

## Federal Issues

### Legislative

#### President Trump Calls For an End to Surprise Medical Bills

On Thursday, President Trump called on Congress to pass bipartisan legislation to end surprise medical bills, and released a set of [principles](#) the White House would like to see addressed by the legislation. The President discussed this issue at a White House event that included remarks from two **patients who shared their personal experiences** with surprise medical bills and a surgical oncologist who talked about his **cancer patients being burdened by medical bills**.

**Why it matters:** With little bipartisanship on health care, this is one issue that appears to have legs. Several members of Congress and their families are rumored to have had personal experiences with surprise bills.

- The President was joined by several **lawmakers who have been working behind the scenes** since last fall, including Senators Bill Cassidy (R-LA), Maggie Hassan (D-NH), Lamar Alexander (R-TN), and John Barrasso (R-WY) and Reps. Kevin Brady (R-TX) and Greg Walden (R-OR). **A Senate bill is in the works** and could be released before Memorial

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Day.

**Trump's priorities:**

- Patients receiving emergency care should not be forced to shoulder extra costs billed by a care provider but not covered by their insurer.
- Patients receiving scheduled care should have information about whether providers are in or out of their network and what costs they may face.
- Patients should not receive surprise bills from out-of-network providers they did not choose.
- Federal health care expenditures should not increase.

- State-Based Exchange and Reinsurance Program  
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- Significant MLR Rebates may be on the Horizon

**Highmark continues to advocate** for a fair solution that protects consumers from surprise medical bills. [AHIP](#) and [BCBSA](#) have joined other organizations representing consumers, businesses, and health insurance providers in announcing a set of [principles](#) to protect patients from surprise medical bills. The [AHA](#) weighed in on Thursday's event with a [statement](#) supporting a ban on balance billing.

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**House Passes Health Bills**

As part of its designated "Health Week," last week, the House of Representatives passed three bills that addressed the ACA and drug pricing.

- By a vote of 230-183 the House passed the "[Protecting Americans with Preexisting Conditions Act of 2019](#)," a bill that would prohibit the Trump Administration from implementing guidance on the ACA's Section 1332 waivers issued in October 2018, which would allow the sale of insurance products that are not compliant with the ACA. The legislation also prohibits the Administration from issuing any new rules or guidance that would weaken ACA-established guardrails, such as essential health benefits or guaranteed issue for individuals with pre-existing conditions.
- The House unanimously approved "[The Orange Book Transparency Act of 2019](#)," which would require the prompt removal of patents that were deemed invalid by the Patent Trial and Appeals Board or a court from the patent database for related drugs.
- The chamber also unanimously cleared "[The Purple Book Continuity Act of 2019](#)," which would require the Federal Drug Administration (FDA) to incorporate more detailed information on biological products and make the data available in a searchable, electronic format.

**More to come:** Several other health bills addressing the ACA and drug pricing that recently passed out of committee are expected to come to the floor before Memorial Day.

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## **Congressional Hearings Continue to Focus on Drug Pricing**

Two hearing on Capitol Hill last week continued the ongoing examination of drug pricing.

On Thursday, The House Energy & Commerce Committee's Subcommittee on Health held its third hearing on the topic of prescription drug pricing, entitled "[Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain.](#)"

**What they looked at:** Subcommittee Chair Eshoo (D-CA) emphasized that her goal in holding the hearing was to "follow the money" and determine the role played by each participant in the drug supply chain, the impact they have on drug prices, and the value they bring to patients. Panelists faced questioning over the cost of research and development, rebates, step therapy, formulary structure, patent exclusivity and generic competition.

- The hearing included testimony from 10 witnesses representing drug **manufacturers, pharmacy benefit managers (PBMs), physicians, pharmacies, insurers,** and others.

Meanwhile, on Tuesday, **Senate Judiciary Committee** members [heard](#) from a panel of policy, industry and academic experts on a variety of topics related to balancing innovation and competition in the drug marketing space.

**The focus:** Much of the discussion was aimed at manufacturer-induced barriers to competition, such as patent abuses, pay-for-delay and antitrust practices.

- Other topics discussed were **pharmaceutical advertising, transparency applications and the rebate system.**

**Legislative paths emerge:** Judiciary Committee members expressed bipartisan interest in advancing the [CREATES Act](#) to remove barriers to low-cost generic drugs.

In addition:

- Senator Grassley (R-IA) emphasized his concerns about **pay-for-delay settlements and abuse of citizen petitions**—both of which are addressed in bipartisan bills he has introduced with Senator Klobuchar (D-MN).
- Senator Blumenthal noted that he was working on bipartisan legislation with Senator Cornyn (R-TX) addressing "**patent thickets**" and "**product hopping.**"

**Highmark joins [AHIP](#), [BCBSA](#) and the [AHA](#)** in working with the [Campaign for Sustainable Rx Pricing](#) (CSRxP), to promote bipartisan, market-based solutions to lower drug prices.

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## **More Health Care Debate this Week**

**On tap on the House floor this week** is the "[Strengthening Health Care and Lowering Prescription Drug Costs Act](#)," a package of bills passed by various House committees over the last several weeks that address drug pricing and Affordable Care Act (ACA) markets.

Included in the package are bills that would:

- Prevent branded drug makers from using Risk Evaluation and Mitigation Strategies (REMS) and limited distribution arrangements to restrict access to adequate samples of reference drugs
- Prohibit "pay-for-delay" agreements under which a brand-name drug manufacturer pays a generic

manufacturer to keep a generic equivalent off the market

- Discourage “exclusivity parking” by a first generic applicant by allowing approval of a subsequent generic application under certain conditions
- Provide \$200 million to support the planning and establishment of state-based Health Insurance Exchanges
- Provide \$100 million annually for the Navigator Program to support ACA outreach and education activities
- Provide \$100 million annually and require HHS to conduct consumer outreach and enrollment educational activities for the ACA marketplaces, with a prohibition on promotion of short-term plans and association health plans
- Prohibit implementation or enforcement of the final rules for expanding short-term, limited duration insurance (STLDI) policies

**Outlook:** While **the drug bills are likely to be taken up by the Senate**, the ACA proposals are not likely to advance further unless negotiated into a broader budget deal with the White House.

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## Federal Issues

### Regulatory

#### **Court Rejects 340B Payment Cuts for 2019**

Consistent with a ruling during late December, a Federal District Court judge [ruled](#) last week that the Administration’s nearly 30 percent cut to Medicare payments to hospitals participating in the 340B Drug Pricing Program was unlawful and ordered the U.S. Department of Health and Human Services (HHS) to resolve the harm caused by the cuts “promptly.”

**Background:** Judge Rudolph Contreras granted a [permanent injunction](#) against the Part B pay reductions of nearly 30 percent that Medicare imposed on many 340B hospitals at the beginning of 2019. The judge in December 2018 [had ruled](#) that similar cuts imposed for 2018 were in violation of federal law, but he had not yet weighed in on the 2019 reductions because a hospital plaintiff first needed to file a Part B claim under the reduced rates for the new year.

- In issuing the newest injunction, the court is sending the issue back to HHS for them to come up with a proper remedy for both the 2018 and 2019 cuts. The court is directing HHS to give a status report by Aug. 5 on its progress toward implementing that remedy.
- HHS [had appealed](#) the December 2018 ruling against last year’s cuts, an appeal that had been on hold while the court considered the process for pursuing a remedy. The administration has the option to continue pursuing this appeal to try to get the injunctions overturned by a higher court.

#### **Why this matters:**

- The latest development does not immediately affect Medicare Part B payment rates for hospitals who received reduced rates in 2018 or those receiving reduced rates this year.
- The court’s order states that HHS “patently violated the Medicare Act’s text” when it used the administrative process to impose the pay cuts. However, the judge also noted that striking down the rules entirely would be “highly disruptive” because the cuts to 340B hospitals were redistributed among all hospitals under Part B. Thus, repaying affected 340B hospitals under budget-neutrality

requirements would involve recouping payments already made to other hospitals, a process the judge described as “an expensive and time-consuming prospect.”

- The plaintiffs [had argued](#) that Medicare could fully reimburse affected hospitals using supplemental payments without being required to use a budget-neutral process. The judge said he instead was following the HHS recommendation to give the department “the first crack” at coming up with a workable solution, but he noted that the court “may reconsider the remedy if the agency fails to fulfill its responsibilities in a prompt manner.”
- Until instructed otherwise, hospitals should continue to submit bills to Medicare for outpatient drugs with any 340B billing modifiers that hospitals have been required to include on their Part B claims.
- The 340B Drug Pricing Program enables Pennsylvania hospitals to care for low-income and uninsured patients by purchasing certain outpatient drugs from pharmaceutical manufacturers at discounted prices. The program allows hospitals to stretch scarce resources to better serve vulnerable patients and communities, and has proven to be a valuable tool as the price of prescription drugs places an increasing financial burden on patients and hospitals.

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## Pharmaceutical Manufacturers Must Disclose Prices

This summer a new policy will go into effect: **drug companies will be required to show their prices in television ads.**

On May 8, the Department of Health and Human Services (HHS) released a final rule addressing the disclosure of list prices for prescription drugs in direct-to-consumer (DTC) advertisements.

- The final rule requires drug manufacturers to disclose list prices (the Wholesale Acquisition Cost) in DTC ads that appear on television (radio and internet advertising are excluded) if the cost for a 30-day treatment is \$35 or more.
- Pricing information must be in clear, legible text onscreen at the end of the ad.
- The regulation relies on lawsuits to ensure compliance, since HHS cannot force companies to comply with the rule.
  - HHS will keep a list of companies who do not comply and those manufacturers would then face the threat of lawsuits from their competitors.

**Insurance Industry Perspective:** AHIP, BCBSA and a number of health care organizations supported the final rule and applauded it as a first step to increase transparency on how drug manufacturers set and increase their prices. However, other health industry experts questioned the rule’s effectiveness in helping lower drug prices.

**What’s next?** There may be legal challenges to the rule itself, while drug manufacturers that violate the rule could face lawsuits from competitors.

**More reading:** The following are links to an HHS [press release](#) and [fact sheet](#).

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## Association Health Plan Lawsuit Update

The U.S. Department of Labor (DOL) issued a [news release](#) and [statement of policy](#) regarding regulatory

enforcement of Association Health Plan (AHP) rules. This is in response to last month's federal court decision ([New York v. Department of Labor](#)) to invalidate portions of the 2018 [final rule](#) expanding AHPs.

The court found the "working owner" and commonality of interest provisions of the AHP rule violated ERISA and must be vacated. On April 26, the Department of Justice filed an appeal.

**Why this matters:** While waiting on a decision on the appeal, the DOL has will not enforce actions against parties who may violate the vacated provisions. HHS has informed DOL it will follow a similar policy of non-enforcement for AHPs. This will protect those employers and working owners currently participating in an AHP while the lawsuit continues.

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### **FDA Announces Final Guidance on Pathway for Interchangeable Biologics**

The Food and Drug Administration (FDA) announced [final guidance](#) last week providing an overview of scientific considerations to be addressed in demonstrating interchangeability along with scientific recommendations for an application or a supplement for a proposed interchangeable product. The rule is intended to assist sponsors in demonstrating a proposed biological product is interchangeable with a reference product for purposes of submitting an application to the agency.

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## State Issues

### Pennsylvania

#### Legislative

#### House Policy Committee Discuss Rx Prices

On Friday, May 2, the House Democratic Policy Committee, hosted by Representative Tony DeLuca (D-Allegheny) and Dan Frankel (D-Allegheny), held a [public discussion](#) about the cost of prescription drugs. The Committee invited various representatives from the health care industry to participate in the discussion including:

- [Corey DeLuca](#), Director Clinical Pharmacy Services, Highmark Inc.
- [Lauren Rowley](#), Pharmaceutical Care Management Association
- [Erin Ninehouser](#), PA Health Access Network
- [Ashlie VanMeter](#), Association of Accessible Medicines
- [Pat Lavella, RPh.](#), Value Drug Company
- [Dr. Adele Towers](#), President, Allegheny County Medical Society
- [Jessica Brooks](#), CEO, Pittsburgh Business Group on Health

In opening remarks, both DeLuca and Frankel noted the importance of finding ways to control the costs of prescription drugs and noted that the pharmaceutical manufacturers were invited to participate but the organization declined to attend.

- **On behalf of Highmark**, Corey DeLuca spoke about the processes that Highmark uses to place prescription drugs on a formulary, stating that Highmark relies on input from a pharmacy and therapeutic committee and Highmark's partnership with AHN.
- Corey DeLuca also discussed the role her pharmacy team plays in reviewing and analyzing the clinical data for emerging drugs as well as those on the market.

**Why this matters:** With pharmaceutical costs continuing to increase, legislators and regulators are taking an increased look at options to help stabilize or reduce these costs.

- Representative DeLuca is also the Democratic chair of the House Insurance Committee and Representative Frankel is the Democratic chair of the House Health Committee—both committees play a significant role in shaping and advancing legislation that impacts the health care industry.

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#### House Insurance Panel to Consider Organ Donation Measure

On Monday, May 13, the House Insurance Committee plans to consider [House Bill 924](#). The legislation, sponsored by Rep. Tarah Toohil (R-Luzerne), provides protections for individuals who are donating organs but does not mandate insurance coverage; however, it does address how insurers treat individuals who are donating organs.

#### Background

House Bill 924 prohibits an insurer from engaging in any of the following actions against an individual based solely upon the individual's status as a living donor:

- Decline to provide an insurance policy to the individual;
  - Limit coverage under an insurance policy of the individual;
  - Discriminate against the individual regarding the premium rating, offering, issuance, cancellation, amount of coverage or any other condition of an insurance policy; and
  - Preclude an insured from donating all or part of an organ or tissue as a condition for receiving or continuing to receive coverage under an insurance policy.
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## **“Take Back Our Hospitals” Rally Planned to Encourage State Officials to Stop Highmark / UPMC Break-Up**

The pending expiration of the Highmark / UPMC consent decree on June 30, 2019 has raised the ire of thousands of insured Allegheny County residents who are concerned about having access to certain non-profit health systems and physicians. On Tuesday, May 14, a rally will be held at the state capitol to give residents an opportunity to share their views with elected officials.

### **Background**

Allegheny County Comptroller Chelsa Wagner has been conducting meetings in the regions to learn about citizens’ concerns about the Highmark / UPMC break-up. Her office partnered with the Pennsylvania Health Access Network and SEIU Healthcare Pennsylvania to collect over 10,000 signatures from constituents seeking a solution to their access issues. The rally is set for 2:30 p.m. in the Capitol rotunda.

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## **State-Based Exchange and Reinsurance Program Subject of House Informational Meeting**

The House Insurance Committee held an informational meeting on Tuesday, May 4 to hear from stakeholders on the state’s proposal to create a state-based exchange and reinsurance program. **Mike Yantis, Highmark vice president, State Government Affairs, offered remarks.** Also presenting comments were the following representatives:

- Jessica Altman, Pennsylvania Insurance Commissioner
- Doug Furness, Capital Blue Cross
- Kimberly Kockler, Independence Blue Cross
- Jennifer Tyler, Geisinger Health Plan
- Sam Marshall, Insurance Federation of Pennsylvania
- Stephanie Watkins, The Hospital and Healthsystem Association of Pennsylvania
- Caleb Wallace, UPMC
- Jessica Waltman, Forward Health Consulting

### **Background**

Chairwoman Tina Pickett (R- Bradford) opened the meeting by explaining that the 1332 State Relief and Empowerment Waiver permits states to design and implement new health care programs. To date, the Centers for Medicare and Medicaid Services (CMS) has approved eight such waivers.

- Insurance Commissioner Jessica Altman stated that Pennsylvania could save an estimated \$50 million by running its own exchange.
- Michael Yantis told the panel that Highmark believes that a state-based exchanged (SBE) should be pursued; however, it should not have the ability to assess fees if federal funding ends. He stressed

that legislation addressing this should be very specific to prevent these assessments.

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## Industry Trends

### Policy / Market Trends

#### Significant MLR Rebates May be on the Horizon

A report issued last week by the Kaiser Family Foundation anticipates stellar financial performance by insurers in the individual market for the 2018 plan year. The report indicates that individual market insurers performed better financially than in prior years, with some insurers even reaching profitability margins that rivaled those prior to the Affordable Care Act's passage in 2010. This profitability will likely lead to a record total amount of medical loss ratio (MLR) rebates for individual market customers. The report estimates around \$800 million dollars in rebates could be paid directly to individuals and families.

#### Why this matters

Although individual company performance could differ from the conclusions set forth in the report, this data could influence state insurance departments as they begin their review of 2020 rate filing submissions.

#### State

The Pennsylvania House of Representatives are in session May 13-15.

The Delaware Legislature is in session May 14-16.

The West Virginia Legislature has adjourned for the year.

#### Congress

The U.S. Congress is in session May 14-17. The U.S. Senate is in session May 13.

**Interested in reviewing a copy of a bill(s)? Access the following web sites:**

Delaware State Legislation: <http://legis.delaware.gov/>.

Pennsylvania Legislation: [www.legis.state.pa.us](http://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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