

March 5, 2018

VIA ELECTRONIC SUBMISSION at www.regulations.gov

Demetrios Kouzoukas
Principal Deputy Administrator and Director, Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

cc: Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter (CMS-2017-0163)

Dear Principal Deputy Administrator Kouzoukas,

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 *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter* ("Draft Call Letter") issued on February 1, 2018 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 the opportunity to provide feedback regarding the Draft Call Letter. Our comments are focused on seven aspects of the Draft Call Letter: (1) Enhancements to the 2019 Star Ratings and Future Measurement Concepts; (2) Medicare Advantage Value-Based Insurance Design; (3) Health Related Supplemental Benefits; (4) Medicare Advantage Uniformity Flexibility (5) the Medication Therapy Management Annual Cost Threshold; (6) Tier Composition; and (7) Specialty Tiers.

II. Enhancements to the 2019 Star Ratings and Future Measurement Concepts

In the Draft Call Letter, CMS proposes ways to continue to improve the Star Ratings Program. We applaud this continued push for improvement in quality of care provided by MA and Part D plans. First, Novartis applauds CMS in its efforts to propose both new measures and changes to existing measures that will ensure that the full measures set remains consistent with clinical guidelines and updates being made by the measure stewards. In particular, the National Committee for Quality Assurance (NCQA) is in the process of making changes to its measures so that the measures accurately reflect current treatment guidelines, thus CMS is attempting to remain in lock-step with the measure steward by proposing changes and giving ample notice to plans of upcoming changes. This is a critically important step in the measure lifecycle and maintenance process. When guidelines and measures are out of sync, they can be a source of confusion and potentially prevent patients from accessing appropriate care.

Second, CMS states that the Categorical Adjustment Index (CAI) will be applied for certain measures as a way to apply sociodemographic status risk adjustment, while continuing to research how, why, and when such adjustment should be made. We recognize that sociodemographic status plays a part in how some patients access and react to health care, which in turn, affects a plan's quality measure scores. We support CMS's efforts to ensure a level playing field for plans but also encourage CMS not to eliminate any disparities in care, through risk adjustment, that otherwise might be revealed in measure scores. For measures where the measure steward has recommended reporting a stratified rate for non-low income subsidy (LIS)/dual-eligible/disabled populations alongside separate rates for the LIS/dual-eligible/disabled populations, CMS could construct a new improvement metric to encourage plans to address and ameliorate health care disparities. CMS could also consider use of new structural measures to assess if plans have appropriate supports in place for LIS/dual-eligible and/or disabled populations to achieve optimal health outcomes.

Third, CMS is considering inclusion of telehealth and remote access encounters in four measures. In order for these new encounter opportunities to occur, we assume that MA plans would provide coverage and payment for these activities. To the extent that is the case, we support improving

access to care, including through remote technologies, since such technologies can aid physicians and other clinicians in managing care and hold promise in providing more regular monitoring.

CMS proposes removal of an asthma measure, Asthma Medication Ratio, as a result of NCQA's removal of the Medicare population as one of the denominator populations for this measure. This measure assesses whether patients are receiving necessary controller medications so that they are not overly reliant on rescue inhalers. We are concerned that this measure is being removed without any proposal of a new measure for evaluating appropriate medication control of asthma. Asthma is a common chronic condition in the Medicare population; in fact, according to the Medicare Chronic Conditions Dashboard, using 2015 data, asthma is the 11th most prevalent chronic condition among Medicare beneficiaries.¹ Removal of this measure would create a measurement gap in the Star Ratings measure set. We encourage CMS to work with measure developers on ways to evaluate proper management of asthma in older adults.

Lastly, CMS states that a new measure that evaluates Adherence to Non-Infused Disease Modifying Agents Used to Treat Multiple Sclerosis is being considered for future inclusion. Novartis supports inclusion of this measure. We have long been a leader in the treatment of multiple sclerosis. We recognize that adherence is needed to achieve optimal efficacy and better health outcomes.

III. Medicare Advantage Value-Based Insurance Design

As the agency notes in the Draft Call Letter, the Medicare Advantage Value-Based Insurance Design (MA-VBID) test is an opportunity for Medicare Advantage Organizations (MAOs) to offer supplemental benefits or reduced cost sharing to enrollees with CMS approved chronic conditions, focused on the services that are of highest clinical value to them. Specifically, the model is testing whether the additional flexibility provided to MAOs to develop and offer interventions can improve health outcomes and lower expenditures for MA enrollees.

Novartis is supportive of efforts to move from volume-based reimbursement to value-based reimbursement and we have continuously engaged with both CMS and the private sector in developing these models. We believe VBID offers an opportunity to increase quality of care and health outcomes, while also lowering costs. We understand that in the MA-VBID test, enrollees can never receive fewer benefits or have to pay higher cost-sharing than other enrollees as a result of the model. We believe this is an important feature, critical to protecting beneficiaries. As with any value-based design, we encourage CMS to ensure the model consistently enables patient access to therapies, including prescription drugs that meet their needs.

We support CMS's efforts to advance VBID models and encourage the agency to continue to seek stakeholder feedback as it moves forward.

¹ Medicare Chronic Conditions Dashboard; Comparison of Geographic Areas by Chronic Conditions, 2015. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/chronic-conditions-state/cc_state_dashboard.html. (accessed 26 February 2018)

IV. Health Related Supplemental Benefits

Currently, CMS defines a supplemental health care benefit as an item or service (1) not covered by Original Medicare, (2) that is primarily health related, and (3) for which the MA plan must incur a non-zero direct medical cost. CMS has interpreted a “primarily health related” item or service as one with the primary purpose of preventing, curing, or diminishing an illness or injury. Under this interpretation, the agency has not previously permitted an item or service as a supplemental benefit to the extent its primary purpose is daily maintenance.

In the Draft Call Letter, CMS recognizes the value of certain items and services that can diminish the impact of injuries or health conditions and reduce avoidable emergency and health care utilization. CMS proposes to expand the scope of the supplemental benefit standard such that MA plans may offer additional supplemental benefits as long as they are healthcare benefits. To accomplish this change, CMS proposes the following new interpretation of “primarily health related”: the item or service must diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. CMS makes clear that supplemental benefits will not include items or services solely to induce enrollment. We appreciate CMS’s interest in seeking stakeholder feedback as it prepares to issue detailed guidance for MAOs on this topic.

Novartis supports the agency’s expanded interpretation of items and services that would qualify as a supplemental health care benefit. This new interpretation will allow MA plans greater flexibility in providing such benefits to beneficiaries. We believe this expansion of benefits will increase treatment options and provide patients with more opportunities to manage their health. We encourage the agency to implement this new interpretation broadly and to make certain that supplemental benefits are offered as part of a comprehensive care plan that incorporates the value of prescription therapies, as appropriate. We agree that items and services offered solely to induce enrollment would not meet the standard of a supplemental health care benefit.

V. Medicare Advantage Uniformity Flexibility

In the Draft Call Letter, CMS has determined the agency has the authority to permit MA organizations to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees are treated the same and have the same access to targeted benefits. CMS indicates that such flexibility is not unlimited and, as such, MA plans are prohibited from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health-status related factors. CMS reminds MA plans considering implementation of flexibility in the uniformity requirements that they must ensure compliance with non-discrimination responsibilities and obligations.

Novartis supports the agency’s proposal to enable greater flexibility under the uniformity requirements. We believe this additional flexibility has the potential to better align incentives, leading to care that is higher in value. We appreciate CMS’s efforts to ensure the additional flexibility does not result in discriminatory benefit designs. We urge the agency to take proactive

steps to prevent and identify potential discrimination that would undermine the goals of this proposal. For purposes of monitoring compliance with the non-discrimination responsibilities, we encourage the agency to collect relevant data from plans that would assist the agency in protecting beneficiaries from discriminatory practices. Such data could include beneficiary cost-sharing amounts and the rationale for additional benefits along with the impact of those benefits on quality, outcomes, costs and overall value. Finally, the agency should ensure transparency with respect to a plan's offerings so beneficiaries fully understand what they are purchasing, including the associated costs and full scope of the benefit.

VI. Medication Therapy Management Annual Cost Threshold

Generally, enrollees must meet the following criteria to participate in a Part D plan's Medication Therapy Management (MTM) program: (1) have multiple chronic diseases; (2) take multiple Part D drugs; and (3) are likely to incur annual Part D drug costs that meet or exceed a certain threshold. CMS proposes that the 2019 MTM program annual cost threshold will be the 2018 annual cost threshold of \$3,967 increased by the annual percentage increase (API), which will be finalized in the 2019 Call Letter.

We recommend the agency lower the annual Part D cost threshold and, in turn, allow more beneficiaries to benefit from MTM as it can increase medication adherence and help ensure that patients are taking their medications correctly and safely. As we have noted in previous comment letters, nonadherence decreases health outcomes and increases cost to the health care system as a whole.² Therefore, we strongly urge the agency to expand access to MTM as doing so can help improve health outcomes while decreasing cost.

VII. Tier Composition

CMS proposes to continue its policy of allowing Part D sponsors to have flexibility in determining the cost-sharing structure that is most appropriate for their benefit design, with the goal of maintaining transparency and a meaningful benefit offering for enrollees. CMS expects sponsors to evaluate and be prepared to submit written justification demonstrating the cost-sharing structure chosen provides value for beneficiaries. According to the agency, the justification should include detailed information about the generic drugs on the non-preferred drug tier, such as expected utilization, the formulary alternatives represented on lower tiers, and any tier placement strategy with respect to utilization management. CMS indicates sponsors may be asked to make modifications to their benefit structure or formulary tiering if the submitted justification is not accepted.

While we understand the importance of allowing plans to tailor benefit design, we encourage the agency to ensure the design truly provides beneficiaries with meaningful access to prescription drugs. We appreciate that in the Draft Call Letter CMS emphasizes its commitment to evaluating

² 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/>.

the design and seeking justification from sponsors as required. We strongly encourage CMS to thoroughly evaluate written justifications and request modifications when the cost-sharing structure may adversely impact beneficiary access to critical therapies.

VIII. Specialty Tiers

As CMS describes in the Draft Call Letter, Part D sponsors may establish a specialty tier in which it places very high cost and unique items. Plans are permitted to exempt items on the specialty tier from the tiering exception process. For an item to be placed on the specialty tier, it must exceed an established dollar-per-month threshold. Similar to prior years, CMS conducted an analysis and determined that it will maintain the \$670 threshold for CY 2019.

Given the cost-sharing structure of Part D, beneficiaries prescribed drugs on a plan's specialty tier are typically at risk for high out-of-pocket costs and many of those beneficiaries are among Medicare's most vulnerable. For these reasons, we urge CMS to increase the proposed \$670 specialty tier cost threshold for CY 2019. We believe an increased adjustment is important to ensure patient access to appropriate treatment.

We are also very concerned that even with maximum cost-sharing limits, plans can still impose high cost-sharing on beneficiaries, which can result in significant access barriers for beneficiaries to necessary medicines. Research shows that high cost-sharing can adversely impact beneficiary access and adherence to needed therapies.³ Such high cost-sharing in situations where a beneficiary must take a specific medicine and has no appropriate alternative could be considered discriminatory based on a particular patient's clinical needs or health status. Novartis encourages CMS to reconsider lowering the cost sharing thresholds for the specialty tier.

While outside the scope of the Draft Call Letter, we would also like to encourage CMS, in future rulemaking, to eliminate the provision allowing Part D sponsors to exempt the specialty tier from the tiering exception process. As we stated previously in our comments 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*, we believe this exemption effectively discriminates against beneficiaries needing drugs on the specialty tier and can lead to barriers to access or significant financial hardship.

IX. Conclusion

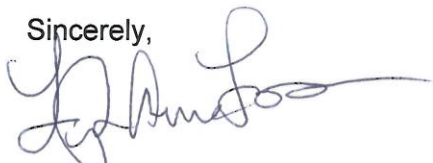
Novartis appreciates the opportunity to comment on the Draft Call Letter. In finalizing the policies discussed in this letter, we urge the agency to ensure that beneficiaries maintain meaningful access to therapies that are critical to their health and wellbeing. We encourage CMS to continue soliciting feedback from stakeholders as the Part D prescription drug benefit evolves.

³Doshi, JA. et al. "Biologic Therapy Adherence, Discontinuation, Switching, And Restarting Among Patients With Psoriasis In The US Medicare Population". *Journal of the American Academy of Dermatology*. 2016;74(6):57-1065.e4.

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Novartis greatly appreciates CMS's 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,

A handwritten signature in blue ink, appearing to read "Leigh Anne Leas", with a long horizontal flourish extending to the right.

Leigh Anne Leas
Vice President and US Country Head, Public Policy
Novartis Services, Inc.