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Federal and National Issues

Legislative Issues

RX Pricing a Focus of House and Senate Hearings

The U.S. Senate Finance Committee and the U.S. House Oversight and Reform Committee on Tuesday held separate hearings to examine the root causes of, and find solutions to, the rising costs of prescriptions drugs.

The Finance Committee's hearing, "**Drug Pricing in America: A Prescription for Change, Part I**," focused on examining drug importation, enacting the CREATES Act to discourage anti-competitive practices and speed generics to market, the 340B program, the role of pharmacy benefit managers (PBMs), rebate loopholes and pricing transparency through DTC advertising.

Meanwhile, the House Oversight Committee's hearing, "**Examining the Actions of Drug Companies in Raising Prescription Drug Prices**," featured a broad discussion, ranging from

allowing Medicare to negotiation with drug companies, increasing competition with generics and biologics, reexamining the way drug patents are structured and transparency, including DTC advertising.

- **Testifying at the hearings** were patient advocates, researchers and industry experts as well as individuals who told personal stories of how the skyrocketing cost of insulin has impacted their lives.

Highmark supports the Campaign for Sustainable Rx Pricing to promote bipartisan, market-based solutions to lower drug prices. The coalition submitted testimony to both hearings.

Also weighing in: Health and Human Services (HHS) Secretary Alex Azar, who penned an op-ed that outlined the need for more steps to be taken and highlighted the steps the Administration has taken to lower drug prices based on President Trump's Rx Blueprint.

House Panel Looks At Pre-Existing Condition Protections

On Tuesday, the House Ways and Means Committee held a hearing titled "Protecting Americans with Pre-Existing Conditions," to examine pre-existing protections built into the ACA.

Why it matters: The status of the ACA is in jeopardy due to a Texas court case that could result in the law being overturned.

- **Democrats** highlighted pre- and post-ACA realities, with a focus on the protections put in place that allow consumers to purchase insurance coverage regardless of their health status.
- **Republican** committee members focused on the rising costs of healthcare and the need to bend the cost curve, also pointing out that premiums in the individual market have risen significantly.
- However, there was **bipartisan agreement** that pre-existing protections should be preserved.

Other committees are soon to follow, with the House Energy and Commerce Committee and the House Education and Labor Committee planning their own pre-existing conditions hearings in the coming weeks.

CBO Estimates Impact of AHP and STLDI Regulations

The Congressional Budget Office (CBO) has released a report estimating the impact of the Administration's regulations for expanding association health plans (AHPs) and short-term, limited duration insurance (STLDI).

Key findings include:

- **Approximately 5 million additional people** are projected to be enrolled in AHPs or short-term plans each year over the next decade as a result of the regulations. However, **only 20 percent are projected to be newly insured**. The rest would have otherwise purchased coverage in the small-group or nongroup markets.
- **Premiums** for coverage in the fully regulated small-group and nongroup markets **are projected to be roughly 3 percent higher** than they would have been without the rules. This translates into an average premium increase in 2028 of approximately $350 to $400 for single coverage and $900 to $950 for family coverage.

The bottom line: Premiums for fully regulated coverage are projected to rise "because people who continue to purchase coverage in the fully regulated markets are expected to have higher average health care costs than those who purchase AHPs or short-term plans."

- The report suggests that because federal subsidies partially offset these higher costs, a noticeable **decline in insurance coverage is not expected**.

GAO Report Examines Insurers' Experiences With ACA Exchanges

The Government Accountability Office (GAO) has published a new report examining the experiences of insurers that participate in the ACA Exchanges. The report is based on data from nine insurers that offer Exchange coverage in California, Florida, Massachusetts, Minnesota, and Mississippi.

The report focuses on: (1) the claims costs of insurers participating in the Exchanges; and (2) the factors driving selected insurers' decisions concerning Exchange participation, premiums, and plan design.

- The report found **claims costs were higher than expected** in the early years (2014-2016) due predominantly to:
  - enrollees being sicker than expected
  - higher costs for some services
  - misuse of special enrollment periods
  - continued purchase of transitional plans
- Factors examined in the context of insurers' **decisions about Exchange participation**, premiums, and plan design include
  - claims costs
  - federal funding changes, including the termination of cost-sharing reduction benefits and the phase-out of federal reinsurance and risk corridors programs
  - state requirements and funding

The bottom line: Looking forward, insurers told the agency that changes in federal and state policies would continue to affect decisions, particularly on premium changes.

Regulatory Issues

HHS Proposes to Overhaul Medicare and Medicaid Drug Rebates

Background

Last week, a proposed rule was issued by the HHS Office of Inspector General that would prohibit pharmacy benefit managers (PBMs), Medicaid managed care plans, and Part D plan sponsors from accepting rebates (or "discounts") negotiated with drug manufacturers on behalf of Medicare and Medicaid enrollees. Instead, plans and PBMs would have a choice to arrange for fixed fee arrangements with drug manufacturers or pass through any rebates to enrollees at the pharmacy counter (point-of-sale reductions). While this proposal would not apply to commercial insurance, including employer-sponsored coverage, HHS Secretary Alex Azar urged Congress to extend similar reforms to the commercial market.

Impact on beneficiaries and federal spending

HHS cites multiple actuarial studies that find this proposal will lead to lower Part D spending for Medicare beneficiaries as a whole, because the projected reductions in out-of-pocket costs will be larger than potential increases in premiums. For example, the projected decrease in beneficiary spending on premiums and cost-sharing in 2020 is $1.0 to 1.4 billion. However, HHS also states that studies find that the proposed changes would result in increases in federal spending in 2020 ranging from $2.8 billion to $13.5 billion.

Insurance industry response

The following is an excerpt from a statement issued by Matt Eyles, president and CEO of AHIP, following the release of the proposed rule:

"We cannot achieve savings if our leverage and negotiating power is weakened through well-intentioned but misguided actions like this proposed rule. Savings from rebates go directly to consumers, resulting in lower premiums and out-of-pocket costs for millions of hardworking Americans.

From the start, the focus on rebates has been a distraction from the real issue – the problem is the price. Manufacturers have complete control over how drug prices are set. Already this year, more than three dozen drug makers have raised their prices on hundreds of medications.

Insurance providers are part of the solution. We believe the Administration should go back to the drawing board and start over with this proposed rule, and instead take actions that will lower drug prices and hold drugmakers accountable for the prices they set."

More information
A pre-publication version of the proposed rule is available here. Additional information can also be found in this HHS press release and fact sheet.

The rule is scheduled for publication on February 6 and will be open for comment until April 8.

CMS Releases Part II of 2020 Advance Notice and Draft Call Letter for Medicare Advantage and Part D Plans

On January 30, the Centers for Medicare & Medicaid Services (CMS) issued Part II of the 2020 Advance Notice, describing proposed factors and policy changes affecting Medicare Advantage (MA) and Part D payments for 2020. The Advance Notice must be released annually 60 days prior to the issuance of the final MA rates and Medicare Part D payment-related information for the upcoming contract year. The following are links to a CMS press release and fact sheet.

Part II of the Advanced Notice includes:

- (1) CMS' estimate of Medicare fee-for-service growth rates—a key factor in determining capitation rates;
- (2) proposed "normalization" factors that CMS would use to reduce risk adjustment payments; and
- (3) the continuation of certain payment policies for plans operating in Puerto Rico.

CMS previously released Part I of the Advance Notice on December 20, 2018. Part I described proposed changes to the risk adjustment model, along with CMS' plans to increase the percentage of risk scores based on diagnoses obtained from encounter data.

Why this matters
CMS estimates that the factors and proposals in Parts I and II would, on average, increase plan payments by 1.59 percent for 2020, with varying impacts on individual plans.

The January 30 release also includes the Draft 2020 Call Letter, which provides relevant information to MA and Part D plan bidding for the upcoming contract year, addresses a number of program policy issues. Topics include:

- proposals relating to the Star Ratings System;
- new plan flexibility to offer additional types of supplemental benefits for enrollees with chronic illnesses, under a provision in the Bipartisan Budget Act of 2018; and
- proposals on other issues of importance to Medicare Advantage and Part D plans.

Comments are due March 1, and the Final Notice and Call Letter will be released by Monday, April 1.

State Issues

Pennsylvania

Legislative

Governor Wolf to Unveil First Budget of His Second Term

On Tuesday, February 5, Governor Tom Wolf will deliver his first budget address of his second gubernatorial term. He is likely to revisit a number of familiar themes, including an increase in education spending, a severance tax on natural gas drilling, tougher gun control measures, and an increase in the minimum wage. The state's independent budget office projects that state legislators will need to plug a $1.6 billion deficit.

House Insurance Committee Approves Bill Addressing Medication Synchronization

The House Insurance Committee voted on January 29 to approve House Bill 195, legislation that regulates how insurers manage the medication synchronization process, defined as the coordination of prescription drug filling or refilling by a pharmacy or dispensing physician for a health insurance enrollee taking two or more maintenance medications for the purpose of improving medication adherence.

Background

House Bill 195 is a reintroduction from the 2017-2018 session, House Bill 1800. The bill's sponsor, Rep. Eric Nelson (R-Westmoreland), says the proposal benefits seniors, busy families and individuals by minimizing trips to the pharmacy, particularly for those individuals who may have transportation challenges as well as increasing adherence to prescribed prescription regimens.

House Bill 195 is currently in the House Appropriations Committee awaiting further consideration.

House Committee Examines Impact of Surprise Balance Billing

On February 4 and 5, the House Insurance Committee will conduct two informational meetings to examine the effects of surprise balance billing and payment methodologies. The issue is also described as emergency department out-of-network surprise bills / out-of-network providers. On February 4 representatives from FAIR Health, an all payer claims data service, will share their experience with surprise balance billing in other states.

On Tuesday, Highmark, along with representatives from Capital Blue Cross (CBC), Independence Blue Cross (IBC) and the Insurance Federation of Pennsylvania (IFP) will offer the insurer perspective on the issue. Also presenting comments will be a panel of health care providers, including the Hospital and Healthsystem Association of Pennsylvania (HAP), emergency physicians and ologists.

Background

Consumers are increasingly being exposed to surprise balance bills from providers and/or health care facilities that do not participate in their health insurer's network. The expenses, which can mean thousands of dollars in unexpected medical costs, are usually billed in charges and not the negotiated rates providers agree to accept when they join a health insurer's network. Members usually become aware of these situations only after receiving medical care.

Regulatory

DEP Revised Radiology Health Regulations Take Effect

The Pennsylvania Department of Environmental Protection's (DEP) Environmental Quality Board (EQB) amended radiological health regulations to include clarification and guidance regarding radiation safety and update the standards for protection against radiation. DEP updated the regulations, which have not been updated since 2009, to account for advancement in radiological technology.

The final rule was published in the October 27, 2018, ***Pennsylvania Bulletin***; the rule took effect January 27, 2019.

The rule includes the following key changes of importance to hospitals:

- Section 221.16 (Training, Competency, and Continuing Education) now requires individuals who operate or supervise x-ray equipment during diagnostic or interventional procedures be trained and competent in 18 newly specified subject areas.
- Individuals who operate or supervise x-ray equipment must be registered or credentialed and privileged in the applicable specialty by a professional organization that is recognized by the department.
- Individuals who perform *high-risk* procedures are required to complete continuing education every two years, while individuals performing *low-risk* procedures are required to complete continuing education every four years. The continuing education records must be maintained for five years for DEP's inspection. The final rule does not specify a required number of educational hours for high- and low-risk users. Documenting the completion of radiation safety training will satisfy the regulation.

Why this matters

- The EQB recognizes that the Department of Health (DOH) has regulations regarding radiation sources (28 Pa. Code Chapters **51**, **127**, and **565**) that might be affected by this rulemaking.
- DEP and DOH will collaborate to ensure DOH regulations are consistent with DEP regulations.
- Hospitals should review the final rule to ensure their written policies are consistent with the updated regulations.

West Virginia

Legislative

Senate Gives Green Light to Prior Authorization Bill, House Action Pending

The Senate voted 33-0-1 to advance a restrictive prior authorization measure, House Bill 2351. The proposal reflects demands made by Senate Majority Leader Dr. Tom Takubo, which are counter to those offered by the House Health Committee.

Background

House Bill 2351 was referred back to the House of Delegates, where it is pending a decision on whether it will agree to the changes made by the Senate or seek further amendments since it differs significantly from the original House bill. Under review by the House Health Committee leadership are the definition of "episode of care" and language creating an expedited prior authorization process, known as gold carding.

Meanwhile, the West Virginia Hospital Association has voiced concern over the "episode of care" issue, leaving the State Medical Association in its support of the provision. Also developing is

attention from the Bureau of Medical Services and the Public Employees Insurance Agency (PEIA).

Why it matters
The bill passed by the Senate would restrict health insurers' ability to conduct utilization management through prior authorization. For example, the legislation would:

- Require payers to issue a prior authorization for all services related to a specific medical condition or episode of care;
- Require a two-day response from a carrier for emergent conditions and seven days for standard prior authorization requests;
- Prohibit prior authorizations for prescriptions written at discharge and for three days or less, provided the cost of the medication does not exceed $5,000 per day; and
- Require payers to exempt providers from prior authorization for specific procedures or services for a period of six months if a provider has a 100% approval rating (an average of 30 procedures) over a six month period.

Insurers currently performing electronic prior authorizations would be required to implement all of these policies by January 1, 2020 and would need to make available a comprehensive list of all procedures, devices, services, etc. subject to prior authorization disclosed on their forms and online.

New Bill Would Regulate Pharmacy Benefit Managers

A new bill (SB 489) addressing the regulation of pharmacy benefit managers (PBMs) was introduced last week in the Senate. The measure proposes a new regulatory and reporting mechanism for PBMs. The proposal, which was referred to the Senate Health Committee, will likely be on the panel's voting schedule on Tuesday, February 5.

Why this matters
PBMs continue to receive major scrutiny from independent pharmacists, with some believing they are not sufficiently regulated by the states. As a result, state legislatures are seeking solutions to improve oversight.

Senate Bill 489 targets PBMs directly, prohibiting them from creating discriminatory pricing structures for entities qualified as 340(b) pharmacies under federal law—a provision that will seek to protect the interests of hospitals and Federally Qualified Health Clinics.

State
The Pennsylvania General Assembly is in recess the week of February 4-6.

The Delaware General Assembly is in recess until March 5.

The West Virginia Legislature is in session January 9 – March 9.

Congress
The U.S. Senate is in session February 4 and the U.S. Congress is in session February 4-8.

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.

West Virginia Legislation: http://www.legis.state.wv.us/

For copies of congressional bills, access the Thomas website – http://thomas.loc.gov/.