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January 16, 2018

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
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 Program, and the PACE Program (CMS-4182-P)

Dear Administrator Verma:

Astellas US LLC (Astellas) appreciates this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) concerning its proposed rule on Contract Year (CY) 2019 Policy and Technical Changes to the Medicare Advantage and Part D programs (the Proposed Rule).[1] Astellas is an innovative company with global headquarters in Tokyo, Japan and has a growing presence in the Americas. In the U.S., our fundamental goal is to improve the health of individuals by developing and marketing treatments for unmet medical needs in the therapeutic areas of oncology, urology, cardiology, infectious disease, and immunology.

As a manufacturer of products used by Medicare beneficiaries, Astellas is committed to the continued success of Medicare Part D. Astellas appreciates CMS' ongoing efforts to improve the Part D program to ensure that beneficiaries have affordable access to their prescribed medications. With that shared goal in mind, our comments focus on CMS' Request for Information (RFI) regarding the application of manufacturer rebates to drug prices at the point-of-sale, its proposal regarding Part D tiering exceptions, maximum out of pocket protections in Medicare Advantage, and a proposal to smooth cost-sharing in Medicare Part D. Our comments supplement the comments submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA), of which we are a member.

Briefly stated, our comments can be summarized as follows:

- We strongly support the inclusion of the RFI regarding passing some level of rebates through to patients at the point-of-sale. Astellas urges CMS to initiate rulemaking to put in place a Part D drug point-of-sale rebate policy as soon as possible.

[1] 82 Fed. Reg. 56336 (Nov. 28, 2017).

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- We strongly recommend that CMS not finalize the proposed new limitations on tiering exceptions and remove the regulation allowing plans to refuse to consider tiering exceptions for specialty tier drugs.
- We urge CMS to adopt a maximum out of pocket in Medicare Advantage (MA) Part D, similar to the maximum out of pockets caps included in MA Parts A & B.
- We request CMS consider establishing a policy that would allow Part D plans to offer beneficiaries, on a voluntary basis, a "balanced copay" financing option, which would even out their monthly cost-sharing payments.

I. Request for Information Regarding the Application of Manufacturer Rebates to Drug Prices at the Point-of-Sale

Astellas is pleased that CMS is considering requiring that Part D plan sponsors pass through a minimum portion of manufacturer negotiated rebates and all pharmacy price concessions to beneficiaries at the point-of-sale. We believe that requiring Part D plans to pass through a portion of negotiated rebates at the point-of-sale could reduce out-of-pocket costs at the pharmacy for millions of beneficiaries, lower government low income subsidy (LIS) cost-sharing subsidies and reinsurance payments, and strengthen the Part D program's competitive incentives by encouraging Part D plan sponsors to focus on negotiating for the best value for patients, rather than the largest rebates. Therefore, we appreciate CMS developing the pass-through approach and seeking comments on it. We do think that Part D patients with higher-cost drug regimens would still face some affordability challenges if CMS proposed and finalized a change to Part D along the lines of the RFI, and we would welcome an opportunity to discuss with CMS additional ideas to reduce cost-sharing for Part D patients carrying a large cost-sharing burden.

Currently, Part D plan sponsors negotiate drug rebates with manufacturers and usually apply the aggregate savings from such negotiated rebates as direct or indirect remuneration (DIR) at the end of the year to reduce their overall plan liability, rather than use the savings to lower the drug costs for beneficiaries who fill prescriptions for the medicines that generated those rebates.[2] The DIR approach results in higher overall beneficiary and government (with regard to the millions of low income beneficiaries whose cost-sharing is subsidized by Medicare) out-of-pocket spending on drugs.[3]

This has significant consequences: as CMS notes, "the higher cost-sharing that results can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare."[4] Studies have repeatedly shown that higher patient cost-

[2] 82 Fed. Reg. at 56419.

[3] 82 Fed. Reg. at 56420.

[4] 82 Red. Reg. at 56420 (footnotes omitted).

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sharing leads to delayed initiation of treatment (or abandonment of prescriptions) and lower adherence rates,[5] which in turn could result in worse outcomes for patients, as well as higher Medicare spending.[6] In addition, Part D beneficiaries who pay cost-sharing that is not based on a drug's negotiated price[7] are challenged to meet personal and programmatic goals: they cannot effectively minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drugs.[8]

Therefore, to improve patient access to needed medicines and to allow beneficiaries to directly benefit from the significant price negotiations taking place in the Part D market today, we urge CMS to initiate rulemaking to put in place a Part D drug point-of-sale rebate policy as soon as possible. In the interim, CMS should use its existing authority related to the Part D bidding process to alert plans to the opportunity for voluntary negotiated point-of-sale rebate agreements with manufacturers; and conduct outreach to ensure that manufacturers and plans are aware of the opportunity to negotiate Part D rebate agreements with provisions addressing point-of-sale pass-through arrangements, so that beneficiaries may share in the savings from manufacturer rebates immediately. This is an important step to provide patients some immediate relief from the problems CMS describes (i.e., paying higher cost-sharing, which CMS also describes as increasing costs to the taxpayers since patients trying to minimize their own cost-sharing will not select the drug that minimizes cost to the taxpayers).

Implementing voluntary negotiated point-of-sale rebate agreements could also allow plan sponsors and manufacturers to gain experience with point-of-sale rebates. Working through issues related to negotiation, calculating the negotiated price, reporting DIR, and operationalizing passing rebates through to beneficiaries at the point-of-sale may also help inform CMS' effort to develop and refine a final policy. CMS should also consider providing guidance on plans and manufacturers negotiating arrangements in which a certain portion of the total rebate would be passed through directly to the patient's cost-sharing, as this would have a greater impact for the beneficiary. For example, if the beneficiary is responsible for a 25%

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[5] See, e.g., Doshi, JA, Li P, Huo H, Pettit AR, Armstrong, KA, Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. J Clin Oncol. 2017 Dec 20. Doshi JA, Li P, Huo H, et al. High Cost-sharing and Specialty Drug Initiation under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia. Am J Manag Care. 2016;22(4 Suppl):s78-86. Doshi JA, Takeshita J, Pinto L, et al. Biologic Therapy Adherence, Discontinuation, Switching, and Restarting Among Patients with Psoriasis in the US Medicare Population. J Am Acad Dermatol. 2016;74(6):1057-1065.e4.; Doshi JA, Hu T, Li P, Pettit AR, Yu X, Blum M. Specialty Tier-Level Cost-sharing and Biologic Use in the Medicare Part D Initial Coverage Period Among Beneficiaries with Rheumatoid Arthritis. Arthritis Care Res (Hoboken) (2016); Teresa Gibson et al., Cost-Sharing Effects on Adherence and Persistence for Second-Generation Antipsychotics in Commercially Insured Patients. Managed Care. 2010; 19(40): 40-47.

[6] See, e.g., MacEwan JP, et al. The Relationship Between Adherence and Total Spending Among Medicare Beneficiaries with Type 2 Diabetes. Am J Manag Care. 2017; 23(4):248-252.

[7] The Social Security Act (SSA) § 1860D-2(d)(1) states that negotiated prices "shall take into account negotiated price concessions, such a discounts, direct or indirect subsidies, rebates, and direct and indirect remunerations, for covered Part D drugs."

[8] 82 Fed. Reg. at 56421.

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coinsurance, a $1.00 in rebates fully passed through to the patient's cost-sharing would reduce the patient's cost-sharing amount by $1.00, but $1.00 in rebates passed through based on the drug's negotiated price would reduce the patient's cost-sharing by $0.25.

As part of CMS' process for developing a point-of-sale rebate policy, the RFI specifically asks for feedback regarding the methodology CMS is considering to calculate the applicable average rebate amount, a specified minimum percentage to be applied at point-of-sale. The CMS methodology outlined in the Proposed Rule considers requiring that the manufacturer rebate amount applied to the point-of-sale price for a drug be based on the Part D plan's average rebate amount calculated for the rebated drugs in the same category or class, rather than a drug-specific rebate amount, in order to maintain the confidentiality of any manufacturer rebates for an individual drug. CMS states that it believes this "average rebate" approach will help maintain fair competition among drug manufacturers, as well as Part D plans, by preventing competitors from reverse engineering the particulars of proprietary rebate arrangements.[9]

While we appreciate and share CMS' goal of strictly protecting the confidentiality of manufacturer rebates, we believe CMS' "average rebate" approach could create incentives that may lead to reduced competition. By averaging the rebates offered by manufacturers across the class, CMS could create a free rider problem: for example, if one manufacturer provides a 0.5% rebate for a medicine in a particular therapeutic class, but other manufacturers of competing medicines in that same class provide 50% and 55% rebates, respectively, then requiring a pass through of the average rebate amount across the entire therapeutic class would allow the first manufacturer's medicine to unfairly benefit from the rebates provided by its direct competitors. Manufacturers would still have incentives to provide rebates to Part D plans (or their PBMs) to improve their drug's tier placement; however, the average rebate approach would likely compress those rebate amounts, and/or cause manufacturers of drugs within the same class to offer rebates at roughly the same level, as manufacturers try to avoid subsidizing the cost-sharing on competitors' products. This approach may also discourage manufacturers from providing significant rebates on a drug that accounted for a small percentage of the sales in its class. Because rebates on such a drug would have little effect on the average percentage rebate for the class, the manufacturer's rebates would have no appreciable effect on its drug's negotiated price, and thus, could be futile from its perspective.

Therefore, we believe that the average rebate approach would suppress price competition between drugs in the same class instead of promoting price competition. It would also thwart CMS' goal of enabling beneficiaries to "[seek] and [find] the lowest-cost drug[s]," so that they could efficiently minimize costs to the taxpayer while minimizing their own costs.[10] Moreover, as CMS acknowledges, it is unclear how the

[9] 82 Fed. Reg. at 56422.

[10] 82 Fed. Reg. at 56421.

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"average rebate" approach could work in a case where there is only one rebated drug in a particular category or class.[11]

Instead of averaging the rebate amount across a class and forcing manufacturers that wish to provide substantial rebates to subsidize competitors, CMS should establish a drug-specific point-of-sale rebate methodology that avoids disclosing the manufacturer rebate on a drug. We believe this could be done by designing a multi-pronged approach that would avoid the disclosure of commercially-sensitive data. Competitors and others are unlikely to determine the actual amount of a rebate using a multi-pronged approach that allows for two or more different pass-through calculations, even though the list price and the point-of-sale negotiated price are publicly known. For example, a drug's negotiated price could be determined by the lowest amount resulting from several different formulas that link a drug's negotiated price to its net-of-rebate cost. We understand that PhRMA is evaluating ideas for operationalizing such a multi-pronged approach that it could discuss with CMS to spur further thinking on this strategy.

We urge CMS to consider this type of multi-pronged approach, as we are concerned that the "average rebate" strategy outlined in the RFI could reduce price competition and keep the Part D program and its enrollees from realizing the significant benefits point-of-sale rebates could otherwise offer. At the same time, CMS must think through the implications of potential multi-pronged approaches carefully to ensure that it operationalizes this strategy in a way that will not permit reverse-engineering of rebate levels in any possible scenario.

II. Limitations on Part D Tiering Exceptions

Astellas has serious concerns about CMS' regulation permitting plans to make drugs on specialty tiers ineligible for tiering exceptions, as well as its proposals to establish new limitations on tiering exceptions. The Medicare statute provides that:

> [A] Part D eligible individual who is enrolled in [a plan with a tiered formulary] may request an exception to the tiered cost-sharing structure. Under such an exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for the treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A [prescription drug plan (PDP)] sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial

[11] 82. Fed. Reg. at 56422.

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> of such an exception shall be treated as a coverage denial for purposes of [appeals].[12]

This is a simple, yet crucially important, beneficiary protection. It gives beneficiaries a right to request tiering exceptions -- i.e., the right to request lower cost-sharing -- for any non-preferred drug if there is a preferred drug with lower cost-sharing that treats the same condition and the beneficiary's physician determines that the preferred drug would be less effective or have adverse effects for the beneficiary. CMS' proposals to limit tiering exceptions -- like the existing "specialty tier" regulation -- have no basis in the statutory language and undermine its protections.

First, the statutory language quoted above is inconsistent with CMS' existing regulation allowing plans to designate drugs on a specialty tier (i.e., high cost drugs) as ineligible for a tiering exception. While the statute authorizes CMS to create guidelines for plans to "mak[e] a determination with respect to such a [tiering exception] request," it does not authorize plans to refuse to entertain exception requests when the prescribing physician has determined that the preferred drug would be less effective or have adverse effects for the beneficiary. Moreover, excluding high cost drugs from the exceptions process contravenes the very purpose of the tiering exception provision: beneficiaries would likely have the greatest need for a tiering exception in a case where the non-preferred drug is "high cost" and could be relegated to the specialty tier. While we recognize that the Proposed Rule did not propose to eliminate the regulation permitting plans to refuse to consider tiering exception requests for specialty tier drugs, we urge CMS to revisit this concept and propose its elimination in the next Part D rulemaking cycle.

Second, the Proposed Rule would also create new restrictions on tiering exceptions. Specifically, CMS would permit plans to limit the availability of tiering exceptions for brand name drugs and biological products to cases where the non-preferred drug for the beneficiary's condition was the "same type" of drug -- i.e., tiering exceptions for brand name drugs (as defined under 42 C.F.R. § 423.413) could be restricted to the lowest cost-sharing for a preferred brand name drug for the beneficiary's condition, and tiering exceptions for biologicals could be restricted to the lowest cost-sharing for a preferred biological for the beneficiary's condition.[14] Then CMS would narrowly interpret the statutory language "for treatment of the same condition" such that it would shrink to the same condition "as it affects the enrollee -- that is, taking into consideration the individual's overall clinical condition, including the presence of comorbidities and known relevant characteristics of the enrollee and/or the drug regimen, which can factor into which drugs are appropriate alternative therapies for that enrollee."[15] This would mean that a beneficiary could only

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[12] Social Security Act (SSA) § 1860D-4(g)(2).

[13] "*Brand name drug* means a drug for which an application is approved under section 505(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(c)), including an application referred to in section 505(b)(2) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(b)(2))." 42 C.F.R. § 423.4.

[14] 82 Fed. Reg. at 56372.

[15] 82 Fed. Reg. at 56372-73.

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seek a tiering exception (assuming the beneficiary's drug was not on the specialty tier in the first place) if the beneficiary identified a preferred drug of the same type that happened to treat a narrow subset of the beneficiary's condition associated with the beneficiary's own individual comorbidities and other "relevant characteristics." Nothing in the statute permits these limitations and we are concerned that if finalized they would end beneficiaries' ability to seek tiering exceptions in many cases.

With regard to the proposed drug-type restriction, the FDA approval pathway (i.e., whether a drug was approved through a new drug application (NDA) or biologics license application (BLA)) for the preferred drug that provides the basis for an exception request is irrelevant under the statute: all the statute requires is "a preferred drug for treatment of the same condition." Additionally, as a practical matter, this approach might limit the availability of a tiering exception in many cases. For instance, there may be conditions for which all biological treatments are on a plan's non-preferred tier and the preferred tiers only include generics and brand name drugs approved under section 505(c) of the Federal Food, Drug, and Cosmetics Act. Under CMS' proposal, a plan with such a formulary design could prevent a patient prescribed a non-preferred biological from seeking a tiering exception, even if his or her physician had determined that the preferred drugs would be less effective or would have adverse effects for the beneficiary. The plain language of the statute clearly does not permit such limitations on tiering exception requests.

Similarly, there is no statutory foundation for CMS' proposed interpretation of "same condition." The statute permits beneficiaries to seek exceptions if their physician determines that the "preferred drug for treatment of the same condition" would be ineffective or have adverse effects, and to obtain the drug they take at the same cost-sharing as the "preferred drug for treatment of the same condition."[16] Under the Proposed Rule, plans could "slice and dice" the beneficiary's condition to the point where no alternative treatment (let alone a drug of the "same type") existed to treat the narrowed-down condition. For instance, a physician might determine that a preferred drug was clinically inappropriate for a particular patient because he or she had a certain comorbidity. Once the plan learns of that comorbidity, the plan could take the position that the preferred drug, which a physician has determined is clinically inappropriate for the patient because of the co-morbidity, is also not a treatment for the "same condition" taking into account the co-morbidity. The result would be that the plan could then prevent that beneficiary from requesting a tiering exception that would apply the preferred, yet clinically inappropriate, drug's lower cost-sharing amount to the non-preferred, yet clinically appropriate, drug. Presumably, there would often be some "relevant characteristics of the beneficiary and/or the drug regimen" that made the preferred drug less effective or safe for the beneficiary, thus permitting the plan to conclude that the preferred drug did not treat the beneficiary's specific "condition." Thus, carried to its logical conclusion, the Proposed Rule's gloss on "same condition" could effectively deny many beneficiaries their statutory right to seek tiering exceptions.

[16] Social Security Act (SSA) § 1860D-4(g)(2). .

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The Part D program has been successful in providing Medicare beneficiaries with affordable access to the medications they need because the law creates a careful balance between plan flexibility and beneficiary protection. CMS must preserve that statutory balance. Accordingly, we urge CMS to remove the regulation allowing plans to refuse to consider tiering exceptions for specialty tier drugs (in a future rulemaking where CMS proposes such a change) and not to finalize the proposed new limitations on tiering exceptions.

III. Maximum Out-of-Pocket (MOOP) Limit for Medicare Parts A and B Services (§§ 422.100 and 422.101)

CMS requires Medicare Advantage (MA) plans to cap beneficiaries' annual cost-sharing for Parts A and B services at a MOOP limit, which may not exceed an annual limit set by CMS.[17] The mandatory MOOP is approximately the 95th percentile of projected out-of-pocket spending for Parts A and B services under the fee-for-service program -- currently $6700. CMS proposes to amend the regulatory text to specify that it has the flexibility to vary the mandatory MOOPs from year to year, 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."[18] Astellas supports this proposal.

Additionally, we strongly urge CMS to extend the MOOP to Medicare Advantage Prescription Drug (MA-PD) plans. The Part A/B MOOP has successfully protected MA beneficiaries against oppressive out-of-pocket costs, helping improve their adherence to treatment regimens, which can improve their health, and reducing the likelihood that the MA benefit design will discriminate against sicker patients by discouraging them from enrolling. Extending the MOOP to benefits offered by a MA-PD plan would promote adherence and protect against discrimination more effectively; it would also help MA-PDs better coordinate Parts A, B, and D-covered care for their enrollees. Additionally, including MA-PD plans in the MOOP may help curb spending on Parts A and B services, including hospitalizations, which can increase with poor adherences to medication regimens.

CMS has the legal authority to extend the MOOP to MA-PD plans. In establishing the MOOP for local MA plans,[19] CMS relied on two MA provisions: (1) the prohibition on discriminatory benefit designs in Social Security Act (SSA) § 1852(b)(1)(A), and (2) SSA § 1857(e)(1), which authorizes CMS to add "necessary and appropriate" terms to its contracts with plans. Part D has a substantially similar non-

[17] 82 Fed. Reg. at 56361. CMS also sets a lower voluntary MOOP, which Medicare Advantage plans may observe in order to obtain greater flexibility on cost-sharing for individual Part A and B services.

[18] Id. at 56495 (proposed 42 C.F.R. §§ 422.100(f)(4), 422.101(d)(2), (3)(ii)).

[19] Regional MA plans have MOOPs by statute.

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discrimination provision in SSA § 1860D-11(d)(2)(D) and § 1860D-12(b)(3)(D) extends SSA § 1857(e)(1) to Part D.

With regard to the practicalities, we recognize that the Part D benefit design creates additional complexities. However, under the authority in SSA § 1860D-21(c)(2), CMS may waive Part D provisions to the extent they duplicate or conflict with Part C provisions, or as may be necessary in order to improve coordination of Part C and D benefits.[20] Leaving MA-PD cost-sharing uncapped conflicts with CMS' goal in establishing the Part A/B MOOP – to "avoid discouraging enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of [SSA] section 1852(b)(1)"[21] -- by discouraging enrollment by beneficiaries with high drug costs (e.g., beneficiaries who require the chronic use of medications or who need higher- cost medications). The absence of a MA-PD MOOP also frustrates MA-PD plans' ability to coordinate Part C and D benefits: as noted above, excessive cost-sharing on medications may reduce adherence and increase spending on Part C services (including Part B drugs, which compete with Part D drugs in some therapeutic areas). Plan efforts to encourage effective disease management may falter due to enrollees having perverse financial incentive to curb their use of Part D drugs (which lack a cost-sharing cap) and substitute Part A/B items and services that may be less clinically appropriate and have higher costs to Medicare but have a cost-sharing cap.

CMS could either establish a separate MA-PD MOOP that would apply separate from the existing Part A/B MOOP or establish a single MOOP that applies to all Parts A, B, or D items and services covered by an MA-PD plan. Either of these approaches is within CMS' legal authority and could improve adherence and health outcomes for MA-PD enrollees while improving plans' ability to coordinate Parts C and D benefits. We urge CMS to include such a proposal in its next Part D rulemaking.

IV. Smoothing Out Cost-Sharing Payments in Part D

Under the Medicare Modernization Act (MMA), cost-sharing payments by Medicare Part D enrollees can vary significantly during the course of a year. For example, under "defined standard" Part D coverage, a beneficiary's cost-sharing percentage for covered drugs in 2018 would be: 100% during the deductible period (up to $405 in 2018); 25% during the initial coverage period (from $405 to $3,750 in total

[20] Social Security Act (SSA) § 1860D-21(c)(2) refers to waiving Part D provisions to improve coordination of "this part with the benefits under this part," but CMS has long recognized that it provides for CMS to "waive any Part D requirement for an MA-PD plan that conflicts with or duplicates a requirement of Part C or the waiver of which is necessary to promote coordination between benefits provided under Parts C and D." 70 Fed. Reg. 4168, 4275 (Jan. 28, 2005). See also 42 C.F.R. 423.528(b) ("CMS waives any provision of [Part D] otherwise applicable to MA-PD plans or MA organizations under paragraph (a) of this section [generally applying Part D rules to Part D benefits provided by MA-PDs] to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to MA organization or MA-PD plans … or as may be necessary in order to improve coordination of [Part D] with the benefits under Part C").

[21] 74 Fed Reg. at 54657.

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drug costs in 2018); 35% for brand-name drugs and 44% for generic drugs during the coverage gap (in 2018, between $3,750 and $8,418 in total drug costs or $5000 in TrOOP); and roughly 5% in the catastrophic coverage period (above $5000 in TrOOP in 2018).[22] Given this variation in cost-sharing rates over the course of the year, some non-LIS beneficiaries with higher drug costs (such as beneficiaries with maintenance prescriptions for chronic conditions) may have difficulty budgeting for their out-of-pocket drug costs earlier in the year before they attain catastrophic coverage.

As a result, beneficiaries may go without a needed medication, delay treatment, or skip doses to make the medication last longer -- harming beneficiaries' health and ultimately harming the Medicare Program. Studies have repeatedly shown that higher cost-sharing leads to reduced or delayed initiation of treatment and lower adherence rates, which then can result in worse outcomes for patients as well as higher overall Medicare spending.[23]

As it considers new policies for addressing beneficiaries' out-of-pocket burden (such as point-of sale rebates, discussed above), CMS should consider establishing a policy that would allow Part D plans to offer beneficiaries, on a voluntary basis, a "balanced copay" financing option, which would even out their monthly cost-sharing payments and thus help them to adhere to their prescribed drug regimens year-round. The balanced copay concept would start with a benefit design recognized as "qualified prescription drug coverage" under the MMA (the "baseline" benefit design) and would then level out the cost-sharing payments that participants otherwise would pay under the baseline design without changing the expected value of annual cost-sharing payments.

In the 2005 Part D final rule, CMS discussed "additional products, such as financial services" that Part D plans might market to Medicare beneficiaries in conjunction with Part D benefits.[24] In discussing this issue, CMS stated in part that:

> We do not want to restrict beneficiaries from receiving materials…about health-related services and non-health-related services that may be of benefit to them in managing their health or payments for health care.[25]

Because the underlying cost-sharing would remain the same, we believe that plans could offer balanced cost-sharing as a separate, complimentary financing service that helps enrollees "manag[e] their

[22] Kaiser Family Foundation, Fact Sheet, The Medicare Part D Prescription Drug Benefit (October 2, 2017), available at https://www.kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/.

[23] See the studies on these issues cited in footnotes 5 and 6 in section I.

[24] 70 Fed. Reg. 4194, 4224 (Jan. 28, 2005) (Part D final rule).

[25] 70 Fed. Reg. 4194, 4224 (Jan. 28, 2005) (Part D final rule).

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payments for health care" without altering the underlying "qualified prescription drug coverage" benefit design.

Allowing Part D plans to offer this type of financing option – the same type of service utilities offer their customers, smoothing out payments over the course of the year -- could have a significant impact on the health and wellbeing of Part D beneficiaries, particularly those with chronic or potentially life-threatening conditions who require maintenance or specialty medications. We hope that CMS will explore such an option and would be pleased to discuss this idea with CMS.

Part D has been (and continues to be) a tremendously successful benefit that generally meets beneficiaries' needs very well. But some Part D enrollees with a high cost-sharing burden cannot keep incurring large out-of-pocket costs each month until they reach catastrophic coverage and their cost-sharing finally declines some; as a result, they give up and stop filling prescriptions or skip doses to stretch out their prescriptions – and therefore may never reach catastrophic coverage. This is disturbing because research shows that even people with very serious, life-threating diseases (like cancer) may abandon their prescriptions at the pharmacy due to cost-sharing.[26] Throughout this Proposed Rule, there is a creativity and willingness to try new ideas that will serve the MA and Part D programs and their enrollees well; we believe CMS could make major improvements in the programs by bringing that spirit to the problem of beneficiaries with high cost-sharing burdens, and we hope our suggestions will be useful in that effort.

* * *

We hope these comments are useful to CMS in developing a final rule and refining the point-of-sale rebate proposal. Please feel free to contact Emily Wheeler at (202) 741-1965 or Emily.Wheeler@astellas.com if we can provide any further information that would be helpful to you.

Sincerely,

Joseph F. Devaney

Vice President, Policy & Government Affairs

[26] See, e.g., Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions. Sonya Blesser Streeter, Lee Schwartzberg, Nadia Husain, and Michael Johnsrud Journal of Oncology Practice 2011 7:3S, 46s-51s.

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