



Issues for the week ending June 28, 2024

Federal Issues

Legislative

Ways and Means Committee Advances 4 Health Bills

On Thursday, June 27, the Ways and Means Committee held a [markup](#) and favorably reported four health care related bills addressing obesity and health care innovation.

Chairman Jason Smith (R-MO) highlighted American innovation and need to encourage medical breakthroughs. Specifically, he called out a report published by Rep. Schweikert (R-AZ) and the Joint Economic Committee that finds over the next decade, obesity will cost taxpayers more than \$4 trillion and the disease will lead to an additional \$9 trillion in medical expenses. Chairman Smith further commented that without the passage of H.R. 4181, the Treat and Reduce Obesity Act, over 1 million Americans will lose access to weight loss medicines as they transition into Medicare in the coming years.

Ranking Member Richard Neal (D-MA), who voted against two of the measures,

In this Issue:

Federal Issues

Legislative

- Ways and Means Committee Advances 4 Health Bills
- Senate Finance Chairman Requests Greater PBM Oversight from CMS

Regulatory

- Supreme Court Overrules Chevron in Significant Administrative Law Decision
- CMS Issues FAQ Guidance on Medicaid and CHIP Coverage of Peer Support Services
- CMS Issues Addendum to 2024-2025 Medicaid Managed Care Rate Development Guide
- HHS Issues Information Blocking Final Rule
- FDA Releases New Draft Guidance on Interchangeability
- HHS Announces Quarterly Update to List of Part B Drugs Subject to Inflation Rebate Program
- CMS Accepting Applications for State-Based Maternal Health Model

commented that many of the bills were not fully vetted and “poison pills” need to be addressed before the legislation moves forward, noting that adding obesity medications to Medicare would cost tens of billions of dollars. He criticized Republicans for rationing access in Medicare, rather than lowering costs to ensure broad access.

Bills passed include:

- [H.R. 1691](#), the Ensuring Patient Access to Critical Breakthrough Products Act of 2023, reported favorably by a vote of 36 – 5.
- [H.R. 2407](#), the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act, reported favorably by a vote of 38 – 0.
- [H.R. 8816](#), the American Medical Innovation and Investment Act, reported favorably by a recorded vote of 40 – 0.
- [H.R. 4818](#), the Treat and Reduce Obesity Act of 2023, reported favorably as amended by a recorded vote of 36 – 4.

- **CMS Announces Release of State RFA for the Cell and Gene Therapy Access Model**
- **ACIP Recommends Updates to Several Vaccines**
- **Medicaid Redeterminations Updates**
- **Hospital Industry Urges Senate, House Members to Halt Enforcement of Nurse Staffing Mandate**
- **New Hospital Price Transparency Requirements Take Effect July 1**
- **Mississippi Judge Denies Makers’ and PhRMA’s Request for Preliminary Injunction in 340B Case**

State Issues

Delaware

Legislative

- **The Delaware General Assembly Wraps Up Session**

New York

Legislative

- **Governor Signs Legislative Package**

Pennsylvania

Legislative

- **Pennsylvania Legislative Update**
- **Telehealth Bill Reaches the Finish Line**

Senate Finance Chairman Requests Greater PBM Oversight from CMS

On June 24, Senate Finance Committee Chairman Ron Wyden (D-OR) sent a [letter](#) requesting CMS provide greater oversight of Pharmacy Benefit Managers (PBMs). In part, the letter asks CMS “to conduct immediate oversight and rigorous regulatory enforcement of specific Medicare Part D program requirements for plan sponsors and their PBMs.” The letter further contends that PBM contracting practices are straining the finances of pharmacies and directly contributing to their closures.

Why this matters: PBMs continue to face scrutiny from Congress. Legislation reforming PBM practices and requiring greater transparency could be part of an end of year health package.

Wyden outlines several actions that CMS could immediately take using the Medicare statute:

- Enforce “Any Willing Pharmacy” requirements by ensuring that PBMs reimburse pharmacies at a minimum of the cost to acquire and dispense covered prescription drugs.
- Enforce, such as through auditing, the pharmacy price concessions provision that requires all pharmacy price concessions be applied to negotiated prices at the point of sale under Part D.
- Implement standardized pharmacy measures which are long overdue, including the evaluation and reporting of plan performance measures which CMS has finalized in rulemaking yet has not fully come to fruition.
- Review formal or informal complaints about PBM contracting practices under Part D received over the past 18 months to determine if the number of complaints is higher than in prior years.
- Respond to this letter with information, within 60 days, on the number of formal or informal complaints received about PBM contracting practices over the past 18 months, a description of the type of complaints received, and the disposition of the complaints.

Federal Issues

Regulatory

Supreme Court Overrules Chevron in Significant Administrative Law Decision

The U.S. Supreme Court issued a [decision](#), *Loper Bright Enterprises v. Raimondo*, overruling a longstanding interpretive doctrine requiring courts to defer to an agency’s action when the underlying statute is ambiguous – commonly known as the Chevron doctrine. The 6-3 decision was written by Chief Justice Roberts and joined by two separate concurring opinions written by Justices Thomas and Gorsuch. Justice Kagan issued a dissenting opinion joined by Justices Sotomayor and Jackson.

Notably, the Chief Justice’s opinion clarifies that today’s decision “does not call into question prior cases that relied on the Chevron framework.” It further indicates that in cases where an agency’s action was previously found to be lawful under the Chevron doctrine, those cases remain binding legal precedent “despite the Court’s change in interpretive methodology.”

Why this matters: While the decision does not fully articulate the scope of the “interpretive methodology” courts should employ moving forward, it does emphasize it is the independent role and function of the courts to decide all relevant questions of law an agency’s action may implicate.

- In his opinion, Chief Justice Roberts observes that while courts have traditionally applied some degree of “due respect to Executive Branch interpretations of federal statutes,” they are not bound to those interpretations. In addition, the decision appears to suggest courts should look to the Administrative Procedure Act and other implementing laws to determine what, if any, deference Congress believes a court should apply to an agency’s policymaking or factfinding efforts.

Potential impacts of the decision include:

- Additional challenges to regulations and sub-regulatory guidance (increased litigation)
- Potential hesitancy to provide guidance until a better understanding of what is in scope (chilling effect on agency guidance)
- Potential private party hesitancy to act in reliance on challengeable regulations (risk management issues)

AHIP and BCBSA are carefully reviewing and assessing the impact the decision may have on health plans and the broader healthcare industry and expects to convene a variety of outreach efforts over the coming weeks and months to update members on the decision and its potential impacts.

Go Deeper: [Read the decision here.](#)

CMS Issues FAQ Guidance on Medicaid and CHIP Coverage of Peer Support Services

The Centers for Medicare & Medicaid Services (CMS) released a frequently asked questions (FAQ) document clarifying policies on Medicaid and CHIP coverage of peer support services.

Why this matters: States are encouraged to expand peer support services for individuals with mental health conditions and substance use disorders, including in emergency and inpatient settings, while ensuring payment rates support a living wage for providers.

The document emphasizes the importance of peer support providers' lived experiences and highlights research showing the benefits of peer support, such as improved treatment engagement and reduced emergency services. States have discretion in setting provider qualifications and supervision requirements, with guidance from the Substance Abuse and Mental Health Services Administration (SAMHSA). Additionally, states can cover peer support services for parents/legal guardians and youth, incorporating these services into schools and ensuring they are part of individualized care plans. Children's Health Insurance Program (CHIP) programs can also include peer support services, though it is not mandatory. States must submit detailed plans for Medicaid and CHIP coverage, outlining services, provider qualifications, and mechanisms to prevent over-billing.

CMS Issues Addendum to 2024-2025 Medicaid Managed Care Rate Development Guide

CMS released an addendum to the 2024-2025 Medicaid Managed Care Rate Development Guide for state to accommodate the provisions of the Medicaid and CHIP Managed Care Access, Finance and Quality final rule that takes effect July 9, 2024.

Why this matters: The guide provides details around information that must be included in the states' actuarial rate certifications for CMS to review and approve for rating periods between July 1, 2024, and June 30, 2025. The addendum identifies changes to in lieu of services and state directed payments as provisions that states should factor into rate setting.

HHS Issues Information Blocking Final Rule

The U.S. Department of Health and Human Services (HHS) released a [final rule](#) that establishes disincentives for health care providers that have committed information blocking. This final rule exercises the Secretary's authority under the 21st Century Cures Act (Cures Act) to establish "disincentives" for health care providers who engage in practices that the health care providers knew were unreasonable and were likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information (EHI), except as required by law or covered by a regulatory exception.

Why this matters: HHS finalized the following disincentives for providers that have been determined by the Office of the Inspector General (OIG) to have committed information blocking and for which OIG refers its determination to CMS:

- **Medicare Promoting Interoperability Program:** An eligible hospital or critical access hospital (CAH) that commits information blocking will not be a meaningful electronic health record (EHR) user in an applicable EHR reporting period. Under this program, eligible hospitals will have their annual market basket update reduced by three quarters while CAHs will have payment reduced to 100 percent of reasonable costs instead of 101 percent.

- **Merit-Based Incentive Payment System (MIPS):** A MIPS eligible clinician that commits information blocking will not be a meaningful user of certified EHR technology in a performance period and will therefore receive a zero score in the Promoting Interoperability performance category of MIPS. The Promoting Interoperability performance category score typically can be a quarter of a clinician or group's total MIPS score in a year. The final rule clarifies that if an eligible clinician who reports as part of a group is found to have committed information blocking, the penalty would only apply to the individual, not to the group.
- **Medicare Shared Savings Program:** An Accountable Care Organization (ACO), ACO participant, or ACO provider or supplier may be deemed ineligible to participate in the program for a period of at least one year. In this rule, HHS clarifies CMS will consider relevant facts and circumstances before applying this disincentive.

The rule notes HHS may establish additional disincentives through future rulemaking. The rule also notes OIG will exercise its enforcement discretion not to make any determinations regarding conduct occurring prior to the effective date of this rule for information blocking disincentives.

FDA Releases New Draft Guidance on Interchangeability

The FDA recently [announced](#) draft guidance on "[Considerations for Demonstrating Interchangeability with a Reference Product](#)." In this draft guidance, FDA proposes changing the standards for biosimilar products to obtain an interchangeable designation. Rather than completing switching studies, FDA proposes allowing biosimilar manufacturers to submit data that demonstrates a biosimilar meets the switching standard without conducting a switching study.

Why this matters: This draft guidance is based on updated scientific thinking and experience related to both biosimilars and interchangeable biosimilars. FDA issued the interchangeability [guidance for industry in 2019](#) before receiving and reviewing any applications for an interchangeable biosimilar. Since publication of the interchangeability guidance, experience has shown that for the products approved as biosimilars to date, the risk in terms of safety or diminished efficacy is insignificant following single or multiple switches between a reference product and a biosimilar product.

FDA has generally recommended switching studies in the past as part of the data package needed to demonstrate interchangeability of a biosimilar; however, of the 13 approved interchangeable biosimilars, nine were approved without additional clinical data.

The FDA is seeking comments on the revised approach. [Responses are due by August 20, 2024.](#)

Go Deeper: [Read more about the draft guidance here.](#)

HHS Announces Quarterly Update to List of Part B Drugs Subject to Inflation Rebate Program

The Department of Health and Human Services (HHS) issued a [press release](#) announcing the 64 Part B drugs subject to the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act for the upcoming quarter, July 1 – September 30.

Why this matters: The Inflation Reduction Act requires pharmaceutical companies pay rebates to Medicare when prices for certain prescription drugs covered by Medicare Part B and D rise faster than the rate of inflation. Medicare beneficiary cost-sharing may be lower for these drugs and biologicals.

By the Numbers: HHS estimates that **750,000 Medicare beneficiaries** use these drugs annually.

Looking Ahead: CMS indicated that the federal government intends to invoice drug manufacturers for 2023 and 2024 Part B inflation rebates “no later than fall 2025.”

Go Deeper: The [impacted prescription drug list](#) is available in the quarterly ASP public file.

CMS Accepting Applications for State-Based Maternal Health Model

The Centers for Medicare & Medicaid Services (CMS) announced it is accepting applications for the Transforming Maternal Health ([TMaH](#)) model from state Medicaid programs through a [Notice of Funding Opportunity](#) (NOFO) until September 20, 2024. CMS anticipates announcing the recipients selected to participate in the model in Fall 2024.

- TMaH is a CMS Innovation Center demonstration that will test value-based payment and care delivery approaches. It focuses exclusively on improving maternal health care for people enrolled in Medicaid or the Children's Health Insurance Program (CHIP) with a goal of reducing disparities in access and treatment.
- TMaH is a state-based model where state Medicaid agencies are the only eligible applicants. CMS will select up to 15 state Medicaid programs to participate and receive up to \$17 million in funding to support model implementation. TMaH is expected to run for 10 years, starting with a three-year pre-implementation period (January 2025 – December 2027).

While state Medicaid agencies are the only eligible applicants and are designated recipients of federal funding, they are required to collaborate with provider partners

(OB/GYNs, midwives, doulas, other clinical staff), partner care delivery locations (hospitals, birth centers, federally qualified health centers), and partner organizations (community-based organizations, managed care plans).

CMS Announces Release of State RFA for the Cell and Gene Therapy Access Model

CMS released a [Request for Applications \(RFA\) for States](#) for the Cell and Gene Therapy (CGT) Access Model. As [previously announced](#), sickle cell disease (SCD) will be the first focus of the CGT Access Model.

Overview: The CGT Access Model is “a [voluntary model](#) for states and manufacturers that tests whether a CMS-led approach to developing and administering outcomes-based agreements (OBAs) for cell and gene therapies improves Medicaid beneficiaries’ access to innovative treatment, improves their health outcomes, and reduces health care costs and burdens to state Medicaid programs.”

Why this matters: The CGT Access Model State RFA is open to all states, the District of Columbia, and all U.S. territories participating in the Medicaid Drug Rebate Program. States can choose to begin participation in the model between January 2025 and January 2026. After

CMS-Manufacturer negotiated Key Terms are disclosed to states in December 2024, states can apply to participate, but no later than February 28, 2025. CMS’s Innovation Center anticipates testing this Model for 11 performance years. CMS indicates states may choose to begin performance in the Model with only their fee-for-service (FFS) members and bring their managed care lives into the Model as late as January 1, 2026.

Go Deeper: Additional information can be found on the [State RFA fact sheet](#).

ACIP Recommends Updates to Several Vaccines

The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) [voted](#) to update recommendations on several vaccines. ACIP voted:

- 11-0 to recommend a single lifetime dose of RSV vaccine for adults 60-74 who are at increased risk of severe RSV; all adults ages 75 and older are recommended to receive the RSV vaccine.
- 11-0 to recommend the new 2024-2025 formulation of the COVID-19 vaccine to all individuals ages 6 months and older, with a vaccine approved or authorized for the appropriate age.
- 11-0 to recommend the 2024-2025 trivalent formulation of the influenza vaccine.

- 11-0 to recommend that PCV21 pneumococcal vaccine be available as an option to adults aged 19 and older who currently have a recommendation to receive a dose of other PCV vaccines.
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Medicaid Redeterminations Updates

A round-up of redeterminations news from KFF, CMS, and the CCC:

1. **KFF published the 22nd [annual survey](#)** of state Medicaid and CHIP programs to learn about how state Medicaid programs are approaching eligibility, enrollment, and renewals, both during and after the unwinding. The survey was conducted in March 2024 with the Georgetown Center for Children and Families. A key takeaway includes progress made by all states to improve *ex parte* renewal rates, and engagement of health plans was cited among the strategies that improved unwinding outcomes. In a related webinar (recording and slides available [here](#)), among several topics covered, officials CMS, Ohio, and North Carolina all had positive comments on the role of MCOs during the unwinding.
 2. **CMS released a [deck](#) on scheduled state timelines for completing unwinding-related renewals.** According to the slides, only six states (HI, SC, NC, AK, DC, and NY) have completion dates after July 2024. However, the analysis excludes “certain populations whose renewals were extended due to certain unwinding-related waivers, strategies, and flexibilities,” and therefore does not offer a complete picture.
 3. **The Connecting to Coverage Coalition (CCC) released its [policy paper](#)** detailing lessons learned during the unwinding and recommendations for ensuring access to coverage going forward. AHIP was one of 26 organizations that signed the paper.
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Hospital Industry Urges Senate, House Members to Halt Enforcement of Nurse Staffing Mandate

The American Hospital Association (AHA) June 24 sent letters to Senate and House members supporting legislation that would prevent enforcement of the Centers for Medicare & Medicaid Services’ final rule on minimum staffing requirements for long-term care facilities.

In the letters, AHA expressed concerns that the requirements would stymie innovation in care delivery and potentially lead nursing homes to reduce capacity or close, including those performing well on quality and safety metrics. This final rule could also lead to delays in urgent medical care as patients coming into hospital emergency departments (EDs) may experience longer waits as EDs and inpatient beds are occupied by patients awaiting nursing home placements. Lastly, this final rule could exacerbate the already serious shortages of nurses and skilled health care workers across the care continuum.

CMS estimates that 79% of LTC facilities would have to increase staffing to meet the proposed standards, including the new standard requiring 24/7 RN staffing.

Why this matters: All segments of the healthcare delivery system are experiencing unprecedented workforce shortages. Hospitals fear that the nurse staffing mandates for long-term care facilities will have a significant negative ripple effect on hospitals' ability to discharge patients to post-acute care.

New Hospital Price Transparency Requirements Take Effect July 1

On July 1 changes to the Centers for Medicare & Medicaid Services' Hospital Price Transparency Rule take effect.

Going forward, hospitals are required to use a standard machine-readable file format, which includes some new data elements, such as the negotiated rate methodology and an accuracy and completeness statement.

Background: Under CMS's Hospital Price Transparency regulations set forth at 45 CFR part 180 et seq., hospitals are required to display standard charge information through both a machine-readable file and a consumer-friendly format.

In the CY 2024 Outpatient Prospective Payment System (OPPS) Final Rule, CMS dictated the form and format that hospitals must use for the machine-readable file to increase standardization of the machine-readable file, such that hospitals must now conform to a CMS template layout, data specifications, and data dictionary.

Further, per that same rule, hospitals must now place a footer at the bottom of the hospital's homepage that links to the webpage that include the machine-readable file and also affirm in the machine-readable file that the hospital has included all applicable standard charge information in accordance with the requirements of 45 CFR part 180, and that such information is true, accurate, and complete as of the date of the file.

Lastly, CMS also updated modifications to the enforcement provisions at 45 CFR 180.70 to improve CMS's enforcement capabilities and increase transparency.

The CMS fact sheet regarding the hospital price transparency changes contained in the CY2024 OPPS Final Rule is available [here](#).

Why this matters: The CMS changes are intended to improve the transparency of the enforcement process. The effective date by which hospitals would be required to comply with some of these new requirements was delayed to either July 1, 2024, or January 1, 2025, due to comments submitted in response to the proposed rule.

Mississippi Judge Denies Drug Maker's and PhRMA's Request for Preliminary Injunction in 340B Case

A Mississippi judge on July 1 denied Novartis Pharmaceuticals' and PhRMA's request for a preliminary injunction against enforcement of state law protecting 340B pricing for contract pharmacy arrangements.

The American Hospital Association (AHA), along with 340B Health, the Mississippi Hospital Association and the Rural Hospital Alliance last month filed an amicus brief in the U.S. District Court for the Southern District of Mississippi defending the state's law.

In a related matter, the AHA, 340B Health, the Maryland Hospital Association and the Mid-Atlantic Association of Community Health Centers June 26 filed an amicus brief in a federal district court in Maryland, defending Maryland's law protecting 340B pricing for contract pharmacy arrangements.

Litigation background: As drug manufacturers have put conditions on covered entities' use of contract pharmacies, several states have intervened with the enactment of laws to prohibit manufacturers from engaging in such practices.

These state laws have prompted legal challenges. Five states — Arkansas, Louisiana, Maryland, Mississippi, and West Virginia — are all facing legal battles in federal court over their respective contract pharmacy laws. The Pharmaceutical Research and Manufacturers of America (PhRMA), a trade association of drug manufacturers, is spearheading the challenges. At least one manufacturer (Novartis) has separately filed its own lawsuit to challenge one or more of the laws.

The main argument from these challengers is that the 340B statute overrides, or preempts, these state laws and renders them unconstitutional. The challengers also assert in some cases that the laws are unconstitutional because they are excessively vague or interfere with Congress's authority to regulate interstate commerce.

Several of the cases are newly filed and have not yet produced any substantive rulings. To date, PhRMA's suit challenging the Arkansas contract pharmacy statute is the only case that has undergone both district and appellate court review. In that case, the Eighth Circuit Court of Appeals held that neither the 340B statute nor the federal Food, Drug, and Cosmetic Act preempts the Arkansas law. In support for this conclusion, the court drew from the Third Circuit's analysis in the consolidated AstraZeneca, Novo Nordisk, and Sanofi cases, noting that one may infer from the absence of any express terms in the 340B statute regarding the delivery of covered drugs that Congress did not intend to prevent states from regulating in this area.

Why this matters: For more than 30 years, the 340B Drug Pricing Program has provided financial help to hospitals and other covered entities serving vulnerable communities to manage rising prescription drug costs. In recent years, the drug manufacturers have sought ways to challenge and destroy the program.

State Issues

Delaware Legislative

The Delaware General Assembly Wraps Up Session

June 30 was the final day of session for the Delaware General Assembly. Touting the passage of a sustainable budget, Governor Carney signed a **\$6.1 billion Fiscal Year 2025 operating budget**; a **\$168 million one-time supplemental appropriation**; a **\$98.4 million grants-in-aid bill**; a **\$1.1 billion Capital budget**, and **codified the Budget Stabilization Fund**.

It was a very busy year for health insurance mandates. Below is a list of health insurance bills that passed both chambers this legislative session. Under Delaware law, the Governor has 10 days (excluding Sundays) to act on legislation sent to his desk from the originating chamber. If the Governor does not act within the 10 days it becomes effective without signature. The originating chamber has until the end of the calendar year to officially present the bills to the Governor for signature.

Legislation that Passed:

- **HS 2 for HB 273 w/ SA 1**- RELATING TO HEALTH COVERAGE FOR SPEECH THERAPY.
- **HB 274** - RELATING TO INSURANCE COVERAGE OF ALLERGEN INTRODUCTION DIETARY SUPPLEMENTS FOR INFANTS.
HB 281 w/ HA 3 + SA 1 - RELATING TO STATE HEALTH CARE INSURANCE - Medicare Advantage program offering prohibition. Enacted w/o signature
- **HS 1 for HB 253 w/ HA 1** - RELATING TO MAMMOGRAMS. – removes prescription requirement and lowers to 40 years of age.
- **HS 2 for HB 110** - RELATING TO INSURANCE COVERAGE FOR TERMINATION OF PREGNANCY.
- **HB 15 w/ HA 1** -RELATING TO OVARIAN CANCER – Commercial coverage for screening. Signed into law
- **HB 16 w/ HA 1**- RELATING TO OVARIAN CANCER. – Medicaid and SOD coverage for screening
- **HS 1 for HB 302** - RELATING TO PROSTATE CANCER SCREENING – coverage mandate
HB 283 w/ HA 1- RELATING TO INSURANCE-License and filing fees
- **HB 345** - RELATING TO COVERAGE FOR DOULA SERVICES -Additional visits for Medicaid Recipients. Signed into law
- **HB 362**- RELATING TO COVERAGE FOR DOULA SERVICES -Commercial
- **HB 364**- RELATING TO CANCER COVERAGE – Associated Conditions of Metastatic Cancer
- **HS 1 for HB 383 w/ HA 1, HA 2 + SA 1**- RELATING TO PROHIBITING DISCRIMINATION AGAINST 340B DRUGS AND COVERED ENTITIES BY MANUFACTURERS AND PHARMACY BENEFITS MANAGERS.
- **HS 1 for HB 5 w/ HA 1**- RELATING TO REIMBURSEMENT OF SCHOOL-BASED BEHAVIORAL HEALTH SERVICES – Medicaid Application

- **SB 194 w/ SA 1**- RELATING TO PRACTICE OF PHARMACY – Pre and Post HIV Treatment
- **SB 232**- RELATING TO INSURANCE COVERAGE FOR CONTRACEPTIVES - OTC
- **SB 220** - RELATING TO HEALTH INSURANCE FOR CHILDREN AND PERSONS ON MEDICAID – signed into law
- **SB 272 w/ SA 1**- RELATING TO HEALTH INSURANCE, AND TO PHARMACIST CARE – Allows for Pharmacist Reimbursement as a Provider
- **Key Bills That Did Not Advance**
- **SB 10**- RELATING TO HEALTH INSURANCE AND PRE-AUTHORIZATION REQUIREMENTS.
- **HB 441**- RELATING TO INSURANCE COVERAGE FOR PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND NEUROMUSCULAR MASSAGE THERAPY.
- **SB 143**- RELATING TO HEALTH INSURANCE – Clean Claim/Prompt Pay
- **SB 204** - RELATING TO DENTAL CARE FOR ADULT MEDICAID RECIPIENTS

Also of Note

- **HS 2 for HB 350 w/ HA 1 + SA 1** - RELATING TO HOSPITAL COSTS – Creates the Diamond State Hospital Cost Review Board. Signed into law.

State Issues

New York

Legislative

Governor Signs Legislative Package

The Governor signed three bills that were part of a legislative package to support LGBTQ+ New Yorkers and people living with HIV/AIDS, which Governor Hochul signed during a ceremony at the Stonewall National Monument Visitor Center to cap off Pride Month.

- A.8834-B/S.8144-C – The legislation prohibits discrimination against individuals who were prescribed pre-exposure prophylaxis (PrEP) medication for HIV prevention by prohibition insurers to deny these individuals insurance coverage – accident and life as well as health.
- S.1001-A/A.1619-A — The legislation prohibits insurers from applying prior authorization for coverage for PrEP prescription medications used for the treatment or prevention of HIV infection.
- S.9842/A.10461 — The legislation prohibits health insurers from applying copayments for PrEP and PEP medications that have an A or B rating in the current recommendations of the United States Preventative Services Task Force.

Highmark does not apply prior authorization or copayments to PReP and PEP, so there is no fiscal impact to these bills.

The Governor also signed A.9564-B/S.8749-B, legislation that extends the effective date for two years until January 2026 for plans to include space on enrollment forms for consumers to opt to sign up with the Donate Life organ donor registry.

State Issues

Pennsylvania

Legislative

Pennsylvania Legislative Update

BUDGET: The June 30th Budget Deadline has passed with no agreement on the FY 2024-2025 State Budget. Both the House and the Senate return to Session this week to continue negotiations with the Governor's Office.

HOUSE ACTIONS:

- **Contraceptives:** House Bill 1140, Representative Kruger's legislation which would mandate all private and Government insurance policies to provide coverage for all forms of contraceptives was amended and passed by the House by a vote of 133 to 69. It is awaiting committee assignment in the Senate.
- **Speech Therapy:** House Bill 2268, Representative Markosek's legislation removing limitations on coverage for speech therapy for childhood stuttering, was amended and advanced by the House. The amendment removed coverage requirements for MA and CHIP policies and was advanced to the Senate by a vote of 181-21. The bill is awaiting committee assignment in the Senate.

SENATE ACTIONS:

- **PBMs:** House Bill 1993, Representative Benham's PBM legislation, which is the House companion to Senate Bill 1000, was passed by the House with a vote of 198 to 4. The bill has been referred to the Senate Health and Human Services Committee for its consideration. Senate Bill 1000 continues to be negotiated upon with all stakeholders. It is expected that the Senate will take action on either of the bills this week.
- **Data Protection:** House Bill 1201, Representative Neilson's Data Protection legislation was reported from the Senate Communications and Technology Committee with a unanimous vote and is expected to be acted upon by the Senate

this week. We are awaiting confirmation from Senate Staff that TPAs and other subsidiaries would fall under the Insurance exemption.

- **Provider Reimbursement:** House Bill 1664, Representative Scott’s “Virtual Credit Card” legislation, outlining means which insurers can reimburse providers, was amended by the Senate and advanced through the Appropriations Committee. The bill was amended from its original text, making the legislation applicable only to dentists, to include all health care providers, and would require insurers to offer means other than digital reimbursement to providers, and enter into agreements to cover such items as processing fees and technologies required for providers to accept digital reimbursements. The legislation is before the Senate for its consideration as a whole.
- **Telemedicine:** Senate Bill 739, Senator Vogel’s legislation requiring coverage of telemedicine services, received final actions in the Senate, with the Senate voting to concur with House amendments by a vote of 49-1. The legislation is now awaiting Governor Shapiro’s signature to become law.

GOVERNOR’S ACTIONS:

- **Biomarkers:** House Bill 1754, Co-Sponsored by Representative Mullins and Leader Cutler, providing for coverage by all non-MA or CHIP policies, for biomarker testing of specific diseases was unanimously passed by the Senate and was signed into law by Governor Shapiro as Act 39 of 2024.

Telehealth Bill Reaches the Finish Line

On Wednesday, the General Assembly gave final approval to Senate Bill 739, sponsored by Senator Elder Vogel (R-Beaver). The bill, nearly a decade in the making, defines reimbursement requirements for telehealth services and ensures payment cannot be denied simply because care is provided via telehealth. The bill also ensures that payment or reimbursement may not be conditioned upon the use of an exclusive or proprietary telemedicine technology or vendor.

The bill now heads to Governor Shapiro’s desk for approval.

Telehealth increases access to primary and specialty care, particularly for at-risk populations, and empowers patients to manage chronic conditions and avoid hospital stays.

Why this matters: Improving access to telehealth has been a longtime priority for insurers and providers. Telehealth helps meet patients where they are, increasing access to routine and preventative care to improve health outcomes. It also extends the reach of providers at a time when the commonwealth’s growing need for care is outpacing the professionals available to deliver it.

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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