



July 16, 2018

The Honorable Alex M. Azar II
Secretary of Health and Human Services
U.S. Department of Health and Human Services Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Request for Information - HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs [CMS-2018-0075]

Dear Secretary Azar,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (the Blueprint). The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 152,000 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.

Physicians are keenly aware of how drug pricing affects their patients. Prescription drugs are a crucial component of a physician's toolkit and have undoubtedly improved the lives of millions of patients worldwide. The rising prices, and in turn costs, of these life-altering and lifesaving drugs is a priority issue for ACP and its members. In 2016, ACP released the policy paper *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians* which details the complex issues that inform the drug pricing debate and the comprehensive efforts needed to ensure affordability and accessibility of prescription drugs for patients¹. When patients are unable to afford medications or do not adhere to their recommended treatment plan they risk developing more serious health conditions which add costs to the health care system and significantly impact a patient's quality of life. The very benefits of these therapies – for specialty, brand name, or generic drugs – are lost when patients are simply not able to access or afford their cost.

¹ Daniel H, for the Health and Public Policy Committee of the American College of Physicians. *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*. *Ann Intern Med*. 2016;165:50–52. doi: 10.7326/M15-2768

In the two years since ACP's paper was published, expenditures on prescription drugs have fluctuated and continue to make up a growing share of health care spending. According to the CMS Office of the Actuary, average annual prescription drug spending growth in the U.S. for 2017-2026 is anticipated to be 6.3%, the fastest area of growth among major health care sectors and primarily attributed to prices for high-priced specialty drugs². A recent Senate investigation found the price of the twenty most-prescribed brand name drugs in the Medicare program increased in cost an average of 12% per year for five years and included twelve drugs that increased their prices over 50% during the five-year period³. The report also shows that revenue from the most commonly prescribed drugs increased by \$8.5 million even though 48 million fewer prescriptions were written. A report by the U.S. Department of Health and Human Services Office of the Inspector General also showed reimbursement for all brand name drugs in Medicare Part D increased 77% between 2011 and 2015 despite a 17% decrease in prescriptions written for those drugs⁴. Out-of-pocket costs are intrinsically linked to the list price of a drug, and although there are potential areas of improvement for health plan coverage, formulary design, or pharmacy benefit manager transparency, the foundation of these discussions is price.

ACP is encouraged that HHS has expressed a willingness to consider a broad range of proposals in order to address prescription drug costs and create a more sustainable marketplace. ACP supports improving transparency, ensuring robust competition, and assessing how effectiveness and value play into drugs costs as these are central components to consider in reducing the price and cost of prescription drugs. The College appreciates the Administration's continued interest in addressing the issue of prescription drug costs and the solicitation of comments on a broad number of related policies. While this is an important step, ACP urges HHS to use the rulemaking process to continue to seek input from stakeholders prior to implementation of any policy. The complex nature of drug pricing and reimbursement necessitates an understanding of how all participants in the prescription drug supply chain are affected by potential changes as well as efforts to mitigate unintended negative consequences.

Improving Transparency

ACP strongly supports transparency in prescription drug pricing as well as in the pricing of other health care goods and services. Information on the price, cost, and comparative value of prescription drugs should be publicly available, including production costs, research and development costs that contribute to a drug's price including those drugs that were previously

² Cuckler GA, Sisko AM, Poisal JA, Keehan SP, Smith SD, Madison AJ, Wolfe CJ, Hardesty JC. National Health Expenditure Projections, 2017-26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. *Health Aff (Millwood)*. 2018 Mar;37(3):482-492. doi: 10.1377/hlthaff.2017.1655.

³ U.S. Senate Homeland Security & Governmental Affairs Committee, Minority Office. *Manufactured Crisis: How Devastating Drug Price Increases Are Harming America's Seniors*. Accessed at [https://www.hsgac.senate.gov/imo/media/doc/Manufactured Crisis - How Devastating Drug Price Increases Are Harming America's Seniors - Report.pdf](https://www.hsgac.senate.gov/imo/media/doc/Manufactured+Crisis+-+How+Devastating+Drug+Price+Increases+Are+Harming+America's+Seniors+-+Report.pdf)

⁴ U.S. Department of Health and Human Services. Office of the Inspector General. *Increases in Reimbursement for Brand-Name Drugs in Part D*. Data Brief OEI-03-15-00080. Accessed at <https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf>

licensed by another company, and rigorous transparency standards should be in place for drugs developed using tax-payer funded research. For example the drug sofosbuvir was primarily developed through research grants from the National Institutes of Health which also carried out the Phase 2 clinical trials⁵. When sofosbuvir came to market as the brand name drug Sovaldi, the price of the drug - \$1,000 per pill – strapped public health plans, sparked public outrage, and spurred a Senate investigation into the pricing of the drug. Legislators discovered through their investigation that despite considerable government investments, the drug was priced and marketed with little concern for patient access. By requiring transparency related to the development and production of the drug, and robust transparency for drugs developed with government investments, pharmaceutical manufacturers may be held accountable to the public.

In the Blueprint, HHS has identified several areas where transparency may be improved, such as making Medicare and Medicaid prices more transparent, holding drug makers accountable for their price increases, highlighting drugs that have not taken price increases, and recognizing when competition is working with an updated drug pricing dashboard. ACP is supportive of those efforts and the need for health care price transparency is particularly important as physician reimbursement and the health care system as a whole moves toward paying for high-quality and high-value care. While price is an important aspect of transparency, **price should not be used as the sole criterion for choosing health care goods or services**, including prescription drugs, and this should be communicated clearly to consumers. Price should also be accompanied by quality or effectiveness indicators. HHS has also suggested requiring Part D Plan sponsors to provide additional information about drug price increases and lower-cost alternatives in the Explanation of Benefits they currently provide their members. This information may be valuable for some beneficiaries; however, it could cause confusion if the information is not presented in a clear, meaningful way that also includes quality or effectiveness data as noted above.

The agency has asked what steps can be taken to improve price transparency in Medicare, Medicaid, and other forms of health coverage so that consumers can seek value when choosing and using their benefits. ACP's recent policy paper *Improving Health Care Efficacy and Efficiency Through Increased Transparency* identifies the need for transparency in health care and supports the development of patient-targeted decision-making tools by payers, health plans, or other health care organizations. These tools should be written with consideration for the patient's health literacy, numeracy, and language access and should aggregate price, cost, and quality information. Tools should communicate the total estimated price in-network or out-of-network, a personalized estimate of the patient's potential out-of-pocket cost responsibility, quality or outcomes data, and data that have been updated in a timely manner⁶. ACP supports efforts such as the development of an all-payer claims database and legislation at

⁵ Osinusi A, Meissner EG, Lee Y, et al. Sofosbuvir and Ribavirin for Hepatitis C Genotype 1 in Patients With Unfavorable Treatment Characteristics A Randomized Clinical Trial. *JAMA*. 2013;310(8):804–811. doi:10.1001/jama.2013.109309

⁶ American College of Physicians. *Improving Health Care Efficacy and Efficiency Through Increased Transparency*. Philadelphia: American College of Physicians; 2017: Position Paper.

the state level to prohibit gag clauses or similar contractual arrangements that interfere with the transparency of relevant health care data.

Direct-to-Consumer Advertising

The President has also called on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising. Pharmaceutical companies spent around \$6 billion on direct-to-consumer advertising in 2017⁷ and it is estimated an individual watching an average amount of television sees nine drug ads per day⁸. **ACP believes that direct-to-consumer advertising is inappropriate and may undermine the patient-physician relationship.** Since direct-to-consumer advertising is unlikely to be banned, ACP supports oversight and strengthened regulation of the practice. ACP is supportive of disclosing list prices in direct-to-consumer advertising and supports the Drug-price Transparency in Communications Act which, among other provisions, would require manufacturers to include the wholesale acquisition in direct-to-consumer advertising and marketing to physicians.

Ensuring Robust Competition

Competition is one of the most effective ways of driving down prescription drug prices and keeping costs in check. A recent report by the Association for Accessible Medicines (AAM) found the average price of a generic drug co-pay to be \$6.06 compared to over \$40 for a brand name drug⁹. The AAM also found that patients not infrequently abandoned or filled and did not pick up a prescription at the pharmacy. Having only one competitor product on the market may not be enough competition to impact cost. A Food and Drug Administration (FDA) analysis of retail generic drugs between 1994 and 2004 showed only a small reduction in price compared to the brand product when one competitor entered the marketplace (94% of brand price) and a greater drop in price when two competitors entered the market (52% of brand price)¹⁰.

ACP's Clinical Guidelines Committee advises that generic drugs should be prescribed whenever possible rather than more expensive trade-name drugs¹¹. **ACP policy supports policies or**

⁷ Entis, Laura. "DTC pharma ad spending slipped 4.6% in 2017: Kantar" *MM&M*. March 12, 2018. Accessed at <https://www.mmm-online.com/commercial/dtc-pharma-ad-spending-slipped-46-in-2017-kantar/article/750421/>

⁸ Klara K, Kim J, Ross JS. Direct-to-Consumer Broadcast Advertisements for Pharmaceuticals: Off-Label Promotion and Adherence to FDA Guidelines. *J Gen Intern Med*. 2018 May;33(5):651-658. doi: 10.1007/s11606-017-4274-9.

⁹ Association for Accessible Medicines. Generic Drug Access & Savings in the U.S.: Access in Jeopardy. 2018. Accessed at <https://accessiblemeds.org/sites/default/files/2018-07/AAM-2018SR-070918-D.pdf>

¹⁰ U.S. Food and Drug Administration. Generic Competition and Drug Prices. Accessed at <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm>

¹¹ Choudhry NK, Denberg TD, Qaseem A, for the Clinical Guidelines Committee of the American College of Physicians. Improving Adherence to Therapy and Clinical Outcomes While Containing Costs: Opportunities From the Greater Use of Generic Medications: Best Practice Advice From the Clinical

programs that would increase brand-name and generic drug competition, particularly for those sole-source products, and the College supports the FDA’s Drug Competition Action Plan, enhanced opportunities for information sharing between manufacturers and physicians, and closing loopholes that allow certain manufacturers to “game” the system. HHS solicits comments on access to reference product samples and specifically, if there are actions that could be taken to facilitate access to products that are under distribution such as Risk Evaluation and Mitigation Strategies (REMS) limitations imposed by the manufacturer. ACP supports the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act which address the anti-competitive practice of brand manufacturers unnecessarily denying samples to generic manufacturers to prevent a generic from coming to the market¹². The CREATES Act is a narrowly focused solution that provides injunctive relief for generic manufacturers who have exhausted all other avenues in obtaining a sample, including seeking assistance from the FDA. Current patent protection and market exclusivity policies may also create challenges to lower-cost generic drug or biosimilar entry. **ACP opposes extending market or data exclusivity periods beyond the current exclusivities granted to small-molecule, generic, orphan, and biologic drugs. ACP supports robust oversight and enforcement of restrictions on product-hopping, evergreening, and pay-for-delay practices as a way to increase marketability and availability of competitor products.**

Additionally, The Blueprint identifies that HHS supports improved availability, competition, and adoption of biosimilar drugs and solicits comments on what resources or tools may be useful to health care professionals and patients to build confidence about the safety and efficacy of biosimilars. Lower-cost alternatives to higher priced biologic drugs, biosimilars are likely to result in cost savings to plans and patients. RAND estimates the potential cost saving of biosimilars to be \$54 billion over 10 years, variable by class¹³. **ACP believes that biosimilar drug policy should aim to limit patient confusion between originator and biosimilar products and ensure safe use of the biosimilar product to promote the integration of biosimilar use into clinical practice.** Building on the generic experience, resources should help to communicate to physicians the regulatory standards for approval and naming practices between biosimilar and reference products which may cause confusion for physicians and patients.

Understanding and Assessing Value

The concept of value, the benefit of a drug relative to its cost, takes on a different meaning subject to the person or entity considering it. Patients may find more value in lower levels of toxicity from a drug than the cost of the drug, whereas others may emphasize price over other novelty. When attempting to incorporate value into the drug pricing policy conversations, HHS

Guidelines Committee of the American College of Physicians. Ann Intern Med. 2016;164:41–49. doi: 10.7326/M14-2427

¹² American College of Physicians. Letter to Senate Judiciary Committee Leaders. Accessed at https://www.acponline.org/acp_policy/letters/senate_letter_in_support_of_creates_act_2017.pdf

¹³ Mulcahy AW, Hlavka JP, Case SR. Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Santa Monica, CA: RAND Corporation, 2017. <https://www.rand.org/pubs/perspectives/PE264.html>.

should engage physicians, patients, public and private health plans, manufacturers, and government officials to create a harmonized understanding of value in prescription drug pricing, cost, and potential value-based payment. **ACP supports research into novel approaches that would further value-based decision making and encourages research into policies that would tie price to innovations and clinical value such as value frameworks, bundled payments, indication-specific pricing, or evidence-based benefit designs that include explicit consideration of the pricing, out-of-pocket cost, value, and comparative effectiveness of prescription medications.**

The request for information solicits comments on whether Medicare or Medicaid should pay the same price for a drug regardless of the diagnosis for which it is being used. ACP supports study of whether or not indication-specific pricing would result in cost savings and what, if any, unintentional negative outcomes such as a reduction in access to certain medications, might result from such a proposal. The independent and non-partisan Institute for Clinical and Economic Review identified as a potential policy recommendation that indication-specific pricing could be tested through the Centers for Medicare and Medicaid Innovation¹⁴. Policymakers should also take into consideration patient individuality and physician discretion when considering whether or not to develop indication-specific pricing models. ACP believes physicians should have the ability to continue prescribing covered drugs for accepted off-label uses when they feel in their professional judgment it is an appropriate course of treatment for a patient.

Additional Comments

Part of President Trump's FY2019 Budget Request includes a 5-part plan which supports reducing the minimum number of drugs required in each category or class from two drugs to one as well as expanding the ability of plans to use utilization management tools for specialty drugs or drugs in the six protected classes. ACP is concerned that relaxing Medicare Part D formulary standards could result in reduced access to needed medication, restrictive plan formularies, greater burden in accessing medications, or difficulties for beneficiaries in finding plans that cover all their medications¹⁵.

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 upon the drug's effectiveness, safety, and ease of administration rather than solely based on cost. Furthermore, physicians' adherence to evidence-based,

¹⁴ Pearson SD, Dreitlein B, Henshall C. Institute for Clinical and Economic Review. Indication-Specific Pricing of Pharmaceuticals in the United States Health Care System: A Report from the 2015 ICER Membership Policy Summit. March 2016. Accessed at https://icer-review.org/wp-content/uploads/2016/03/Final-Report-2015-ICER-Policy-Summit-on-Indication-specific-Pricing-March-2016_revised-icons.pdf

¹⁵ Cubanski J. What's in the Administration's 5-Part Plan for Medicare Part D and What Would it Mean for Beneficiaries and Program Savings? Kaiser Family Foundation Issue Brief. June 2018. Accessed at <https://www.kff.org/medicare/issue-brief/whats-in-the-administrations-5-part-plan-for-medicare-part-d-and-what-would-it-mean-for-beneficiaries-and-program-savings/>

scientifically supported practice guidelines should result in payment without excessive demands for documentation and without filing appeals.

Conclusion

We appreciate the opportunity to comment on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs and your consideration of our comments. We welcome the opportunity to further work with the Department to address the critical issue of high prescription drug prices. Please contact Hilary Daniel, Senior Analyst, Health Policy and Regulatory Affairs, by phone at (202) 261-4546 or via email at hdaniel@acponline.org with any further questions or if you need additional information.

Sincerely,



Ana Maria Lopez, MD, MPH, FACP
President
American College of Physicians