Highmark's Weekly Capitol Hill Report

Issues for the week ending August 8, 2025

Federal Issues

Regulatory

FDA Announces New Precheck Program for Drug Manufacturing

The Food and Drug Administration (FDA) announced last week a new program that aims to strengthen the domestic pharmaceutical supply chain.

To help bolster pharmaceutical supply chain resiliency in the U.S., on May 5, 2025, the President issued Executive Order (EO) 14293, "Regulatory Relief to Promote Domestic Production of Critical Medicines." EO 14293 sets forth a policy intended to streamline the regulation of manufacturing pharmaceutical products to facilitate the restoration of a robust domestic pharmaceutical manufacturing base.

EO 14293 directs FDA to review existing regulations and guidance that pertain to the development of domestic pharmaceutical manufacturing and take steps to "eliminate any duplicative or unnecessary requirements…; maximize the timeliness and predictability of agency review; and streamline

In this Issue:

and accelerate the development of domestic pharmaceutical manufacturing."

The program, FDA PreCheck, seeks to "increase regulatory predictability and facilitating the construction of manufacturing sites in the United States." Federal officials said the initiative aims to make the nation less reliant on overseas sources for active pharmaceutical components.

The PreCheck program will include a two-phase approach to facilitate new U.S. drug manufacturing facilities.

1. The Facility Readiness Phase provides manufacturers with frequent FDA communication at development stages, including facility design, construction, and pre-production.

2. The Application Submission Phase seeks to make the development of the Chemistry, Manufacturing, and Controls section of the application more efficient through pre-application meetings and early feedback.

The FDA will host a public meeting on September 30 about the plan. Additional information is available online.

Why this matters: A resilient supply chain for medical products, and specifically, pharmaceuticals and biological products, is critical for the safety and security of the United States. The globalization of pharmaceutical production over the past several decades complicates these challenges.

Until the 2000's, pharmaceutical manufacturing was largely a domestic enterprise. In the last several decades, however, such manufacturing has increasingly

- **Webinar to Discuss Nurse Licensure Compact**

Industry Trends

Policy / Market Trends

- **2026 Rate Filings Update; ACA Premiums Could Rise by Median of 18%**
- **Pharma Tariffs Could Reach 250%, Trump Says**
- **Democratic Attorneys General Sue Over Planned Parenthood Funding Exclusion**
- **CMS Administrator Discusses Medicaid Funding, Drug Pricing and Community Engagement Verification**

moved offshore. Today, more than half of the pharmaceuticals distributed in the U.S. are manufactured overseas. As of 2025, approximately 53% of brand drug products and 69% of generic drug products are manufactured outside of the United States. As of 2025, only 9% of API manufacturers are in the U.S., compared to 22% in China and 44% in India

USPSTF Comment Opportunity on Draft Recommendation on Screening and Interventions to Reduce Unhealthy Alcohol Use

The U.S. Preventive Services Task Force (USPSTF) released a draft recommendation statement and draft evidence review on screening and behavioral counseling interventions for unhealthy alcohol use in adolescents and adults. The USPSTF recommendation has a "B" grade and recommends screening for unhealthy alcohol use in primary care settings in adults 18 years or older, including those who are pregnant, and providing persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce unhealthy alcohol use. The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening and brief behavioral counseling interventions for alcohol use in primary care settings in adolescents aged 12 to 17 years. These recommendations are consistent with the 2018 USPSTF recommendation statement on this topic.

Following the June 2024 circuit court ruling in the *Braidwood Management, Inc. v. Becerra* case, health plans subject to the ACA preventive services mandate will continue to be required to cover all applicable preventive services recommendations from the Health Resources and Services Administration (HRSA), the Advisory Committee on Immunization Practices (ACIP) and USPSTF issued before and after 2010 without cost-sharing.

The USPSTF is accepting public comments until September 2.

CMS Releases 2026 Preliminary Medicare Part D Bid Information and Revised Premium Stabilization Demonstration Parameter

On July 28, the Centers for Medicare & Medicaid Services (CMS) released preliminary technical information for Medicare Part D plans for Contract Year (CY) 2026 including a National Average Monthly Bid Amount (NAMBA) of $239.27, an increase from $179.45 in 2025. The direct subsidy will be $200.28, an increase from $142.67 in 2025. Concurrently

with this release, CMS announced it will continue the voluntary Part D Premium Stabilization Demonstration (demonstration) originally implemented in 2025 but with less generous premium stabilization for CY 2026.

As with the 2025 demonstration, standalone prescription drug plans (PDPs) including Employer Group Waiver Plan (EGWP) PDPs are eligible to participate but Medicare Advantage Prescription Drug Plans (MAPDs) are not. For the first time, CMS notably rejected some standalone PDP bids due to significant year-over-year premium increases.

CMS will release final Part D premiums at the individual plan level in September in the 2026 Medicare Advantage and Part D Landscape, following Part D sponsor decisions to participate in the demonstration.

HHS Halts $500M in mRNA Vaccine Projects for Respiratory Viruses
HHS is pulling $500 million in funding and canceling contracts for 22 vaccine development projects using messenger RNA technology. This decision impacts vaccines targeting respiratory infections such as COVID-19 and flu. The department says it will shift resources toward alternative vaccine approaches, such as whole-virus vaccines and platforms that aim to provide broader protection.

Full Story: The Associated Press (8/6)

CMS Announces Connecting Kids to Coverage Outreach and Enrollment Cooperative Agreement Grantees
The Centers for Medicare & Medicaid Services (CMS) announced the 2025 grantees for the Connecting Kids to Coverage (CKC) Outreach and Enrollment Cooperative Agreement program. The program provides funding to increase child enrollment in Medicaid and the Children's Health Insurance Program (CHIP) and improve retention of eligible children, parents and pregnant women in these programs. The 25 grantees, which include federal health safety net organizations, providers, tribal organizations, and non-profit organizations, will receive grants ranging from $850,000 to $3 million across a five-year performance period. Grantees may use funding to support activities aimed at educating families about the availability of Medicaid and CHIP coverage, identifying kids likely to be eligible for coverage, and assisting families in applying for and renewing coverage. Read More

---

CMS Releases State Health Official Letter on Medicaid Enterprise System Compliance
CMS released a State Health Official (SHO) letter titled *Streamlining Medicaid Enterprise Systems (MES) Templates to Improve Monitoring and Oversight to Ensure Fiscal Integrity*. The letter provides states with updated guidance on complying with regulatory requirements for MES modules and solutions, with a focus on process and template

simplification to help states appropriately follow CMS guidelines regarding Advanced Planning Document (APD) and operational reporting submissions. The letter also highlights CMS's ongoing efforts to reduce state streamline reporting and oversight processes. Read More

State Issues

Pennsylvania

Regulatory

Pennsylvania Insurance Department to Consider IRO Fees As Part of the Approval Process

The Pennsylvania Insurance Department (Department) under Act 146 of 2022 is required to monitor and publish the fees charged by Independent Review Organizations (IROs).

Why this matters: These fees are charged by the IROs to insurers, Medical Assistance and CHIP Managed Care Organizations when they conduct independent external reviews of adverse benefit determinations and grievances.

The Department grants approval to IROs that meet certain statutory criteria. Such approval is valid for two (2) years unless an IRO no longer satisfies the minimum statutory requirements or is no longer accredited.

The Department may also decline to certify an IRO if its fees are deemed to be unreasonable. As such, the Department is reminding IROs that moving forward it will be evaluating whether the fees charged by IROs are reasonable and customary in accordance with section 2164.9(d) of Act
146.

The Department Notice with a list of approved IROS with their fees is available here: https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol55/55-32/1085.html

---

Network Adequacy for Prescription Drug Coverage

Concerns around prescription drug access, as a result of the Rite Aid bankruptcy and subsequent closures has been brought to the attention of the Pennsylvania Insurance Department (Department). People are concerned about many things, including but not limited to, continuity of patient care, including continuity related to prescription medications. The Department has addressed these concerns and their expectations in a Notice issued in the August 9th issue of the *Pa.Bulletin*.

The Department has set forth its expectations for both insurers and pharmacy benefit managers (PBM), acting for insurers. The main expectation is that either or both will ensure that continuity of care is prioritized for every patient. They also set for both state and federal network adequacy provisions supporting their position.

The Department reminds both insurers and PBMs that the provisions are in place to ensure that covered individuals have adequate and available access to services, including through retail pharmacies. Therefore, in accordance with network adequacy requirements, the Department expects that health insurers will inform the Department promptly if the health insurer becomes aware that it is unable to meet the Commonwealth's time or distance standards related to pharmacy access for patients affected by a Rite Aid closure. **If a health insurer informs the Department that it or a PBM is unable to meet the Federal and State network adequacy provisions due to a Rite Aid closure, it must provide an explanation about plans to provide alternative access options, including but not limited to:**

- the use of out-of-network pharmacists (with in-network cost-sharing) or other arrangements to close any network gaps;
- the use dedicated support methods, such as hotlines or web portals;
- implementation of affirmative notification processes, when possible, to notify affected patients of impending pharmacy closures and to highlight available prescription transition processes;
- approval of automatic transference of prior authorizations and approved drugs to the patient's new pharmacy without requiring reauthorization.
- Expedited prior authorizations for specialty medications and controlled substances to avoid treatment delays.
- Reduced or simplified documentation requirements such that the requirements do not create undue hardship for pharmacies processing high patient volumes.
- PBMs should exercise good judgment in their handling of pharmacy audits because of the increased volume of pharmacy services provided by other pharmacies due to the Rite Aid bankruptcy and store closures.

The Department notes that while this notice is specific to commercial insurance coverage subject to the Department's jurisdiction, insurers and PBMs are strongly encouraged to demonstrate similar flexibility to ensure adequate and accessible retail pharmacy access for all those for whom they provide or oversee prescription drug coverage. Pharmacy audits with respect to other health care coverage arrangements should similarly prioritize customer access and service. The notice also does not require an insurer to cover any particular prescription that it is not otherwise required to cover.

The full Notice is available here: https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol55/55-32/1086.html

---

Webinar to Discuss Nurse Licensure Compact

The State Board of Nursing is hosting a webinar about the implementation of the Nurse Licensure Compact for employers. *The webinar for employers is scheduled for August 26, 2025.*

The webinar, from the National Council of State Boards of Nursing (NCSBN), will provide information about a multistate licensee's ability to practice in Pennsylvania as a registered (RN) or licensed practical nurse (LPN), without a Pennsylvania-issued RN or LPN license, based upon the multistate license, so long as the licensee's principal state of residence is not in Pennsylvania.

In cases where the multistate licensee is changing the primary state of residence to Pennsylvania, a Pennsylvania-issued multistate license must be applied for within 60 days of the change of residence.

The **webinar information and additional resources** are available online.

Industry Trends

Policy / Market Trends

2026 Rate Filings Update; ACA Premiums Could Rise By Median of 18%

Average proposed rate increases by state for the individual market, with and without enhanced premium tax credits (eAPTCs), that have been made public since the last update are as follows:

- Idaho: Average proposed rate increase of 9.9%; 5.6% if eAPTCs are extended
- Missouri: Average proposed rate increase of 22.8%; 17.6% if eAPTCs are extended
- Nevada: Average proposed rate increase of 17.5%; 13.2% if eAPTCs are extended
- North Carolina: Average proposed rate increase of 28.9%; 24.6% if eAPTCs are extended
- Pennsylvania: Average proposed rate increase of 19.2%; 15.5% if eAPTCs are extended
- Utah: Average proposed rate increase of 14.2%; 9.9% if eAPTCs are extended

Affordable Care Act premiums are forecast to jump by a median of 18% in 2026, with some insurers proposing hikes as high as 54%, according to an analysis by KFF. This increase follows a 7% increase last year and is driven by escalating health care costs and the potential loss of enhanced premium tax credits.

- **Full Story:** The Hill (8/6)

Pharma Tariffs Could Reach 250%, Trump Says

President Donald Trump said he plans to impose tariffs on imported pharmaceuticals starting small and potentially rising to 150% within a year and a half and up to 250% later, the highest he's discussed so far, aiming to push drug manufacturing back to the US. The pharmaceutical industry warns that such tariffs and policies could raise costs, disrupt supply chains and limit investment, even as companies like Eli Lilly and Co. and Johnson & Johnson expand US operations.

Full Story: CNBC (8/5)

Democratic Attorneys General Sue Over Planned Parenthood Funding Exclusion

California Attorney General Bob Botna and 22 other Democratic attorney generals sued the Trump Administration over the provision in the federal reconciliation bill (H.R. 1) prohibiting federal Medicaid funding for Planned Parenthood and similar providers for one year following enactment (referred to as the "Defund Provision." The lawsuit argues the Defund Provision is impermissibly ambiguous and violates Congress' Spending Clause power. They highlight the provision is likely to increase health risks, including delayed diagnoses of sexually transmitted infections and cancer and increased unintended pregnancies, which will result not only in widespread and devastating effects on the health of their most vulnerable residents, but also increased costs of $30 million over the next five years and $52 million over the next ten years in Medicaid programs. The coalition asked the court to enjoin the Trump Administration from implementing the provision in order to prevent the tremendous harm this will have on public health and welfare of their states, as well as the increased costs to the states. The other states involved in the coalition are Connecticut, New York, Colorado, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Rhode Island, Vermont, Washington, Wisconsin, and the District of Columbia, and Pennsylvania. The lawsuit is separate from one filed by Planned Parenthood clinics in Massachusetts and Utah along with Planned Parenthood Federation of America, the umbrella organization that oversees state affiliates which run the clinics. In that case, U.S. District Judge Indira Talwani ruled that her preliminary decision to block the legislation's funding cut would remain in place. Read More

---

CMS Administrator Discusses Medicaid Funding, Drug Pricing and Community Engagement Verification

On Sunday, CBS News published an interview with CMS Administrator Dr. Mehmet Oz. In the interview, Oz addressed the upcoming community engagement requirements and spoke to the Trump administration's efforts to leverage new technologies to help Medicaid beneficiaries document their compliance with these requirements. Oz noted that the administration has invested in pilots in Louisiana and Arizona to easily connect workers with their payroll providers via an app, and expressed interest ultimately leveraging these apps to connect individuals to employment offices and help them verify that they qualify for an exemption from community engagement requirements. In the interview, Oz highlighted the Trump administration's goals around reducing Medicaid drug prices and developing rural health infrastructure, noting that Rural Health Transformation Program applications will be available to states in early September. Read More

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/.**