Highmark's Weekly Capitol Hill Report

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Federal Issues

Legislative

House Subcommittee Advances Price Transparency and PBM Legislation

On Wednesday, the House Energy and Commerce Health Subcommittee held a markup to advance legislation on price transparency, pharmacy benefit managers (PBMs), and consolidation in the health care industry.

The subcommittee passed 5 bills, including:

- H.R. 3281 – Transparent Price Act (21 – 0)
- H.R. 2666 – Medicaid VBPs for Patients (MVP) Act (16-11)
- H.R. 3285 – Fairness for Patient Medications Act (Voice Vote)
- H.R. 3284 – Providers and Payers COMPETE Act (27-0)
- H.R. 3290 – To amend title III of the Public Health Service Act to ensure transparency and oversight of the 340B drug discount program (16-12)

The Transparent Price Act was adopted with a significant amendment that included provisions aimed at PBMs, including the PBM Accountability Act and preventing spread-pricing in Medicaid programs.

Notably, amendments to prohibit copay accumulators and to further regulate Part D pharmacy payments were withdrawn.

Key provisions of the legislation advanced include:

- Pharmacy reimbursement transparency: Issuers would be required to report the average amount paid to each participating pharmacy for each National Drug Code (NDC), net of rebates, discounts, and price concessions.
- Vertical integration in Parts C and D: Would, among other things, require new reporting from Medicare Advantage (MA) plans on utilization, payment amounts to providers, diagnoses for risk adjustment, and other data, separated by whether the MA plan has a common ownership interest with the provider, and would require Part D plans to report on payment rates and DIR to pharmacies, separated by whether the plan has a common ownership interest with the pharmacy.
- PBM and issuer transparency: The Act incorporates the PBM Accountability Act, which requires PBMs and issuers to report substantial information to plan sponsors on prescription drug use, pricing, and rebates. Specifically, four reports are required: 1) a summary report of gross spending on prescription drugs, total rebates and remuneration, total net spending on prescription drugs, amounts paid to brokers, and gross manufacturer copayment assistance for all beneficiaries in the plan; 2) a report for every single drug, at the NDC level, of utilization (by beneficiary, fill, and unit count), dispensing channel, unit cost, and beneficiary out-of-pocket spending; 3) for drugs with gross spending above $10,000, a list of all other drugs in the same therapeutic class and the rationale for formulary placement of the drug; and 4) a report for each therapeutic class detailing gross spending, utilization, formulary management, and out-of-pocket spending, with additional reporting for therapeutic classes with

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3 or more drugs, including total rebates and other remuneration in the class and net spending in the class.

- Cost-sharing limits: For all drugs that had annual rebates greater than 50% of annual gross spending in the prior year across all plans (as reported under RxDC), prohibits plans from charging cost-sharing, including deductible payments, that exceed the previous annual net price after rebates for that specific plan, divided by 12 (monthly net price).
- Newly-covered drugs: For highly-rebated drugs (across all plans) that were not covered by a particular plan's formulary in the previous year, the plan may not negotiate any rebate from the manufacturer unless the rebate is reflected at the point of sale.

Next Steps: The full Energy and Commerce Committee is scheduled to consider the legislation this week.

House Committee Examines Health Care Affordability

On Wednesday, the House Ways and Means Health Subcommittee held a hearing on health care affordability and anticompetitive and consolidated markets.

Why this matters: Committee members expressed concern that the current system isn't working to lower health care costs or improve quality and identified consolidation in many facets of the health care ecosystem as part of the problem.

The hearing focused significantly on pharmacy benefit managers (PBMs), issuers, and health plan design considerations. Members of the committee called for more PBM transparency and less vertical integration.

A number of members throughout the hearing also identified drug manufacturers' high list prices and anti-competitive schemes as a major barrier to patients accessing low-cost drugs. There was also broad

criticism of drug companies' ability to raise the list price of certain drugs and their ability to game the patent system in order to prevent generics from entering the market.

Some members and witnesses cited hospital and provider consolidation as a cause for lack of competition and higher costs. They also claimed the lack of site-neutral rules in Medicare creates an incentive to send patients to owned-entities where hospitals and providers can charge a higher rate for services with no added quality benefit.

Federal Issues

Regulatory

FTC Proposes Health Breach Notification Rules

On Thursday, the Federal Trade Commission (FTC) proposed regulations to clarify how it plans to enforce the Commission's Health Breach Notification Rule that lays out companies' responsibilities when they operate as vendors of personal health records and are not covered by the comprehensive regulatory regime for health information that would apply under HIPAA for health providers and plans and their business associates.

Why this matters: The rule is intended to address situations where health data is accessed in a manner that triggers a responsibility by the company to notify individuals and protect their information. An application of this rule could include companies' use of such data for marketing and sale of data. The proposed regulations aim to better explain how the rule applies to health apps and other digital health tools that don't fall under HIPAA. The proposal, if finalized, would clarify that health apps, including those offering health services and supplies — broadly defined to include fitness, sleep, diet, and mental health products and services, among a laundry list of categories — would be subject to regulations requiring them to notify customers if their identifiable data is accessed by hackers or business partners or shared for marketing without patient approval. This rule stems from recent FTC enforcement actions regarding the Breach Notification Rule.

Comments on the proposals are due 60 days after the rule is published in the *Federal Register.*

Appeals Court Keeps Preventive Services Requirements in Place Temporarily

The U.S. Court of Appeals for the Fifth Circuit issued an administrative stay in *Braidwood Management Inc. v. Becerra ("Braidwood")*. The order has the effect of temporarily restoring the requirements of the preventive services mandate under section 2713 of the Affordable Care Act while the Fifth Circuit considers the Department of Justice's request for a partial stay pending appeal of Judge Reed O'Connor's March 30 order in the case.

Why this matters: The order has the effect of temporarily restoring the requirements of the preventive services mandate under section 2713 of the Affordable Care Act while the Fifth Circuit considers the Department of Justice's request for a partial stay pending appeal of Judge Reed O'Connor's March 30 order in the case.

Background: On March 30, 2023, Judge O'Connor issued a decision in *Braidwood,* with an order enjoining the federal government from enforcing certain preventative services mandated by the ACA, namely the

mandatory requirement for group health plans and health insurance issuers to cover, without cost-sharing, services rated “A” or “B” by the U.S. Preventive Services Task Force (USPSTF) since March 23, 2010. The decision largely focused on the scope of the remedy available to plaintiffs in light of a prior ruling made by the same court last year. That earlier decision found that the United States USPSTF violates the Constitution’s Appointments Clause.

CMS Releases Medicaid Unwinding FAQ

CMS released Medicaid Continuous Enrollment Condition Unwinding Marketplace Frequently Asked Questions (FAQ).

Why this matters: The FAQ document outlines the flexibilities the federally-facilitated Marketplace (FFM) has implemented (beyond the Unwinding SEP) to help consumers successfully transition from Medicaid to Marketplace coverage and provides answers to common questions on coverage transitions. The FAQ can be found here.

Inflation Adjusted Amounts for HSA Deductions, HDHP Deductibles, and EBHRAs

The Internal Revenue Service (IRS) has released Rev. Proc. 2023-23, establishing for 2024 limits on annual deductions to health savings accounts (HSAs) and limits on deductibles for high deductible health plans (HDHPs) linked to HSAs, as well as the maximum amount that may be made newly available for the plan year for an excepted benefit health reimbursement arrangement (EBHRA).

HSA Annual Deduction Limit

For calendar year 2024, the annual limitations on deductions for HSAs are:

- *Individual with Self-Only Coverage:* $4,150
- *Individual with Family Coverage:* $8,300

High Deductible Health Plan

For calendar year 2024, a “high deductible health plan” is defined as a health plan with:

- *Annual Deductible:* Not less than $1,600 for self-only coverage or $3,200 for family coverage
- *Annual Out-of-Pocket Expenses (Deductibles, Co-Payments, and Other Amounts, but Not Premiums):* Not exceeding $8,050 for self-only coverage or $16,100 for family coverage.

Maximum Amount Newly Available for EBHRAs: For plan years beginning in 2024, the maximum amount that may be made newly available for the plan year for an EBHRA is $2,100. See Treas. Reg. § 54.9831-1(c)(3)(viii). See § 54.9831-1(c)(3)(viii)(B)(1) for further explanation of this calculation.

Variation from Maximum Out-of-Pocket Limits: Recall that the HDHP limits on out-of-pocket expenses and the maximum out-of-pocket limits under the Affordable Care Act (ACA) are NOT the same. The

maximum out-of-pocket limits for the ACA in 2024 will be in accordance with the 2024 PAPI Parameters Guidance.

CMS Provides Comment Opportunity on Part D Manufacturer Discount Program Draft Guidance

On May 12, the Centers for Medicare & Medicaid Services (CMS) issued memorandum to solicit comments on draft guidance to pharmaceutical manufacturers and Part D plan sponsors for implementing the Medicare Part D manufacturer discount program in accordance with provisions from the Inflation Reduction Act (IRA). The draft CMS guidance covers significant changes to the current Part D benefit design including: sunset of the current Part D coverage gap discount program as well as requirements for the new Part D manufacturer discount program effective January 1, 2025.

In the draft guidance, CMS states that “because the administrative requirements of the Discount Program largely mirror those for the Coverage Gap Discount Program, CMS intends to implement the program in a similar manner, with some operational enhancements based on stakeholder feedback and extensive program experience.”

Comments are due to CMS by June 12 at 5:00 p.m.ET.

CMS Releases Guide for Delivery of School-Based Services

The Centers for Medicare & Medicaid Services (CMS) released guidance entitled “Delivering Service in School-Based Settings: A Comprehensive guide to Medicaid Services and Administrative Claiming.”

Why this matters: The guide clarifies how payments can be made to school-based providers under Medicaid and the Children’s Health Insurance Program (CHIP), discusses strategies to reduce administrative burden and simplifying billing for local education agencies (LEAs), offers examples of the types of providers that can participate in Medicaid within a school setting and provides best practices for enrolling qualified providers. The guide also outlines new flexibilities around billing (both for States and LEAs that use cost-based reimbursement and those that use rate-based reimbursement), documentation to support billing, provider qualifications and third party liability.

Read More:

- Delivering Service in School-Based Settings: A Comprehensive Guide to Medicaid Services and Administrative Claiming
- Informational Bulletin
- Fact Sheet

State Issues

Delaware

Legislative

Prompt Pay Bill Introduced

Senate Bill 143 – which would make several changes intended to improve the claims payment process by health insurers – was introduced last week.

Why this matters: This legislation will require operational changes that are under review by Highmark staff.

Overview

- **Prompt Payment of Undisputed Portion of Clean Claims**
  - If part of a claim is disputed, the insurer shall transmit payment for any undisputed portion of the claim within *30 days* of receipt of the claim
  - If the legitimacy of the claim or the appropriate amount of reimbursement is in dispute, the health insurer shall: transmit payment for any undisputed portion of the claim and send notice of receipt of the claim and notify the provider that the insurer refuses to reimburse as well as the reason for the refusal.

- **Erroneous Denials** - If an insurer erroneously denies a provider's claim for reimbursement because of a claims processing error within the minimum 180 days a provider has to submit a claim for reimbursement and the provider notifies the insurer, the insurer shall reprocess the provider's claim without the provider having to resubmit the claim, and without regard to timely submission deadlines.

- **Payment of Interest –** If an insurer fails to pay a clean claim or violates any other portion, the insurer shall pay interest in the amount of the claim that remains unpaid 30 days after receipt of the initial clean claim for reimbursement at the monthly rate of: 1.5% from the 31st day through the 60th day; 2% from the 61st day through the 120th day; 2.5% after the 120th day. The interest paid shall be included in any late reimbursement without the necessity for the person who filed the original claim to make an additional claim for that interest.

- **Prompt Payment After Successful Appeals** - If an insurer overturns a denial via the appeal process the insurer has 30 days to remit payment.

Coordination of Benefits Provisions

- **Validate insurance prior to taking recovery actions** - Insurers who engage in coordination of benefits auditing are required to validate identified coverage is effective for the date of service and is a valid medical insurance prior to taking any recovery action against the provider. If the insurer fails to validate identified coverage, and inappropriately recovers their payment, insurer shall reimburse the provider within 30 days of receiving notice of the inappropriate recovery.

- **Notification of Reclamation** - Insurers who engage in reclamation with other insurers must issue a written notice to the provider of their reclamation action documenting their receipt of payment from the other insurer within 60 days.

- **Retroactive Denials and Claim Submission** - If an insurer retroactively denies reimbursement for services as a result of coordination of benefits, the health care provider shall have 12 months from the date of the denial, unless the entity responsible for payment permits a longer time period, to submit a claim for reimbursement for the service to such entities.

Latest Revenue Forecast Less than Governor’s Recommended Budget

The most recent state revenue forecast from the non-partisan Delaware Economic and Financial Advisory Council (DEFAC) revealed a modest increase. The latest projection predicted an increase of just over $11 million in useable revenue compared to the previous estimate published last month. However, that number is about $25 million less than the forecast on which the governor's recommendations were based. DEFAC's predictions set an appropriations limit for budget writers. The Joint Finance Committee will be meeting the last two weeks of May to finalize the fiscal year 2024 operating budget which begins July 1. They now have $6.5499 billion with which to work.

State Issues

New York

Legislative

Update on Biomarker Testing Mandate and Step Therapy Legislation

With only 10 days left in the legislative session, a number of health care bills will receive consideration this week in various committees.

- **Biomarker testing coverage (S.1196/A.1673)** — This legislation would require health insurance policies and Medicaid to cover biomarker testing.
  - **Why this matters:** While biomarker testing is valuable when it can inform a condition's diagnosis and treatment, the bill sets an overly broad set of criteria for covering tests that don’t align with evidence-based policies.
- **Step therapy restrictions (A.901/S.1267)** – The provisions of this legislation include prohibiting requiring a member to try and fail on more than one drug before covering the prescribed drug and prohibiting requiring the use of a step therapy drug for longer than thirty days.

Bills in Committees this Week:

- **Prenatal vitamins (S.1965A.3865)** — requires health insurance coverage of prenatal vitamins.
- **Step therapy override notice (S.2677/A.463)** —requires plans to have a written procedure for notice of an adverse determination to a step therapy override.
- **Goldcarding (S.2680/A.859)** — would exempt health care professionals from preauthorization requirements when their requests are regularly approved by health insurers.
- **Rewards programs (S.2684/A.791)** — would allow insurers to apply to the Department of Financial Services to offer voluntary incentives or rewards programs by providing DFS with greater flexibility in reviewing incentive programs.

- **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.
- **Collective negotiation (A.6019/S.4785)** — allows providers to collectively negotiate with health insurers.
- **Medicaid school-based health center services (A.6029/S.2339)** — would allow school-based health center (SBHC) services to remain outside the Medicaid Managed Care (MMC) benefit package.
- **Medicaid medically tailored meals (A.7244/S.4790)** — would 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.
- **NYSHIP hospital prices report (A.5817/S.4097-A)** — would direct the New York State Health Insurance Plan to collect health care claims data to issue a report on variation in hospital prices.
- **Ambulance direct reimbursement (A.250/S.1466-A)** — would require health plans to directly reimburse ambulance service providers regardless of whether they are in-network or out-of-network providers.
- **Opioid co-pay prohibition (A.3476/S.790)** — would prohibit co-pays for certain short-term opioid drug prescriptions.
- **Continuity of care extension (A.5129/S.6576**) — 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.

Last week's bill actions:

- **Crisis stabilization services reimbursement (S.5367)** —The proposal mandates the same reimbursement level for crisis stabilization services provided by different types of providers. The bill was advanced by the Senate Mental Health Committee and is now in Senate Finance.
- **Utilization Review Criteria (S.3400/A.7628)** —The Senate Health Committee advanced this proposal that would impose new standards on health plans' utilization review criteria. It now goes to the Finance Committee. The Assembly companion bill is in the Insurance Committee.
- **Utilization Review** (S.3402/A.689 — The Senate Health Committee also advance legislation that would amend current law to require that a non-timely plan utilization review response be deemed "approved." It now goes to the full Senate for consideration. The Assembly companion is in the house's Insurance Committee.
- **Telehealth (S.6733/A.7316)** — This bill that would expand health care services provided via telehealth and require telehealth payment parity for Federally Qualified Health Centers for care delivered where neither the provider nor the patient were located in a clinic moved through the

Senate Health Committee and was referred to the Finance Committee. The Assembly bill is in the Health Committee.

Regulatory

Essential Plan Post Public Health Emergency COVID Coverage

The NY State of Health issued guidance for COVID-19 testing and immunizations in the Essential Plan (EP) following the expiration of the public health emergency.

- **For testing,** EP issuers are required to continue to cover point-of-care COVID-19 testing, including laboratory tests, without limitation or cost-sharing, as well as cover over the counter or at-home COVID tests without cost sharing through September 30, 2024.
    - Plans are not required to provide coverage for COVID-19 laboratory tests and visits to diagnose COVID-19 when rendered by an out-of-network provider unless the services are emergency services that are provided in a hospital.
- **For vaccinations,** plans must continue to cover immunizations with no cost-sharing when obtained from an in-network provider. The prohibition on cost-sharing for immunizations extends to any charge for administration of the immunization, any charge for the office visit when the primary purpose of the visit is the immunization or when the other services provided are preventive care services that are required to be covered under language in the EP Model Contract.
    - Plans are not required to cover COVID-19 immunizations provided by out-of-network providers.

State Issues

Pennsylvania

Regulatory

Shapiro Administration Strengthens Mental Health Parity Review For 2024 Health

Pennsylvania Acting Insurance Commissioner Michael Humphreys announced the Pennsylvania Insurance Department (PID) has strengthened its review of mental health and substance use disorder coverage in 2024 health plans. Insurers under PID regulation must file their plans with the Department for approval.

Why this matters: Now, for 2024 filings, PID is enhancing its compliance review of mental health and substance use disorder parity requirements to prevent potential violations.

In his Budget Address, Governor Josh Shapiro voiced concern over the effective enforcement and compliance of mental health parity laws. The Governor has made mental health and substance use disorder treatment parity a priority in his administration.

Since January, the PID has:

- **Strengthened travel time and distance standards for in-network providers**. These standards require insurers to maintain provider networks that have in-network providers within a reasonable distance or within a reasonable travel time for consumers.
- **Reviewed large group filings for parity compliance**. With these reviews, an additional 1.2 million covered lives will have their benefits reviewed for mental health parity compliance before the policies are available for purchase. PID also reviews all individual and small group health insurance plans for parity compliance.
- **Reviewed parity analyses for student health filings for the 2024 school year.** An additional 40,000-50,000 covered lives will have their benefits reviewed for parity compliance before the policies may be sold.
- **Updated its Quantitative Treatment Limitation and Financial Requirement analysis template for insurers.** The template assists PID in determining a plan's compliance with requirements under the Mental Health Parity and Addiction Equity Act. Updating the template improves the Department's ability to identify cost-sharing or treatment limitations under a plan's benefits. It also helps the Department to hold insurers accountable by verifying that what is in a plan's schedule of benefits matches PID's analysis of the plan.

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/.**

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