July 25, 2019

MEMORANDUM

TO: ART WOOD, JIM ROMANO, MIKE HERBERT

FR: NATHAN THOMSON

RE: THE PRESCRIPTION DRUG PRICING REDUCTION ACT OF 2019

This morning, July 25th 2019, the Prescription Drug Pricing Reduction Act (PDPRA) passed out of committee following a hearing from the Senate Committee on Finance. The act which, received a measure of bipartisan support, aims to make significant changes to Medicare B, Medicare D, and Medicaid.

As it relates to the patient assistance field, the bill comes with an amendment from Senators Hassan (D-NH), Whitehouse (D-RI), and Brown (D-OH), which would direct the Government Accountability Office to “study the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expenditures within the Medicare and Medicaid programs.”
A number of other amendments were offered but ultimately not brought along with the bill:

- **Whitehouse Amendment #1**: “This amendment prohibits pharmaceutical manufacturers from claiming tax deductions for amounts paid or incurred relating to manufacturer patient assistance programs for individuals with comprehensive health insurance.”

- **Hassan Amendment #5 (offered with Senator Whitehouse)**: “This amendment would require patient assistance programs as defined by the HHS Office of the Inspector General to report annually to CMS the total dollar amount of copayment assistance received by drug manufacturers, the total dollar amount given to Medicare beneficiaries, and the specific drugs for which the copayment assistance dollars were provided.”

- **Hassan Amendment #7 (offered with Senator Whitehouse)**: “This amendment would require that any manufacturer of opioids report annually to the Medicare Open Payments Database the dollar amount of any charitable contributions to patient advocacy organizations, patient assistance programs, and other healthcare professional associations and organizations that engage in lobbying or advocacy activities before Congress or the Department of Health and Human Services. Such reporting shall include the dollar amount provided to each recipient organization.”
  - During the hearing, Senator Hassan withdrew all of her amendments except #4, but spoke to this one personally. In February the Senator confronted Janssen executive Jennifer Taubert during a Finance Committee hearing on prescription drug costs.

- **Hassan Amendment #8**: “This amendment would require that drug manufacturers report annually to the Medicare Open Payments Database the dollar amount of any charitable contributions to patient advocacy organizations, patient assistance programs, and other healthcare professional associations and organizations that engage in lobbying or advocacy activities before Congress or the Department of Health and Human Services. Such reporting shall include the dollar amount provided to each recipient organization.”

There were two major amendments that were voted on this morning, but ultimately did not pass. From the Republican side, an amendment was offered to eliminate the inflation caps in the bill. The republicans argued that this cap amounts to “price fixing,” and that it will cause list prices to go up. On the Democrat side, an amendment was offered to allow Medicare to negotiate its own prices. Both of these amendments failed to be adopted, almost entirely on party lines.

Broadly, the PDPRA can be broken up into four areas: Medicare Part B, Medicare Part D, Medicaid, and Price Increases. Some of the key provisions are noted below:
**Medicare Part B:**

- Manufacturers will have to exclude the value of coupons provided to privately insured individuals from each drug’s Average Sale Price (ASP), as reported to the HHS Secretary. **Manufacturers would not have to exclude contributions to patient assistance programs or foundations.**
- Manufacturers will be required to pay a rebate to Medicare for the amount that their Medicare Part B drugs or biologicals increased above the inflation rate.
- Manufactures will be required to refund the amount of payment made to providers for unused amounts of prescription drugs, biologicals, and biosimilars packaged as single-dose vials.

**Medicare Part D:**

- The Part D benefit will be completely redesigned; this would eliminate the donut hole and cap out-of-pocket costs at $3100. Part D will become a three-phase program: The deductible ($415), the initial coverage phase ($3100), and the catastrophic phase (drug costs above $3100). A majority of costs will be shifted from Medicare to manufacturers. Please see the graphic below:

![Figure 1. Medicare Part D Standard Coverage Benefit for 2019](image-url)
Part D plans will have to conduct financial audits relating to PBMs beginning in 2022.
The HHS Secretary will have to publicly disclose DIR information submitted by health plans.
Manufacturers will be required to provide rebates to Medicare for each six-month period in which list prices for Part D-covered brand drugs are increased above inflation.

**Medicaid:**
- States will be given the option to cover gene therapies through risk-sharing agreements, as long as the eligible drugs can reduce or cure disease symptoms in three or less administrations.
- States with Medicaid formularies will be required to establish committees to review their formularies.
- PBMs will be required to provide drugs on a pass-through basis, in an attempt to eliminate price spreading.

**Price Increases:**
- Manufacturers will have to provide justification for price hikes if they increase by more than 100 percent in 12 months, or 300 percent in three years.
This Bill will now move towards the Senate floor where it will be debated and voted on. Members on both side of the committee expressed reservations about the bill and signaled that they wanted to see added language. Chairman Grassley (R-IA) indicated his desire for language that would bring back the “rebate rule,” which was abandoned by the White House earlier this month. Ranking Member Wyden (D-OR) stated that Democrats would not allow floor debate unless amendments protecting pre-existing conditions and allowing Medicare Negotiation were also given floor votes.

Elsewhere in Washington, it has been reported that HHS Secretary Alex Azar was making calls to Senators in support of the bill. Some have interpreted this as White House support for the PDPRA. President Trump and Secretary Azar met with representatives from PhRMA, Pfizer, and Amgen on Wednesday. President Trump has yet to comment.

After the bill was passed out of committee, PhRMA CEO Stephen J. Ubl released a statement deriding the bill, saying that it was “the wrong approach to lowering drug prices.” Tom DiLenge of BIO also weighed in; “The proposal does almost nothing to hold insurance companies and middlemen accountable for shifting more of the cost burden onto patients.”

Over the coming weeks, the GR department will continue to monitor the atmosphere in the Senate and we will continue to analyze this legislation. The Senate will be in recess from August 5-September 6.