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VIA ELECTRONIC DELIVERY

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington D.C. 20201

Re: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program [CMS-4182-P]

Dear Administrator Verma:

Amgen Inc. (Amgen) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) Medicare Advantage (MA) Program (Part C) and Prescription Drug Benefit Program (Part D) Proposed Rule for calendar year (CY) 2019, published in the Federal Register on November 28, 2017.¹ Amgen is a science-based, patient-driven company committed to using science and innovation to dramatically improve patient lives. Amgen is also dedicated to improving access to innovative drug and biological therapies and promoting high-quality care for Medicare beneficiaries.

As a threshold matter, Amgen supports the comments and recommendations from the Pharmaceutical Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO) and our comments provide additional feedback on the following issues:

- We support requiring pass through of a portion of manufacturer rebates at the point of sale to the beneficiary to lower beneficiary out of pocket costs. However, CMS should not base the pass through on the average rebate of the drug category or class, instead the rebate should be based on the specific product. We recommend CMS consider other mechanisms to protect the confidentiality of commercially sensitive information.

¹ 82 Fed. Reg. 56,336 (Nov. 28, 2017), hereinafter "Proposed Rule."

- CMS should treat biosimilars as branded products consistently throughout the Part D benefit, including with regard to cost-sharing and the mid-year generic substitution proposal.
- We disagree with the proposed tiering exceptions framework that limits exceptions to the same types of products. We also encourage CMS to require plans to make specialty tier drugs eligible for tiering exceptions.
- We support the proposal to add flexibility in the MA uniformity requirements to the extent flexibility lowers patient cost-sharing, and encourage CMS to adopt the same flexibility for Part D plans.
- CMS should ensure that proposed changes to maximum out-of-pocket and patient cost-sharing limits do not alter existing limits on cost-sharing for Part B drugs.

Below we address our comments on each of these issues in greater detail.

1. Amgen Supports CMS Requiring Pass Through of a Portion of Manufacturer Rebates at the Point of Sale to the Beneficiary. However, CMS Should not Base the Pass Through on the Average Rebate of the Drug Category or Class, the Rebate Should be Product Specific. We Recommend CMS Consider Other Mechanisms to Protect the Confidentiality of Commercially Sensitive Information.

In the Proposed Rule, CMS requests information regarding the application of manufacturer rebates and pharmacy price concessions to drug prices at the point of sale (POS). CMS's request stems, in part, from its analysis of negotiated rebates and price concessions showing that the negotiated price concessions have not been passed on to consumers at the POS.²

Amgen supports CMS's efforts to reduce Medicare beneficiary cost burden at the pharmacy counter by passing through a portion manufacturer rebates and pharmacy price concessions. Amgen believes that requiring pass through of a portion of manufacturer rebates to patients at the POS will help to decrease patient cost-sharing, thereby increasing patient access to needed drugs and biologicals. While Amgen supports the goal of reducing beneficiary cost-sharing in this manner, Amgen is concerned that such a requirement, if implemented incorrectly, could have unintended consequences that would disadvantage patients.

Amgen is very concerned with the idea that CMS raises of basing the pass through rebate amount on the plan's average rebate amount calculated for the rebated drugs in the same category or class.³ While Amgen appreciates CMS's concern with maintaining the confidentiality of the manufacturer-sponsor/PBM contracts with respect to any individual drug, this concept creates the potential for negative unintended consequences. For example, basing the rebate pass through on an average of a drug category or class could disadvantage manufacturers who provide larger discounts and the patients taking those drugs. That is, a manufacturer that offers a higher rebate on a drug in a given drug category or class could subsidize the entire therapeutic class by raising the average rebate amount to the advantage of other manufacturers in the same category or class. In that scenario, the manufacturer offering

² *Id.* at 56,419.

³ *See id.* at 56,422.

the lower rebate could benefit from a higher average rebate on the drug at the POS, while not offering that higher rebate to the plan. Further, patients taking those drugs with a higher manufacturer rebate could face higher POS cost-sharing than if the required minimum rebate pass through were not averaged across the class. If averaged by class or category, it could serve to reduce the overall rebates into the program as manufacturers would be less likely to provide optimal value to support their products if not guaranteed to be directly provided to the patient for which the product is prescribed and the rebate provided. This result could disincentivize manufacturers from offering higher drug rebates. Therefore, CMS should utilize a methodology that is based on product-level rebates and consider the alternative methodologies in the PhRMA comment letter to protect confidential information.

Amgen agrees with PhRMA's suggested approach to preserve confidentiality and allow room for negotiation by recommending CMS consider setting a minimum pass through requirement at a level meaningfully less than 100 percent. Additionally, we support CMS considering a multi-pronged approach as recommended by PhRMA. For example, PhRMA outlined an approach that allows the POS price to reflect the minimum of two or more different pass through calculations whereby the patient co-pay would be based on the method that results in the lowest price. As described in PhRMA's comment letter, this could be either a minimum percentage pass through of the rebate, no more than 25 percent above the negotiated true net price, or some other additional calculation. A multi-formula approach to determining the POS rebate amount could be an effective way to protect the confidentiality while ensuring that the pass through of rebates has a greater impact in reducing patient cost-sharing obligations. We note that analysis by the actuarial firm Milliman, which is included in the PhRMA comment letter, suggests that passing through 50 percent of manufacturer rebates and 100 percent of pharmacy concessions could result in up to \$73B in net savings to the federal government over ten years, even though costs would likely increase in the first year of implementation. Therefore, Amgen supports requiring a minimum pass through percentage coupled with a multi-formula calculation.

We are concerned that requiring plans to pass through a portion of rebates may result in behavioral changes that could impact beneficiary access to drug therapy, such as the implementation of more restrictive formularies, as reflected in the Milliman analysis included in the PhRMA comment letter. Therefore it will be important that CMS continue robust oversight to ensure that plans do not have discriminatory formulary designs. Additionally, CMS should consider improvements to the Part D risk adjustment model, including the addition of adjusters based on drug utilization. We note that beginning in the CY 2018 benefit year a subset of prescription drugs will be included in the risk adjustment model used for non-grandfathered plans operating in the individual and small group markets inside and outside the Affordable Care Act (ACA) Exchanges. In this model, there will be risk adjustment factors for diagnosis, the prescription drug category, and for a diagnosis / prescription drug category combination. The inclusion of prescription claims as indicators of chronic illness in the Part D risk adjustment model, along with the calibration of the model to reflect the expected costs associated with these claims, could help to ensure plans are compensated fairly and appropriately incentivize the optimal treatment of chronic disease (including drug therapy) which are key goals of risk adjustment.

Finally, Amgen opposes targeting the rebate requirement to only specific drugs or drug categories or classes with high price, high rebate arrangements.⁴ Limiting the pass through requirement to a subset of drug categories or classes would mean that beneficiaries would continue to experience higher cost-sharing for those exempted drugs and would not benefit from

⁴ *Id.* at 56,423.

the price reductions made available to the plan sponsor. For these reasons, Amgen encourages CMS to adopt a pass through requirement that applies to all rebated drugs.

2. Amgen Encourages CMS to Treat Biosimilars as Branded Products Consistently Throughout Part D

Although CMS had previously determined that biosimilars were not generics under Part D, CMS proposes to revise regulations to treat biosimilars as generics for the purposes of copayments for low income subsidy (LIS) individuals and non-LIS Part D enrollees in the catastrophic portion of the benefit. CMS indicates this proposal is in response to stakeholder concerns that the current approach may disincentivize beneficiaries from choosing lower cost alternatives.⁵ Amgen supports efforts to promote the development of a robust biosimilar marketplace in Medicare to help increase competition and cost savings. While Amgen supports the idea of ensuring LIS beneficiaries and non-LIS enrollees in the catastrophic phase have access to biosimilars, we have concerns with the CMS proposal to treat biosimilars as generic products in Part D. We appreciate the agency's efforts to clarify the intention to limit this proposal only to the non-LIS catastrophic cost-sharing and LIS cost-sharing, however, we believe that the proposed change could generate more confusion and potentially lead to conflation with other provisions in the Part D statute and regulations where generic drugs are mentioned (e.g., mid-year generic substitution, as discussed below). Importantly, biosimilars are different from generic drugs. For example, the FDA treats biosimilars differently than it does generic drugs, with a separate, lengthier, and more costly approval process and a greater analytical and clinical data burden than for generic drugs. In addition, biosimilars are made from proteins and are produced within living organisms, making it more difficult to create exact copies. We believe CMS's proposal to treat biosimilars as generic drugs for cost-sharing could lead to additional erosion of the important distinctions between biosimilar products and generic drugs. For these reasons, we do not think it is appropriate for CMS to selectively treat biosimilars as a generic drug under some components of the Part D benefit. Amgen recommends that CMS consistently treat biosimilars as branded products throughout Part D.

That said, should CMS finalize the proposed change to the regulation, Amgen urges CMS to retain the proposed regulatory language clarifying that the revised definition of generic applies only for the purposes of cost-sharing reductions under sections 1860D-2(b)(4) and 1860D-14(a)(1)(D)(ii)-(iii) of the Social Security Act.

3. Amgen Opposes Allowing Plans to Limit Tiering Exceptions to Tiers with the Same Types of Products, and Encourages CMS to Require Plans to Make Specialty Tier Drugs Eligible for Tiering Exceptions

CMS proposes updates to the tiering exceptions policy that would permit plans to limit the availability of tiering exceptions to a preferred tier that contains the same type of alternative drug(s) for treating the patient's condition. That is, CMS proposes that tiering exceptions for brand name drugs would be assigned to the lowest applicable cost-sharing associated with brand-name alternatives, tiering exceptions for biological products would be assigned to the lowest applicable cost-sharing associated with biological alternatives, and tiering exceptions for non-preferred generics would be assigned to the lowest applicable cost-sharing associated with

⁵ *Id.* at 56,417.

alternatives that are either brand or generic drugs. CMS also proposes to continue to allow plans to exempt specialty tier drugs from tiering exceptions.⁶

Amgen opposes allowing plans to limit tiering exceptions based on the type of drug needed to treat a patient's condition. First, this proposal could disadvantage patient access to needed biologicals. If, for example, there are no biological alternatives on a plan's formulary, under the proposed regulatory language, a plan could deny tiering exception requests for biologicals, which would leave the patient with potentially prohibitive higher cost-sharing obligations for a needed medication. Second, where a patient can demonstrate a medical need for a non-preferred biological over a preferred alternative drug, CMS should not allow plans to deny this request. As CMS described in the Proposed Rule, the tiering exception procedures are designed to "ensure that beneficiaries with a medical need for a non-preferred drug are afforded the type of drug access and favorable cost-sharing called for under the law."⁷ Limiting tiering exceptions to tiers with the same product type, regardless of whether the non-preferred alternative drug or biological is medically necessary for the patient, contradicts the basic purpose of tiering requests. For these reasons, Amgen opposes the proposed revisions, and instead recommends that CMS require plans to grant tiering exceptions for alternative drugs or biologicals that are of a different product type.

In addition, Amgen encourages CMS to reconsider its policy for allowing plans to exempt specialty tier drugs from tiering exceptions. The specialty exemption limits patient access to needed drugs by allowing plans to impose high cost-sharing obligations between 25 and 33 percent, without allowing those patients to appeal for lower cost-sharing amounts. Further, Amgen agrees with BIO in its recommendation that CMS regularly update the specialty tier eligibility cost threshold to ensure it does not unduly discriminate against vulnerable beneficiaries. Amgen echoes the concerns stated by PhRMA that CMS has yet to provide an update on the analysis on the impact of tiering exceptions for specialty medicines mentioned in the 2017 Call Letter.⁸

4. Amgen Recommends CMS Exclude Biosimilars from the Mid-Year Generic Substitution Proposal

CMS proposes to permit Part D sponsors to make mid-year changes as the result of the introduction of a new therapeutically equivalent generic drug.⁹ Consistent with our above comment regarding treating biosimilars as branded products throughout Part D, Amgen supports CMS's proposal to exclude biosimilars from any such changes and asks CMS to ensure that biosimilars are excluded from any generic substitution proposals going forward.¹⁰ More broadly, Amgen urges CMS not to adopt its proposed changes for mid-year substitutions of generics without advance notice. Amgen supports the current structure that requires advance notice as it protects patient choice and access to medical therapies while also allowing plans flexibility to make the appropriate substitutions that could reduce program and beneficiary

⁶ *Id.* at 56,372.

⁷ *Id.* at 56,371

⁸ CMS, Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter 203 (Apr. 4, 2016), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf>.

⁹ 82 Fed. Reg. at 56,413.

¹⁰ *Id.* 56,417

costs. Amgen believes the proposed changes would potentially compromise continuity of treatment for Part D beneficiaries and provide inadequate notice of such changes.¹¹ Amgen agrees with PhRMA and BIO that this proposal erodes necessary patient protections.

5. Amgen Supports the Proposal to Add Flexibility in the MA Uniformity Requirements to the Extent Flexibility Lowers Patient Cost-Sharing, and Encourages CMS to Adopt the Same Flexibility for Part D Plans

CMS proposes to allow MA plans the flexibility to reduce cost-sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees who meet specific medical criteria.¹² Amgen believes this increased plan flexibility aligns Medicare with value-based insurance design (VBID) trends seen in the commercial market and thus generally supports the proposal. For example, Amgen supports the proposed patient protections to guard against VBID being used in a discriminatory way by prohibiting plans from offering supplemental benefits for several disease conditions, while excluding other higher-cost conditions and requiring plans to treat similarly situated enrollees the same. However, Amgen is concerned that CMS has chosen to grant this flexibility through interpretation of existing regulations instead of through promulgation of revised regulations. Specifically, Amgen is concerned that the lack of regulatory language clarifying MA plan flexibility could allow MA plans to raise or otherwise make more burdensome patient cost-sharing obligations. Amgen thus urges CMS to promulgate regulatory language that would permit MA plan flexibility only for the purposes of reducing cost sharing for certain covered benefits and to offer lower deductibles for enrollees who meet specific medical criteria. This is consistent with CMS's goals of ensuring that plans have the flexibility to offer cost-sharing reductions tailored to beneficiary medical needs while adhering to the non-discrimination requirements.

Amgen also recommends that CMS adopt similar benefit and cost-sharing flexibility in Part D, provided that such flexibility is similarly limited to benefit plan design changes that lower patient out-of-pocket expenses. Exclusion of Part D drugs from the proposed increased benefit design flexibility could disadvantage patients with conditions routinely managed with prescription drugs, and allowing Part D plans to reduce patient out-of-pocket cost-sharing obligations -- for example, to encourage medication adherence -- is in line with the value-based insurance design changes CMS proposes to make for MA plans as well as with Part D's medication therapy management program. Amgen encourages CMS to adopt similar flexibility in Part D through regulatory language that limits plan flexibility to benefit plan design changes that lower patient out-of-pocket expenses.

6. Amgen Encourages CMS to Ensure that Proposed Changes to Maximum Out-of-Pocket and Patient Cost-Sharing Limits do Not Alter Existing Limits on Cost-Sharing for Part B Drugs

The Proposed Rule would make certain changes to regulations regarding maximum out-of-pocket (MOOP) limits.¹³ Amgen appreciates CMS's efforts to ensure that cost-sharing is not discriminatory and to establish future MOOP limits using the most appropriate data. CMS indicates that allowing plans the flexibility to offer lower voluntary MOOP limits can potentially

¹¹ *Id.*

¹² *Id.* at 56,360.

¹³ *Id.* at 56,361-62.

improve plan benefit design. However, Amgen is concerned that plans could use this flexibility to discriminate against vulnerable patients and to deter patients from accessing the care they need. Amgen appreciates that CMS has acknowledged this risk of discrimination and sets maximum cost-sharing limits for certain services in the annual Notice and Call Letter process in order to ensure that the cost-sharing obligations are not discriminatory.¹⁴ Amgen urges CMS to continue to ensure in the future that plans cannot discriminate against patients by imposing higher cost-sharing obligations for certain individual benefit categories, including Part B drugs. Specifically, Amgen urges CMS to continue the practice of capping maximum cost-sharing for Part B drugs to 20 percent or \$50 based on the cost-sharing for Part B drugs in Original Medicare.¹⁵

Amgen also recommends that CMS consider whether the lack of similar cost-sharing limits for Part D benefits creates the potential for Part D plans to discourage enrollment of certain beneficiaries. In particular, Amgen suggests CMS keep this potential for plans to discriminate against certain beneficiaries in mind as it evaluates the rebate pass through proposals discussed above. CMS should also consider future rulemaking to strengthen protections against discriminatory cost-sharing for Part D-covered drugs.

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We appreciate your consideration of our comments on the CY 2019 Medicare Advantage (MA) Program (Part C) and Prescription Drug Benefit Program (Part D) Proposed Rule. Please contact Jason Spangler, MD, MPH by phone at (202) 585-9659 or by email at jspangle@amgen.com if you have any questions regarding our comments.

Thank you for your attention to these important matters.

Regards,



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¹⁴ See, e.g., CMS, Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information 124-28 (Apr. 3, 2017), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf>.

¹⁵ *Id.* at 126.