January 16, 2018

*Submitted Electronically*

The Honorable Seema Verma

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

P.O. Box 8013, Baltimore, MD 21244-8013

**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 Ms. Verma,

Novo Nordisk Inc. (“NNI”) appreciates the opportunity to comment on the 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 (“Proposed Rule”). Headquartered in Denmark, and with nearly 5,000 U.S. employees, NNI is a global health care company with over 90 years of innovation and leadership in diabetes, obesity, hemophilia and growth hormone disorders.

As a company focused on improving the lives of people living with chronic conditions, Novo Nordisk is committed to the goal of ensuring patients have access to high-quality, affordable health care, and to improving patient protections in health insurance coverage. NNI supports the marked effort on the part of the Centers for Medicare and Medicaid Services (CMS) to increase flexibility and reduce administrative burden overall for Medicare Advantage (MA) plans, and to reduce costs in the MA and Part D programs. NNI especially acknowledges and appreciates CMS’ proposals to formulate policies that will reduce out-of-pocket (OOP) expenses for consumers, without compromising quality of care or access to care. However, we are concerned that several of CMS’ proposed changes could scale back important patient protections surrounding access to care, cost sharing and overall out of pocket expenses, that could disproportionately impact individuals living with chronic diseases. We request that CMS reconsider those proposed changes and remove them from the final rule.

The overarching summary of NNI’s comments can be found immediately below, and NNI’s comments on specific provisions in the Proposed Rule are provided as they appear in the draft document.

1. **Flexibility in the MA Uniformity Requirements § 422.100(d)**
   1. NNI supports reforming MA uniformity requirements to allow greater flexibility, granted these flexibilities ensure patient protections against discriminatory practices
   2. NNI supports implementing similar uniformity requirement reforms in Medicare Part D
2. **Maximum Out-of-Pocket (MOOP) limit and Cost-Sharing Limits for Medicare Parts A and B Services § 422.100, § 422.101**
   1. NNI supports continuing MOOP limits on Parts A and B services in MA but would like to ensure that proposed changes do not increase overall OOP expenses or erode patient protections
   2. NNI recommends the adoption of a MOOP limit in Medicare Part D to increase parity in benefit design throughout Medicare and protect patients from high OOP costs
3. **Medicare Advantage and Part D Prescription Drug Program Quality Rating System**
   1. NNI supports codifying in regulation some aspects of the Star Ratings program, but believes proposed changes for measure additions will increase regulatory burden and could delay important benefits for people living with chronic diseases
   2. NNI supports maintaining the current process for seeking comment on Star Ratings changes
4. **Expedited Substitution of Certain Generics and Other Midyear Formulary Changes § 423.100, § 423.120, § 423.128**
   1. NNI opposes changes to the advanced notice proposal as it is not in the best interest of consumers and could harm patients, particularly those with chronic diseases, who are especially sensitive to changes in their health care regimens
5. **Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing**
   1. NNI opposes treating follow-on biological products or biosimilars as generics for non-LIS catastrophic and LIS cost sharing. These changes could lead to inappropriate considerations of bioequivalence between originator and follow-on products, and will not significantly protect patients from high cost sharing and out-of-pocket expenses
6. **Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA plan Offerings with Meaningful Differences §423.265**
   1. NNI supports the removal of meaningful differences, while ensuring that changes to plan offerings are closely monitored and beneficiaries are equipped with the tools to effectively navigate plan offerings
   2. NNI opposes the continued utilization of the out-of-pocket cost calculator (OOPC) tool due to unintended consequences of the use of the tool
7. **Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale (POS)**
   1. NNI supports a POS rebating strategy but recommends changes to the proposed methodology to decrease beneficiaries OOP costs
   2. NNI would like to see CMS develop methodology to limit OOP spending overall in Medicare Part D and to address benefit design changes that increase beneficiary OOP exposure

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**Flexibility in the Medicare Advantage (MA) Uniformity Requirements**

**Description:** CMS is proposing to modify its interpretation of uniformity requirements that apply to Medicare Advantage (MA) plans. Currently MA plans must offer all enrollees access to the same benefits at the same level of cost sharing. Under the newly proposed requirements, MA plans would be permitted new flexibility 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.[[1]](#footnote-1)

**Comments:**

While there is a variety of evidence showing the benefits of value-based insurance design (VBID), CMS traditionally has limited MA plans’ ability to vary their benefits because of a narrow interpretation of benefit uniformity. NNI is very much supportive of VBID, and as such, generally supports the changes included in the Proposed Rule to increase the flexibility of uniformity requirements for MA plans, assuming the allowed flexibility is intended to provide patients with greater access to high quality health care. We believe allowing greater flexibility in designing MA benefits to align with VBID principles will advance the interests of consumers and plans alike. Furthermore, NNI urges CMS to consider adopting similar reforms to uniformity requirements for plans in Part D as well, to ensure parity in benefits and coverage throughout Medicare.

However, we believe it is imperative that CMS carefully define patient protections to guard against VBID being used in a discriminatory way. We also believe it is essential to carefully monitor and assess benefit design changes following implementation of the proposed flexibility reforms, so that plans do not adopt discriminatory practices that would adversely impact patients with higher costs, especially individuals living with chronic conditions. In addition to the protections outlined in the Proposed Rule, NNI suggests that CMS adopt the following protections:

* VBID should not lead to cost-sharing increases for other covered items or services, or reductions in the number of medicines on a health plan’s formulary
* VBID cost sharing must be based on an appropriate assessment of value, not price
* Value assessments should be based on the full body of available evidence, based on a range of study designs
* Value must incorporate relevant clinical quality and patient-centered measures and account for changes in evidence, medical practice, and innovations

Additionally, CMS notes that the proposed benefit and cost-sharing flexibility applies only to Part C benefits and not to Part D benefits. However, NNI believes that in order to maintain continuity across the Medicare program, uniformity reforms that allow for meaningful value-based insurance design should be available to Part D plans as well. NNI looks forward to providing further comments on changes to uniformity requirements when the operational details of this policy are outlined in the 2019 Call Letter.

**Maximum Out-of-Pocket (MOOP) limit and Cost-Sharing Limits for Medicare Parts A and B Services**

**Description:** Current law requires MA plans to apply a maximum out-of-pocket (MOOP) limit on annual patient cost sharing for Part A and B covered services. CMS sets this mandatory MOOP (currently $6700) at approximately the 95th percentile of projected out-of-pocket spending for Part A and B services (i.e., only about 5 percent of Medicare fee-for-service beneficiaries are expected to incur annual Part A and B cost-sharing charges exceeding $6700).[[2]](#footnote-2) CMS proposes to amend the MA regulations to specify that it may vary the MOOP from year to year as necessary to “strike a balance between limiting maximum beneficiary out-of-pocket costs and potential changes in premiums, benefits, and cost sharing with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.”[[3]](#footnote-3)

**Comments:**

NNI continues to support limits on enrollee out-of-pocket cost sharing (deductibles, coinsurance, and copayments) for services rendered under Parts A and B in Medicare Advantage. These limits were intended to help ensure that individuals who use higher-than-average levels of health care services, such as people living with chronic diseases, are not discouraged from enrollment. Incorporating appropriate cost-sharing standards and thresholds is imperative to ensure that beneficiaries are not unduly burdened by their out-of-pocket costs, which can hinder appropriate use of the healthcare system and deter patients from accessing the care they need.

While increasing flexibility for plans who voluntarily offer lower MOOP limits can allow for improved plan design, it will be important to ensure that vulnerable patient populations are not disadvantaged as a result. Specifically, NNI is concerned with CMS’ statement that it is considering increasing the MOOP limit, or allowing multiple MOOP levels. While potentially lowering costs for a broader population, these changes could result in higher OOP expenses for certain beneficiaries with inherently greater health care expenses, such as people living with diabetes. The overall percentage of eligible beneficiaries with access to an MA plan (excluding employer and dual eligible special needs plans) offering a voluntary MOOP limit has decreased from 97.7% in 2011 to 68.1% in 2017.[[4]](#footnote-4) The percentage of total enrollees in a voluntary MOOP plan decreased from 51% to 21% over the same period of time, and will diminish even further, to 18%, moving into 2018[[5]](#footnote-5), [[6]](#footnote-6). This suggests that a significant percentage of plans will default to the highest MOOP if increased.

CMS’ adoption of MOOP limits in Parts A and B of Medicare in 2011 reflected a commitment to ensuring patient access to health care at a reasonable cost. NNI encourages CMS to consider a commensurate MOOP limit in Medicare Part D. We believe the lack of similar standards for Part D benefits leaves open the risk for plans to discourage enrollment for certain beneficiaries who incur inherently higher Part D costs, such as people living with diabetes and other chronic diseases. Extending the MOOP limit to Part D could improve adherence to Part D prescribed drug regimens and diminish cost-related abandonment of essential medicines.[[7]](#footnote-7) Because Part D does not include a MOOP limit, patients, especially those with co-morbid conditions, or that require specialty medicines, can be exposed to extremely high OOP costs. The Part D benefit is structured such that the final level of cost-sharing, the “catastrophic threshold”, is indefinite. Beneficiaries who reach the catastrophic threshold must pay the greater of a nominal copayment or 5% co-insurance. For high-priced medications, this relatively small coinsurance rate can translate into significant out-of-pocket costs.[[8]](#footnote-8) Between 2007 and 2015, the number of non-low-income subsidy (LIS) beneficiaries whose spending exceeded the catastrophic threshold more than doubled.[[9]](#footnote-9) The increasing incidence of beneficiaries reaching the catastrophic threshold warrants serious attention and action on the part of CMS to ensure that beneficiaries are able to obtain essential medicines to maintain their health. We urge CMS to adopt MOOP limits in Medicare Part D, and extend this highly effective patient protection to the whole of Medicare.

**Medicare Advantage and Part D Prescription Drug Program Quality Rating System**

**Description:** CMS is proposing to codify many aspects of the existing Star Ratings System for the MA and Part D programs in an effort to provide greater stability and transparency to the program.  These proposed changes include establishing clearer rules governing the adding, updating, and removal of measures.  CMS believes this is the appropriate time to codify the Star Ratings methodology, due to the maturity of the quality rating program and lower likelihood for extensive changes on an annual basis.

**Comments:**

NNI applauds CMS for its work to date to make the MA and Part D quality rating system a best-in-class program. Moreover, we appreciate CMS’ efforts to continuously enhance the program, and we support CMS’ proposal to codify certain well-established aspects of the quality rating system through rulemaking. However, NNI is concerned with CMS’ proposal to add measures through formal rulemaking. NNI is concerned that the proposed efforts will prove burdensome and duplicative, and have the potential to add several years to a process that is already protracted in function. More specifically, we are concerned that requiring measure additions and substantive changes to go through a formal rulemaking process will increase the interval of time between the development of a novel measure and when that measure is finally adopted into the Star Ratings.

While we recognize the desire to ensure ample opportunity for comment, and to ensure plan sponsors have enough lead time to incorporate new measures, we note that there are currently opportunities for public comment during both the measure development process as part of the annual preview period for proposed measures in the Fall and proposed measure additions via the annual Call Letter. We also note the need for CMS to ensure flexibility when adding or removing measures--more flexibility than the formal rulemaking cycle allows--as quality measure development and maintenance is a dynamic process that evolves with the science and discovery of new therapeutics, as well as improved technology and data collection capabilities to support these measures with a greater focus on patient outcomes—and in itself can take several years. As such, we believe the current practices to solicit public comments through sub-regulatory guidance appropriately balances the need for plan predictability while keeping measures relevant from a quality improvement standpoint.

If CMS does move forward with this codification, we believe there should be, at a minimum, exceptions permitted to add or remove measures that address public health issues and patient safety—such as those identified by the HHS ADE Action Plan (e.g., major bleeds due to anticoagulation use, and hypoglycemia)—that are particularly relevant and important to vulnerable populations. These exceptions would prove essential to ensure that the important issues impacting people with chronic diseases can be addressed in an expedited manner, not delayed by a lengthy regulatory process.

**Expedited Substitution of Certain Generics and Other Midyear Formulary Changes**

**Description:** CMS is proposing to allow plans to immediately—at any time of the year and without 60-day notification—remove a brand medicine from the formulary or increase brand cost sharing when adding a newly available, therapeutically equivalent generic. Though CMS would require plans to provide general notification that such changes are possible, it would no longer require direct advance notice to affected beneficiaries when making a change. CMS is also proposing to decrease the amount of direct notice for other mid-year changes from 60 to 30 days and to limit the 60-day refill upon notice to one month.

**Comments:**

Under current policy, Part D sponsors have generous latitude to make substitutions to their formularies – when therapeutically equivalent generics or bioequivalent products to originator biologics become available—after appropriate notification has been given to the impacted beneficiary. NNI strongly believes the appropriate use of generics is good for patients and the Part D program, but we also believe the current structure of substitutions balances CMS’ goal of reducing costs, while also protecting consumer choice and access to medicines. Therefore, NNI does not support the changes proposed for midyear substitutions, specifically as it relates to the elimination of the 60 days advanced notice, as they would not improve patient choice or access to high quality products without potentially compromising continuity of treatment.

Advanced notice allows beneficiaries to consult with their health care providers concerning changes to their prescription drug regimen prior to moving forward with changes, whether it concerns requesting an exception, changing to a different medication, or accepting changes in their formulary. Under the proposed change, beneficiaries who receive no notice of a planned change could be alarmed upon filling a prescription if the name, color, or shape of their drug is different. Furthermore, changes to drastically increase the cost sharing of a branded product following the availability of a generic substitute, without advance notice, could precipitate higher rates of abandonment and/or non-adherence. Patients living with chronic diseases, who already experience higher health care costs relative to the general population, are especially sensitive to increases in cost sharing and could be disproportionately affected by this policy change.

Although the Medicare Payment Advisory Commission (MedPAC) proposed a similar policy change that would allow plans to remove brand drugs upon addition of therapeutically equivalent generics, the proposal did not extend to the elimination of advance notice for beneficiaries affected by these types of changes.

We would also like to ensure that CMS includes language in this change to prohibit formulary substitutions of biological products for either biosimilars or follow-on biologics that are not considered to be “therapeutically equivalent”. This position would be consistent with CMS’ position outlined in reference to the treatment of follow-on biological products as generics for non-LIS catastrophic and LIS cost sharing in the Proposed Rule.

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

**Description:** Generics and multiple source drugs have lower maximum copays for LIS enrollees, and for non-LIS enrollees in catastrophic coverage. In 2015 guidance on Part D biosimilar issues, CMS concluded that biosimilars were not “generics” under the Part D regulatory definition in 42 C.F.R. § 423.4 (because it is limited to drugs approved under section 505(j) of the Food, Drug, and Cosmetic Act) or “multiple source drugs” (because the relevant Part D provisions reference a Medicaid rebate statute provision defining “multiple source” drugs as those having therapeutic equivalents listed in FDA’s Orange Book).[[10]](#footnote-10) Therefore biosimilars currently are treated as brand drugs for purposes of the maximum LIS and catastrophic coverage copays. The proposed rule would revise the definition of a “generic” in 42 C.F.R. § 423.4 such that biosimilars would be classified as generics solely for purposes of the maximum LIS and catastrophic coverage copays.

**Comments:**

NNI appreciates CMS’ effort to further reduce health care costs for some of Medicare’s most vulnerable beneficiaries. However, we have significant concerns with CMS’ suggestion to classify follow-ons as generics, even in very specific situations, based on the precedent it may set around treatment of follow-on biologics across the entirety of the Part D program, and ramifications it may have beyond Part D.

We appreciate that CMS denotes the fact that biosimilars are not interchangeable and that CMS does not intend for biosimilars to be treated as generics in all situations. However, we would like to note that CMS considers biosimilars more like brand name drugs for purposes of midyear formulary changes, and if they are treated as generics for the proposed purposes it may incorrectly signal product interchangeability. NNI would also like to express our concern that the approach of treating biosimilars more like generic products with branded equivalents could spillover into other parts of Medicare, notably part B, where specialty biologic medicines are frequently dispensed. We urge CMS to continue to recognize that biosimilars—unlike generics—should not be treated as interchangeable unless approved and designated as so by the FDA.

**Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA plan Offerings with Meaningful Differences**

**Description:** CMS is proposing to eliminate the meaningful difference requirement between enhanced alternative (EA) Prescription Drug Plans (PDPs). CMS also intends to revisit the use of the out-of-pocket cost (OOPC) model as method for determining meaningful difference between basic and enhanced PDPs.

**Comments:**

NNI supports CMS’ effort to increase the availability of suitable PDP offerings to beneficiaries and to decrease plan premiums, and as such is supportive of CMS’ proposal to eliminate the meaningful differences requirement between two EA plans. While the intent of the meaningful differences policy was laudable, NNI believes that eliminating the meaningful difference requirements would ensure a more robust offering of plans to meet patients’ specific health needs. We also would support the elimination of the meaningful differences policy between enhanced alternative and basic, as we believe that employing the current Out-of-Pocket Cost (OOPC) tool to assess meaningful differences is not the best means by which to accurately reflect the value of a Part D plan for a beneficiary. The OOPC tool relies on data that are several years out of date, which is especially problematic when there are products that may have been released after the time frame on which the OOPC relies. Furthermore, the tool makes assumptions not likely in the real world; for example, if a plan does not have a particular product listed on formulary, the OOPC assumes that patients will simply pay for all of the cost OOP, which is not an accurate prediction of real-world occurrences.

NNI would like to ensure that if plans respond to the removal of meaningful differences by significantly increasing their offerings, beneficiaries are able to easily filter through available plans to select the option that best fits their needs, using a set of intuitive, clear filters—for example, a filter outlining the differing levels of cost sharing (deductibles, coinsurance, and copayments). This functionality would be in keeping with CMS’ desire to provide greater flexibility without overwhelming the beneficiary with too much choice. If CMS determines that plans respond by increasing choice to too great of an extent, we encourage CMS to consider an alternative to the OOPC calculator when determining that a plan is indeed meaningfully different from another offered by the same plan sponsor.

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

**Description:** CMS is soliciting feedback on a potential future proposal to require Part D plan sponsors to pass through a minimum portion of manufacturer negotiated rebates and all pharmacy price concessions to beneficiaries at the point-of-sale. Currently, plan sponsors are allowed, but generally do not apply rebates and price concessions to lower the negotiated price of a drug at the point-of-sale. Rebates and price concessions not applied in this manner are instead reported to CMS at the end of the coverage year as direct and indirect remuneration (DIR).

**Comments:**

NNI was pleased to see CMS’ Request for Information (RFI) to lower prescription drug costs for consumers at the point of sale (POS) in Medicare. The Medicare Part D program has succeeded in providing prescription drug coverage for more than 40 million seniors, at a far lower cost than anticipated, and with very high satisfaction rates among beneficiaries. However, the program is not without its challenges, and fundamental changes to the program may be warranted.

Across all insurance channels, manufacturers offer rebates to pharmacy benefit managers (PBMs) and health plans to secure formulary access for patients. While negotiated rebates can result in substantial savings – reducing the list prices for some medicines by as much as 70% – in most cases Part D plans still require beneficiaries to pay cost sharing based on the full list price of their medicine (when in the deductible, coverage gap, catastrophic coverage, or paying coinsurance), even in situations where the plan receives a substantial rebate.[[11]](#footnote-11) As noted in the RFI, these negotiated rebates have grown significantly over the last few years[[12]](#footnote-12). While these rebates have been used to lower costs in other parts of the benefit, such as keeping premiums low for all Part D beneficiaries, the individuals who are actually taking the rebated drugs effectively bear a higher percentage of the true cost of their medications each year. For some, this may mean that their drugs are no longer affordable, leading to adherence or persistence issues—which ultimately may result in increased medical costs for the individual and the government. While we typically think of affordability being an issue for patients taking high-cost drugs, individuals living with chronic conditions like diabetes or obesity who depend on multiple medications may also have a problem affording their drugs. Requiring Part D plans to share a portion of negotiated savings could result in lower out-of-pocket (OOP) costs at the pharmacy for millions of these Part D beneficiaries.

While NNI supports a POS rebating strategy to lower beneficiary expenditures, we urge CMS to further develop the proposal outlined in the RFI, given the potentially unintended consequences and operational challenges that this proposal presents. For example, implementing a new program of this scale and with this complexity may cause PBMs to raise their administration fees, which will only add costs to the system. As you consider a potential POS policy, we also remind CMS that the rebates negotiated with Part D plans are separate from a manufacturer’s mandatory coverage gap discount—this “double dipping” means, in some cases, manufacturers are paying in excess of 100% rebate on coverage gap claims. Therefore, we encourage CMS to meet with manufacturers, payers, PBMs, and patient advocates to develop a POS rebating policy that would be most appropriate for the Part D program.

However, if CMS wishes to move forward with the proposal as written, NNI opposes the therapeutic class average methodology proposed by CMS in the RFI and we urge the agency to pursue an alternative methodology. To sustain market incentives and avoid undermining the competitive structure of Medicare Part D, it is critically important that CMS design the rebate pass-through policy in a way that both avoids the disclosure of commercially-sensitive drug-level rebate data and prevents the cross-subsidization of competing products in a therapeutic class. Policies that could result in the cross-subsidization of competing medicines – such as requiring plans to pass through an average rebate amount calculated at the therapeutic class level (as proposed in the RFI) – may discourage manufacturers from negotiating more competitive rebates with Part D plans and could reduce the total rebate dollars plans receive.

Additionally, preliminary assessments of CMS’ proposed methodology in the RFI suggests that there could be unintended consequences in the form of tighter formulary management and increased premiums. While beneficiaries would see lower prices at the pharmacy, plan premiums would likely increase as a result of such a POS rebate policy. Estimates concerning the amount by which plans could be expected to raise their premium have not been reliably assessed and, as such, it is possible to imagine that plans may protect their interests by raising premiums by an amount that could be greater than the savings realized by consumers following the implementation of POS rebates. Assessments of the RFI have also suggested that plans may adopt strategies to more strictly manage formularies, and mandate more widespread use of generics. While steering towards generic products is often appropriate, generics are not always available, and in such cases it is imperative that CMS ensures beneficiaries continue to have access to the breadth of therapeutic options necessary to meet their medical needs.

NNI suggests that CMS view this POS proposal as one step in solving the overall OOP issue that certain Medicare beneficiaries face, but not the final one. Patients with chronic illnesses, such as diabetes, are at particularly high risk of facing high drug and other out-of-pocket costs given their need for chronic drug therapy, and frequent need for multiple drugs to treat comorbid conditions.[[13]](#footnote-13) People with diabetes, in particular, often require daily medication to control their blood sugar levels, in addition to concurrent chronic treatment for other associated conditions.[[14]](#footnote-14) People living with diabetes incur average medical expenditures of about $13,700 per year, of which about $7,900 is attributed to diabetes.[[15]](#footnote-15) While the implementation of POS rebates may serve to decrease OOP costs for beneficiaries, patients living with diabetes will still be exposed to very high overall costs of care. In 2011, 40.9% of older adults with diabetes reached either the Part D coverage gap, or found themselves above the catastrophic threshold. As CMS considers how to further refine and implement a shared savings policy, we believe serious attention should be paid to the fact that there is not a statutory MOOP limit for consumers in Part D. Although beneficiary cost sharing decreases to 5% once a consumer reached the catastrophic coverage threshold, this low rate can still be prohibitively costly for individuals, often on fixed incomes, taking multiple medicines.

Finally, while CMS’ shared savings proposal would shift the mechanics of the prescription drug supply chain so that patients benefit from rebates, it does not address rising patient costs attributable to insurance benefit design. Rising use and rates of co-insurance and the proliferation of high deductible health plans (HDHPs) (in the commercial market) create significant financial barriers to accessing necessary and high-quality health care for consumers. The proportion of Americans enrolled in high deductible health plans (HDHPs) has significantly increased, from 26.3% in 2011 to over 39% in 2016.[[16]](#footnote-16) Of consumers enrolled in HDHPs, over 15% reported difficulty paying medical bills, which demonstrates the financial hardship fomented by this type of health coverage.[[17]](#footnote-17) As CMS further develops methods by which to share savings with consumers, and lower health care costs overall, special attention should be paid to addressing the rising costs associated with changing benefit designs, both in Medicare (coinsurance) and the Marketplace (HDHPs).

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Novo Nordisk appreciates this opportunity to offer our suggestions on the proposed rule on the 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. If you have any questions or need any further information relating to our comments, please do not hesitate to contact me at salr@novonordisk.com or (609)987-5800.

Sincerely,



Steve Albers

Corporate Vice President, Market Access & Public Affairs

Novo Nordisk Inc.

1. 82 Fed. Reg. 56360. [↑](#footnote-ref-1)
2. 82 Fed. Reg. at 56361. In addition to the mandatory MOOP, CMS sets a lower voluntary MOOP; Medicare Advantage plans may adhere to this lower MOOP in order to obtain greater flexibility on cost-sharing for individual Part A and B services. [↑](#footnote-ref-2)
3. 82 Fed Reg. at 56495 (proposed 42 C.F.R. §§ 422.100(f)(4), 422.101(d)(2), (3)(ii)). [↑](#footnote-ref-3)
4. 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] [↑](#footnote-ref-4)
5. 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] [↑](#footnote-ref-5)
6. Q1 Medicare: Education and Decision Support Tools for the Medicare Community. Available online at: <https://q1medicare.com/q1group/MedicareAdvantagePartDQA/FAQ.php?faq=What-is-MOOP-or-the-Medicare-Advantage-maximum-out-of-pocket-limit-&faq_id=605&category_id=149> [↑](#footnote-ref-6)
7. The Impact of Medicare Part D on Beneficiaries With Type 2 Diabetes: Drug Utilization and Out-of-Pocket Costs, 2008. Available online at: <http://avalere.com/research/docs/The_Impact_of_Medicare_Part_D_Diabetes_Takeda.pdf> [↑](#footnote-ref-7)
8. Kaiser Family Foundation Issue Brief, “No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending” (Nov 2017) [↑](#footnote-ref-8)
9. Kaiser Family Foundation Issue Brief, “No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending” (Nov 2017) [↑](#footnote-ref-9)
10. March 30, 2015 Memo from Amy K. Larrick to Part D Sponsors, “Part D Requirements for Biosimilar Follow-On Biological Products.” [↑](#footnote-ref-10)
11. Quintiles IMS Institute. Estimate of Medicare Part D Costs after Accounting for Manufacturer Rebates. October 2016. [↑](#footnote-ref-11)
12. 82 Fed. Reg. at 56419, November 28, 2017. [↑](#footnote-ref-12)
13. American Diabetes Association Standards of medical care for patients with diabetes mellitus. Diabetes Care. 2017;22 [↑](#footnote-ref-13)
14. American Diabetes Association Standards of medical care for patients with diabetes mellitus. Diabetes Care. 1999;22(Suppl 1):S32–41. [↑](#footnote-ref-14)
15. American Diabetes Association. Cost of Diabetes. http://www.diabetes.org/advocacy/news-events/cost-of-diabetes.html [↑](#footnote-ref-15)
16. Cohen RA, Zammitti EP. High-deductible health plans and financial barriers to health care: Early release of estimates from the National Health Interview Survey, 2016. National Center for Health Statistics. 2017. Available from: https://www.cdc.gov/nchs/nhis/releases.htm. [↑](#footnote-ref-16)
17. Cohen RA, Zammitti EP. High-deductible health plans and financial barriers to health care: Early release of estimates from the National Health Interview Survey, 2016. National Center for Health Statistics. 2017. Available from: https://www.cdc.gov/nchs/nhis/releases.htm. [↑](#footnote-ref-17)