Highmark's Weekly Capitol Hill Report

Issues for the week ending May 26, 2023

Federal Issues

Legislative

House Committee Clears Price Transparency/PBM Legislation

On Wednesday, the House Energy and Commerce Committee held a markup that included 7 pieces of legislation aimed at improving transparency and lowering healthcare costs.

The most prominent bill was H.R. 3561, the Promoting Access to Treatments and Increasing Extremely Needed Transparency (PATIENT) Act of 2023. This legislation includes increased transparency requirements for Pharmacy Benefit Managers (PBMs) and would eliminate the practice of spread pricing in Medicaid. The bill also includes polices to reauthorize and increase funding for healthcare workforce programs including community health centers, the National Health Service Corps, and teaching health centers. The bill passed 49-0.

Why this matters: Packaging these policies together suggests Congress will attempt to use the widely bipartisan PBM legislation as a vehicle for other health care priorities. Despite little common ground on legislation this year, political pressure continues to build for policymakers to address the practices of PBMs.

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Specifics of the transparency legislation include:

- **Price Transparency:** Codifies the Transparency in Coverage rules requiring health plans to make personalized pricing information available to enrollees as well as post machine-readable files containing in-network negotiated rates, prescription drug prices, and out-of-network allowed amounts.

- **Part C/D Transparency:** Requires Medicare Advantage (MA) and Part D plans to report data with respect to how they interact with health care providers they share common ownership with—including physician groups, PBMs, and pharmacies.

- **PBM Transparency:** Requires PBMs to annually provide employers with detailed data on prescription drug spending, including the acquisition cost of drugs, total out-of-pocket spending, formulary placement rationale, and aggregate rebate information.

- **Cost-Sharing Limits on Highly-Rebated Drugs:** Requires that for all drugs with annual rebates greater than 50% of annual gross spending in the prior year across all plans (as reported under RxDC), plans are prohibited from charging cost-sharing, including deductible payments, that exceed the previous annual net price after rebates for that specific plan, adjusted by the volume dispensed.

- **Medicaid Spread Pricing:** Bans spread pricing in Medicaid.

- **Site-Neutral Payments**: Aligns the amount Medicare pays for the provision of physician-administered drugs across outpatient settings.

- **Extension of several health care programs** for fiscal years 2024-2025, including the Community Health Center Fund, elimination of the Disproportionate Share Hospital (DSH) cuts, and the Special Diabetes Program.

Regulatory

- **Pennsylvania Insurance Department is Accepting Comments and Holding a Public Forum on the Reinsurance Program**

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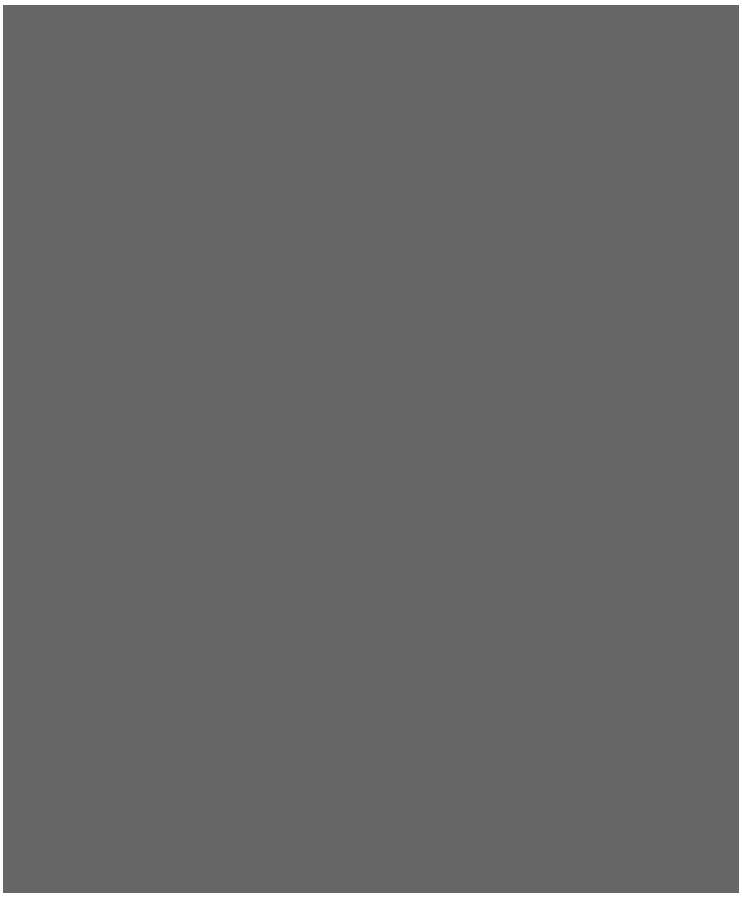
- **HHS Announces New Plan to Address Maternal Health Crisis**

The Committee also voted to advance H.R. 2666, the Medicaid VBPs for Patients (MVP) Act, and H.R. 3284, the Providers and Payers COMPETE Act.

- H.R. 2666 would codify for 5 years a technical rule that allowed manufacturers to report a range of prices offered through value-based purchasing arrangements (VBP) as their "best price" under the Medicaid Drug Rebate Program.

- H.R. 3284 would require the Department of Health and Human Services, during each of its annual payment rules, to consider the implications that its proposals may have on further consolidating the health care system by studying both horizontal and vertical consolidation among both providers and payers.



Federal Issues

Regulatory

CMS Releases Proposed Rule on Medicaid Prescription Drug Transparency

The Centers for Medicare & Medicaid Services (CMS) released a new Notice of Proposed Rulemaking (NPRM) entitled, *Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program*.

Why this matters: The NPRM would make a number of changes related to the Medicaid drug rebate program, including:

- **Implement** certain statutory definitions and enforcement provisions from the Medicaid Services Investment and Accountability Act of 2019 (MSIAA) that are designed to address misclassification of drugs, along with other changes that CMS characterizes as addressing program integrity and program administration.

- **Seek** greater transparency regarding prices including development of additional survey tools to verify manufacturers' drug prices.
    - For example, the proposed rule would provide additional tools for CMS and states, such as a drug price verification survey, which would verify drug prices to increase transparency about why certain drug prices are expensive for Medicaid and help states better negotiate what the Medicaid program pays for high-cost drugs.
- **Set** requirements for pharmacy benefit manager cost reporting, set requirements for managed care pharmacy benefit identification cards, remove the cap on the amount manufacturers are required to pay in Medicaid drug rebates, require manufacturers to pay back past rebates if CMS identifies a drug misclassification and account for stacking of price concessions in determining best price for a drug.
- **Impose** Medicaid managed care organization (MCO) requirements. It would address spread pricing in the Medicaid program by requiring additional reporting of incurred claims costs, affecting MLR calculations.
- **Require** MCOs assign and exclusively use unique Medicaid BIN, PCN, and group number identifiers for all Medicaid managed care beneficiary identification cards for pharmacy benefits.

Next steps: Comments on the NPRM must be received by July 25, 2023. The pre-publication version of the NPRM may be viewed in the Federal Register. Read the full CMS press release here.

CMS Releases 2023-2024 Medicaid Managed Care Rate Development Guide

CMS released Medicaid Managed Care Rate Development Guide for rating periods between July 1, 2023 and June 30, 2024. The guide is meant to serve as a resource for states to use when setting capitation rates with managed care plans and provides details around information that must be included in the states' actuarial rate certifications for CMS to review and approve. Read More

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DOL Confirms "Outbreak Period" July 10 End Date

Department of Labor (DOL) Assistant Secretary Lisa Gomez confirmed in an Employee Benefits Research Institute webinar (around minute 9:00) that the **Outbreak Period will end July 10**, consistent with FAQ 58 issued by the Departments of Labor, Health and Human Services, and Treasury.

Why this matters: The Outbreak Period ends the extended timeframes allowed for HIPAA special enrollment, COBRA continuation of coverage, and internal claims and appeals. The end of the Outbreak Period also triggers a 60-day special enrollment period for consumers losing Medicaid or CHIP to enroll in employer-sponsored insurance.

Background: The Outbreak Period rule required plans to put deadlines on hold starting March 1, 2020 through the end of the "outbreak period," defined as 60 days following the end of the national emergency, for HIPAA special enrollment, COBRA continuation coverage, and internal claims and appeals and external review periods. On April 10, President Biden signed into law H.J.Res. 7, ending the COVID-19 national emergency sooner than expected, rather than on May 11, 2023 as previously announced.

CMS Releases FAQs on Benefit Coordination and Medicare Eligibility

CMS released Frequently Asked Questions (FAQs) on benefit coordination and Medicare eligibility.

Why this matters: These FAQs clarify that pursuant to the essential health benefits (EHB) and actuarial value (AV) requirements under the Affordable Care Act, a health insurance issuer offering non-grandfathered health insurance coverage in the individual and small group market may not change the plan payment level or refuse to pay for otherwise covered services on the basis that an individual is eligible for Medicare due to age but not actually enrolled in Medicare. You can access the FAQs here.

State Issues

New York

Legislative

Legislators Urge Coverage for Undocumented Immigrants

There was a renewed effort to expand coverage for undocumented immigrants in New York with Assemblymember Jessica González-Rojas last week urging passage of legislation she sponsors (S.2237A/A.3020A) that would direct the Commissioner of Health to amend the state's recent 1332 waiver request to include individuals who would otherwise meet the criteria to enroll in the Essential Plan but are currently precluded from participating based on their immigration status.

The Assemblymember held a news conference to announce that the Centers for Medicare and Medicaid Services has indicated states can use pass-through 1332 federal funds to provide healthcare to undocumented people, noting Colorado and Washington have done so.

Read Assemblymember González-Rojas's news release and the coalition letter here.

Activity on Priority Bills

Here is a summary of last week's activity on several health care bills:

- **Flexibility for plan incentive programs (S.2684/A.791) —** The Senate Insurance Committee took up this proposal that would provide the Department of Financial Services greater flexibility in reviewing health plans' proposals to offer voluntary incentives or rewards. The Assembly bill was in the Insurance Committee and, if it moves forward, it would now go to Rules.
- **Biomarker testing coverage (S.1196/A.1673) —** The Senate Insurance Committee advanced this proposal that would require health insurance policies and Medicaid to cover biomarker testing. Highmark and HPA have opposed the measure as being too broad and have been working with the sponsors to narrow the language.

- **Written notice for step therapy overrides (S.2677/A.463) —** Also making its way through Senate Insurance was this bill that would require plans to have a written procedure for notice of an adverse determination to a step therapy override. The Assembly companion measure is in the Rules Committee.
- **Gold carding (S.2680/A.859) —** The Senate Insurance Committee also approved this legislation that would create a "gold card" process, exempting health care professionals from preauthorization requirements when their requests are regularly approved by health insurers. The Assembly bill is in the Insurance Committee.
- **Antiretroviral drugs (S.1001)/A.1619) —** prohibits the preferred drug program, managed care programs and insurers from restricting or imposing delays in the distribution of antiretroviral drugs prescribed to a person for HIV or AIDS. The bill was in the Assembly Insurance Committee and would now have to go to Rules.
- **Provider collective bargaining (A.6019/S.4785) —** The Assembly Health Committee advanced this proposal that would allow providers to collectively negotiate with health insurers. The Senate Health Committee did not consider the bill and it would have to go to Rules.
- **Medicaid SBHC services (A.6029/S.2339) —** The Assembly Health Committee also advanced a measure that would allow school-based health center (SBHC) services to remain outside the Medicaid Managed Care (MMC) benefit package. The Senate bill was last referred to the Finance Committee.
- **Medicaid tailored meal coverage (A.7244/S.4790) —** Legislation to require all Medicaid health insurance plans to cover medically tailored meals and medical nutrition therapies for individuals limited in activities of daily living by one or more chronic condition moved through the Assembly Health Committee. The Senate bill was in the Health Committee and would now have to go to Rules.
- **NYSHIP hospital price data collection (A.5817/S.4097-A) —** The Assembly Governmental Employees Committee approved this proposal that would direct the New York State Health Insurance Plan to collect health care claims data to issue a report on variation in hospital prices. The Senate bill has moved through the committee process and can now be considered by the full Senate.
- **Ambulance direct reimbursement (A.250/S.1466-A) —** The Assembly Insurance Committee advanced this bill that would require health plans to directly reimburse ambulance service providers regardless of whether they are in-network or out-of-network providers. The Senate bill is up for consideration by the full Senate.
- **Coverage continuation extension (A.5129/S.6576) —** The Assembly Insurance Committee also advanced a proposal that would extend the length of time health plan enrollees could continue to receive services from a health care provider who disaffiliates from 60 or 90 days to 1 year, or longer in cases of terminal illness. The Senate bill was in the Insurance Committee and would now have to go to Rules.

Also this week, the Senate Health and Finance Committees will hold a joint hearing to consider the nomination of James McDonald, MD, MPH, as Commissioner, Department of Health.

State Issues

Pennsylvania

Legislative

State House Committee Approves $100M for PA Mental Health Needs

The state House Human Services Committee unanimously approved legislation last week that would allocate $100 million in federal funding to address Pennsylvania's mental health needs, according to the bill's author state Rep. Mike Schlossberg.

Background: As part of the 2022-23 state budget, the General Assembly established the Behavioral Health Commission on Adult Mental Health, a 24-person group tasked with providing recommendations to the General Assembly on how to appropriate $100 million in one-time federal American Rescue Plan funding to address behavioral health needs in Pennsylvania. The commission, composed of experts in the behavioral health field, advocates and providers, as well as Schlossberg and other legislators, created a set of recommendations.

The legislation would take the following recommendations from the commission and expand the efforts to address the needs of struggling youth:

- $34 million toward behavioral health workforce improvements.
- $25.5 million for criminal justice and public safety initiatives.
- $40 million to expand access to mental health services and supports.
- $500,000 to evaluate the overall impact of these initiatives.

Next steps: House Bill 849 moves to the full state House of Representatives for consideration.

Regulatory

Pennsylvania Insurance Department is Accepting Comments and Holding a Public Forum on the 1332 Waiver Reinsurance Program

The Commonwealth is accepting public comments on its 1332 State Innovation Waiver Reinsurance (PA-Re) Program beginning Thursday, June 1, 2023, and ending Friday, June 30, 2023.

The Commonwealth's Reinsurance Program was approved in July 2020, by the Centers for Medicare & Medicaid Services, effective for the period of January 1, 2021 through December 31, 2025 with a provision for a possible extension at the end of the initial term.

Why this matters: The goal of Pennsylvania's Reinsurance Program is to favorably impact premium rates for Pennsylvanians purchasing health insurance coverage in the individual market. This is particularly important for those who do not qualify for federal tax credits.

In addition to accepting public comments, an in-person public forum will provide additional opportunities to learn about and comment on the PA-Re Program on June 28, 2023, from 1 p.m. to 2 p.m. More information on the public forum can be viewed in the notice. This public forum assumes the PA-Re Program will continue as it has since it was first approved. Information is available for review at www.insurance.pa.gov/PA1332Waiver.

This required forum is distinct from the request for comment on a possible suspension of the program, a comment period that has been available through the notice published at 53 Pa.B. 2273 (April 22, 2023).

Industry Trends

Policy / Market Trends

HHS Announces New Plan to Address Maternal Health Crisis

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced more than $65 million would be awarded to 35 HRSA-funded health centers to address the maternal mortality crisis. The U.S. has the highest maternal mortality rate among developed nations, and Black and America Indian/Native women who give birth are 2 to 3 times more likely to die from pregnancy-related causes than White women. The HHS plan aims to address health disparities and improve maternal health outcomes.

The funds designated by HHS will be disturbed to several HSRA-supported maternal health programs including:

- **Alliance for Innovation on Maternal Health Patient Safety Bundles** which are setting the standard for improving maternal care processes and patient outcomes in hospitals and other delivery settings across the country.
- **Rural Maternity and Obstetrics Management Strategies (RMOMS) Program** which builds networks in rural communities to strengthen pre-natal, delivery and post-pregnancy support services.
- **State Maternal Health Innovation Programs** which directly support states to address the disparities in maternal health outcomes by building state coalitions of diverse stakeholders to inform state action, improve the collection and use of maternal health data, and launch new service delivery activities such as the use of mobile vans in remote regions and creating a course for how to treat mothers with substance use disorder respectfully and effectively.
- **Maternal Health Workforce Programs** which train new certified nurse midwives, train more community-based doulas, provide loan repayment incentives for nurses to practice in high-need communities, and build and deploy metrics identifying the areas with the greatest maternal health workforce needs.

The full list of supported programs can be found here.

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/.**