# Highmark's Weekly Capitol Hill Report

**Issues for the week ending August 25, 2023**

## Federal Issues

Legislative

### Congress Reconvenes from the August Recess on Sept. 5

**Congress reconvenes next week –** marking the start of busy fall work period with action on "must pass" bills.

- **Fiscal Year 2024 Appropriations:** With the current fiscal year set to expire on Sept. 30, Congress' top priority will be passage of a short-term continuing resolution (CR) before the end of the month to avoid a government shutdown as lawmakers work to reach agreement on an end-of-year (EOY) omnibus appropriations package. There is bipartisan support in the Senate, but the GOP House majority remains at odds over strategy.
- **Health Program Reauthorizations:** Another priority in September will be reauthorization of several health care-related programs which are set to expire Sept. 30. This includes the Pandemic and All-Hazards Preparedness Act (PAHPA); community health centers; the SUPPORT Act (substance use disorder programs);

## In this Issue:

and the Community Mental Health Services Demonstration Program.

**At this time, it is unclear what, if any, policy riders will be included as part of the September CR.** Key provisions in play include: Ukraine funding/Hawaii relief; hospital billing reforms, and improved access to generics.

- **In addition,** House and Senate leaders continue efforts to develop health care packages in their respective chambers with an eye towards inclusion of key health care provisions in EOY omnibus legislation.
    - **House:** Ways and Means, Energy and Commerce and Education and Workforce Committee Republicans continue working to come together on policies related to fair hospital billing, telehealth and price transparency – policies that could form the basis of a House GOP package on affordability. Floor action is possible in September. The package will not receive consideration in the Senate, but some provisions could be on the table for end-of-year negotiations.
    - The Energy and Commerce Committee has also signaled its intent to hold hearings examining drugs shortages draft legislation and Medicare innovation, which could include coverage of wearable technology and the PBM "de-linking" policy considered by the Senate Finance Committee in July.
    - **Senate: I**t is still possible Majority Leader Chuck Schumer (D-NY) will push for a floor vote on a health care package that could include an insulin co-pay cap for the commercial market, PBM transparency legislation and bills to increase generic and biosimilar competition. Timing is uncertain given floor time availability and ongoing work by committees on PBM proposals. Many predict all these policies will fall to end-of-year negotiations.

- **QHP Model Contract Updates**

**Pennsylvania**

***Legislative***

- **PA Senate Returns to Focus on Outstanding Budget Items**

***Regulatory***

- **Out of State Nurses Working in Pennsylvania**

- The Senate Finance Committee may pick up steam on proposals raised at their July 26th PBM markup such as any willing pharmacy, anti-steering, and transparency requirements.

## Federal Issues

Regulatory

### Federal District Court Issues Mixed Ruling in *TMA III* No Surprises Act Lawsuit

Judge Kernodle sitting in the U.S. District Court for the Eastern District of Texas issued a decision in lawsuits filed by the Texas Medical Association and various air ambulance providers (*TMA III*) challenging regulations and guidance establishing the methodology used to calculate the qualified payment amount (QPA) and other independent dispute resolution (IDR) processes under the No Surprises Act.

**Why this matters:** The decision largely favors providers, with the court finding many of the challenged portions of the regulations conflict with the plain terms of the Act and should be set aside and vacated.

However, the court did uphold two key regulations establishing certain plan disclosure requirements and defining the geographic regions used in calculating the QPA for air ambulance claims. Following the decision, the Coalition Against Surprise Medical Billing (CASMB) issued a statement addressing the court's ruling and urging the Administration to move quickly to seek a stay (or pause) the court's vacating of certain regulations in order to avoid significant disruption to the IDR process and harm to patients.

- Specifically, the decision found numerous portions of the challenged regulations conflict with the Act's statutory language. That includes striking down regulations or guidance that the QPA calculation should: (1) include (a) contracted rates for services that providers have not provided and (b) out-of-specialty rates; and (2) exclude incentive-based or retrospective payments or payment adjustments. The court also struck down regulations that allow self-insured group health plans to use rates from all plans administered by a third-party administrator in calculating the QPA.

- In addition, the court found that the 30-day deadline for notice or denial of payment is strictly calculated from when a plan first receives a "bill" from a provider, and not, as the agencies had interpreted in guidance, from when a plan receives a "clean claim" or the information "necessary to decide a claim."

- In regard to air ambulance claims, the court found that agency guidance requiring two separate IDR processes for a single medical air transport (one for a liftoff rate service code, another for a per-mile rate service code) violated the Act, and that the agencies improperly excluded single-case agreements from the QPA. That later decision conflicts with a recent ruling in federal district court in

the District of Columbia, where the court found the agency had properly excluded such agreements from the QPA.

We will continue to review the decision and its impact on the QPA calculations and IDR process.

**As a reminder, the IDR portal is currently suspended for new claims as of August 4, due to the decision in *TMA IV*.** That separate lawsuit challenged the agencies' IDR fee increase and other claim batching-related requirements.

**The Coalition Against Surprise Medical Billing issued a statement** in response to the decision: "**This ruling is bad for patients, jeopardizing their protections under the *No Surprises Act* and very likely raising costs.** The *No Surprises Act* has prevented roughly 20 million surprise bills – a small fraction of which have been subject to arbitration and thus affected by the three other lawsuits filed by Texas physicians."

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## CMS Issues Draft Guidance on Medicare Part D Prescription Payment Plan

The Centers for Medicare & Medicaid Services (CMS) published a 56-page draft guidance related to the Medicare Part D Maximum Monthly Cap on Cost-Sharing Payments Program established by the Inflation Reduction Act. CMS is now referring to the program, sometimes referred to as the Out-of-Pocket (OOP) Smoothing Program, as the Medicare Prescription Payment Plan.

**Background:** The program enables those with Part D drug coverage the option to pay OOP costs in monthly payments spread out over the plan year, instead of paying OOP costs upfront at the pharmacy point of sale, starting in 2025.

CMS also issued a press release, fact sheet, and timeline of key dates with the draft guidance.

**Why this matters:** CMS states this part one guidance will be finalized by spring 2024 and contains guidance on calculations for monthly payment amounts, billing instructions, pharmacy reimbursements, a process for claims adjudication, thresholds for identifying Part D enrollees likely to benefit from the program, a discussion on interactions with the Part D Low-Income Subsidy program, requirements related to Part D enrollee election into the program, procedures for termination of participation in the program, participant protections under the program, participant dispute resolution process requirements, and data submission requirements.

- According to the fact sheet, examples of requirements included in the draft guidance are: a requirement that Part D sponsors must process election requests within 24 hours; a specification that sponsors may not exclude any Part D drugs; indication that once an individual opts into the program all of their Part D OOP prescription drug costs must be billed monthly; and enrollee protections such as a minimum grace period and a hearing process.

**Next Steps:** CMS will release part 2 of the guidance with a 30-day comment period in early 2024, which CMS indicated will contain information on Part D enrollee outreach and education, plan bid information, and monitoring and compliance requirements.

**Comments on the draft guidance are due to CMS by September 20.**

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## CMS Announces First 10 Drugs Selected for Medicare Drug Price Negotiations

CMS issued a press release and fact sheet announcing the first ten Part D drugs selected for negotiation under the Medicare Drug Price Negotiation Program.

The list includes the blood thinners Eliquis and Xarelto and the diabetes drugs Jardiance and Januvia, as well as Farxiga, which can be used to treat diabetes and heart failure.

- **Rounding out the list:** Entresto, used to treat heart failure; Enbrel, a rheumatoid arthritis drug; the blood cancer drug Imbruvica; Stelara, used to treat psoriasis and Crohn's disease; and the diabetes drug Fiasp.

**Of note:** Insulin is already subject to a $35 monthly co-pay cap for Medicare prescription drug plan enrollees under a different provision of the Inflation Reduction Act.

- The negotiations for these drugs will take place in 2023 and 2024 and any negotiated prices will become effective in 2026.

**Background:** The medicines up for negotiation were chosen from a list of the 50 products with the highest spending in Medicare's prescription drug program, Part D.

- The selected drugs accounted for $50.5 billion in total Part D gross covered prescription drug costs, or about 20% of Part D prescription costs between June 1, 2022 and May 31, 2023, according to the Health and Human Services Department.

- Some of the highest-cost Medicare drugs were not eligible for this round of negotiations, either because they still have market exclusivity, they're the only option for a rare disease or another factor.

CMS announced opportunities for public engagement during the negotiation process for these ten drugs. CMS states that the agency will host patient-centered listening sessions for each selected drug this fall. CMS states that "the public is also invited to submit data on selected drugs, therapeutic alternatives to the selected drugs, data related to unmet medical need, and data on impacts on specific populations by October 2, 2023."

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## FDA Approves RSV Vaccine for Pregnant People

The Food and Drug Administration (FDA) approved Abrysvo, a vaccine manufactured by Pfizer, to protect pregnant people and their newborn babies from severe illness caused by respiratory syncytial virus (RSV).

The vaccine can be administered to pregnant people between 32- and 36-weeks' gestation to prevent lower respiratory tract disease from RSV in newborns and infants up to 6 months of age. In a press release, the FDA noted that in safety studies, although not commonly reported, pre-eclampsia occurred in 1.8% of pregnant individuals who received Abrysvo compared to 1.4% of pregnant individuals who received placebo. The FDA is requiring the company to conduct postmarketing studies to assess the signal of serious risk of preterm birth and to assess hypertensive disorders of pregnancy, including pre-eclampsia.

Abrysvo was approved for use in individuals 60 years and older by the FDA earlier this year. The next step will include review by the Advisory Committee on Immunization Practices (ACIP) regarding recommendations and subsequent review by the Director of CDC.

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## HHS Announces Funding for COVID-19 Vaccine & Therapeutics Development

The U.S. Department of Health and Human Services (HHS) announced that it would provide more than $1.4 billion in funding for Project NextGen to support the development of the next generation of COVID-19 vaccines and therapeutics.

The funding, provided through the Administration for Strategic Preparedness and Response (ASPR), seeks to support clinical trials to enable the rapid development of more effective and longer-lasting COVID-19 vaccines, a new monoclonal antibody, and other transformative technologies that can streamline the manufacturing processes.

**The funding will be distributed accordingly:**

- $1 billion to four of ASPR's Biomedical Advanced Research and Development Authority (BARDA) Clinical Trial partners to support vaccine Phase IIb clinical trial studies and speed the development of new vaccine candidates.
- $326 million to Regeneron to support the development of a next-generation monoclonal antibody for COVID-19 prevention – to address a critical gap in care for those who cannot take existing vaccines.
- $100 million to the non-profit organization managing the BARDA Ventures investment portfolio to expand investments in new technologies that will accelerate responses in the future.
- $10 million to Johnson & Johnson Innovation (JLABS) for a competition through Blue Knight, a BARDA-JLABS partnership, intended to enable more efficient development and manufacturing strategies in the future.

HHS anticipates additional awards to be announced before the end of the fiscal year.

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## Medicare Shared Savings Program

On Aug. 24, CMS announced the Medicare Shared Savings Program saved more than $1.8 billion in 2022 while continuing to deliver high-quality care. This is the second-highest annual savings accrued to Medicare since the program's inception over a decade ago. Earlier this year, in the CY 2024 Physician Fee Schedule Proposed Rule, CMS proposed changes that would promote participation among health care providers and promote equity, particularly in rural and underserved areas. CMS continues to explore opportunities to advance value-based care overall.

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## CMS Issues Memos on Dual Eligible Special Needs Plans

The Centers for Medicare & Medicaid Services (CMS) sent a memorandum to Medicare Advantage Organizations with a Dual Eligible Special Needs Plan (D-SNP) to share updates to the Medicare Managed Care manual on the requirement for D-SNPs to have contracts with state Medicaid agencies.

The updated section of the manual clarifies that D-SNPs must submit to CMS a state Medicaid agency contract (SMAC) for each state it seeks to operate in for the upcoming contract year by the first Monday in July of each year. D-SNPs with evergreen SMACs are still required to submit contracts to CMS by the first Monday in July. The manual update also outlines the minimum regulatory requirements that must be included in each SMAC.

CMS also sent a memorandum to Medicare Advantage Organizations to share updates to the Medicare Managed Care manual on requirements for SNPs to include questions on health-related social needs in health risk assessments. The new section of the manual includes information about screening instruments SNPs can use to meet these requirements and suggestions how SNPs can consider equity and accessibility when selecting screening instruments.

## Delaware

Regulatory

### DOI Re-Issues Bulletin on False or Misleading Representations of Premium Rate Setting

The Delaware Department of Insurance (DOI) has reissued Universally Applicable Bulletin No. 1 regarding false or misleading representations concerning how insurance premium rates are set in Delaware. Applicable to all insurers, intermediaries, and underwriters, the bulletin is in response to the DOI receiving complaints that insurers and brokers have been claiming that premium increases were required by the DOI.

The DOI expects producers to obtain a full explanation of the premium increase from the insurance company when inquired by an insured. However, the DOI specifically notes that the above statement violates 18 Del.C. § 2304(2) with administrative penalty provisions in Delaware code allowing for fines and license revocation if the person knows or reasonably knows they are violating the statute.

## State Issues

### New York

Regulatory

### QHP Model Contract Updates

With New York's Qualified Health Plan model contract set to expire on December 31, 2023, the New York State of Health has proposed updates to Appendix C of the current QHP Contract (program provisions). Below is a short list of the more substantive revisions:

**QHP Updates**

- Contractor shall submit a link providing access to its formulary;  page 13

- Deletion of reference to transaction ID number; p. 19
- Addition of SEPs related to HRA and QSEHRA access and COBRA; consistent with federal regulation; p. 24
- Use of SEPs, consistent with federal regulation; p. 25
- Deletion of eligibility and enrollment provisions related to SHOP requirements prior to 7/1/2018; p. 27-29
- Tagline requirements; p. 36
- Member ID card update; p. 38
- Contractor notice to Enrollees regarding non-payment of premium; p. 41
- Deletion of termination provisions related to SHOP coverage prior to 7/1/2018; pp.42-43
- Processing of complaints;  p. 46-47

NYSOH has asked for feedback on these updates – requesting any comments of questions no later than September 6, 2023. As such, the NY Health Plan Association is asking for any comments from plans by September 1, 2023.

It is NYSOH's goal to get a new 5-year model Contract completed and out to the individual plans as soon as possible after September 6, to allow for the time required for internal approvals, signatures, etc.

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## State Issues

### Pennsylvania

Legislative

**PA Senate Returns to Focus on Outstanding Budget Items**
The Pennsylvania Senate returns to Harrisburg this week at a critical time in the state budget process. More than $1.1 billion in state funding remains in legislative limbo, despite Gov. Josh Shapiro having signed Pennsylvania's main budget bill more than three weeks ago.

Disagreements between the GOP-led Senate and Gov. Shapiro have stalled progress on this funding, which includes programs ranging from education to emergency services. Senate President Pro Tempore Kim Ward announced last week that the Senate would return three weeks earlier than originally scheduled to resume work on the underlying code legislation, emphasizing that some matters "continue to be negotiated."

Several education programs are still awaiting the green light, including $100 million in Level Up funding intended to support the Commonwealth's poorest school districts.

**Related programs stuck in limbo include:**

- $10 million for student teachers, $100 million for school mental health services, $50 million for emergency hospital relief, and $20.7 for increased ambulance service reimbursements. These programs cannot move forward until necessary code bills are signed into law.
- Additionally, $175 million in funding for Pennsylvania's Whole-Home Repairs program, which provides homeowners with up to $50,000 in direct loans/grants from the Department of Community

and Economic Development for home repairs and upgrades, remains caught up in negotiations. This amount represents a $50 million increase over the amount federally funded for the past two years, the difference coming out of state revenues.
- The state's $7.5 million allocation for public defense (its first-ever) is also on hold. Supporters argue this funding is overdue as most states fund public defense in some capacity. They also assert this funding would help municipal governments alleviate a significant budgetary burden.

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Regulatory

### Out-of-State Nurses Working in Pennsylvania

The Shapiro administration has announced that it will implement one component of the Nurse Licensure Compact (NLC) effective September 5, 2023.

**Why this matters:** This step means registered nurses (RN) and licensed practical nurses (LPN) who hold multi-state licenses (MSL) from other compact member states/territories will be able to provide in-person and telehealth services to Pennsylvania patients.

Pennsylvania nurses will not yet be able to obtain multi-state licenses through the compact. In order to allow this, Pennsylvania must have the ability to certify to other compact states that it has performed an FBI criminal background check on Pennsylvania applicants—a process that requires the state gaining FBI-approved access to its criminal history database for that purpose. State leaders continue to work with the Department of Justice and the FBI to resolve barriers to implementing this component of the compact.

**How it works:** Health care facilities licensed by the Department of Health (DOH) who are seeking to utilize nurses with multi-state licenses must submit an **exception request form**. On the exception request form, the facility must identify the regulation from which it is seeking an exception and include a brief narrative which states that the facility is requesting the exception for the purpose of employing or contracting with eligible multi-state licensed nurses and will outline its process to verify their multi-state license prior to employing or contracting with eligible multi-state licensed nurses.

- Requests will be published in the *Pennsylvania Bulletin* for a 10-day public comment period. After the period concludes and comments are considered, DOH will issue a written determination to the facility. As with any exception, DOH reserves the right to revoke any exception granted for any justifiable reason. Exception requests will not require onsite surveys.

- DOH's facility-specific guidance is available on the **Nurse Licensure Compact webpage**. To verify the status of a nurse's multi-state license, facilities can go to the **National Council of State Boards of Nursing's (NCSBN)** central repository for licensing information and click "Quick Confirm."

- The hospital does not have to notify the State Board of Nursing that the multi-state licensed nurse is working in Pennsylvania. The **State Board of Nursing** has additional information about this first step to implement the NLC at its website.

**Impact:** This new pathway for nurses to work in Pennsylvania supports the broader effort to grow the health care workforce, helping hospitals to meet a growing need for care throughout the commonwealth. Pennsylvania's hospital community is focused on a comprehensive strategy that will grow and support its

dedicated health care teams, expand the training and education pipeline, and strengthen care in communities.

Hospitals have continued to advocate with the Department of State to fully implement Pennsylvania's participation in all the various licensure compacts. The pathway announced by the Shapiro administration for the nurse licensure compact is a step in the right direction.

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**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/.**