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VIA ELECTRONIC FILING TO: <http://www.regulations.gov>

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
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Washington, DC 20201

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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]¹

Dear Administrator Verma:

Lilly USA, LLC (Lilly) 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 (the Proposed Rule). Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies, as well as through the analysis and distribution of health information. Ultimately, our goal is to develop products that save and improve peoples' lives.

Lilly strongly supports the Center for Medicare & Medicaid Services' (CMS's) commitment to improving quality, accessibility, and affordability in the Medicare Advantage and Part D programs. Lilly has been a strong supporter of Medicare Advantage and Medicare Part D since the program's inception and remains committed to ensuring that Medicare Part D beneficiaries have access to all critical therapies. We also applaud the agency for its active interest in pursuing innovative approaches that can modernize the Medicare Part D program for all beneficiaries. We believe that the long-running success of the program since its inception in 2003 is due, in large part, to an appropriate balance between beneficiary protections and market-based principles that have fostered private competition, kept costs down, and maintained patient access. In 2017, nearly 9 in 10 seniors were satisfied with their Part D coverage, and 8 of 10 believe their drug plan is a good value.² While it is true that Part D has been roundly successful, affordability challenges have become problematic for a growing number of beneficiaries. Specialty drugs, for example, increasingly account for a rising number of new drug approvals. In 2016, approximately 3 out of every 5 new drugs approved by the Food and Drug Administration (FDA) were specialty drugs, and future growth trajectories in specialty spending are estimated to

¹ 82 Fed. Reg. 56336, 56527 (November 28, 2017).

² 2017 Morning Consult Senior Satisfaction Survey. Published in [MedicareToday.org](http://medicaretoday.org/resources/senior-satisfaction-survey/). <http://medicaretoday.org/resources/senior-satisfaction-survey/>. August 2017.

quadruple by 2020.³ Given these realities, the Medicare Payment and Advisory Commission has stated that the financial sustainability of Part D has become “a growing concern because of sizeable increases in expenditures on high-cost enrollees”.⁴ Lilly supports a range of ideas – many of which CMS has offered in this Proposed Rule – to improve affordability for patients, while also maintaining an appropriate level of safeguards to protect beneficiary access and choice. Lilly is a member of and supports the comments submitted by both the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO); however, we would also like to amplify our support for, and concerns with, areas of particular interest. We therefore urge CMS to consider the following recommendations in finalizing the Proposed Rule for CY2019:

- CMS should proceed with exploring policies that require a portion of manufacturer rebates and pharmacy price concessions to be applied to drug prices at the point-of-sale (POS), along with additional safeguards to protect the confidentiality of manufacturer and plan sponsor rebate agreements
- CMS should not finalize its proposal to define biosimilars as “generics” for non-LIS catastrophic and LIS cost-sharing purposes as this will create confusion and may have limited positive impact on patient affordability
- CMS should finalize its proposal to expand flexibility under the Medicare Advantage uniformity requirements, and should extend this flexibility to include Part D benefits in both the value-based insurance design (VBID) and maximum out-of-pocket cap (MOOP) provisions
- CMS should base coinsurance for tiering exceptions on the lowest applicable cost-sharing for the tier containing a preferred alternative drug, but should abandon the proposal to limit such exceptions to conditions and preferred alternatives of the “same type”
- CMS should not finalize policies that weaken beneficiary notification requirements for mid-year formulary changes
- CMS’s proposals related to certain aspects of the Star Ratings System for MA and Part D (5-Star Program) must not create unnecessary delays in the addition of new quality measures, and should focus on improvements in patient-centered care and incentives for the use of new technology
- As CMS continues its efforts to curtail opioid abuse, the agency should ensure that the Medicare program contains sufficient incentives for patients and providers to access new, non-opioid treatment options
- CMS should eliminate the Meaningful Difference (MD) threshold for both Medicare Advantage and Prescription Drug Plans (PDPs), and pursue alternatives to the Out-of-Pocket Cost (OOPC) Tool that can provide beneficiaries with more useful decision support during open enrollment
- CMS’s clarification that Medication Therapy Management (MTM) Programs are considered a “quality-improving activity” under existing Medical Loss Ratio (MLR) requirements will help promote better health outcomes

³ sPCMA, a division of the Pharmaceutical Care Management Association. The Management of Specialty Drugs. https://www.pcmnet.org/wp-content/uploads/2017/04/sPCMA_The_Management_of_Specialty_Drugs.pdf. April 2017.

⁴ Medicare Payment and Advisory Commission (MedPAC). Report to the Congress: Medicare and the Healthcare Delivery System. <http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf>. June 2016.

Our recommended changes are discussed in more detail below.

I. CMS should proceed with exploring policies that require a portion of manufacturer rebates and pharmacy price concessions to be applied to drug prices at the point-of-sale (POS), along with additional safeguards to protect the confidentiality of manufacturer and plan sponsor rebate agreements

CMS is soliciting feedback on a future proposal to require Part D plan sponsors to pass through a minimum portion of manufacturer rebates and all pharmacy price concessions to beneficiaries at the point-of-sale. This policy is being considered in response to an imbalance that CMS has observed in the amount of rebates collected relative to the amount of financial relief that is actually passed on to patients. Lilly supports CMS's efforts to identify mechanisms through which patients can directly benefit from the discounts and rebates provided by manufacturers to Part D plans. We are confident that CMS recognizes the potential for unintended consequences associated with the implementation of POS price concessions and we expect any changes to be made only after complete notice-and-comment rulemaking.

In the Request for Information section of the Proposed Rule, CMS states that when the Part D Program began, the agency believed that market competition would encourage Part D sponsors to pass through to beneficiaries a high percentage of the manufacturer rebates and other price concessions at the point-of-sale, and any efforts to mandate a specified percentage of rebate-sharing would undercut market forces.⁵ However, in 2016, CMS found that over a five-year period beginning in 2010, Direct and Indirect Remuneration (DIR) growth (attributable to rebates) had significantly outpaced growth in total drug spending (total DIR grew about 22 percent per year, while total Part D gross drug costs grew about 12 percent per year).⁶

To be sure, plan sponsors use negotiated rebates to keep premiums low. As a result, premiums have been largely stable since 2006. On the other hand, CMS has found that a rebate-driven approach to premium stability may come at the expense of higher cost-sharing for beneficiaries, higher reinsurance costs to the government, and unpredictable pharmacy reimbursement. Furthermore, studies have shown that, in some instances, substantial reductions in patient out-of-pocket (OOP) spending may portend only modest premium increases.⁷

For beneficiaries, the affordability challenges resulting from this dynamic are especially pronounced due to growth in benefit designs that apply coinsurance, rather than a fixed copay, to a growing share of treatments. The use of coinsurance tiers within PDPs has increased dramatically since 2013, with 63 percent of all drugs on coinsurance tiers in 2017 versus only 38 percent of drugs in 2013.⁸ In 2017, approximately 97 percent of PDP enrollees were in a plan with either two or three coinsurance tiers, and the average coinsurance for the non-preferred

⁵ 82 Fed. Reg. at 56419.

⁶ Centers for Medicare & Medicaid Services, Medicare Part D – Direct and Indirect Remuneration (DIR), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html>, January 2017. CMS observed that total DIR grew about 22 percent per year and PMPM DIR grew nearly 14 percent per year between 2010 and 2015. During the same period, total Part D gross drug costs only grew about 12 percent per year and PMPM Part D gross drug costs only grew nearly 5 percent per year.

⁷ Milliman Inc. Mitigating Out of Pocket Costs for Prescription Drugs. <http://us.milliman.com/uploadedFiles/insight/2017/mitigating-OOP-rx-drugs.pdf>, December 2016.

⁸ Avalere Health. Key Trends in the Part D Landscape: Considerations for 2017. Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. August 2017.

brand tier was 43 percent for most beneficiaries.⁹ For nearly all in-network medical services (except for pharmacy services), the patient pays a coinsurance based on a discounted price negotiated by the plan sponsor, rather than a list price at the point-of-sale.¹⁰

At the same time, manufacturer rebates in Part D have grown substantially in recent years. According to an examination by IQVIA (formerly QuintilesIMS) of the 12 most commonly used therapy classes by Part D patients, plan sponsors received an average 35 percent discount off of manufacturer list prices, and net costs to plans for prescription drugs ranged from 31 to 54 percent of the list price after accounting for manufacturer rebates and patient cost-sharing.¹¹ In other classes of widely used drugs with multiple competitors and less clinical differentiation across products, rebates can be substantially higher – in some cases, all or nearly all list price increases are offset by rebates and price concessions.¹² For these reasons, Lilly believes that rebate-sharing with patients across all product categories can be a highly effective way to support enhanced patient affordability, better adherence, and improved outcomes, while also alleviating pressure on the government's liability for reinsurance costs.

To preserve competition, rebate pass-through must be balanced with confidentiality protections. The ability of plan sponsors to conduct private negotiations, pitting manufacturers against one another, has been the key to fostering successful competition and extracting substantial discounts from manufacturers. In the Proposed Rule, CMS suggests that such confidentiality may be preserved by calculating a minimum percentage of the “cost-weighted average of rebates provided by drug manufacturers for covered Part D drugs in the same therapeutic category or class”.¹³ We believe that this approach is problematic for many reasons. First, this approach can lead to the cross-subsidization of rebates by certain manufacturers with products that have a disproportionately high share of the market. It is typical for rebates to vary considerably across drugs in the same category or class. A weighted-average approach to sharing a minimum percentage of rebates means that market share leaders would most heavily influence the rebate calculation. Another unintended consequence of this approach is that smaller competitors may feel less inclined to offer a competitive rebate if the cost-weighted average is being driven by other competitors. Additionally, in classes where there may be only one rebated product, the weighted average would be the actual rebate for that particular product, and manufacturer/plan sponsor confidentiality would be undermined. Finally, calculating a weighted average at the therapeutic category or class level can be complex and administratively burdensome, as CMS is well aware in the administration of Part B Average Sales Price (ASP) reimbursement. First, CMS and plan sponsors must identify a suitable classification system across all products, and this list must be maintained on a regular basis to account for new market entrants and/or product removals. Furthermore, ambiguity could arise related to the appropriate classification of a product that has indications across multiple therapeutic classes. Timeliness is also a concern – once data is collected and a weighted average is calculated, it is almost certainly out of date and

⁹ Id.

¹⁰ Milliman Inc. Mitigating Out of Pocket Costs for Prescription Drugs. <http://us.milliman.com/uploadedFiles/insight/2017/mitigating-OOP-rx-drugs.pdf>. December 2016.

¹¹ Murray Aitken, IQVIA (formerly IMS Institute). Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates <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>. October 2016.

¹² IQVIA. Medicines Use and Spending in the U.S. A Review of 2016 and Outlook to 2021 <https://www.iqvia.com/institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2016>. May 2017.

¹³ 82 Fed. Reg. at 56421.

unlikely to represent current market product mix, prices, and rebates. All of these factors can distort the average rebate calculation and subject it to variability over time.

To remedy these concerns, Lilly supports the alternative construct proposed by PhRMA in their comment submission. We agree that a multi-formula, product-specific approach would better protect contract confidentiality and would be administratively simpler than a cost-weighted, average class-based approach. Under the product-specific methodology, the negotiated price would reflect the minimum of two or more different pass-through calculations – whichever formula results in the lowest net price dictates the amount of the rebate passed through to the beneficiary at the point-of-sale. As an example, for each individual product, the pass-through amount could be determined by calculating both:

- a minimum percentage of the rebate applied to the negotiated price at the point-of-sale (with manufacturers and plans free to negotiate a pass-through percentage greater than any established minimum) and;
- a negotiated price that is no more than 25 percent above the true net price paid by the plan sponsor

Depending on factors such as the rebate percentage, the price of the drug, and the pass-through percentage agreed upon between manufacturers and plan sponsors, either of the above formulas may result in a lower negotiated price. The lowest price would always prevail, and individual contracting terms would be protected because the multi-formula test would obscure the exact methodology used. This methodology would also be less burdensome than a class-weighted option, because it would require a straightforward calculation for each product, obviating the need for an intricate drug classification and monitoring system. Because pass-through amounts would be determined at the product level, plan sponsors would be able forecast more easily the pass-through amounts expected for the upcoming plan year during annual contract negotiations with manufacturers.

Finally, we concur with PhRMA that the agency should implement safeguards to prevent plan sponsors or their agents from reclassifying or redefining any portion of a rebate agreement (i.e. from either the base rebate component or the price protection component) as a bona fide service fee, which is not considered a DIR-related price concession and therefore would be excluded from any pass-through provisions. CMS should create protections that prevent plans from pursuing even higher rebates from manufacturers to offset the amount shared with beneficiaries. CMS may also consider establishing a confidential “hotline” that concerned stakeholders could call for guidance if there are concerns that the classification of the rebates and/or administrative fees is inaccurate or creating an un-level playing field across competitors. Alternatively, for purposes of determining the Part D pass-through amounts, CMS could deem any payments by manufacturers based on the percentage of a drug’s list price to be rebates subject to pass-through.

In the Proposed Rule, CMS also seeks to assess any impact that a rebate pass-through policy would have on plan, beneficiary, and manufacturer behavior. CMS projects that a pass-through policy could result in a 10-year overall net increase in federal government costs, because increases in direct subsidies and low-income premium subsidies would outweigh savings in

reinsurance subsidies.¹⁴ However, this analysis does not take into consideration any of the behavior change that is likely to result from such a policy.¹⁵ In fact, an analysis conducted by the Milliman that accounts for varying degrees of likely behavior change found that a pass-through policy could generate net savings for the federal government of up to \$73 billion over the same 10-year period.¹⁶ The dynamics that underpin this analysis are clear:

- Plan sponsors are likely to make benefit design changes such as increased cost-sharing on higher cost therapies, wider coinsurance spreads between preferred and non-preferred tiers, and apply more restrictive utilization management requirements. CMS may need to consider closer scrutiny of these practices to protect beneficiaries from any potentially discriminatory effects. Perhaps most importantly, sponsors will have a stronger incentive to focus on access for medications with the lowest net costs. These changes could contain upward pressure on premiums and mitigate any increases in the government's direct subsidy payments.
- Beneficiaries are likely to benefit through lower costs at the point-of-sale, which could lead to improvements in medication adherence and health outcomes. A great body of evidence has shown that beneficiaries with consistently higher drug adherence were also less expensive in terms of Parts A and B service use.¹⁷
- Manufacturers are likely to respond to competitive pressure from plan sponsors with more competitive pricing and launching new products at lower price points.

CMS has also asked for commenter feedback on how rebate-sharing could be implemented without reducing manufacturer coverage gap discount liability, given that beneficiaries are likely to move more slowly through the coverage gap and fewer patients will reach the catastrophic phase.¹⁸ While we understand the potential concern from the agency, we hasten to point out that viewing changes in the amount of coverage gap discounts paid solely in terms of how it affects manufacturers may be shortsighted. Any reduction in manufacturer coverage gap discount liability observed would *also* be the outgrowth of a more stable Part D benefit design, which will yield lower patient coinsurance and relief for the federal government and taxpayers via lower reinsurance liability. Furthermore, this proposal is likely to unleash numerous competitive forces that are likely to increase costs for manufacturers. For example, more aggressive utilization management techniques and tighter formulary control by plans, stronger plan incentives to pursue lower-cost drugs, and heightened demands for competitive contracting offers will come together and collectively pressure manufacturer finances. Crucially, these cost trends can be expected to counterbalance any savings anticipated by a reduction in manufacturer coverage gap discount liability.

II. CMS should not finalize its proposal to define biosimilars as “generics” for non-LIS catastrophic and LIS cost-sharing purposes as this will create confusion and may have limited positive impact on patient affordability

¹⁴ 82 Fed. Reg. at 56425.

¹⁵ 82 Fed. Reg. at 56425.

¹⁶ Milliman. Reducing Part D Beneficiary Costs Through Point-of-Sale Rebates. January 2018.

¹⁷ Stuart, B et al. Increasing Medicare Part D Enrollment In Medication Therapy Management Could Improve Health And Lower Costs. Published in Health Affairs. <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2012.0848>. July 2013.

¹⁸ 82 Fed. Reg. at 56421.

As a manufacturer of Basaglar, a follow-on biologic for the treatment of people with diabetes who require basal insulin, Lilly shares the agency's goals for promoting a viable and competitive marketplace for biosimilars in Part D. Doing so would increase competition, drive prices down, and create additional treatment options for beneficiaries. In our CY 2018 Part D Call Letter response, we repeatedly argued that CMS should use its regulatory authority to create a sustainable pathway for biosimilars to be adequately covered by Part D sponsors and made affordable for beneficiaries. We have also highlighted problems with the status quo for biosimilars in Part D and have proposed solutions to improve their attractiveness to plan sponsors during formulary development. With this context in mind, we oppose CMS's proposal to define biosimilars as generics for the maximum LIS and non-LIS catastrophic coverage not on philosophical grounds, but based on clear policy reasons. Simply put, we believe this incremental step would be only marginally effective in the first place, and could actually make it more difficult to implement needed reforms that would allow biosimilars to be meaningfully attractive to both plan sponsors and patients in the future.

First, this new definition for biosimilars would create additional confusion about their status by augmenting the inconsistent treatment that presently exists across the Medicare and Medicaid programs. CMS is proposing to treat biosimilars as "generics" for the purposes of LIS cost-sharing and non-LIS catastrophic cost-sharing in Part D, yet the agency treats biosimilars like single source drugs for the purposes of the Part D transition and mid-year formulary change policies, and in the context of the Medicaid Drug Rebate Program.¹⁹ CMS also recently revised its Part B reimbursement policy to treat biosimilars covered under Medicare Part B as single source medicines.²⁰ On the other hand, in the Part D coverage gap, biosimilars are not considered "applicable drugs" for the purposes of the Coverage Gap Discount Program (i.e. treated as multi-source drugs), and manufacturers are exempt from paying coverage gap rebates for these drugs.²¹ Creating a new carve-out for biosimilars as generics for the purposes of LIS and non-LIS catastrophic coverage only introduces more confusion related to their appropriate treatment. Indeed, the proposed approach would also be inconsistent with the FDA's position that biosimilars are not generic drugs.²² CMS acknowledged as much by emphasizing in the Proposed Rule that the new definition of biosimilars as generics was being limited only to the aforementioned instances "to avoid causing any confusion or misunderstanding that CMS treats follow-on biological products as generic drugs in all situations".²³ CMS went on to argue further that "treating biosimilar biological products the same as generic drugs would incorrectly signal that CMS has deemed biosimilar products to be therapeutically equivalent...which could jeopardize Part D enrollee safety and may generate confusion in the marketplace through conflation with other provisions".²⁴ Lilly believes that the biosimilar proposal, even if limited in scope, increases the likelihood of this eventuality and should be reconsidered.

¹⁹ CMS, Medicaid Drug Rebate Program Notice: Biosimilars and Medicaid Drug Rebate Program (Mar. 30, 2015), available at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-092.pdf>.

²⁰ 82 Fed. Reg. at 53182.

²¹ SSA § 1860D-14A(g)(2).

²² Food & Drug Administration (FDA).

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#highly>

²³ 82 Fed. Reg. at 56417.

²⁴ 82 Fed. Reg. at 56417.

Second, the policy change would marginally improve affordability for patients. Among those receiving the low-income subsidy, treatment of biosimilars as generics would yield a per-prescription copayment of \$1.25 for dual eligibles and \$3.70 for non-dual LIS patients, based on the adjusted amounts for 2018.²⁵ In the absence of this change, however, dual eligible and non-dual LIS patients would still have relatively modest copayments of \$3.35 and \$8.35, respectively, in 2018.²⁶ For non-LIS beneficiaries in the catastrophic phase, SSA § 1860D-2(b)(4) requires the maximum catastrophic coverage copay (adjusted for 2018) to be the greater of: \$3.35 for a generic or preferred multiple source drug and \$8.35 for any other drug; or 5 percent coinsurance.²⁷ Accordingly, all non-LIS beneficiaries in the catastrophic phase would default to the 5 percent coinsurance option anyway (as they would under current treatment), unless the monthly biosimilar price was less than \$67. Given the prevailing prices for biosimilars on the market today, the rules under the Medicare Part D statute would virtually negate any positive impact of defining biosimilars as generics in the catastrophic phase. Finally, only 5.5 percent of non-LIS beneficiaries reached the catastrophic phase in 2016, which suggests that the benefits of this policy could be even further limited.²⁸

Finally, and most importantly, this policy change may actually impede efforts to create a truly sustainable biosimilar marketplace by creating a precedent that biosimilars are “generics”. By creating yet another separate category where biosimilars are treated as multi-source products (rather than single-source products), CMS may make it less likely for policymakers to act on treating biosimilars like their single-source/innovator counterparts in the Part D coverage gap discount program – as Lilly and others have repeatedly advocated for. This change is necessary in order to make biosimilar drugs viable for both plan sponsors and beneficiaries. The treatment of biosimilars like multi-source drugs in the coverage gap exempts them from manufacturer discounts and markedly increases plan sponsor liability as a result. Additionally, beneficiary coinsurance in the coverage gap is also higher for biosimilars vs. single-source products for CY 2018 and 2019 (44% vs 35% and 37% vs 30% respectively). A recent analysis by Milliman persuasively clarifies why this change is needed. Comparing a hypothetical single-source drug priced at \$4,000 to a biosimilar drug priced at \$3,400, and a 20 percent rebate on both drugs, “the beneficiary and plan sponsor pay more for the biosimilar medication, despite the fact that the total net price of the (biosimilar) medication is 15 percent below the innovator brand product.”²⁹ Treating biosimilars as multi-source products in the coverage gap – instead of making them “applicable drugs” to the coverage gap discount program – virtually ensures ongoing cost challenges and poor incentives for uptake among plan sponsors and beneficiaries. Narrowly defining biosimilars as generics in certain instances will do nothing to remedy this fatal flaw.

In sum, we believe that defining biosimilars as generics for LIS and non-LIS catastrophic cost-sharing would create marginal benefit at the expense of increased confusion related to their status. By perpetuating the inconsistent treatment of biosimilars in the Medicare program, CMS may inadvertently make it less likely for policymakers to act on a far more beneficial policy change that could markedly improve biosimilar formulary access and affordability for patients.

²⁵ CMS, Final Updated Part D Benefit Parameters for 2018, for Defined Standard Benefits, Low Income Subsidies, and Retiree Drug Subsidies.

²⁶ Id.

²⁷ Id.

²⁸ PhRMA. Part D Landscape Review. Data on file with author. September 2017.

²⁹ Milliman Inc., prepared for the AIDS Institute. The AIDS Institute, Financial Incentives in Medicare Part D. <http://theaidsinstitute.org/sites/default/files/attachments/Milliman%20Report%20-%20Final.pdf>. November 2016.

We respectfully ask that CMS consider these trade-offs, and instead of finalizing this proposal, CMS should support legislative efforts to enhance biosimilar affordability by revising the definition of “applicable drug” to include both single-source and biosimilar products.

III. CMS should finalize its proposal to expand flexibility under the Medicare Advantage uniformity requirements, and should extend this flexibility to include Part D benefits in both the value-based insurance design (VBID) and maximum out-of-pocket cap (MOOP) provisions

We support CMS’s proposed changes to the Medicare Advantage uniformity requirements that would give plans 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.³⁰ We also appreciate CMS’s acknowledgement of plan sponsors’ non-discrimination responsibilities by circumscribing this flexibility such that sponsors may only lower, and not raise, cost-sharing for benefits tailored to a particular condition, and may not exclude certain high-cost conditions from tailored benefits when they are being provided for other conditions. Giving sponsors the flexibility to experiment more widely with value-based insurance design (VBID) will encourage an evidence-based approach towards improving access to high-value services that can lower overall system costs.

Given this promise, we think CMS has missed an opportunity to further enhance value-driven care by excluding Part D from this new flexibility. A large body of evidence has demonstrated that adherence to prescription drugs can have a significant and positive impact on patient care, while also reducing costs over the long term. The Congressional Budget Office (CBO) has found that every 1 percent increase in the utilization of prescription medicines decreases Medicare spending in Parts A and B by 0.20 percent. CBO further validated the benefits of prescription drugs by announcing in 2012 that this methodology would be incorporated into the budgetary impact assessments of future legislative proposals affecting the Medicare program.³¹ Additionally, a study by IQVIA found that better use of medicines could eliminate up to \$213 billion in US health care costs annually (representing 8 percent of the nation’s health care spending), and nearly half of this savings came from improved outcomes related to medication adherence.³²

Incorporating Part D into MA flexibility can also positively influence the trajectory of value-based agreements in the Medicare program – a key priority for CMS, as articulated in the Innovation Center (CMMI) New Direction Request for Information (RFI) released on September 20, 2017.³³ VBID can complement health plans’ interest in exploring value-based arrangements, because both VBID and value-based arrangements encourage consideration of how the value of a medicine varies between different patients. VBID flexibility will create incentives for plans to

³⁰ 82 Fed. Reg. 56360

³¹ Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare’s Spending for Medical Services. November 2012. Available at: <https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>

³² IQVIA. Avoidable Costs in US Healthcare: the \$200 Billion Opportunity from using medicines responsibly. http://www.imshealth.com/files/web/TMSH%20Institute/Reports/Avoidable_Costs_in%20US_Healthcare/IHII_AvoidableCosts_2013.pdf. June 2013.

³³ Centers for Medicare & Medicaid Services. Available at: <https://innovation.cms.gov/Files/x/newdirection-rfi.pdf>

apply data-driven insights in determining whether a particular treatment or service is “high-value”. This data can help inform the same plan analyses to assess whether a drug is an appropriate candidate for a value-based contract with a manufacturer. Given the likelihood that plans may use the same infrastructure to support both efforts, allowing plans greater flexibility to pursue VBID designs may also encourage more value-based arrangements between plans and biopharmaceutical companies.

Finally, CMS proposes to vary the MOOP from year-to-year “based on changes in market conditions and to ensure the sustainability of the MA program and benefit options”.³⁴ In announcing this policy, CMS states its aim to ensure beneficiary access to affordable and sustainable benefit packages. We support this idea and strongly encourage the agency to add Part D costs to the MOOP. The MOOP provides a critical affordability protection for MA beneficiaries, and doubtless is one of many plan features that has contributed to the rapid growth in Medicare Advantage enrollment over the past several years.³⁵ Although CMS does not address Part D costs in the context of the MOOP directly in the Proposed Rule, the evidence to support such a change is compelling. Among all Medicare Advantage plans in 2017, one quarter of all drugs were placed in a coinsurance tier, with 37 percent of all brand drugs placed in the non-preferred tier and 40 percent of brand drugs placed in the specialty tier.³⁶ This type of cost-sharing may not be sustainable given the high degree of script abandonment seen at far lower levels of cost-sharing. According to recent data by IQVIA, when beneficiary cost-sharing exceeded \$250 – a threshold that is not at all uncommon within Medicare Advantage plans – 71 percent of new specialty prescriptions were abandoned.³⁷ Poor medication adherence also forecloses an opportunity for plan sponsors to reap the benefits of lower Part A and B spending brought about by the use of a high-value prescription drug – a key tenet of value-based care that would be consistent with the agency’s goals in proposing changes to the MA uniformity requirements in the first place. Applying Part D costs to the MOOP would provide a critical financial safeguard for patients with costly conditions. Accordingly, we encourage CMS to include Part D drugs in the proposed changes to the MA uniformity requirements related to both the VBID and the MOOP provisions.

IV. CMS should base coinsurance for tiering exceptions on the lowest applicable cost-sharing for the tier containing a preferred alternative drug, but should abandon the proposal to limit such exceptions to conditions and preferred alternatives of the “same type”

In the Proposed Rule, CMS seeks to codify guidance that was proposed in the CY 2018 Advanced Notice and Call Letter related to its tiering exceptions policy, by basing eligibility for tiering exceptions on the lowest applicable cost-sharing for the tier containing a preferred alternative drug and not based on tier labels.³⁸ As stated above, the average coinsurance for the

³⁴ 82 Fed. Reg. 56361.

³⁵ Kaiser Family Foundation. Medicare Advantage Spotlight 2017. <https://www.kff.org/medicare/issue-brief/medicare-advantage-2017-spotlight-enrollment-market-update/>. June 2017.

³⁶ Avalere Health. Key Trends in the Part D Landscape: Considerations for 2017. Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. August 2017.

³⁷ Amundsen Consulting, division of IQVIA. Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment. November 2017.

³⁸ Centers for Medicare & Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2018.pdf>

non-preferred brand tier was 43 percent in 2017 and the average percent of drugs on coinsurance tiers for PDPs increased from 38 percent in 2013 to 63 percent in 2017.³⁹ Given the negative impact that these trends could have on affordability, we supported CMS's tiering exception concept at the time and continue to believe this change could make it easier for beneficiaries to access a prescribed therapy at a reasonable OOP cost, without being obligated to pay a higher coinsurance rate dictated by an assigned tier label. Additionally, while a Part D plan sponsor would not be required to offer a tiering exception for a brand name drug to a preferred cost-sharing level that applies only to generic alternatives, Part D plan sponsors would be required to offer a preferred cost-sharing level that applies to tiers that contain both branded and generic alternatives, even if the tier is labeled "generic".⁴⁰ Both of these ideas could meaningfully improve beneficiary protections and make it more likely that patients are paying a coinsurance for a prescribed therapy that is no greater than the lowest prevailing coinsurance for a preferred alternative.

However, CMS also introduces new restrictions on this guidance that would substantially limit a patient's ability to pursue a tiering exception, effectively undermining the spirit of the proposal. CMS would permit plans to limit the availability of tiering exceptions to cases only when a preferred tier alternative is of the "same type" to the prescribed non-preferred therapy. This means that tiering exceptions would be granted in the following situations: for generics only if there are other preferred alternative generics; for brands only if there are other preferred alternative brands; and for biologicals (including biosimilars) only if there are other preferred alternative biologicals. Beneficiaries may be denied tiering exception requests if preferred alternatives are not of the "same type". In addition, preferred alternatives must also be "the same type of alternative for treating the enrollee's condition".⁴¹

These new restrictions could effectively eliminate a patient's ability to request a tiering exception even if there are numerous preferred alternatives on the sponsor's formulary. Under current policy, a patient could appeal the tier placement of a non-preferred biological when preferred alternatives exist, irrespective of the regulatory approval pathway of the preferred alternative. However, under this proposed guidance, if a patient's prescribed therapy happens to be the only biologic in a therapeutic class that contains several non-biologic preferred alternatives, the patient would no longer be eligible for a tiering exception. Even in cases where preferred formulary alternatives of the "same type" are present, plan sponsors would be permitted to impose an additional standard of determining whether the preferred alternative treated the "same condition" as the prescribed non-preferred therapy. These new restrictions add both unnecessary complexity and new impediments to the tiering exception process and seem to go beyond the original intent of the Part D statute.

This guidance also appears to be at odds with CMS's own observations in the CY 2018 Draft Call Letter that "plan sponsors are being more restrictive in their application of these exceptions than the statute and regulations contemplate", further adding that "tiering exception requests are consistently associated with significantly lower approval rates than all other types of coverage

³⁹ Avalere Health. Key Trends in the Part D Landscape: Considerations for 2017. Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. August 2017.

⁴⁰ 82 Fed. Reg. at 56371-2.

⁴¹ Id at 56872.

and exception requests”.⁴² Given this rationale, and the growth of benefit designs that have dramatically shifted the cost of care to beneficiaries, we are confused as to why the agency would propose a policy that creates an additional barrier to access. We ask the agency to proceed with its initial proposal to base coinsurance for tiering exceptions on the lowest applicable cost-sharing for the tier that contains a preferred alternative, but to not finalize its additional limitations on tiering exceptions requests that require formulary alternatives to be of the “same type” and for the “same condition”.

Finally, CMS reiterates its position that drugs placed in the specialty tier will continue to be ineligible for tiering exceptions. We would like to restate our belief that this prohibition on cost-sharing exceptions runs counter to the agency’s well-established nondiscrimination principles. In using cost criteria alone to define whether a product is eligible for specialty tier placement, the line between “non-preferred brands” and “specialty products” can be easily blurred. With a cost threshold of \$670, plan sponsors can easily add brands to the specialty tier that do not exhibit any of the characteristics that are germane to “specialty drugs” in the first place – notably, unique manufacturing, storage, route of administration, or conditions treated. Therefore, in many cases CMS’ current specialty tier criteria can lead to forced and artificial distinctions among similar drugs. This can also create unequal outcomes for beneficiaries, given that one plan sponsor may cover a product that meets or exceeds the specialty tier threshold in a non-preferred brand tier, while another may place the same product in the specialty tier. Consequently, the former beneficiary would be afforded rights to a tiering exception, whereas the latter would not. To mitigate the risk of discrimination based on health status, we ask the agency to ensure the equitable provision of beneficiary appeal rights by revising its specialty tier policy to allow all product tiers to be eligible for tiering exception requests.

V. CMS should not finalize policies that weaken beneficiary notification requirements for mid-year formulary changes

In the interest of balancing formulary continuity with requests from Part D sponsors for greater flexibility to make mid-year formulary changes, CMS proposes to no longer require direct advance notice to affected beneficiaries when replacing a brand with a therapeutically equivalent generic, and to reduce the beneficiary notification associated with other mid-year formulary changes from 60 days to 30 days. We appreciate the agency’s desire to give plans flexibility to introduce lower cost treatments to the marketplace in a timely fashion. However, we are concerned that these proposals will weaken protections that are important to Medicare beneficiaries and could create breaks in continuity of coverage. Changes to beneficiary notice of formulary changes, particularly the reduction of notice on mid-year changes from 60 to 30 days, compresses the amount of lead-time a beneficiary has to follow up with his or her provider to discuss the most appropriate course of therapy in the wake of a formulary change. Reducing notice from 60 to 30 days also creates a very limited window for a beneficiary (or his or her provider) to seek an exception to the formulary change, if desired. To the extent that a beneficiary cannot, or does not, make contact with his or her provider within the 30 days

⁴² Centers for Medicare & Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter. <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2018.pdf>

following the initial notice of a formulary change, there is an increased risk that the beneficiary may discontinue therapy altogether. The existing notice that beneficiaries are accustomed to has worked well since the inception of the Part D program, and we recommend against creating a new precedent that could negatively affect formulary continuity. Finally, we do appreciate CMS's clarification that the proposed policy on generic substitution would not apply to follow-on biological products under current FDA guidance.⁴³ The agency has stated repeatedly that biosimilar products are not "therapeutically equivalent" to their innovator reference products, and we ask CMS to maintain this consistent treatment of biosimilars going forward.

VI. CMS's proposals related to certain aspects of the Star Ratings System for MA and Part D (5-Star Program) must not create unnecessary delays in the addition of new quality measures, and should focus on improvements in patient-centered care and incentives for the use of new technology

In the Proposed Rule, CMS seeks to codify many aspects of the 5-Star Ratings methodology, as well as the process for adding, updating and removing measures.⁴⁴ We appreciate CMS's desire to increase program transparency and more clearly explain the principles surrounding methodological changes the 5-Star Program. CMS notes that it has used a sub-regulatory approach through the annual Advance Notice and Call Letter to propose and finalize changes to the quality Star Ratings System since the ratings first became a component of payment for MA and MA-PD plans. While it may be reasonable and appropriate to subject certain minor program changes to formal rulemaking, such as the measure weighting system, we strenuously disagree with the agency's proposal to subject the addition of new measures to a formal rulemaking and comment process. The process of endorsing, proposing, reviewing, and adopting new quality measures into the program is already lengthy and laborious. There is currently a two-year lag in the data collection periods to any corresponding performance year, and by CMS's own acknowledgement, "the rulemaking process will create a longer lead time for changes, in particular to add a new measure to the Star Ratings or to make substantive changes to measures".⁴⁵

We are concerned that adding more lead-time to an already arduous process would stifle the adoption of new quality measures aligned with the latest innovative advances in medicine and technology. As we have indicated in previous comments to CMS, Lilly is concerned that federal quality reporting programs contain an insufficient number of measures tied directly to improvements in patient outcomes. Robust outcome measures also enable plans and providers to assess the value of certain drug therapies in clear and quantifiable ways. We support the important role that quality measures play in value-based care, and to reach their maximum potential, measures must be consistent with evolving standards of care. The current sub-regulatory process through the annual Part D Call Letter provides ample lead-time for stakeholder involvement and transparency. Additionally, measures under consideration are placed on the Display Page for testing before being formally added to the Star Ratings Program. This process already strikes an appropriate balance between stakeholder input and testing of new

⁴³ 82 Fed. Reg. 56415

⁴⁴ 82 Fed. Reg. 56378

⁴⁵ 82 Fed. Reg. 56384

measures, while also ensuring that Star measures reflect the latest treatment guidelines and current standards of care.

We also agree with comments by PhRMA that CMS should proceed with codification of the existing weighting of outcome and intermediate outcome measures (including maintaining a current weighting of 3 for medication adherence measures), and that CMS should move forward with the proposal to increase the weighting of the patient experience measures. The voice of the patient can be an important harbinger of plan performance in key areas such as the ease of access to needed drugs/treatments and plan sponsor responsiveness to appeal requests.

Finally, CMS solicits feedback on whether to add measures that evaluate quality from the perspective of adopting new technology (e.g. the use of telemedicine).⁴⁶ As we stated above, incentives for the adoption of innovation are critically important and should be prioritized by CMS. As a recent example, diabetes stakeholders are currently investing in new technologies – including connected devices, mobile health apps and data sharing – to satisfy unmet needs for people with diabetes and to improve outcomes. This form of mobile health technology can integrate diabetes devices and drugs together into “connected systems” that give diabetes patients and providers new insight into dosing patterns and blood glucose levels to support successful self-management, which may reduce the risk of, and costs associated with, long-term hyperglycemia and severe hypoglycemic events among patients requiring insulin. By aligning quality measures to these new technologies, CMS could create incentives for more widespread adoption of treatments that may significantly improve medication adherence and health outcomes.

VII. As CMS continues its efforts to curtail opioid abuse, the agency should ensure that the Medicare program contains sufficient incentives for patients and providers to access new, non-opioid treatment options

In the Proposed Rule, CMS outlines plans to implement the Comprehensive Addiction and Recovery Act of 2016 (CARA) Part D drug management program provisions, which would designate opioids as “frequently abused drugs” and require beneficiaries identified as “at-risk” to obtain such “frequently abused drugs” from specified pharmacies or providers.⁴⁷ Lilly applauds the agency’s ongoing efforts to address the epidemic of opioid abuse. As the Center for Disease Control (CDC) has pointed out, while opioids may have a clinical role in an acute setting, the risk of abuse and diversion is heightened when they are used chronically, with uncertain clinical benefit.⁴⁸ These shortcomings illuminate the substantial unmet need that presently exists for non-addictive treatment alternatives for various pain management subtypes. A recent study found that the economic costs of pain in the US ranged from \$560–\$635 billion, with \$261–\$300 billion in health care costs and \$299–\$355 billion in lost productivity.⁴⁹

Looking ahead over the next several years, new, non-opioid pharmacologic therapies may become available, and access to these options, along with the adoption of new quality measures

⁴⁶ 82 Fed Reg. 56377.

⁴⁷ 82 Fed Reg. 56339.

⁴⁸ Center for Disease Control. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

⁴⁹ Gaskin, DJ, Richard P. The economic costs of pain in the United States. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/22607834>

that raise patient awareness of these therapies will be needed. We strongly concur with comments submitted by PhRMA and BIO that the agency should find ways to expand access to novel and safer treatments as part of the broader effort to address opioid abuse in the Medicare program. We ask the agency to ensure that plan formularies provide adequate access and do not inappropriately apply utilization management techniques to novel, non-addictive treatment alternatives. Additionally, quality measures that support the use of new non-opioid pharmacologic therapies could contribute meaningfully to better patient health outcomes. We encourage CMS to evaluate measures that encourage providers to engage patients in understanding the range of treatment options available and how to better manage their pain. These measures should include regular assessments of functional status improvements over time to address the high rates of inadequate relief and functional restoration with existing therapies. Additionally, as the management of chronic pain requires consistent provider-patient engagement, CMS should evaluate the need for new measures that track whether providers are documenting such interactions within pain treatment plans.

VIII. CMS should eliminate the Meaningful Difference (MD) threshold for both Medicare Advantage and Prescription Drug Plans (PDPs), and pursue alternatives to the Out-of-Pocket Cost (OOPC) Tool that can provide beneficiaries with more useful decision support during open enrollment

CMS is proposing to eliminate the meaningful difference requirement entirely for Medicare Advantage plans, and between the first and second enhanced plans for PDPs. CMS also stated its desire to revisit the use of the OOPC model used to establish meaningful difference between basic and enhanced PDPs.⁵⁰ We applaud CMS's decision, and ask the agency to eliminate the meaningful difference test in all instances for PDPs, and pursue a suitable replacement that will provide more meaningful decision support for beneficiaries during open enrollment.

Lilly has repeatedly advocated for the elimination of the OOPC test due to glaring technical flaws with the calculator that inadvertently promote formulary "gaming" behavior, access barriers for certain beneficiaries enrolled in basic plans, while offering little clarity to beneficiaries related to true differences between plans. Because the OOPC calculator renders higher "values" for older products with higher market share, sponsors may engage in artificial decision-making that encourages removal of these "high value" drugs from basic plan formularies in order to make enhanced plan formularies appear richer – and more "meaningfully different". This dynamic disproportionately hurts low-income beneficiaries more inclined to enroll in basic plan coverage, and we believe this runs counter to both the agency's intentions and to a central tenet of the Part D program. At a minimum, we believe that CMS should change the OOPC model's current assumption that non-formulary drugs will be paid 100 percent by members, and instead value these drugs at the sponsor's exception tier co-insurance level, as the agency originally proposed but never finalized in the CY 2014 Draft Call Letter.⁵¹ However, a better approach would be to eliminate the OOPC tool altogether in favor of decision support

⁵⁰ 82 Fed Reg. 56369

⁵¹ Centers for Medicare and Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter, page 144. <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Advance2014.pdf>

tools on Medicare's PlanFinder Tool that would go much further in clarifying true differences in plan options for beneficiaries.

We urge CMS to explore additional prompts on PlanFinder with personalized information about a patient's specific drug profile that could encourage more tailored comparison shopping. This information could provide clearer information about how a plan's out-of-pocket costs impact overall affordability beyond just premium cost. For example, PhRMA has suggested the inclusion of a flag for the type of enhancement each plan uses (e.g., reduced cost-sharing on tiers, coverage of additional drugs, improved benefit design, additional gap coverage) as a way to help beneficiaries distinguish plans and make better plan choices. CMS should also explore opportunities to improve the financial literacy of consumers by creating educational forums or tools outlining the structure and implications of different plan designs prior to and after open enrollment. Additional versions of these resources could also be provided to State Health Insurance Assistance Program (SHIP) counselors to enable more continuous, "hands-on" education throughout the year. Modifications such as these would address the agency's concerns with the proliferation of plan designs and the potential risk of beneficiary confusion. At the same time, they would be more effective than the OOPC model – a construct that yields more information for sponsors than beneficiaries – in highlighting the differences between plan designs.

IX. CMS's clarification that Medication Therapy Management (MTM) Programs are considered a "quality-improving activity" under existing Medical Loss Ratio (MLR) requirements will help promote better health outcomes

In the Proposed Rule, CMS clarifies that MTM Programs will always count as "quality-improving activities" under the MLR requirements as a way to enhance their adoption among plan sponsors. MTM programs contribute strongly to patient health by promoting medication adherence and reducing the risk of drug-drug interactions. We appreciate this clarification and encourage CMS to continue looking for ways to expand opportunities for patients to participate in MTM programs.

Lilly is grateful for the opportunity to comment on the CY 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs Proposed Rule. We sincerely appreciate your thoughtful consideration of the issues discussed in this letter and look forward to working with you in the future to help ensure that patients have meaningful access to affordable health care benefits and coverage under the Part D Program.

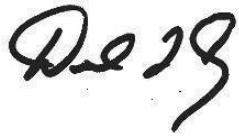
Please do not hesitate to contact Ryan Uργο at (732) 266-6512 and urgo_ryan_v@lilly.com or Derek Asay at Asay_Derek_L@Lilly.com and (908) 268-8720 with any questions.

Sincerely,

Administrator Verma

January 16, 2018

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A handwritten signature in black ink, appearing to read "Derek Asay". The signature is stylized with a large, looped "D" and a long, sweeping tail.

Derek Asay

Senior Director, Government Strategy