American College of Physicians
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The American College of Physicians Comments regarding the Prescription Drug Pricing Reduction Act (PDPRA) of 2019
July 24, 2019

The American College of Physicians (ACP) applauds Chairman Grassley and Ranking Member Wyden on the introduction of The Prescription Drug Pricing Reduction Act (PDPRA) of 2019 and we appreciate your sustained bipartisan effort to lower drug costs for our patients. We are currently reviewing all of the provisions included in this bill but would like to provide you with several of our key recommendations for this legislation before the mark-up of this bill later this week.

ACP is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 159,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Our comments will provide our key recommendations regarding several sections of the PDPRA that change current law to improve transparency in drug pricing and changes to Medicare to lower out-of-pocket costs for beneficiaries. We will also share our support for several policies to lower drug prices that we urge you to add to PDPRA during the mark-up of this legislation as well as other policies that may not be considered by the Finance Committee but we believe are key components that should be included in legislation considered by the Senate to lower drug costs.

ACP Supports Provisions in PDPRA to Improve Transparency in Drug Pricing

Section 141. Drug Manufacturer Price Transparency: The provision would add a new SSA Section 1128L, effective July 1, 2022, requiring drug manufacturers to report to the Secretary of Health and Human Services (HHS) information and supporting documentation needed to justify price increases for prescription drugs and biological products, as measured by the WAC or changes in the WAC in cases where the Secretary determines the manufacturer's price increase met or exceeded certain thresholds. The Secretary would be required to publicly post the price justifications, as specified in the provision.

The Secretary would notify a manufacturer within 60 days of identifying a drug as an applicable drug. After being notified, the manufacturer would have 180 days to provide a price justification to the Secretary, which would be posted on the CMS website no later than 30 days after receipt, along with a summary written in a way that would be easily understandable to Medicare and Medicaid beneficiaries. A price justification would not be required if a

manufacturer, after it received notification, reduced the list price for an applicable drug so that, for at least 6 months, it no longer met the qualifying criteria. Drugs that qualify based on new launch price would remain applicable drugs until the Secretary determines there is a therapeutic equivalent. The required information for the price justifications may include: individual factors contributing to the price increase; the role of each factor in the price increase; and manufacturer spending for materials and manufacturing, patents and licenses, or purchasing or acquiring the drug from another company, if applicable. Manufacturers may also describe the percentage of total research and development spending for the drug that came from federal funds; total manufacturer research and development spending on the drug; total revenue and net profit from the drug each year since approval; total costs for marketing and advertising the drug; and additional information about the manufacturer such as total revenue and net profit for the period of the price increase, metrics for setting executive compensation, and other information such as total spending on drug research and development or clinical trials on drugs that failed to receive FDA approval.

Drug manufacturers would be subject to current Medicare civil monetary penalties of $10,000 per day for failing to submit a timely price justification and up to $100,000 per false information item for knowingly submitting false information.

ACP Comment: ACP is pleased to support Section 141, the Drug Manufacturer Price Transparency Provisions in the PDPRA. This section includes our key recommendations to increase transparency in the pharmaceutical marketplace that we provided to you earlier this year in our statement to the Senate Finance Committee on Drug Pricing in America: A Prescription for Change. Section 141 includes our key recommendations to improve drug pricing by requiring drug companies to disclose:

- **Actual material and production costs to regulators -** Pricing methodologies for biomedical products are notoriously covert, and it is difficult to pinpoint to what extent a price reflects research, development, marketing, or administration costs.
- **Research and development costs contributing to a drug's cost, including those drugs which were previously licensed by another company -** Pharmaceutical companies are often publicly held and disclose information on their research and development marketing portfolios which has allowed outside analysts to review how, and how effectively, companies use their research and development budgets. The average amount that a company spends on research and development per drug may vary, depending on the number of drugs each company is developing and how many gain regulatory approval.
- **Rigorous price transparency standards for drugs developed with taxpayer-funded research -** Companies that use basic research funded through the government as part of the development of a drug should be held to a high standard of pricing scrutiny. The National Institutes of Health (NIH) have historically made the largest government

investments in basic research and play a key role in spurring innovations and breakthroughs.

ACP supports several bills that have been introduced in the 116th Congress to improve the disclosure of information from pharmaceutical companies concerning their research and development costs and information regarding price increases of their products. These bills include:

- **The Prescription Drug STAR Act (H.R. 2113),** this legislation would require drug manufacturers to publicly justify large price increases for existing drugs and high launch prices for new drugs, and would require the Secretary of HHS to publicly disclose the aggregate rebates, discounts, and other price concessions achieved by pharmaceutical benefits managers on a public website.

- **The Fair Accountability and Innovative Research (FAIR) Pricing Act (S. 1391/H.R. 2296),** This legislation, sponsored by Senator Baldwin, would require manufacturers to disclose and provide more information about planned drug price increases, including research and development costs.

ACP Comments regarding Medicare Part D Benefit Redesign in PDPRA

Section 121. Medicare Part D Benefit Redesign: This provision would make substantial changes to the structure of the Part D benefit in order to simplify the benefit design and realign incentives to encourage more efficient management of drug spending. Starting January 1, 2022, it would: (1) change enrollee cost-sharing in the initial coverage limit and the coverage gap; (2) cap enrollee cost sharing above the catastrophic out-of-pocket threshold; and (3) change the amount of annual out-of-pocket spending needed to trigger catastrophic coverage. In addition, the provision would modify Part D financing mechanisms to (1) lower federal reinsurance during the catastrophic coverage period; (2) sunset the existing manufacturer discount program in the coverage gap; and (3) institute a new manufacturer discount program in the catastrophic coverage phase of the benefit.

To simplify and reduce cost sharing for Part D enrollees, this provision would eliminate the coverage gap and establish 25 percent cost-sharing between the annual deductible and the catastrophic threshold. It would also completely eliminate cost-sharing during catastrophic coverage. The catastrophic out-of-pocket threshold would be set at $3,100 in 2022 and indexed to growth in Part D spending. This amount reflects the true out-of-pocket spending enrollees face before reaching catastrophic coverage under Part D today. Additionally, the provision would reduce federal reinsurance payments so that Medicare is responsible for 20 percent and insurers for 60 percent, respectively, of total drug spending during catastrophic coverage.

Finally, this provision would sunset the current coverage gap discount program in which manufacturers pay 70 percent of drug costs. Instead, the provision would establish a new

manufacturer discount program in which manufacturers provide discounts for drugs and biologics utilized during catastrophic coverage. Under the provision, manufacturers that choose to have their drugs covered under Part D would enter into agreements with the Secretary to provide 20 percent discounts off negotiated prices during catastrophic coverage, including for LIS beneficiaries. Insurers would subtract the anticipated manufacturer discounts from the actuarial value of the Part D benefit when submitting annual bids to CMS.

ACP Comment: Although ACP is supportive of provisions in PDPRA to lower out-of-pocket spending for Medicare Part D beneficiaries, we believe the best way to lower drug prices in the Medicare Part D program would be to allow the Secretary of HHS to negotiate covered Part D drug prices on behalf of Medicare beneficiaries. **We understand that Senator Stabenow may offer an amendment during the markup of PDPRA that would allow the Secretary to negotiate drug prices in Medicare and we urge your support of this amendment**.

ACP supports the provision in the PDPRA to cap annual out-of-pocket spending for Medicare Part D beneficiaries who reach the catastrophic phase of coverage. In addition, ACP supports the adoption of a cap on out-of-pocket drug costs to protect Medicare beneficiaries from excessive exposure to these costs, too often the case today. Although we are supportive of these policies, we urge the Committee to consider the full gamut of likely ramifications of these changes to Medicare Part D, particularly when programmatic changes of this magnitude are being put forward.

One potential result, for example, is that such a cap on beneficiary out-of-pocket costs is substantially likely to be offset at least in part by higher premiums, unless accompanied by other measures that address the underlying reason for high out-of-pocket costs, like excessive pricing.

Notable among these is the application of any cap brought about by Part D reforms on a quarterly as opposed to an annual basis. This will help beneficiaries better afford their medications at the time they have to pay out-of-pocket for them—rather than at the end of a full calendar year. That could be many months after they have incurred the expense. Limiting beneficiary out-of-pocket expenses on a quarterly basis will make it much less likely they will forgo needed medications because they cannot afford them.

Additional Recommendations to lower the costs of prescription drugs

We understand that the since the Finance Committee has jurisdiction over the Medicare and Medicaid programs, the PDPRA implements changes to these programs to lower drug costs. ACP also supports additional reforms to lower drug prices through promoting competition for brand name and generic products.

We remain concerned about anti-competitive practices by a few manufacturers of brand name drugs to prevent or delay other companies from developing alternative lower-cost products. These few brand name manufacturers utilize the FDA's Risk Evaluation and Mitigation Strategies (REMS) process and its accompanying Elements to Assure Safe Use (ETASU) requirements in a manner that prevents development of lower-cost alternatives. In some

instances, the REMS process and ETASU requirements have been used to deny the availability of drug samples and participation in FDA safety protocols. Using the REMS process and ETASU requirements in this way by a few brand name drug companies keeps lower-cost generics and biologicals off the market, thereby decreasing patient access to lower-cost medications.

- **ACP supports the passage of S. 340 - the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act -** This legislation attempts to stop brand name companies from mis-using the REMS process and ETASU requirements by determining when the denial of adequate samples and impending participation in joint-safety protocols have occurred and creates a pathway for the lower-cost manufacturer to bring a cause of action in federal court for injunctive relief.

Another way to improve competition for brand name and generic drugs would be to pass legislation to prevent tactics that brand name drug companies use to block the approval of other drugs to compete with their products in the marketplace including product hopping or evergreening, and pay-for-delay tactics. Drug companies use product hopping over ever greening to prevent generic competition from entering the market by making small adjustments to a drug with no real therapeutic value that grants the company longer patent protection. Companies also use tactics known as pay-for-delay, also known as a "reverse payment settlement", a patent settlement strategy in which a patent holder pays a generic manufacturer to keep a potential generic drug off the market for a certain period.

- **ACP supports the passage of S. 1209, the Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act (S. 1209),** which would amend the law to remove incentives for drug manufactures to file excessive patents to keep generic drugs off the market, and would lift legal barriers that delay generic entry in to the market.

Conclusion

As we mentioned, ACP is conducting a thorough review of this legislation and may provide more detailed comments regarding PDPRA at a later date, but we hope this statement is helpful in providing you with our initial thoughts about this legislation. We commend the Finance Committee for developing this legislation that implements changes to Medicare and Medicaid to lower drug prices and we look forward to working with you and the Congress to continue to lower the cost of drugs for our patients.