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January 16, 2018

VIA ELECTRONIC SUBMISSION at www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
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; Proposed Rule(CMS-4182-P)

Dear Administrator Verma:

Novartis Services, Inc. is submitting this letter on behalf of Novartis Pharmaceuticals Corporation ("NPC"), Sandoz Inc. ("Sandoz") and Alcon Laboratories, Inc. ("Alcon"). We refer to NPC, Sandoz, and Alcon collectively herein as "Novartis." We appreciate the opportunity to provide comments in response to the *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* Proposed Rule issued on November 16, 2017 ("Proposed Rule") by the Centers for Medicare & Medicaid Services (CMS).

NPC researches, develops, manufactures, and markets innovative medicines aimed at improving patients' lives. We offer a broad range of medicines for cancer, cardiovascular disease, inflammatory disease, infectious disease, neurological disease, eye disease, organ transplantation, respiratory disease, and skin conditions.

Sandoz is a leader in generic pharmaceuticals and biosimilars, providing access to a broad portfolio of high-quality, cost-effective prescription drugs. Sandoz launched the first biosimilar approved under the Biologics Price Competition and Innovation Act pathway in the United States.

Alcon is a leader in the research, development, manufacturing, and marketing of eye care products, including surgical devices and vision care products.

Novartis' mission is to discover new ways to improve and extend people's lives. We use science-based innovation to address some of society's most challenging healthcare issues. We discover

and develop breakthrough treatments and find new ways to deliver them to as many people as possible.

I. Overview of Novartis' Comments

Novartis appreciates CMS' interest in obtaining stakeholder feedback regarding changes to the Medicare Part D benefit. Prescription medicines are a critical component of achieving positive health outcomes and improving quality of life for patients. Therefore, it is essential that patients are able to access the most appropriate medicines for their condition and circumstance. We encourage CMS to ensure that any policy changes preserve or expand patient access to affordable prescription therapies.

Our comments are focused on four aspects of the Proposed Rule: (1) the request for information regarding manufacturer rebates; (2) Part D tiering exceptions; (3) expedited substitutions of certain generics; and (4) treatment of follow-on biological products as generics in certain circumstances.

As discussed more fully below, we are particularly interested in ensuring beneficiaries share in the savings achieved through manufacturer rebates. In addition, we appreciate CMS' request for comments on the tiering exceptions proposals. We believe the exceptions process should apply to the specialty tier and urge CMS not to finalize any new barriers to the exceptions process. For purposes of the expedited substitution of generics, we urge CMS to require advance notice to beneficiaries, prior to the substitution. Such notice is important to avoid beneficiary confusion and, potentially, a disruption in therapy. We also applaud CMS' efforts to put forth policies designed to provide greater access to biosimilars in Part D. In furtherance of that goal, as discussed more fully below, we believe changes to the current structure of the coverage gap discount program must be made to incentivize increased use of lower-cost biosimilars in the Part D program.

II. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

In the Proposed Rule, CMS requests information on whether it should require Part D sponsors to include a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. CMS recognizes that manufacturer rebates and pharmacy price concessions have the potential to lower beneficiaries' premiums. However, the rebates and price concessions are not reflected in the beneficiaries' cost-sharing. CMS notes that Part D sponsors are allowed, but generally not required, to apply rebates and other price concessions at the point of sale to lower the price upon which beneficiary cost-sharing is calculated. CMS notes that "only very rarely" have sponsors elected to include rebates and other price concessions in the negotiated price at the point-of-sale.

We commend CMS for requesting information on this important topic. We share CMS' concern that beneficiaries and taxpayers are not benefitting from manufacturer rebates and discounts as

originally anticipated when the Part D program was established. We believe it is important to reduce beneficiary costs and better align incentives for Part D sponsors with the interests of beneficiaries and taxpayers.

While the sum of manufacturer rebates and discounts has greatly risen, currently amounting to over $100 billion per year, the price that patients pay for their prescription medicines has not comparably decreased.[1] In addition, the share of gross drug expenditures realized by non-manufacturer entities such as plan sponsors has increased. These expenditures are largely composed of the rebates and discounts paid by manufacturers.[2] In 2015, more than one-third of a brand medicine's list price was rebated back to health plans, the government, or kept by other stakeholders.[3] Rebates can reduce net cost of certain diabetes, asthma, high cholesterol, and hepatitis therapies by up to 30 percent to 55 percent.[4] However, patients are typically paying cost-sharing amounts based on the list price of the drug, which does not take into account these substantial discounts.

Novartis, like many other pharmaceutical manufacturing companies, negotiates with sponsors to provide rebates and price concessions on our products, which are intended to benefit the patient. In 2016, the gross price, or list price, of our products increased by 6.2 percent, but the net price, or the amount paid by sponsors, decreased by 2 percent. This difference is largely a result of the rebates and price concessions that were negotiated by sponsors and other stakeholders in the supply chain. In the U.S., the total amount of annual rebates and discounts on Novartis products increased from 38 percent in 2012 to 48 percent in 2016.[5] Unfortunately, patients are not receiving a corresponding discount when they pay for their prescription medicines.

We encourage the agency to implement a requirement that sponsors include a minimum percentage of manufacturer rebates and discounts in the drug's negotiated price at the point of sale to lower patient costs and better align incentives. We believe this change alone could result in significantly reduced costs for millions of beneficiaries and material savings for taxpayers. Importantly, as CMS explores this policy more fully, we urge the agency to ensure it maintains the confidentiality of proprietary information and avoids cross-subsidization of competing medicines, as we believe these requirements are critical to preserving competition. We appreciate that CMS appears to understand this concern and is interested in protecting the confidentiality of such information, including the manufacturer/sponsor/PBM pricing relationship with respect to an individual product.

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[1] The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized By Stakeholders. Berkeley Research Group (January 2017). Available at https://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf.

[2] *Id.*

[3] Follow the Dollar Report, Pharmaceutical Manufacturers of American (November 2017). Available at http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf.

[4] Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. QuintilesIMS (October 2016).Available at https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/estimate-of-medicare-part-d-costs-after-accounting-for-manufacturer-rebates.pdf?la=en&hash=7E7A1481237F5B1DC1547A629130EF2CB2E68652.

[5] Novartis 2016 US Transparency and Patient Access Report. Available athttps://www.novartis.com/sites/www.novartis.com/files/us-transparency-patient-access-report-2016.pdf.

III. Part D Tiering Exceptions

CMS proposes to revise existing policy related to tiering exceptions. As CMS recognizes in the Proposed Rule, under the current regulatory framework, there may be times when the tiering exceptions are applied more stringently than appropriate. Excessively restrictive tiering can impact enrollee access to therapies and/or require them to pay more for the therapy than they should. We believe that ensuring enrollee access to a properly functioning tiering exceptions process is critical. When the requisite criteria are met, these exceptions enable beneficiaries to obtain prescription drugs in a higher cost-sharing tier at the more favorable cost-sharing applicable to alternative drugs on a lower cost-sharing tier of the plan's formulary. However, we are concerned by CMS' proposal to allow plans to place additional limitations on tiering exceptions requests. For instance, CMS proposes limiting the exceptions process for certain drug types (e.g., brand, biologics, and follow-on biologics) to a preferred tier that contains the same type of alternative drug for treating the enrollee's condition. CMS also proposes an interpretation of "same condition" that we believe will limit exception requests and negatively impact beneficiaries. Given the importance of the exceptions process as a protection for beneficiaries, we urge CMS not to finalize any new barriers to tiering exceptions.

In addition, CMS proposes to retain the current regulatory provision that permits plan sponsors to disallow tiering exceptions for any drug that is on a plan's specialty tier. Patients with certain health conditions that require medication on a specialty tier are often particularly vulnerable. Prescription therapies, in these cases, can become cost prohibitive for individuals who rely on a specific therapy to sustain or improve their quality of life. As we have noted in previous comment letters, studies have found a link between cost sharing and medication adherence.[6] Nonadherence decreases health outcomes and increases cost to the health care system as a whole.[7] We encourage CMS to eliminate the tiering exemption for the specialty tier in future rulemaking, as this exemption effectively discriminates against beneficiaries needing drugs on the specialty tier and can lead to significant financial hardship or barriers to access.

Finally, CMS believes the proposed changes to the tiering exceptions regulations will make the process more accessible and transparent for enrollees. To that end, we encourage CMS to ensure that enrollees have easy access to plan information describing the tiering exceptions in plain language so they are better equipped to manage their care, including the associated costs.

IV. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

[6] Dusetzina SB, et al., Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. J Clin Oncol. 2014 Feb 1;32(4):306-11. Available at https://www.ncbi.nlm.nih.gov/pubmed/?term=J+Clin+Oncol.+2014+Feb+1%3B32(4)%3A306-118; and Doshi JA, et al., Impact of cost sharing on specialty drug utilization and outcomes: a review of the evidence and future directions. Am J Manag Care. 2016 Mar;22(3):188-97. Available at https://www.ncbi.nlm.nih.gov/pubmed/?term=Am+J+Manag+Care.+2016+Mar%3B22(3)%3A188-97.

[7] Egede LE, et al., Longitudinal effects of medication nonadherence on glycemic control. Ann Pharmacother. 2014 May;48(5):562-70. Available at https://www.ncbi.nlm.nih.gov/pubmed/24586059 ; and Aurel O Luga and Maura J McGuira, Adherence and health care costs. Risk Manag Healthc Policy. 2014; 7: 35–44. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/.

In this section, CMS proposes certain changes designed to provide plans with greater formulary flexibility, including enabling immediate generic substitutions for branded products in certain instances. More specifically, CMS proposes to permit Part D plan sponsors that meet the necessary requirements to immediately remove brand name drugs (or to make changes in their preferred or tiered cost sharing status) when those sponsors replace the brand drugs (or add to their formularies) therapeutically equivalent newly approved generics, rather than waiting until the direct notice and formulary change requests requirements have been met. The generic would need to be offered at the same or a lower cost-sharing amount and with the same or less restrictive utilization management criteria. This substitution policy would not apply to follow-on biologics. Under this proposal, enrollees would only have to be notified in advance that plans have the ability to make such changes. After making a substitution, plans would be required to provide information to affected enrollees (among others) about any specific generic substitutions that occur.

While we are supportive of generic substitution when appropriate, we are concerned about the lack of advance notice to beneficiaries prior to the substitution. In the Proposed Rule, as support for these changes, CMS refers to MedPAC recommendations made in 2016 relating to Part D. Those recommendations do include streamlining formulary changes to enable plans to remove brand-name drugs upon addition of therapeutically equivalent generics, but they do not change the beneficiary notice requirements. MedPAC's discussion of this proposal explicitly states that "[a]ffected enrollees would continue to receive a 60-day written notice before the formulary change…"[8] Like MedPAC, we believe it is important to retain this advance notice requirement for beneficiaries.

As a practical matter, without sufficient notice, many beneficiaries will show up at the pharmacy to get their prescription and will be confused and upset about a substitution for which they had no notice. The drug will look different than what they are used to and will unnecessarily lead to frustration. We urge CMS to require advance notice before substitution. Advance notice gives the beneficiary an opportunity to discuss the change with their provider so that, at a minimum, the beneficiary can understand the nature of the change and have an opportunity to ask questions of the prescriber. Advance notice minimizes any disruption or confusion associated with the substitution and makes it more likely that the beneficiary will continue the course of treatment as prescribed.

In this section, CMS also proposes to decrease the amount of direct notice for other mid-year changes from 60 to 30 days and to limit the 60-day refill requirement to one month. These are established protections for beneficiaries and we urge CMS not to diminish these as proposed.

V. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

[8] MedPAC June 2016 Report to the Congress. Available at http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.

CMS proposes to revise the definition of generic drug to include follow-on biological products solely for the purpose of non-LIS catastrophic cost sharing and LIS cost-sharing in any phase of the benefit. CMS makes clear that they do not consider follow-on biologics to be generics for any other purpose of Part D. CMS believes this provision would improve incentives to use follow-on products over reference products and reduce costs to Part D enrollees and the Part D program.

We applaud CMS for working to provide greater access to biosimilars. As a company, we have invested heavily in this space and understand the positive impact that can flow from a healthy biosimilar market, both in terms of patient access to lifesaving therapies and lower costs to patients and payers.

The emerging biosimilars market in the United States holds great potential to increase patient access to life-saving therapies, lower patient costs, and bring savings to the healthcare system broadly. A recent report from the RAND Corporation, a nonprofit research organization, estimates that biosimilars will lead to a "$54 billion reduction in direct spending on biologic drugs from 2018-2027, or about 3% of total estimated biologic spending over the same period, with a range of $24 to $150 billion."[9] However, savings hinge on a variety of factors, including regulatory and policy changes that shape the biosimilar market. CMS will play a critical role in the development of these important policies.

Within the context of the Medicare Part D program, currently, there is a disincentive to utilize biosimilars because they are excluded from the coverage gap discount program. The impact of this exclusion is significant and has implications for patients, Part D plans, and taxpayers. Under the current structure, patients face a higher cost sharing amount for biosimilars than for branded biologics and they remain in the coverage gap or "donut hole" longer as any discount offered to the plan on the biosimilar would not count toward the patient's true out-of-pocket costs. In addition, the cost of the biosimilar to the plan is higher, making it very unlikely for a plan sponsor to incentivize the use of biosimilars in Part D.[10] The exclusion of biosimilars from the discount program also costs taxpayers. A study conducted by The Moran Company in October 2017 estimates that inclusion of biosimilars in the coverage gap discount program could result in $1 billion in savings to the federal government.[11]

We encourage CMS to use its full authority to develop policy that removes the financial disincentive to utilize biosimilars given the current structure of the coverage gap discount program. To the extent the agency believes certain statutory changes are required, we encourage the agency to work with Congress in making those changes.

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[9] Mulcahy, Andrew W., Jakub P. Hlavka and Spencer R. Case. Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Santa Monica, CA: RAND Corporation, 2017. Available at https://www.rand.org/pubs/perspectives/PE264.html.

[10] As evidence of the concern with this issue, in its November meeting, the Medicare Payment Advisory Commission (MedPAC) discussed the need to refine the coverage gap discount program to "make it more likely that Part D plan sponsors put lower-priced biosimilars on their formularies." (p.15 of transcript). Available athttp://www.medpac.gov/docs/default-source/default-document-library/november-2017-transcriptsf1b311adfa9c665e80adff00009edf9c.pdf?sfvrsn=0.

[11] "Biosimilar Inclusion in Manufacturer Coverage Gap Discount Program: Fiscal Implications," The Moran Company (October 2017). Available at https://accessiblemeds.org/sites/default/files/2017-11/AAM-Biosimilars-in-Coverage-Gap-10-05-2017.pdf.

VI. Conclusion

Novartis appreciates the opportunity to comment on the Proposed Rule. As discussed above, we urge CMS to implement policies that will require beneficiaries to benefit from manufacturer rebates and price discounts. In addition, we appreciate CMS' request for comments on the tiering exceptions proposals. We believe the exceptions process should apply to the specialty tier and urge CMS not to establish any new barriers to the exceptions process. For purposes of the expedited substitution of generics, we urge CMS to require advance notice to beneficiaries, prior to the substitution. Such notice is important to avoid beneficiary confusion and, potentially, a disruption in therapy. We also applaud CMS' efforts to provide greater access to biosimilars in Part D and believe changes to the current structure of the coverage gap discount program must be made to incentivize increased use of lower-cost biosimilars in the Part D program. We strongly encourage the agency to continue engaging stakeholders on these issues to ensure the goal of increasing patient access to affordable treatment is appropriately advanced.

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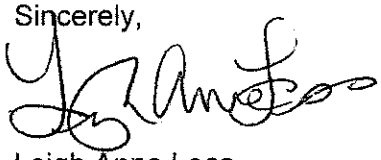
Novartis greatly appreciates CMS' consideration of these comments. We would be happy to discuss them at greater length. If you have any questions, please do not hesitate to contact me at (862) 778-3284.

Sincerely,



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