the submission process.
- The focus of the review will be on the core elements of the infection control plan (as opposed to style, formatting, and grammar).
- Infection control plan submissions will no longer be required for change of ownership unless there is a change in services offered by the hospital.

More information on changes being implemented by DOH is available **online**.

**Why this matters:** The new changes are a welcome development. Despite following the 2022 requirements, suggested edits, and using the resources created by the Bureau of Epidemiology to re-write infection control plans, several health care facilities reported that their plans continued to be denied (some as many as 10 or 11 times).

Facilities were being asked to embed every policy referenced in their plan and to provide a high level of detail for each component of the plan. At the time, infection preventionists expressed concern regarding the level of specificity required and subsequent revisions were pulling staff resources away from prevention activities. It was reported that many felt the changes in later rounds of revision weren't helpful to the integrity of the plan nor did they add value to the overall infection prevention program.

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## Industry Trends

Policy / Market Trends

## HHS Announces Social Worker Licensure Compact to Address Workforce Shortages

On July 16, the Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced a new multi-state social worker licensure compact.

**Why this matters:** The new program seeks to make it easier for social workers to practice across state lines, increase behavioral health access, and better facilitate telehealth services.

**What They're Saying:** In a press release, HHS Deputy Secretary Andrea Palm stated that the compact was a step in the right direction to "allow the workforce to make mental health and substance use disorder services more accessible across the country."

**AHIP Resources:** In their recent issue brief on behavioral health workforce, AHIP outlined recommendations aligned with the recent HRSA announcement to improve workforce challenges, including:

- Multi-state licensure for providers of virtual care, whether through expanded licensure reciprocity agreements, federal regulatory changes, or state action to extend access to virtual behavioral health care nationwide.

- Support flexibility to include a full range of behavioral health provider types in plan networks, including credentialed/certified paraprofessionals. Standard licensure/credentialing/certification requirements may be needed to increase use and improve access.

**Go Deeper:** Read the HRSA release and AHIP's behavioral health workforce issue brief.

**Interested in reviewing a copy of a bill(s)? Access the following web sites:**

Delaware State Legislation: **http://legis.delaware.gov/.**
New York Legislation: **https://nyassembly.gov/leg/**
Pennsylvania Legislation: **www.legis.state.pa.us.**
West Virginia Legislation: **http://www.legis.state.wv.us/**
For copies of congressional bills, access the Thomas website – **http://thomas.loc.gov/.**