January 21, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4180-P, P.O. Box 8013, Baltimore, MD 21244-8013

Submitted via www.regulations.gov

RE: CMS-4180-P, Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma,

The Alliance of Community Health Plans (ACHP) applauds the administration's continued efforts to address the high cost of prescription drugs. As a new Congress gets underway, 2019 represents a fresh opportunity for policymakers to work together to address this long-standing problem.

Year after year drugmakers are permitted to set exorbitant prices for their products. And year after year American patients, insurers and tax payers are expected to pay them. It is clear the industry cannot be left to police itself when it comes to pricing. Action must be taken by regulators and legislators to enact permanent, meaningful relief.

One important way to address the high cost of prescription drugs is to grant health plans the tools they need to more aggressively negotiate with drug manufacturers; an outcome the Center for Medicare and Medicaid Services (CMS or the agency) has already taken steps to achieve. We appreciate the opportunity to comment on CMS' most recent proposal to give health plans greater flexibility to lower drug prices and reduce out-of-pocket expenses under Medicare Advantage and Medicare Part D.

Improvements to Medicare Part D's Protected Class Policy

ACHP has long supported improvements to the Part D program to enhance health plans' ability to negotiate with drug manufacturers, manage coverage and more quickly respond to changes in the pharmaceutical landscape.

We appreciate that CMS has moved in this direction, particularly with respect to providing plans more flexibility to manage drugs that are included under the six protected classes. However, ACHP believes more aggressive measures can be taken to provide health plans with more negotiating power to lower the cost of prescription drugs paid for under Medicare.

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ACHP encourages CMS to eliminate the protected class policy entirely. This policy has only served to insulate manufacturers from market competition and negotiated prices. As the proposed rule itself notes, the circumstances that existed when the protected class policy was originally implemented have changed dramatically since the Part D program began.

An open coverage policy substantially limits Part D sponsors' ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes. While ACHP welcomes the changes the proposed regulation would make to enhance our members' negotiating power and management of these drugs, we firmly believe that this policy can be eliminated while still protecting consumer access to needed therapies.

There are other provisions and requirements that plan sponsors must comply with that protect beneficiary choice and access to needed therapies. CMS checks plan formularies to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes. This step is taken in order to satisfy the Medicare Modernization Act (MMA) requirement that a sponsor's categorization system does not substantially discourage enrollment by any group of beneficiaries. CMS also considers the specific drugs, tiering and utilization management strategies employed in each formulary and identifies outliers from common benefit management practices for further evaluation. Sponsors may be asked to provide written clinical justification for unusual benefit features that are identified as outliers.

Absent elimination of the protected class policy, ACHP supports CMS' proposals to grant plans the flexibility to exclude certain drugs. One of its proposals would allow health plans to exclude new formulations with the same active ingredient or moiety that do not provide a unique route of administration. We note, however, the proposed regulation does not offer a definition for "new formulation." ACHP urges the administration to provide additional clarity in the final rule on what types of products would be considered a new formulation under the regulation.

Finally, if CMS will not eliminate the six protected class policy, ACHP believes Part D sponsors should only be required to include one product from each category or class in their formulary.

Pricing Threshold for Protected Class Drug Formulary Exclusions

ACHP supports the administration's proposal to allow plans to exclude single source protected class drugs whose prices grow faster than the rate of growth of the Consumer Price Index for all Urban Consumers (CPI-U). We discourage CMS from using the Consumer Price Index for Prescription Drugs (CPI-PD).

As recent research suggests, the CPI-PD may have flaws in its methodology that could impact its accuracy. For instance, according to a recent paper released by economists at the Brookings Institute, "the Bureau of Labor Statistics must rely disproportionately on cash transactions that comprise only about seven percent of the retail market, raising concerns about the extent to which they are representative of the overall drug market."[1]

With respect to other aspects of the policy, ACHP believes the Wholesale Acquisition Cost is the best measure for assessing the increase in prices for drugs that could be excluded. We are also supportive of the proposed method for measuring the WAC baseline for products already on the market and products that enter the market after September 1, 2018.

[1] https://www.brookings.edu/wp-content/uploads/2018/01/es_20180103_bosworthcpiindexes_final.pdf

In the proposed regulation, CMS discusses its consideration of whether the agency should apply this price threshold exception to all drugs in the protected classes of a given manufacturer. For example, if a manufacturer makes three protected class drugs, but the WAC for only one of those drugs increases beyond the CPI-U from its baseline WAC, all three of those drugs could be excluded from the formulary. ACHP is supportive of this more aggressive approach. We believe this alternative approach would increase negotiating power of health plans and act as a stronger deterrent to drug manufacturers as they price their products.

Finally, ACHP is supportive of the agency's consideration of an approach where each year, CMS would produce a list of protected class drugs a Part D sponsor could exclude from its formulary. We believe it would be more effective for CMS to act as a central clearinghouse to monitor price increases and produce a list of drugs that could be excluded from Part D formularies for a given contract year.

Medicare Advantage and Step Therapy for Part B Drugs

ACHP, once again, thanks CMS for the new flexibilities it has granted health plans to use utilization management tools such as step therapy for Part B drugs. We believe these steps will help prevent overutilization of medically unnecessary health services and control costs. We agree with CMS that the ability to apply utilization management to Part B drugs will help to drive better deals and reduce drug costs for patients. We recommend the following improvements to the proposed policy:

- Under the proposed rule, MA plans would be permitted to apply step therapy only to new prescription starts. We believe that this restriction misses an important opportunity to encourage the use of lower cost biosimilars when determined to be interchangeable with a reference biologic product. We recommend that CMS finalize the policy to permit step therapy to apply, in addition to new starts, to existing biological use where an interchangeable biosimilar is expected to produce the same clinical result.

- Under the Biologics Price Competition and Innovation Act, an interchangeable biosimilar is a biosimilar that is expected to produce the same clinical result as the reference product in any given patient and the risk in terms of safety or efficacy of switching or alternating between biological products is no higher than using the reference product alone.[2] CMS should instruct Medicare Administrative Contractors to review Local Coverage Determinations (LCDs), and CMS should review National Coverage Determinations (NCDs) to identify and revise, wherever necessary, those NCDs or LCDs that would impose barriers on the ability of plans to apply step-therapy policies as intended under this proposed rule. LCDs and NCDs should ensure that plans may impose a requirement of prerequisite treatment with another pharmaceutical product or biosimilar before prescribing other products for any relevant indications consistent with the finalized rule.

- We request clarification of CMS' proposed requirement that savings resulting from step therapy be passed along to beneficiaries through rewards furnished as part of a drug management care coordination program. We expect that premiums will quickly be adjusted to account for any reduction in cost attributable to the step-therapy policy. As a result, any monetary rewards are likely to be available for only limited time - probably no longer than a single year. We are concerned that beneficiaries may perceive the loss of such rewards in the 2nd year of a step therapy program to be a penalty.

[2] P.L. 111-148.

Including Pharmacy Price Concessions in the Negotiated Price

ACHP appreciates the opportunity to communicate our concerns about the policy under consideration by CMS to apply manufacturer price concessions for Part D drugs at the point of sale. Our members work hard to ensure that enrollees have access to affordable medications through the combination of low and stable premiums and through plan benefit and formulary design. We believe that there are more direct and effective policies to achieve CMS' objectives than requiring Part D plans (and their PBMs) to pass along price concessions at the point of sale.

- Incorporating price concessions at the point of sale increases plan premiums, and therefore, federal subsidies for those premiums. Although CMS's impact analysis correctly anticipates a rise in premiums, we believe that it significantly understates the magnitude of that impact. The additional administrative costs of the policy would also have a significant impact on premiums because of the numerous operational steps needed to pass along concessions in point-of-sale prices.

- ACHP members are concerned about the operational challenges and administrative burden of the CMS outlined policy. Part D sponsors or their PBMs would need to make a number of system modifications which would add to sponsor's administrative costs. Incorporating those amounts at the point of service would not be straightforward: price concessions are often applied across a group of drugs and generally are not applicable to any single claim or product; they often depend on achieving certain manufacturers' product utilization or performance targets which a plan sponsor or its PBM cannot forecast very accurately; and actual amounts are not known until after the manufacturers examine the claims. Further, a considerable portion of price concessions are not received by the Part D plan until six to nine months after the sale date. Thus, the Part D plan sponsor would be required to front those discounts (presumably using a proxy estimate of those discounts) to enrollees at the point of service and then later recoup their discounts from plans.

- The financial and budgetary impact of CMS' proposal to modify the definition of negotiated prices to include pharmacy price concessions seems inconsistent with the administration's objectives to reduce pharmaceutical prices and protect the federal government's trust funds. CMS estimates that applying the proposed definition of negotiated prices across all phases of the Part D benefit including in the coverage gap would, over the 2020 to 2029 period, increase the federal costs of the Part D program by almost $17 billion; raise beneficiaries' share of premium by $5.6 billion; but save pharmaceutical manufacturers almost $6 billion. If not applied in the coverage gap, CMS estimates similar but slightly smaller budgetary impacts for the period: federal costs rise by almost $14 billion, beneficiaries' share of premiums rise by almost $5 billion; and manufacturers save almost $5 billion.[3]

- CMS indicates that one of the issues it seeks to address with the outlined policy is to improve price transparency. We do not agree. First, Part D plan sponsors are already required to report to CMS very detailed, drug-specific information on Part D price concessions and rebates and other components of the Part D Direct and Indirect Remuneration (DIR). It is unclear as to what additional information CMS may gain from requiring the price concessions to be passed through at the point of sale. In addition, the outlined point-of-sale policy could undermine the existing

[3] Under the policy, CMS estimates that beneficiaries' costs at point of sale would be lower so that on average, overall beneficiaries would experience savings. These savings may not be distributed evenly, however. Individual beneficiaries using discounted drugs would pay less for those drugs, while other beneficiaries would only experience higher premiums.

confidentiality between Part D plan sponsors and their PBMs, with the effect of diluting Part D plan competition.

- The application of the proposed revised definition of negotiated prices in the coverage gap appears to be inconsistent with the coverage gap program statute. Specifically, the definition of negotiated prices at section 1860D-14A(g)(6) of the Social Security Act (42 U.S.C. 1395w-114A(g)(6)) narrowly defines the term negotiated prices for purposes of the coverage gap program to be the regulatory definition of negotiated prices established by the agency as of March 23, 2010 with the exclusion of the dispensing fee component of that definition. By specifying the regulatory definition in existence on March 23, 2010, Congress limits the ability of the agency to make changes to that definition.

ACHP opposes CMS' pharmacy price concession policy because it is an administratively complex yet only partial solution to the concerns raised by large price concessions and rebates that are excluded from prices at the point of sale. We do however encourage CMS to continue to pursue policies to systematically reform the use of rebates and other price concessions to improve transparency and negotiations between health plans and manufacturers, including the possibility of reducing or eliminating the use of rebates altogether.

Improving transparency of pharmaceutical costs

ACHP is supportive of enhancing transparency within the pharmaceutical industry, including for patients and prescribers.

We support CMS' interest in including more information on drug coverage and costs for clinicians at the point-of- prescribing. ACHP believes that there are three critical pieces of information that every patient and prescriber should have access to when deciding on an appropriate therapy: clinical appropriateness, coverage and costs.

Accordingly, ACHP and its members are supportive of the potential Real Time Benefits Tools (RTBT) hold. RTBTs may be capable of integrating with prescribers' electronic prescribing (eRx) and electronic medical records (EMR) systems to provide complete, accurate, timely, clinically appropriate and patient-specific real-time formulary and benefit information to the prescriber.

Further, we believe such tools utilized across Part D would not only help lower drug expenditures for the Medicare program, but also improve patient outcomes. Incorporating drug coverage and cost information, including a beneficiary's copayment or coinsurance, at the point of prescribing can help improve medication adherence. Beneficiaries may abandon their prescription when taking it to a pharmacy to be filled because they learn it is not covered or too expensive. Providing that information up front in a healthcare provider's office can help prevent such scenarios from occurring.

However, we are concerned that there is little information about existing products and standards utilized across the industry. While supportive of the concept, we have serious concerns about this gap in information and the timeline in which the administration has proposed sponsors must comply with this provision. We urge CMS to withdraw this provision and work with industry, including health plans, to obtain more data so this policy can be executed in a way that benefits sponsors, health providers, patients and the Medicare program.

Finally, ACHP agrees that including additional information about negotiated drug price changes and lower cost therapeutic alternatives in the explanation of benefits (EOB) would help improve cost transparency of

Part D prescriptions and mitigate drug price increases in the Part D program. Accordingly, we are supportive of this provision.

Conclusion

In addition to the comments above on the proposed rule, we encourage CMS to consider providing additional flexibilities to health plans in future rulemaking and/or demonstration projects. Specifically, ACHP is supportive of the following changes that we believe would further enhance our members' ability to lower drug expenditures and costs:

- Limit 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.

- Eliminate 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.

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

Thank you for consideration of ACHP's recommendations. We welcome the administration's continued 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