July 11, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted via www.regulations.gov

RE: **Request for Information: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs**

Dear Secretary Azar,

The Alliance of Community Health Plans (ACHP) applauds the administration's efforts to address the unsustainable cost of prescription drugs. We appreciate the opportunity to comment on the *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* and are committed to working with the Department to implement solutions that provide immediate and long-term relief for consumers from high drug prices.

ACHP is a national leadership organization bringing together innovative health plans and provider groups that are among America's best at delivering affordable, high-quality coverage and care. The non-profit, provider-aligned health plans that are ACHP members provide coverage in all lines of business for more than 21 million Americans across 32 states and the District of Columbia.

Our members have a long history of managing medical costs while also ensuring that patients we serve have access to innovative therapies. However, our plans' ability to successfully restrain drug spending is reaching its limit.

Inefficiencies in the market coupled with abuses by pharmaceutical manufacturers that stifle competition, have resulted in unaffordable drug prices for consumers, employers, plans and the government. Only the federal government can remedy this situation.

1825 Eye Street, NW, Suite 401 | Washington, DC 20006 | p: 202.785.2247 | f: 202.785.4060 | www.achp.org

The most important course of action the administration can take is to address the prices set by manufacturers. High prices solely determined by manufacturers are responsible for the situation we find ourselves in today.

We offer the following legislative and regulatory recommendations to begin to address the problem of escalating drug prices:

1. Vigorously support the bipartisan efforts already underway in Congress to improve competition and transparency in the pharmaceutical market;

2. Reform the way rebates are utilized to improve negotiations between health plans and drug manufacturers;

3. Adopt established market-based tools utilized under Medicare Part D in Part B;

4. Provide health plans with more flexibility and stronger tools to manage drug costs under Medicare Part D;

5. Implement pilot projects around value-based pricing for drugs;

6. Enhance efforts through a new demonstration project to educate health care providers about the safety and potential savings of using biosimilars.

I. Legislative and Regulatory Solutions to Improve Competition and Transparency

ACHP urges the administration to actively support passage of the *Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act*, bipartisan legislation to eliminate drug company tactics to delay generic competition, such as preventing access to samples necessary to demonstrate that a generic product is equivalent to a branded drug.

We appreciate the Food and Drug Administration's efforts to rein in some of these abuses. However, we believe a legislative solution is needed to ensure that reforms are memorialized in statute and cannot be easily undone.

ACHP also urges the administration to support passage of the *Fair Accountability and Innovative Research (FAIR) Drug Pricing Act,* bipartisan legislation that would provide needed transparency on the way prescription drug prices are set – including information on planned price hikes by companies and advertising and research and development costs. Building an information base about pricing is an essential first step to addressing the issue of high drug costs.

ACHP is committed to promoting price transparency in health care to help consumers make informed purchasing decisions. We applaud the administration for its proposal to require drug companies to display prices of their products in direct-to-consumer advertising and inform physicians of those prices in order to avoid over-utilization of high-cost medicines. We suggest

the Wholesale Acquisition Cost (WAC) as the most relevant cost marker for consumers and purchasers alike so that transactions are transparent at all levels and across the prescription drug supply chain.

II. Reforming the Rebate System

We welcome the administration's attention to rebates in the Medicare Part D program. ACHP believes the use of rebates is in need of systemic reform to improve transparency and negotiations between health plans and manufacturers, including the possibility of reducing the utilization of rebates or eliminating their use altogether.

Unless a health plan operates as its own pharmaceutical benefits manager (PBM), insurers have little visibility on negotiations between a manufacturer and the PBM. This lack of information available to health plans distorts the market, masks true utilization trends and potentially leads to higher drug prices.

Plans that utilize commercial PBMs have no way of knowing how much of the rebate provided by the manufacturer is actually passed on to them. Reducing or completely eliminating rebates to facilitate more transparent negotiations between insurers and manufacturers could ultimately lower drug prices for consumers.

Some health plans have developed alternatives to address how rebates are handled that could serve as a model. For example, Dean Health Plan in Wisconsin established a PBM, Navitus Health Solutions (now a division of SSM Health) to provide full transparency in the rebate process. The arrangement provides 100 percent pass-through of the rebate dollars and a separate per member fee for administrative and other expenses. Other health plans, such as Harvard Pilgrim Health Plan, have entered into value-based contracts in which the rebate serves as a value-based refund. These models should be encouraged to continue.

To lay the groundwork for reforming any future rebate system, we encourage HHS to explore potential implications, including:

- **Overall Costs** – Manufacturers should be required to incorporate 100 percent of the eliminated rebates into the price of the products. Otherwise, the policy could have the unintended consequence of increasing overall costs and premiums.

- **Premiums** – Premiums are a major factor in a beneficiary's choice among Part D plans as well as decisions on participating in the program altogether. Rising Part D premiums, in the absence of other policy changes to reduce the impact on beneficiary out-of-pocket costs, could lead to fewer seniors enrolling and reduced access to prescribed medications. If that happens, the risk pool would deteriorate, reducing the long-term sustainability of the Part D program.

- **Impact on Formularies** – PBMs generally negotiate rebates and serve as plans' intermediaries with manufacturers. Because rebates are typically negotiated in exchange

for securing a drug's inclusion in a plan's formulary, the effect of phasing out rebates on formularies should be studied.

The administration sought comment earlier this year on potential policy approaches for applying manufacturer rebates and pharmacy price concessions to the price of a Part D drug at the point of sale. We believe that proposal would have shifted costs without addressing the underlying issue of high drug list prices. We expressed our concern about the consequences for consumers and the administrative complexities and operational burdens on our member plans. Our earlier recommendations on point-of-sale rebates can be found here.

III. Better Management of Drugs Covered by Medicare Part B

ACHP recommends establishing effective medical and utilization management strategies in Medicare Part B, similar to those currently employed in Medicare Part D, in order to improve competition and reduce costs. We encourage CMS to identify statutory changes necessary to provide these tools to Part B plans. We also recommend that CMS design and implement demonstration projects through the Center for Medicare and Medicaid Innovation to transition selected Part B drugs to Part D and examine the impact on costs to beneficiaries, plans and the federal government. Any evaluation should focus on the impact for consumers on premiums, access to medications, Part D plan choices as well as overall access to coverage for prescription drugs.

ACHP recommends CMS explore options for incorporating in Part B effective market-based tools used successfully in the Part D program to lower drug spending. Our plans have extensive experience using benefit and formulary designs and other tools to keep costs low and premiums stable for consumers. Some of these may require statutory change.

Part D mechanisms that could be used in Part B include utilization management, payment tiers and value-based designs. These strategies encourage consumers to use the most effective treatments and facilitate successful price negotiation. As CMS considers these steps, we urge the agency to assess the potential effects on beneficiaries and minimize any unintended consequences.

ACHP further recommends that CMS explore opportunities to untangle and clarify the overlapping coverage policies for drugs that are reimbursed under Part B on some occasions and under Part D on others. One such approach, proposed in the President's FY 2019 Budget, would be to move some Medicare Part B drugs to Medicare Part D.

Overlapping coverage issues make administering benefits complex and cause confusion for beneficiaries, pharmacists, physicians and plans. It can result in delays or denials of necessary drugs or devices, for example, denials of certain insulin pumps under Part B because they were not accompanied by insulin claims which were submitted under Part D.[1] Clearer definitions of

[1] See https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/correct-coding-insulin-used-with-continuous-external-insulin-infusion-pumps.

Part B *v*. Part D drugs and coverage guidelines would allow plans to better manage pharmaceuticals across all covered drugs.

CMS will need to consider carefully the coverage and financial implications of moving drugs from Part B to D, including the impact on beneficiary access to drugs, drug plans and on premiums in particular:

- 11 million Part B enrollees do not currently have Part D coverage. If high cost or life-saving treatments are shifted to Part D, those beneficiaries may lose access to their existing coverage.

- Most Part B beneficiaries have some form of supplemental coverage. For those whose supplemental plans cover their Part B deductibles and coinsurance, a shift of drugs to Part D will cause their copayments to rise.

- Shifting drugs from Part B to Part D could increase beneficiaries' copayments even without supplemental coverage. A beneficiary's copayments for drugs whose total costs are below about $8,000 (approximately at the Part D catastrophic coverage threshold) are often much lower under Part B compared with Part D. That is the case because their share of Part B costs is 20 percent, whereas their share of Part D costs below the catastrophic threshold is between 25 and 40 percent. A recent analysis of 2016 drug costs confirmed this, estimating that average out-of-pocket costs were about 33 percent higher for Part D-covered new cancer therapies than for those covered in Part B.[2]

IV. Better Management of Drugs Covered by Medicare Part D

ACHP has long supported improvements to the Part D program to enhance plans' ability to negotiate with pharmaceutical manufacturers, manage drug coverage and more quickly respond to changes in the pharmaceutical landscape. We appreciate that CMS has moved in this direction and recommend additional flexibility and stronger tools including:

- Eliminating the protected classes of drugs entirely which have only served to insulate manufacturers from market competition and negotiated prices. Absent this step, Part D sponsors should only be required to include one category or class in their formulary.

- Allowing Part D plans to make mid-year formulary or benefit design changes to address price increases for sole-source generic drugs. This would build upon a recent regulatory change for plan year 2019 allowing Part D plan sponsors to immediately substitute newly released equivalent generics for brand name drugs at the same or lower cost sharing.

---

[2] M. Brow, R. Kane, Avalere Analysis highlights Complexities of Transitioning Medicare Part B Drugs into Part D, Avalere, May 2018, http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d.

- Limiting routine physician exception requests to formulary requirements. These exceptions undermine formulary tiering and other criteria, which are developed by pharmacy and therapeutics committees comprised of pharmacists, primary care physicians and specialists to allow Part D plans to provide clinically sound, cost-effective and affordable pharmacy benefits. For a limited number of exceptions, physicians should be required to provide a clinically-driven rationale specific to an individual patient's needs.

- Eliminating the "any willing provider" rule for pharmacies so that Part D plans have the ability to use tiered or closed networks. Narrow networks can be beneficial for consumers by facilitating better care coordination and cost management for selected specialty medications.

- Eliminating cost-sharing for generics, including biosimilars, to the greatest extent possible under the statute for the millions of beneficiaries receiving the Low-Income Subsidy.

V. Demonstration Projects on Value-Based Pricing for Drugs

ACHP encourages the administration to implement demonstration projects through the Center for Medicare and Medicaid Innovation (CMMI) to test pharmaceutical value-based pricing contracts.

One barrier identified to value-based contracts is the Medicaid best-price rule. A permanent solution may require a legislative change. However, we encourage CMS to use its demonstration and waiver authorities to relax the best price rule to facilitate experimentation with novel pricing models, including outcome-based pricing.

ACHP also encourages CMMI to implement a demonstration project that would link reimbursement to the evidence supporting therapeutics approved through one of FDA's accelerated approval programs. Drugs approved through an accelerated approval pathway may rely on less evidence than products that undergo FDA's normal review process. Despite limited evidence supporting these products, typically they are fully reimbursed by payers including Medicare and Medicaid.

ACHP encourages the Department to explore demonstrations that would address this issue. For example, products approved through an accelerated approval pathway with limited evidence could receive a reduced reimbursement rate at the time of approval. Reimbursement would increase over time as the manufacturer generates additional evidence demonstrating the effectiveness of their product.

ACHP also recommends linking reimbursement to evidence-based standards, including initial pricing assessments developed by the Institute for Clinical and Economic Review. ICER, as an independent and non-partisan research organization, evaluates the clinical and economic value

of prescription drugs by carefully examining all available clinical data and convening key public stakeholders across the health care delivery system.

VI. Supporting a Robust Biosimilars Marketplace

Health plans and professional societies, in partnership with the administration, must lead the way in educating health care providers and building their comfort levels with these complex product substitutions.

ACHP health plans are characterized by close relationships with providers either through integrated delivery systems or carefully managed networks. As a result, we are uniquely positioned to model biosimilar education efforts for the insurance industry as a whole. We have previously shared several concepts with CMS and FDA regarding how our plans approach biosimilar adoption and welcome additional discussions with the Department.

Some member plans have experienced promising results through their efforts to encourage biosimilar adoption. For example, Kaiser Permanente used its existing strong partnership between pharmacists and physicians to review existing evidence as well as their own plan's experience as a small number of doctors began using biosimilars. The strategy consisted of two elements:

- Partnership: Pharmacists conducted extensive literature searches and shared the results with physician specialists in a fair, unbiased way. Together they discussed the FDA approval process for biosimilars, the rigor of testing a biosimilar and studies on switching to biosimilars in Europe. This established a comfort level that allowed physicians to start new patients on biosimilars and then eventually switch additional patients.

- Real world experience: As new starts and switches took hold, pharmacists helped to monitor the patients for adverse effects and disease control. After a few months showing the safety and efficacy in real world experience, other physicians felt comfortable transitioning to the biosimilar.

These and similar efforts to promote biosimilars are beginning to pay off. Kaiser Permanente was able to successfully switch most of its patients using Neupogen to the lower-cost biosimilar Zarxio. For Security Health Plan in Wisconsin, the drug cost plus rebate for the biosimilar Granix PFS 300 mcg/0.5 ml is 60 percent lower than the cost of Neupogen PFS 300 mcg/0.5 ml. This is a *savings of about $500* for every dose administered.

We recommend that CMS focus its efforts to promote biosimilars in two directions: 1) educating physicians about the safety of biosimilars and cost-saving opportunities they present to patients and the health system, and 2) ensuring appropriate reimbursement policies to incentivize the biosimilar market including the development and prescribing of biosimilar products.

Working together, we believe CMS and FDA can support clinicians and patients with information and tools about the benefits of biosimilars as they make treatment decisions. ACHP and its member plans are eager to partner with the Department to take full advantage of the innovative, lower-cost biosimilars being approved by FDA.

However, improving education about biosimilars is not enough. As the administration has recognized, biosimilars have not become as disruptive a force in the market as generics, largely due to the rate at which they are coming into the market and the pace of adoption. Factors such as nuisance patent lawsuits, obstacles to achieving interchangeability and financial incentives all play a role. We encourage the administration to use its regulatory authority to address these problems that have dampened the development and uptake of biosimilars.

VII. Conclusion

Thank you for consideration of ACHP's recommendations. We welcome the administration's engagement on this issue and look forward to working together to enact real and long-lasting change on behalf of American patients. Please contact me at cconnolly@achp.org if you have questions or require additional information.

Sincerely,

Ceci Connolly
President and CEO