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The American College of Physicians Response to the Ways and Means Committee and the Energy and Commerce Committee on their Call for Comments on Bipartisan Medicare Part D Drug Pricing Legislation

June 6, 2019

The American College of Physicians (ACP) would like to express our appreciation to the two House committees of Medicare jurisdiction for their inquiry into this crucial issue for Americans all across our country. This request for feedback on the identification of approaches to dealing with the problem within Medicare Part D. is one that holds great potential. In view of the fact that the approaches being examined are bipartisan in nature, this is even more the case.

Working with the Congress and other stakeholders to identify solutions to the dilemma of prescription drug pricing in America is among the highest priorities of the American College of Physicians (ACP). ACP is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 154,000 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.

We understand that this issue is also a top priority for these two Medicare committees. ACP members see first-hand the choices that patients are all too often forced to make about their health when trying to budget between the cost of their medications and every-day living expenses. All too often, internal medicine physicians learn that patients have can no longer afford their medications, as they have fallen into the “doughnut hole” of drug coverage. These patients must then take brand-name drugs due to lack of cheaper generic alternatives to manage their symptoms.

One of the issues the committees are seeking comments on is embodied in a legislative proposal that would create an out-of-pocket maximum on prescription drugs costs for Medicare beneficiaries in Part D, based on the current catastrophic threshold.

While ACP finds the intent of this proposal to be consistent with the College’s goals of affordable prescription drug pricing and is pleased the committees have similar objectives for reform of Part D, we believe the full gamut of likely ramifications of such changes must also be carefully considered, particularly when programmatic changes of this magnitude are being put forward.

One potential result, i.e., 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, i.e., excessive pricing. See below for a more complete discussion of ACP’s recommendations to address 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'll forgo needed medications because they can't afford them.

In addition, the committees have asked for feedback on the following:

- 1) How the Part D program is addressing the problem of high cost drugs and how the program could better address the costs of these drugs. Specifically, whether or not Congress should consider changing or eliminating the distinction between the initial coverage phase and the coverage gap discount program;

ACP supports closing the "doughnut hole." The College does believe, however that beneficiaries should have to bear some personal responsibility for these costs.

- 2) What share of costs should be attributed to the beneficiary, Part D plans, and manufacturers under the current system and how this share should change if the liability were shifted for the manufacturer from the current coverage gap discount program to the catastrophic phase of the Part D benefit; and

Current ACP policy does not address this point.

- 3) What improvements the Committees should consider with respect to low-to-moderate income Part D beneficiaries and out-of-pocket costs below the catastrophic level.

ACP believes that if the Secretary were given the authority to negotiate prices with pharmaceutical manufacturers – even just in part – see below, this powerful tool would have a very substantial – and positive effect on the ability of Americans to afford their medicines.

Below are among the more recent policies that have been developed by ACP and approved by the College's Board of Regents which rely on potential revisions in Medicare Part D.

1. ACP supports modification to the Medicare Part D low-income subsidy (LIS) program cost-sharing and copayment structures to encourage the use of lower-cost generic or biosimilar drugs, such as eliminating cost-sharing for generic drugs for LIS enrollees.
2. ACP supports annual out-of-pocket spending caps for Medicare Part D beneficiaries who reach the catastrophic phase of coverage.
3. ACP supports the adoption of Medicare Part D negotiation models that would drive down the price of prescription drugs for beneficiaries. ACP supports further study of payment models in federal health care programs, including methods to align payment for prescription drugs administered in-office in a way that would reduce incentives to prescribe higher-priced drugs when lower-cost and similarly effective drugs are available.
4. ACP supports the adoption of Medicare Part D negotiation models that would drive down the price of prescription drugs for beneficiaries.

- a. While ACP reaffirms its support for a full repeal of the noninterference clause, ACP also supports an interim approach such as allowing the Secretary of Health and Human Services to negotiate for a limited set of high-cost or sole-source drugs.
- b. ACP supports a public Medicare Part D plan option that allows the Secretary of HHS to negotiate prices with drug makers. Any Medicare-operated public plan must meet the same requirements as private plans and be consistent with ACP's policy on formularies.

In addition, ACP supports 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.

Advances in medicine have been life-saving but they need to be affordable to society. Non-compliance with medication regimens can lead to more serious health complications, more patients suffering from disease and additional costs to society. The pharmaceutical industry needs a reasonable return on investment but there needs to be a balance between profits and the service they provide in treating and maintaining the health of our patients.

We look forward to working with members of these committees in a bipartisan fashion to develop policies to lower the cost of drugs for our patients and share our perspective as internal medicine physicians on how the rising cost of prescription drugs are making medications unaffordable for our patients. As the Committee examines solutions to lower the cost and price of prescription drugs, we urge committee members to consider the enactment of policies that will achieve the following objectives: promote competition in the pharmaceutical industry, increase transparency in the pricing and costs associated with the development of drugs, implement reforms to Medicare to lower out of pocket costs for seniors, and increase the value of drugs in the marketplace.

Drug Prices Continue to Rise

According to a multitude of studies published over the last several years, drug companies dramatically and repeatedly continue to raise the price of their products to levels that are simply unaffordable to patients.

A recent study found that between 2002 and 2013, the price of insulin increased dramatically, with the typical cost for patients increasing from approximately \$40 a vial to \$130. As a result, according to a published report on the new study “a surprisingly large number of people with diabetes are using less insulin than prescribed because of the rising cost of the drug, putting themselves in danger of serious complications. Those are the findings of a small new study by researchers at Yale University, who found that at one clinic in New Haven, Conn., one in four patients admitted to cutting back on insulin use because of cost.”

A report by the Senate’s Homeland Security and Governmental Affairs Committee found that “The prices of many of the most popular brand-name drugs increased at nearly ten times the cost of inflation from 2012 to 2017. Prices increased for every brand-name drug of the top 20 most-prescribed brand-name drugs for seniors in the last five years. On average, prices for these drugs increased 12 percent every year for the last five years—approximately ten times higher than the average annual rate of inflation. Twelve out of the 20 most commonly prescribed brand-name drugs for seniors had their prices increased by over 50 percent in the five-year period. Six of the 20 had prices increases of over 100 percent. In one case, the weighted average wholesale acquisition cost for a single drug increased by 477 percent over a five-year period.”

Generic drugs, which usually are expected to offer a lower-priced competitive alternative to bioequivalent brand name drugs, are also experiencing price increases. A study in the October issue of Health Affairs shows that the portion of generic drugs that at least doubled in price, year-over-year, represents a small but growing share of the market: from 1 percent of all generic drugs in 2007 to 4.39 percent in 2013. “For consumers, this can mean soaring costs to purchase some drugs that are life-savers, sparking public outrage and leading many to question whether the market — which has historically functioned well — is still working.”

According to an article published in the Journal of General Internal Medicine, between 2010 and 2015 300 off-patent drugs experienced price increases of 100 percent or more, and some drugs were sold at 5500 percent higher than in previous years.

Promoting Competition to Lower Drug Prices

As the Congress continues to examine ways to lower drug costs, we encourage the Medicare committees to use their oversight and legislative authority to develop policies to promote competition for brand-name and generic drugs and biologics. ACP provides the following recommendations to the committee to prevent a number of techniques that brand name drug companies use to block the approval of other drugs to compete with their products in the marketplace including: improving competition for single-source drugs, product hopping, ever greening, and pay for delay tactics.

Improving competition for single-source drugs - Increasingly, the pharmaceutical marketplace is narrowing its focus to highly innovative, biologic, or specialty drugs for which there are few, if any, competitors, creating monopolies and limiting the cost-controlling power of competition. The focus on brand-name drugs and new biologics results in a greater desire for companies to protect the investments in these drugs and keeping them as profitable for as long as possible.

Increase oversight of companies that engage in product-hopping or ever greening – In these practices, companies prevent generic competition from entering the market by making small adjustments to a drug with no real therapeutic value that grant the company longer patent protection, or they remove the drug from market, forcing patients to switch to a reformulated version of the same drug.

Enforce restrictions against pay for delay practices- Pay-for-delay, also known as “reverse payment settlement,” is 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. The Congressional Budget Office estimated that enacting legislation restricting pay-for-delay settlements would cut the federal deficit by \$4.8 billion over 10 years.

Improve Access to Generic Drugs

Limited competition—even in the generic market—can also drive up the cost of a medication. The generic manufacturing market is becoming more consolidated, and progressively some generics are being manufactured by a single company or are disappearing from the market. Limited competition – in almost any sector – limits the cost-containing power of competition.

When there is no competition, patients have little choice. For example, if there is only one costly name brand drug for the patient, they really only have two options – either pay for the drug or forgo treatment and risk escalating their condition. Even the generic market is not immune to this happening, single-source generics are more expensive than other generics; some health plans place these drugs in the preferred drug tier in absence of a competitor, resulting in higher costs to the patient.

There have also been 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 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 of the market, thereby decreasing patient access to lower-cost medications.

Increase Transparency in the Marketplace

For decades, pharmaceutical manufacturers have claimed that drug pricing is based on research and development cost and innovation and is well regulated by market forces. The spike in prices and increase in price for drugs already on the market have made many stakeholders wary, especially because many of these new therapies treat small populations and there are few data to support that overall health care costs are reduced. In 2018, a number of drug manufacturers announced they would not raise prices on drugs, noting the public concern about increasing drug prices. However, these decisions created a false sense of confidence that the issue was being addressed and in late 2018, most of companies reneged on these announcements and raised the prices of their products.

ACP urges the Committee to exercise its oversight authority to urge pharmaceutical 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. Between 1988 and 2005, federal research funding contributed to 45 percent of all drugs approved by the FDA and 65 percent of drugs that received priority review. Without this assistance, the cost of discovery, research, and development on the part of pharmaceutical companies may be prohibitive. At a minimum, pharmaceutical companies should disclose any grants, licensing agreements, or other investments by the federal government

in the discovery, research, and development of the drug, in addition to material, production, and other research and development costs.

Trump Administration Proposed Regulations to Reform Medicare to Lower Drug Costs

President Trump has also been an outspoken advocate for lowering the prices of prescription drugs and has issued a series of proposals designed to accomplish this goal. In May of 2018, the Department of Health and Human Services (HHS) issued a blueprint to lower drug prices that identified four key strategies for reform including: improved competition, better negotiation, incentives for lower list prices, lower out-of-pocket costs. ACP issued a comment letter that shared our views concerning key elements of the blueprint, expressed our key recommendations to lower drug costs, and urged the HHS to use the rulemaking process to continue to seek input from stakeholders prior to the implementation of any policy.

The President also seeks to issue a new regulation that would implement a new International Pricing Index payment model to lower drug costs for patients in the Medicare Part B program. The goal of this proposed rule would be to shift drug prices in the United States to more closely align them with prices in European countries that pay much less for the same drugs. Although ACP does not have direct policy on this pricing model, we did provide a comment letter to HHS that provides our views regarding a number of issues that should be considered before implementation of this rule.

CMS has also announced proposed changes to Medicare Part D designed to lower prescription drug prices for beneficiaries. The proposed rule would seek to allow plans to exclude certain protected class drugs if the manufacturer raises the price of the drug at a rate greater than inflation or if the drug maker brings to market a new formulation of the drug without any meaningful change to original formulation of the drug, regardless of whether or not the original formulation remains on the market or not. Additionally, the proposal introduces prior authorization and step therapy to the protected classes in an attempt to introduce more competition.

The administration also recently announced a new proposed rule that would attempt to lower out of pocket costs for patients using drugs with high prices and high rebates, particularly during the deductible or coinsurance phases of their benefits. This proposal aims to change perverse incentives in the system that allow drug companies to continue to increase the list prices of their drugs. The proposal would create a new safe harbor protecting discounts offered to patients when they purchase their drugs at the pharmacy. It would also create new safe harbor for fixed fee services arrangements between manufacturers and pharmacy benefit managers.

Reforming Drug Formularies to ensure lower costs for patients

When health plans are faced with rising cost associated with high drug prices, they often look to increased cost-sharing, utilization management, or tiered formularies that place all drugs of a certain class into the highest tier, putting patients at risk for not being able to access or afford the medications they need or adhere to drug regimens properly.

Drug formularies divide prescription drugs into 4 or 5 tiers with varying levels of fixed prices (copayments) for all drugs in each tier, with the exception of the highest tier. The highest tier, typically the specialty tier, is subject to either the highest copayment or coinsurance in which the

patient pays a percentage of the cost of the treatment. There has been a shift toward prescription drug plans with coinsurance in the top 2 tiers, typically the specialty tier and a non-preferred brand tier that has no restrictions on which drugs can be placed on the tier. This can lead to higher coinsurance rates than that of the specialty tier. Usually only the specialty tier has been subject to cost-sharing; all other tiers have copayments.

ACP believes that payers that use tiered or restrictive formularies must ensure that patient cost sharing for specialty drugs are not set at a level that imposes a substantial economic barrier to enrollees obtaining needed medications, especially for enrollees with lower incomes. Health plans should operate in a way consistent with ACP policy on formularies and pharmacy benefit management.

The ACP has a comprehensive policy on formulary benefit design including:
ACP opposes any formulary that may operate to the detriment of patient care, such as those developed primarily to control costs

Decisions about which drugs are chosen for formulary inclusion should be based on the drug's effectiveness, safety, and ease of administration rather than solely based on cost.

☑ ACP recommends that pharmacy and therapeutic committees be representative of, and have the support of, the medical staffs that will utilize the formulary.

Improve value within the prescription drug market

ACP supports research into novel approaches that would further value based decision making and encourages research into policies that would tie price innovations to clinical value. We urge the Ways and Means Committee to consider the following options:

Value Frameworks- With the great attention being paid to the price of drugs, determining how to assess the value of a drug, which patients may benefit the most from a certain drug, and the economic value of a drug has charged the conversation.

Bundled Payments- The approach may encourage the use of older, lower-priced drugs before newer, more expensive treatments with similar benefit and in turn affect drug utilization. This shift to paying for value as opposed to the number of services provided mirrors other similar shifts toward an evidence- and value-based system of health care.

Indication Specific Pricing- The variability of disease and how patients react to medications makes indication-specific pricing potentially beneficial for such diseases as cancer.

Evidence Based Benefit Designs- Innovative benefit designs can include incentives that vary by service, type of patient condition, or income. Evidence-based benefit design has also been advocated as a way to reduce health care costs and would be in line with the movement toward evidence-based medicine. Policies that encourage value-based benefit design can help consumers make educated choices about prescription drugs and keep costs low.

Improve the Use of Comparative Effectiveness Research

More and more, physicians, patients, and other stakeholders are questioning the value of drugs relative to their price. Many of the new specialty drugs coming to the market represent real breakthroughs and benefits for patients, and the market should encourage future innovation. Those innovations do not mean that all other drugs should also be priced at the same level. Independent organizations, such as the Institute for Clinical and Economic Review and the Patient-Centered Outcomes Research Institute (PCORI), develop and evaluate clinical effectiveness data compared with other treatments. For example, PCORI has funded millions of dollars in head-to-head CER that can inform physicians and help patients understand all therapeutic options available as they relate to existing therapies and encourage informed decision-making and patient involvement. Establishing an evidence base of clinical effectiveness data is the crux of transitioning to a health care system that pays for and rewards value. Not only do comparative effectiveness data inform value judgments they can also help physicians and patients understand all available options as they relate to existing therapies, encouraging informed decision making and involvement by patients in their health care choices. ACP policy supports CER to measure the effectiveness of health care services and clinical management strategies and that all health care payers, including Medicare and other government programs, should use both comparative effectiveness and cost effectiveness in the evaluation of a clinical intervention. However, cost should not be used as the sole criterion for evaluating a clinical intervention, however, by statute, PCORI is prohibited from using Quality Adjusted Life Years (QALYs), is a metric of cost-effectiveness research that takes into account the quantity and quality of life associated with a treatment and assigns an index number to that treatment, as “a threshold to establish what type of health care is cost effective or recommended”. QALYs are commonly used in cost-utility studies to determine the cost of a treatment per QALY and compare medical interventions; however, they have been criticized for lacking sensitivity to patient preferences or goals. Incorporating QALYs into cost effectiveness studies will help patients, physicians, and policymakers compare the cost and health benefits of treatments and facilitate a better

i <https://news.usc.edu/149667/do-price-spikes-on-some-generic-drugs-indicate-problems-in-the-market/>

ii <https://link.springer.com/article/10.1007/s11606-018-4372-3>

understanding of the value of different treatments. Part of a patient's overall determination of value may include the cost effectiveness of the treatment along with the benefits or risks of a drug.

Conclusion

ACP commends the Ways and Means and Energy and Commerce committees for conducting this inquiry into how reforms in Part D can help address the issue of drug pricing in America and we look forward to working with you, the Administration, and other stakeholders to develop and implement solutions to ensure that every patient has access to the medications they need at a cost that they can afford. Should you have any further questions, please contact Rich Trachtman at rtrachtman@acponline.org.