Highmark's Weekly Capitol Hill Report

Issues for the week ending April 18, 2025

Federal Issues

Regulatory

Executive Order on Lowering Prescription Drug Prices

President Trump signed an executive order (EO) focused on lowering prescription drug prices. This EO expands upon the previous Drug Pricing Blueprint issued under the first Trump Administration in 2018 and argues that the implementation of Medicare negotiation under the Inflation Reduction Act has achieved lower savings than projected.

Why this matters: Some of the directives can be accomplished through administrative action (e.g., rulemaking or guidance) but perhaps the most significant proposal - to modify the Medicare Drug Price Negotiation Program (MDPNP) to align negotiations for small molecule drugs with biologicals - would require Congressional action.

- The EO preamble calls attention to the "pill penalty," the pharmaceutical industry's term for the difference in time since launch for Medicare negotiation eligibility across small-molecule and biologic drugs.
- Currently under the MDPNP, small-molecule drugs are exempt from negotiation for nine

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years, while more complex biologics are exempt for 13 years.

- **Pharmaceutical Industry Support:** Drugmakers have long backed such a change, saying it deters investment in small-molecule drugs. "We applaud the President's efforts to lower medicine costs for patients," Alex Schriver, senior vice president of public affairs at PhRMA, said in a statement.

The EO was accompanied by a fact sheet, which includes estimated savings from some of the EO provisions.

Key provisions of the EO include:

- **Improving upon the Inflation Reduction Act:** Calls for guidance on the Medicare negotiation program for 2028 (within 60 days) and recommendations on how to stabilize and reduce Part D premiums (within 180 days), and directs the Secretary to work with Congress to increase the time since launch when small molecule drugs are eligible for negotiation to align with biologics.

- **Reducing the Prices of High-Cost Drugs for Seniors:** Directs the Secretary to implement a payment model to obtain better value for high-cost drugs in Medicare, including those not subject to negotiation (within 1 year).

- **Appropriately Accounting for Acquisition Costs of Drugs in Medicare:** Directs the Secretary to survey hospitals for their drug acquisition costs to develop Medicare payment adjustments to align with acquisition costs while maintaining budget neutrality (within 180 days). While not referencing the 340B program directly, this would likely reduce payments to 340B hospitals while increasing other payments due to budget neutrality. A similar payment reduction in the first Trump Administration was halted by the Supreme Court due to the lack of a survey.

Industry Trends

Policy / Market Trends

- **Addressing Pharma's 'pay for delay" Schemes Could Save Billions**
- **Keep Americans Covered Launches Campaign on Enhanced Premium Tax Credits**

- **Promoting Innovation, Value, and Enhanced Oversight in Medicaid Drug Payment:** Calls for recommendations to ensure manufacturers pay accurate Medicaid rebates and to promote innovation in Medicaid payment methods, including payments that reflect value (within 180 days).

- **Access to Affordable Life-Saving Medications:** Calls for actions to ensure future grants to Community Health Centers (CHCs) require the CHCs to make insulin and epinephrine available at 340B prices to individuals with low incomes who have high cost-sharing, high deductibles, or no health insurance (within 90 days).

- **Reevaluating the Role of Middlemen:** Calls for recommendations on a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices (within 90 days). This section does not address PBMs by name, which are addressed in a subsequent section.

- **Accelerating Competition for High-Cost Prescription Drugs**: Calls for a report on administrative and legislative options to accelerate approval of generics, biosimilars, and competitive brand products as well as improvement to the over-the-counter conversion process (within 180 days).

- **Increasing Prescription Drug Importation to Lower Prices:** Directs the FDA to streamline the existing state importation program (within 90 days).

- **Reducing Costly Care for Seniors:** Calls for regulations on Medicare site-neutral payments for drug administration (within 180 days). The fact sheet states this can lower prices by 60%.

- **Improving Transparency into Pharmacy Benefit Manager Fee Disclosure:** Directs the

Secretary of Labor to propose ERISA regulations to improve employer fiduciary transparency into PBM compensation (within 180 days).

- **Combating Anti-Competitive Behavior by Prescription Drug Manufacturers:** Calls for the Secretary, the Department of Justice, the Department of Commerce, and the FTC to conduct public listening sessions and issue a report with recommendations to reduce anti-competitive behavior from pharmaceutical manufacturers (within 180 days).

Supreme Court Hears Challenge to ACA Preventive Care Rule

Yesterday, the U.S. Supreme Court heard oral arguments in *Kennedy v. Braidwood* (formerly *Braidwood v. Becerra*), a lawsuit involving the constitutionality of the U.S. Preventive Services Task Force, and by extension, the scope of the ACA's preventive services coverage mandate.

The case also raises important questions regarding the HHS Secretary's authority to oversee the Task Force and implement its recommendations.

A transcript and audio recording of the arguments are available on the Court's website.

When can we expect a decision? A decision is expected in June or early July, before the Court breaks for summer recess.

The Arguments: Over the course of ninety minutes, all nine Justices posed questions covering a number of key legal issues. The hearing largely did not cover policy implications or impacts of the case, and instead focused on legal issues related to the Constiutition's Appointments Clause and the scope of the HHS Secretary's authority over the Task Force. This included discussion of whether Task Force members are "principal officers" requiring Senate confirmation (like the lower courts held), or "inferior officers" properly appointed and overseen by the Secretary (as the government argues).

The Justices also focused on statutory provisions requiring the Task Force to operate independently, and how those provisions impact the HHS Secretary's ability to determine the Task Force's composition, request modification of Task Force recommendations, and delay implementation of Task Force recommendations.

Importantly, a number of Justices, as well as the parties, indicated that a decision by the Court may present additional issues that will need to be sent back down to the lower courts for additional proceedings. If that occurs, the case will continue to be litigated even after a Supreme Court decision.

Why it Matters: An earlier decision by the U.S. Court of Appeals for the Fifth Circuit found that the USPSTF violated the Constitution's Appointments Clause and that the HHS Secretary lacked the authority to properly oversee and approve USPSTF recommendations. If the Supreme Court rules against the government and upholds that decision, it could significantly alter the ACA's requirement that all Task Force preventive services rated "A" or "B" since passage of the ACA be covered without cost sharing.

On the other hand: Should the Court instead rule in favor of the government, the Court may either fully reverse the 5th Circuit's decision or leave some issues open and send (some or all of) the case back down to the lower courts for further proceedings on one or more issues previously not considered. That could include asking the lower courts to review whether the statute allows the HHS Secretary to appoint Task Force members, clarify the scope of the HHS Secretary's authority over the Task Force and its recommendations, determine whether the HHS Secretary properly approved (or "ratified") those recommendations, and fashion an appropriate remedy.

Additional Materials: In advance of the arguments, a number of outlets published articles recapping the history of the case and previewing the arguments, including the Kaiser Family Foundation (link), SCOTUSblog (link) and Georgetown's O'Neill Institute (link).

Request for Public Comments on Pharmaceutical Tariffs

On April 16, the Administration published in the Federal Register a Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. Comments are due by May 7.

The request seeks information on the impact of pharmaceutical imports on national security. Specific areas of inquiry include current and projected US demand for pharmaceuticals and the extent to which domestic production can meet demand, the role of foreign supply chains and their relative concentration and associated risks, predatory foreign trade practices and artificially suppressed prices from state-sponsored overproduction, possible export restrictions from foreign nations, feasibility of increasing domestic production capacity and the impact of trade policies on domestic production, and whether tariffs or quotas are necessary to protect national security. The request does not explicitly seek input on the impact that any changes in trade policy would have on domestic pharmaceutical costs or access.

CMS Issues Guidance Related to Gender Affirming Care for Children

Centers for Medicare & Medicaid Services (CMS) Administrator Dr. Mehmet Oz issued a statement suggesting that federal Medicaid dollars may not be used for gender reassignment surgeries or hormone treatments in minors. Accompanying the statement, CMS issued a State Medical Director Letter (SMDL) intended to "ensure state Medicaid agencies are aware of growing evidence regarding certain procedures offered to children, and to remind states of their responsibility to ensure that Medicaid payments are consistent with quality of care and that covered services are provided in a manner consistent with the best interest of recipients." **Within the SMDL, CMS reminds states of several federal Medicaid requirements:**

- State Medicaid programs have a responsibility to ensure that payments are consistent with "efficiency, economy, and quality of care."

- For certain populations, including children, longstanding federal Medicaid regulations prohibit federal funding for coverage of services intended to permanently render an individual incapable of reproducing.

- States are required to develop a drug utilization review (DUR) program to assure prescribed drugs are appropriate, medically necessary, and are not likely to result in adverse results. CMS encourages states to review the DUR programs to ensure alignment with current medical evidence and federal requirements. CMS specifically notes that additional guidance on DUR approaches is forthcoming.

Read More

- Statement from CMS Administrator

- State Medicaid Director Letter

BCBSA Comments on 2025 Marketplace Integrity and Affordability Proposed Rule

On April 11, 2025, BCBSA submitted comments to CMS on the 2025 Marketplace Integrity and Affordability Proposed Rule, highlighting support for CMS' continued efforts to prevent unauthorized enrollments and plan changes, including proposals to reduce fraud and misuse related to special enrollment periods (SEPs).

Why this matters: Disruptions caused by bad actors jeopardize the coverage individuals need to get and stay healthy.

The details: Specifically, BCBSA provided recommendations on how to carry out the proposed provisions in ways that are the least disruptive to Plans and consumers:

- **End** monthly SEP for individuals with estimated incomes below 150% of the federal poverty level to reduce improper enrollments in the federal marketplace and address adverse selection for issuers

- **Reinstate** verification of SEP eligibility prior to enrollment, allowing state exchanges the flexibility to implement these requirements

- **Finalize** benefit parameters for 2026 within the next few weeks or delay them until 2027 to minimize regulatory uncertainty and enable issuers to finalize products and premiums in a timely manner

- **Shorten** the annual open enrollment period for the federal marketplace beginning with benefit year 2027 to prevent confusion for enrollees and implementation challenges for stakeholders

What's next: CMS will finalize proposals after considering stakeholder feedback.

The big picture: It is critical that the individual marketplace works for the millions of Americans who depend on it for their health coverage. Health insurers will continue to work with policymakers to ensure that the exchanges are effective and accountable.

CMS Sending FTR Recheck Notices to Consumers in April

CMS is conducting the Failure to Reconcile (FTR) Recheck process in which they verify the tax filing status of previously identified enrollees who did not file and reconcile advance payments of the premium tax credits (APTC). Beginning in mid-April, CMS will send notices to enrollees who are identified as being in FTR status. Enrollees who receive these notices should immediately file their federal income tax return and reconcile APTC for the applicable tax years. Enrollees who fail to file and reconcile for two consecutive years may lose their APTC as early as this summer.

Links to additional resources are included below:

- Failure to File and Reconcile (FTR) Operations Frequently Asked Questions
- The Premium Tax Credit – The basics
- How to Appeal a Marketplace Decision

CMS Releases Form Filing Instructions for SERFF for Plan Year 2026

On April 16, 2025, CMS released the form filing instructions for System for Electronic Rates and Forms Filing (SERFF) for Plan Year 2026. These instructions are applicable to issuers in states and territories that are not substantially enforcing one or more provisions of the Public Health Service Act (PHS Act), as amended or extended by the Patient Protection and Affordable Care Act (ACA) and the Consolidated Appropriations Act, 2021 (CAA). Issuers in impacted states and territories (Alabama, American Samoa, Arizona, Arkansas, Connecticut, Delaware, Florida, Guam, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Missouri, New Hampshire, Northern Mariana Islands, Oklahoma, Rhode Island, Tennessee, Texas, Virgina, and Wyoming) can find the instructions here.

State Issues

Delaware

Legislative

Special Enrollment Birthday Rule Bill Introduced

SB 71, allowing special enrollment periods for Medicare beneficiaries, was introduced. **Key provisions include:**

- Creates a special open enrollment period for persons who are already enrolled in a Medicare supplement policy or certificate to cancel their existing policy or certificate and purchase another Medicare supplement policy or certificate that provides the same or lesser benefits. Only persons

who are already enrolled in a Medicare supplement policy or certificate are eligible for the special open enrollment period.

- The special enrollment period begins 30 days before an eligible person's birthday and remains open for at least 30 days following the eligible person's birthday.

- During this special open enrollment period, individuals switching from one Medicare supplement policy to another cannot be denied coverage and coverage and rates cannot be dependent upon the person’s medical history.

- The Act also obligates issuers to notify eligible persons who are enrolled in their Medicare supplement policies or certificates of the dates of the open enrollment period, at least 30 days before it begins, and of any modification to the benefits provided by the policy under which the person is currently insured.

- This Act also allows persons enrolled in a Medicare Advantage plan to cancel their existing policy, enroll in Medicare during the annual Medicare open enrollment period and apply for a Medicare supplement policy.

- For individuals switching from Medicare Advantage to a Medicare supplement policy, the Act prohibits issuers of Medicare supplement policies from denying applications for such policies but does allow issuers to individually rate and apply a pre-existing condition limitation.

- Becomes effective 1/1/26 if enacted this year.

Why this matters:

- It can lead to reduced competition between carriers in the Medigap market and increased premiums when compared to states without a birthday rule.

    - Kaiser Family Foundation found that states with annual open enrollment periods have the highest Medigap premiums in the country.

    - California’s independent legislative review group at UC Berkley analyzed a similar bill last year, which would have **increased premiums 33%** and **decreased Medigap enrollment by 9%** as a result of those premium increases.

State Issues

Pennsylvania

Legislative

IVF House Insurance Committee Hearing Scheduled

The House of Representatives returns to Session on April 22nd after their Easter & Passover breaks. The House Insurance Committee will meet on Wednesday, April 23rd at 9:15 to hold an informational hearing entitled “Putting Families First: Infertility Care in Pennsylvania”. Invited testifiers will be representing In vitro fertilization (IVF) practitioners with no panelists from the insurance industry.

The Senate is scheduled to return on May 5th, with no committee meetings or votes scheduled as of yet.

Industry Trends

Policy / Market Trends

Addressing Pharma’s “pay for delay” Schemes Could Save Billions

Prescription drugs play a critical role in helping millions to enjoy longer, healthier lives. However, the rising costs of medications are putting a strain on state and federal budgets as well as Americans’ wallets — causing over half of American families to worry about affording their families’ prescription drug costs.

The big picture: One factor contributing to rising Rx costs and prescription drug spend: pharmaceutical manufacturers’ push to incentivize generic manufacturers not to go to market to boost profits for more expensive brand-name drugs, otherwise known as a “pay for delay scheme.”

Why this matters: Banning pay for delay schemes, a proposal of BCBSA’s 2025 Affordability Solutions for the Health of America, could help drive $53 billion in estimated cost savings over the next 10 years.

The details: David Merritt, SVP of external affairs at BCBSA, broke down how “pay for delay” schemes work in four steps:

1. A big brand-name drug manufacturer holds the patent for an expensive medication.
2. When the patent for the expensive medication expires, another drug manufacturer can develop a generic alternative that is equally safe, effective and cheaper for patients.
3. Through pay for delay, the brand-name manufacturer creates an incentive for the generic manufacturer not to go to market.
4. Pay for delay preserves monopoly prices and prevents consumer access to these generic alternatives

Yes, and: In addition to pay for delay schemes, Big Pharma also leverages “patent thicketing” to file overlapping patents for existing brand name drugs to delay generic competition.

- **Limiting patent thicketing** would have a $1.8 billion savings impact over 10 years, according to CBO estimates.

What’s next: BCBSA continues to advocate for commonsense solutions that address Big Pharma’s abuse of existing patent systems and promote affordable access to prescription drugs, including the proposals in its Affordability Solutions as well as the passage of legislation like the Affordable Prescriptions for Patients Act and the Drug Competition Enhancement Act.

Keep Americans Covered Launches Campaign on Enhanced Premium Tax Credits
Keep Americans Covered (KAC), has launched a new advertising campaign urging Congress to extend the enhanced premium tax credits this year.

Why this matters: Without these enhanced tax credits, millions of hardworking Americans will face higher premiums, making individual marketplace coverage unaffordable and likely resulting in people losing critical coverage they need to live healthier lives.

The details: The ad champions the tax credits as a lifeline for millions of Americans and underscores the high stakes of allowing them to expire — an average 93% premium increase for 24 million people.

- The campaign targets policy decision-makers and opinion leaders in the Beltway as well as key markets including Alaska, North Carolina, Maine, Texas, Idaho, South Dakota, Florida, Pennsylvania, Louisiana, West Virginia and Utah.

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/.**