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Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4182-P; 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

Pfizer appreciates the opportunity to comment on the Contract Year 2019 Medicare Advantage and Part D proposed rule published in the Federal Register on November 28, 2017.[1] Pfizer is a global leader in healthcare, helping change lives for the better by providing access to safe, effective and affordable medicines and related healthcare services. Pfizer is one of the world's largest research-based biopharmaceutical companies. As part of our mission, we believe that we can best ensure that people everywhere have access to innovative medicines and quality healthcare by working in partnership with all stakeholders including patients, healthcare providers, managed care organizations, governments, and non-governmental organizations. Below we provide detailed comments on various proposals in this proposed rule.

I. Manufacturer Rebates at the Point-of-Sale

Description of the Issue or Question:

CMS is requesting comment on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale.

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

Currently, the Part D negotiated price is the price paid to the network pharmacy or other network dispensing provider for a covered Part D drug dispensed to a plan enrollee that is reported to CMS at the point of sale by the Part D sponsor. Part D sponsors are allowed, but are not required, to apply rebates and other price concessions at the point-of-sale to lower the negotiated price. CMS notes that only a handful of plans have passed through a small share of price concessions to beneficiaries at the point-of-sale. Most plans prefer to use rebates to reduce premiums.

In describing its rationale for issuing the Request for Information (RFI), CMS notes the following:

- Manufacturer rebates have grown dramatically relative to total Part D gross drug costs each year since 2010.
    - Between 2010 - 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs.
- Rebates and price concessions are not reflected in the price of a drug at the point-of-sale.
    - All rebates and price concessions not included in the negotiated price must be reported to CMS as "direct or indirect remuneration" (DIR) at the end of the coverage year. These amounts are then used in CMS' calculation of final plan payments.
- The main benefit to a Part D beneficiary of price concessions applied as DIR at the end of the coverage year (and not to the negotiated price at the point-of-sale) is a lower plan premium.
    - Plans must factor into their bid an estimate of the expected DIR—that is, it must lower its estimate of plan liability by a share of the projected DIR—which has the effect of reducing the price of coverage under the plan.
    - Rebates and other price concessions that Part D sponsors and their PBMs negotiate, but do not include in the negotiated price at the point-of-sale, put downward pressure on plan premiums, as well as the government's subsidies of those premiums.
- DIR received that is above the projected amount factored into a plan's bid contributes primarily to plan profits, not lower premiums.
    - The risk-sharing construct established under Part D by statute allows sponsors to retain as plan profit the majority of all DIR that is above the bid-projected amount.
    - CMS analysis of Part D indicates that in recent years, DIR amounts plans and their PBMs actually received have consistently exceeded bid-projected amounts.
- Plans sometimes opt for higher negotiated prices in exchange for higher DIR and, in some cases, even prefer a higher net cost drug over a cheaper alternative.
    - This may put upward pressure on Part D program costs and shift costs from the plan to beneficiaries who utilize drugs in the form of higher cost-sharing and to the government through higher reinsurance and low-income cost-sharing subsidies.

Suggested Revisions/Comments:

Pfizer supports the concept of passing through some level of manufacturer/plan-negotiated rebates at the point-of-sale so that Medicare beneficiaries can more directly benefit from the significant price negotiations taking place in the Part D program. We applaud CMS for issuing this RFI and for exploring various mechanisms and approaches to applying negotiated rebates at the point-of-sale so that Part D enrollees will see reductions in their out-of-pocket costs for medicines.

Defining the Problem

Medicare Part D is a highly successful program, promoting access to affordable prescription drug coverage for seniors and disabled individuals. Because of the strong incentives to control costs, Part D plans and pharmaceutical companies negotiate significant discounts on covered Part D drugs, which help to control total program costs. Over time, that negotiation has intensified and resulted in significant growth in the level of rebates and discounts being provided to Part D plans. In fact, CMS points out that between 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs.

It is important to recognize when it created Medicare Part D, Congress specified that one required role of Part D sponsors offering coverage is to "*provide enrollees with access to negotiated prices used for payment for covered part D drugs*" even in portions of the benefit in which the patient must pay 100 percent of the costs. The law provides that negotiated prices "*shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs*."[2] Thus, the statute requires that plans reflect rebates and other price concessions in the "negotiated prices" they establish, which are used for calculating patient coinsurance and other Part D purposes. But the statute does not specify what percentage of these price concessions must be used to lower negotiated prices and thus passed through to patients at the point-of-sale or otherwise provide details about implementing the pass through requirement—thus leaving it to CMS to fill in those details, and granting CMS the authority to do so. When CMS promulgated regulations to implement Part D, it made clear that it did not interpret "take into account" to require that Part D plans include all price concessions, including rebates, in the negotiated price. In fact, CMS specifically addressed this and argued that Congress would not have used the "take into account" language if it meant that negotiated price had to include all price concessions.[3]

Thus, CMS directed that Part D plan sponsors could use the savings from manufacturer-negotiated rebates in one of two ways: either by directly reducing the cost of the medicine that generated the rebate at the time a prescription is dispensed, or by applying aggregate rebate savings at the end of the year to reduce overall plan liability and lower premiums for all enrollees. In practice, plans rarely pass through any level of rebate at the point-of-sale and instead apply rebates in aggregate as DIR at the end of the year. This is done for the purpose of computing CMS risk-sharing payments to plans and reinsurance subsidy payments to plans for drugs provided in

[2] Social Security Act (SSA) § 1860D-2(d)(1)(A), (B) (emphasis added).
[3] 70 Fed. Reg. at 4244

the catastrophic phase of the benefit. CMS calculates the risk-sharing payments and reinsurance subsidies it pays to plans based only on their actual net-of-rebate costs.

Pfizer has concerns about the incentives created by this practice. According to CMS, since plan sponsors can retain a portion of this excess DIR as profit, they may have financial incentives to steer utilization toward medicines with high list prices and large rebates. As noted in the RFI, CMS finds that plans "sometimes opt for higher negotiated prices in exchange for higher DIR and, in some cases, even prefer a higher net cost drug over a cheaper alternative." The agency also expresses concern that the current treatment of DIR provides plan sponsors with "weak incentives, and in some cases even, no incentive, to lower prices at the point-of-sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available."[4]

Principles for Passing through Rebates at the Point-of-Sale

Pfizer has identified a number of principles to consider when designing the approach CMS could use to ensure that Part D enrollee benefit more directly from manufacturer rebates. First, it should be done in such a way as to minimize complexity and confusion for Medicare beneficiaries. A process that results in frequent or significant fluctuations in the price beneficiaries are faced with at the pharmacy counter should be avoided. Predictability in out-of-pocket costs is critically important for seniors and people with disabilities. Second, it's critical to construct the process such that it protects commercially-sensitive drug cost data (i.e., data on bids, rebates, and other price concessions) and does not undermine the existing vigorous competition currently seen in this market. Disclosure of commercially-sensitive drug pricing data would undermine the competitive negotiations between plans and manufacturers, and actually have the opposite effect on what this policy is trying to achieve -- lower costs for Medicare beneficiaries. Third, the process should be carefully constructed to minimize the reporting and operational burden on plans, pharmacies, manufacturers and CMS.

CMS Therapeutic Class Proposal Could Result in Lower Rebates in the Part D Program

In the RFI, CMS suggests one approach to implementing manufacturer rebate pass-through. Plans would be required to include in the negotiated price reported to CMS a specified 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. CMS would require Part D plans to pass through a portion [not specified] of manufacturer rebates and all pharmacy price concessions at the point of sale.

> "Part D sponsors would use a specified minimum percentage of the weighted average of rebates provided by drug manufacturers for covered Part D drugs to reduce the negotiated price for covered Part D drugs in each therapeutic category and class."

Plans could apply as DIR at the end of the coverage year only those rebates received in excess of the total point-of-sale rebates.

[4] 82 Fed. Reg. at 56420.

We believe that this approach would actually have the unintended consequence of undermining the incentives for manufacturers to negotiate competitive rebates. Inherent in the current negotiation process – where manufacturers will negotiate rebates for preferable formulary position – are differing levels of discounts for drugs in the same therapeutic class depending on the goal. Some manufacturers may give smaller rebates just to be covered on the formulary, while some may give larger rebates to have their medicine placed on a preferred tier or to avoid utilization management restrictions. A therapeutic class-level rebate that spreads across multiple products would inhibit competition among companies. If the rebates from multiple companies are averaged and then that average used to determine the point-of-sale rebate that gets passed on to the Part D enrollee, companies providing higher rebates would be subsidizing the savings going to patients who are using other manufacturers' medicines. This could ultimately lead toward driving down rebates across therapeutic classes.

Product-Level, Multi-Formula Rebate Pass Through Approach More Effective

Instead, we urge CMS to consider alternative methodologies that allow rebates to be passed through at the product level. One way to determine the point-of-sale rebate, while at the same time protecting the confidentiality of competitive rebate data, would be to use a "multi-formula" approach, where CMS would define two or more calculations that would be required to be performed using the specific drug price and the manufacturer-negotiated rebate. Whichever calculation resulted in the lowest price to the Medicare beneficiary would be considered the final "negotiated price." This could be considered the "floor" for the amount of rebate to be passed through at the point-of-sale. It would be this price off of which cost sharing is derived for Medicare beneficiaries in the deductible, coverage gap, or catastrophic phase of the benefit, or for those who need drugs on co-insurance tiers.

For example, CMS could define three calculations to set the floor:

1. Negotiated price is reduced by X% of the manufacturer rebate [the percentage would be a meaningful majority]
2. Negotiated price is reduced so that it is no more than 25% greater than the true net price paid by the plan

For each drug, these calculations would be made and whichever formula resulted in the most savings to the beneficiary would be used to calculate the negotiated price, which would be the price that shows up in the Medicare Plan Finder.

One of the benefits of the multi-formula approach is that it prevents the "reverse engineering" of the negotiated price to determine the rebate provided by a particular manufacturer for a particular drug, thus protecting pricing data confidentiality and the competitive incentives in the program.

This formulaic approach would be relatively simple to administer, as it only requires a determination of the "lesser of" two or more mathematically straightforward calculations.

That said, we are fully aware that there are a myriad of operational details that would need to be addressed, and we look forward to discussing this in greater detail with the agency over the coming months. We know that it will be critical to balance the benefit to the Medicare enrollee and the operational complexity and burden for CMS, plans, and manufacturers. However, we do believe there are clearly definable ways to achieve that.

Impact on Costs to the Federal Government

We urge CMS to carefully examine the analysis conducted by Milliman that is contained in the comments submitted by PhRMA. That analysis – contrary to other analyses released in the public domain as well as contained in the RFI – shows that, over a ten-year window, this policy change could result in net savings for the federal government of up to $73B. The Milliman analysis described in the PhRMA comments takes into account behavioral changes. That is, their impact assessment takes into account changes that would be made by plan sponsors, Medicare beneficiaries, and pharmaceutical manufacturers in response to the rebate pass-through policy. Examples of changes they consider include changes to plan benefit designs, increasing use of formulary and utilization restrictions (on the part of plans); increased adherence to prescribed treatment regimens for medicines, reduced utilization of physician and hospital services (on the part of Medicare beneficiaries); and deeper discounts and less frequent price increases on drugs (on the part of pharmaceutical companies).

II. Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c))

Description of the Issue or Question:

In the proposed rule, CMS proposes to (1) retain (as revised and re-designated) the current regulatory provision that permits Part D plan sponsors to disallow tiering exceptions for any drug that is on a plan's specialty tier, and (2) establish a number of new limitations on tiering exceptions.

Suggested Revisions/Comments:

Strong beneficiary protections, like tiering exceptions, are vitally important to the success of the Part D program because they ensure that Medicare beneficiaries have affordable access to clinically appropriate treatments. Pfizer is very concerned that CMS' proposed limitations on tiering exceptions, if finalized, would will greatly weaken these crucial beneficiary protections and exceed the agency's statutory authority. The Medicare statute broadly 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 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 of such an exception shall be

treated as a coverage denial for purposes of applying subsection (h) [concerning appeals].[5]

Pfizer urges CMS to eliminate its current regulation that allows plans to prohibit tiering exceptions for drugs on specialty tiers. This policy is inconsistent with the statutory language quoted above, which does not authorize CMS to create categories of drugs for which plans can simply refuse to consider tiering exception requests. CMS' authority is limited to creating guidelines for plans to "mak[e] a determination with respect to such a [tiering exception] request," not guidelines allowing plans to deny beneficiaries the opportunity to seek tiering exception requests in the first place.

Furthermore, it is fundamentally at odds with the purpose of the statutory provision to deny tiering exceptions to the very beneficiaries with the greatest need for them, i.e., those who must take specialty medications because a physician has determined that a preferred alternative would be less effective or have adverse effects. In fact, Senator Grassley, the chief Senate negotiator on the MMA Conference Committee, used HIV/AIDS drugs, which are considered specialty drugs and typically are placed on Part D plans' specialty tiers, as his example when touting the protections offered by the tiering exception provision.[6] We recognize that CMS may not be able to eliminate this provision in this rulemaking, because it did not propose to do so in the proposed rule; however, CMS should take such action in the next Part D rulemaking.

Pfizer also urges CMS not to finalize its proposed new limitations on tiering exceptions. First, CMS proposes to permit plans to limit the availability of tiering exceptions for brand name drugs and biological products to a preferred tier containing the "same type" of drug for treating the enrollee's condition (i.e., a beneficiary requiring a non-preferred biologic could only access the cost sharing for a preferred biologic and a beneficiary requiring a non-preferred "brand name drug" could only access the cost-sharing for a preferred brand name drug.)[7]. The statute, however, is much broader than that -- it gives beneficiaries the right to request tiering exceptions for a non-preferred drug if there is any preferred drug with lower cost-sharing to treat the same condition and the beneficiary's physician determines that the preferred drug would be less effective or have adverse effects for the beneficiary. The statute does not distinguish between drugs based on their FDA approval pathway, nor is there anything in the statute to support CMS establishing such a distinction in the regulations.

While the proposed rule states that this new restriction would "achieve needed balance" and "align[] with how many plan sponsors already design their tiering exceptions criteria,"[8] it is likely to

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

[6] "I am pleased with the backup protections in this bill. That if a plan doesn't carry or doesn't treat as preferred a drug needed by, say, a person with AIDS, a simple note from a doctor explaining the medical need for that particular drug could get that drug covered." 149 Cong. Rec. S15882, S15888 (Nov. 25, 2003).

[7] Brand name drug is defined in 42 C.F.R. § 423.4 as a drug approved under section 505(c) of the Food, Drug, and Cosmetic Act (including a drug approved under section 505(b)(2)).

[8] 82 Fed. Reg. at 56372.

prevent many beneficiaries from being able to seek a tiering exception at all. Part D plans often place most biological products on non-preferred tiers. If there are no biological products on a preferred tier for the same condition, a beneficiary taking a biologic would be unable to seek a tiering exception and would be denied this very important -- and statutorily required -- patient protection. For example, SilverScript Choice, the top PDP by enrollment (that enrolls more than a fifth of beneficiaries with Part D), covers denosumab (trade name Prolia) on the non-preferred drug tier. Prolia is the only biologic medication used to treat osteoporosis. Thus, no patients enrolled in SilverScript Choice who take denosumab would be able to access a tiering exception for this medication, if the policy is finalized as proposed. CMS' claim that plans are already doing this, if correct, is not evidence that this practice complies with the statute -- it would be a sign that CMS needs to adopt regulations explicitly specifying that the statute does not permit this barrier to tiering exceptions.

Second, CMS proposes to interpret the statutory language "preferred drug for treatment of the same condition" as meaning preferred drug for treatment of the 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."[9] This proposal would limit the preferred drugs that may be used to establish the lower cost-sharing amount to preferred drugs that treat a subset of the condition, based on the plan's assessment of the patient's particular presentation of that condition. Like CMS' other proposed limitation, there is no basis for this narrow interpretation in the statute. CMS' reliance on the statutory phrase "for the individual" is misplaced -- that portion of the statute refers to a physician's individualized determination that a preferred drug is inappropriate for a particular patient and has nothing to do with the plan's exceptions process.

Moreover, this limitation could make the exceptions process meaningless. Under this limitation, the very reason that the statute permits a beneficiary to seek an exception -- because his or her physician determines that a preferred drug is clinically inappropriate for that individual (e.g., due to comorbidities, or other "relevant clinical characteristics of the beneficiary and/or the drug regimen") -- would then allow plans to exclude that same preferred drug from the list of "preferred drugs for treatment of the same condition" -- thus ruling out a tiering exception. The result is that plans could nearly always claim that there are no preferred drugs to treat the "same condition," thus turning this important beneficiary protection into a catch-22 that does nothing but frustrate beneficiaries and physicians and waste their time. This is not how Congress intended the tiering exception process to work -- it was meant to be a real protection.

We urge CMS to require adherence to the tiering exception process described in the law, and accordingly: (1) to eliminate 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 (2) not to finalize the proposed new barriers to tiering exceptions.

[9] 82 Fed. Reg. at 56372-73 (emphasis added).

III. Changes to the Days' Supply Required by the Part D Transition Process

Description of the Issue or Question:

CMS is proposing to change the current regulation (42 CFR § 423.120(b)(3)(iii)(B)) requiring that Part D plans provide access to at least a 91 day supply of non-formulary drugs they are already taking for enrollees in the Long Term Care (LTC) setting during the transition to a new plan.[10] The proposal would create a single month's supply minimum that would apply both to the outpatient setting and the LTC setting.

Suggested Revisions/Comments:

CMS established the 91-day supply rule for transitions in the LTC setting in 2010, based on "the often complex needs of LTC residents that often involve multiple drugs and necessitate longer periods in order to successfully transition to new drug regimens."[11] Therefore, Part D plans currently are required to honor multiple fills of non-formulary Part D drugs, during the entire 91-day transition period.

CMS states that it is proposing this change because this original rationale for the longer transition fill requirement in the LTC setting is no longer applicable:

> After more than 10 years of experience with Part D in LTC facilities, we have not seen the concerns that we expressed in the 2010 final rule materialize. We are not aware of any evidence that transition for a Part D beneficiary in the LTC setting necessarily takes any longer than it does for a beneficiary in the outpatient setting. We understand that it is common for Part D beneficiaries in the LTC setting to be cared for by on-staff or consultant physicians and other health professionals with prescriptive authority who are under contract with the LTC facility. Additionally, we also understand that Part D beneficiaries in the LTC setting are typically served by an on-site pharmacy or one under contract to service the LTC facility. Given this structure of the LTC setting, we understand that the LTC prescribers and pharmacies are readily available to address transition for Part D beneficiaries in the LTC setting. In addition, LTC facilities now have many years' experience with the Medicare Part D program generally and transition specifically. While our concerns about the needed timeframe for transition in the LTC setting do not seem to have materialized, we have continuing concerns about drug waste and the costs associated with such waste in the LTC setting.[12]

Pfizer believes that CMS should maintain the current 91-day supply rule for LTC transitions, as CMS does not provide any new information to demonstrate that the concerns it raised in 2010 no longer exist. The lack of evidence that LTC residents need longer transitions that CMS mentions is likely

[10] 82 Fed. Reg. at 56412.

[11] 82 Fed. Reg. at 56412.

[12] 82 Fed. Reg. at 56412.

due to the fact that currently they have longer transitions. Such "evidence" would typically surface in the form of complaints by beneficiaries or their representatives of health problems associated with inadequate transitions. Because the longer time period for LTC transitions under the current rule provides adequate time for smooth transitions in the LTC setting, transition problems are unlikely to occur and thus unlikely to be reported to CMS.

The "complex needs of LTC residents that often involve multiple drugs"[13] that prompted CMS to establish the 91-day supply rule in 2010 have not abated over the last decade. In fact, polypharmacy among LTC beneficiaries has likely intensified over the last decade as the need for managing chronic diseases appropriately has gained greater recognition. The availability of an on-site pharmacy in the LTC setting does not mean that physicians who must manage the medications and interactions for these complex patients can adjust their drug regimens more quickly than they could do in 2010. Finally, it is unclear from the proposed rule preamble exactly how shortening the LTC transition supply period would reduce waste. LTC beneficiaries' physicians generally substitute a new on-formulary drug for the non-formulary drug at the end of the transition period. Because this substitution typically occurs when the transition supply of the non-formulary drug is exhausted, there is no apparent reason why the transition policy would create waste.

In summary, we encourage CMS to maintain the 91-day supply rule for LTC transitions, as the protections it affords these very sick institutionalized patients are as important as ever and outweigh the desire to enhance plan flexibility in this particular instance.

IV. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

Description of the Issue or Question:

CMS currently requires that Part D plans provide 60 days advance notice to CMS, affected enrollees, and certain other parties before removing a drug from their formulary or otherwise making a negative change; in addition, CMS prohibits plans from making any negative changes between the start of the annual coordinated election period and 2 months after the start of the contract year associated with that election period.[14] Plans also must generally submit formulary change requests to CMS (although plans may assume that "maintenance changes," such as adding a new generic to the formulary and removing the therapeutically equivalent brand name drug, are approved by CMS unless they hear otherwise within 30 days).

Under the proposed rule, CMS would permit plans to remove a brand name drug from their formularies (or increase its cost-sharing) immediately upon adding a newly approved generic equivalent to the brand drug to their formularies. The plan would not be required to wait until after it had requested CMS approval for the change or until the first two months of the year had

[13] 82 Fed. Reg. at 56412.

[14] 42 C.F.R. § 423.120(b)(5), (6).

elapsed.[15] In addition, CMS would delete the requirement that plans provide affected enrollees advance notice of such a generic substitution, and instead would allow plans to provide prospective and current enrollees with "general notice that certain generic substitutions could occur without additional advance notice."[16] The proposed rule states that enrollees would receive "the same information they receive under the current regulation -- the only difference being that the notice could be provided after the effective date of the generic substitution."[17]

Suggested Revisions/Comments:

The primary concern we have with this proposal is the elimination of the advance notice requirement. Beneficiaries who are taking a brand name drug that will be removed from the plan's formulary and replaced with a newly approved generic equivalent must be advised of this change at the earliest possible time and before they fill a prescription written for the impacted brand drug. Advance notice of such a change is critically important as it gives beneficiaries the opportunity to discuss options (including seeking an exception or changing medications) with their prescribers. It also helps to avoid confusion and potential disruption in therapy. When they pick up their refill, beneficiaries may not be aware that they are receiving a new generic equivalent instead of the product to which they are accustomed. This can result in confusion and distress, when they receive a drug with a name, color, shape, taste, or other characteristic different from what they were expecting. Moreover, in most cases the beneficiary will not be filling a prescription immediately after a generic substitution occurs, and therefore the plan will be able to notify the beneficiary of the change before he or she arrives at the pharmacy expecting to fill a prescription for the brand name product.

We note also that the proposed rule states that it would "implement MedPAC's recommendation" on expediting generic substitution,[18] but MedPAC did not recommend doing away with advance notice to enrollees of a generic substitution. MedPAC recommended expediting mid-year formulary changes that CMS generally approves (such as removing brand name drugs from the formulary and replacing them with generic equivalents) and specifically stated that: "Plan sponsors would still be required to notify enrollees before making the change, but sponsors would no longer need prior CMS approval."[19]

Accordingly, we recommend that CMS revise the text of proposed 42 C.F.R § 423.120(b)(5)(iv)(C) to state that, before making permitted generic substitutions, a Part D plan must: (1) provide all current and prospective enrollees, in the plan's formulary and other applicable beneficiary communication materials, with a general notice that new generic drugs may be substituted for

[15] 82 Fed. Reg. at 56413. These changes would all be premised on the newly added generic having lower cost-sharing or the same cost-sharing as the brand name therapeutic equivalent had.

[16] 82 Fed. Reg. at 56413.

[17] 82 Fed. Reg. at 56414-15.

[18] 82 Fed. Reg. at 56413.

[19] MedPAC, Report to the Congress: Medicare and the Health Care Delivery System, 194 (June 2016).

their brand name therapeutic equivalents as soon as the generic is approved, and occasionally this may occur immediately before an enrollee fills a prescription written for the brand name drug; (2) notify enrollees of such a generic substitution as soon as it occurs, including providing advance notification at the point-of-sale before the prescription is filled if that is the earliest opportunity to notify the enrollee of the change; and (3) provide enrollees with information on the specific drugs involved and the steps they may take to request coverage determinations and exceptions under 42 C.F.R. §§ 423.566 and 423.578 as part of the advance notification.

V. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (§§ 423.590 and 423.636)

Description of the Issue or Question:

CMS is proposing changes to the adjudication timeframe for Part D standard redetermination requests for payment at § 423.590(b) and the related effectuation provision § 423.636(a)(2). Specifically, CMS proposes to change the timeframe for issuing decisions on payment redeterminations from 7 calendar days from the date the plan sponsor receives the request to 14 calendar days from the date the plan sponsor receives the request. This proposed 14-day timeframe for issuing a decision related to a payment request would also apply to the IRE reconsideration pursuant to § 423.600(d).[20] CMS offers the following reasons for this proposed change in the timeframe:

> We believe affording more time to adjudicate payment redetermination requests (including obtaining necessary documentation to support the request) will ease burden on plan sponsors because it could reduce the need to deny payment redeterminations due to missing information. We also expect the proposed change to the payment redetermination timeframe would reduce the volume of untimely payment redeterminations that must be auto-forwarded to the IRE. In addition, having more time to gather information and process these requests could be beneficial to enrollees because decisions will be more fully informed, potentially resulting in fewer decisions having to undergo further appeal. . . . Allowing plan sponsors and the IRE additional time to process payment appeal requests may assist these adjudicators in allocating resources in a manner that is most efficient and enrollee friendly, for example, ensuring adequate resources are directed to processing more time-sensitive pre-service requests where the enrollee has not yet obtained the drug, particularly during periods of increased case volume.[21]

Suggested Revisions/Comments:

Pfizer believes that the stated potential benefits of this proposed change are speculative at best. The theory that this change would promote more fully informed decisions assumes that plans or

[20] 82 Fed. Reg. at 56437.

[21] 82 Fed. Reg. at 56438.

the IRE currently lack sufficient information for an appropriate redetermination or reconsideration, and that adding 7 calendar days to the timeframe will somehow cure the assumed information deficit. But no evidence is cited for those assumptions.

Instead of doubling the current timeframe, CMS should improve Part D plan accountability by enforcing the current timeframes, which allow sufficient time for decisions that are typically based on a limited set of facts. If CMS believes that the current 7 day timeframe is insufficient, then it should explain why this is the case and delay this proposal until it can propose tying an extended timeframe to specific enhanced performance standards for redeterminations and reconsiderations, with substandard performance resulting in financial consequences for plans.

VI. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences

Description of the Issue or Question:

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

Suggested Revisions/Comments:

Pfizer supports CMS' proposal to eliminate the meaningful difference requirement in an effort to lower Part D premiums and increase beneficiaries' choice of coverage options. Our concern, and experience in the market, has been that such policies often work against the goals of a competitive Part D market, and can limit beneficiary access to enrollment options that meet their needs.

However, it remains important to ensure that distinctions between plans are clear to beneficiaries when they are considering enrollment options. Revising the Plan Finder and the Medicare and You handbook to include 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) would help beneficiaries distinguish plans and make better plan choices. Also, as we recommend below, we encourage CMS to feature a symbol on Plan Finder to prominently indicate which plans offer coverage for vaccines without cost-sharing. Addition of such a symbol may incentivize plan sponsors to offer coverage for vaccines without cost-sharing which, in the aggregate, would have positive health benefits for the Medicare population.

VII. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

Description of the Issue or Question:

Effective January 1, 2019, CMS is proposing the adoption of the National Council for Prescription Drug Programs (NDPDP) SCRIPT Standard Version 2017071, and the retirement of the current NCPDP SCRIPT Version 10.6, as the official electronic prescribing standard for transmitting

prescriptions and prescription-related information using electronic media for covered Part D drugs.[22] The NCPDP SCRIPT standards are used to exchange information between prescribers, dispensers, intermediaries and Part D plans. The proposed updated NCPDP SCRIPT standards have been requested by the industry and could provide a number of efficiencies, which the industry and CMS support.

Suggested Revisions/Comments:

Pfizer supports updating the Part D e-prescribing standards; however, CMS should provide a reasonable timeframe for prescribers to comply with the standard and also must ensure that along with this updated standard, the communications between prescribers, insurers and their intermediaries are transparent. We also request that CMS take all appropriate action to guard against communications that inappropriately steer prescribers to lower cost options for cost control purposes as a result of the new NCPDP SCRIPT standard.

In addition, Pfizer welcomes a more widespread, integrated adoption of electronic prescribing, provided that e-prescribing does not restrict access to the treatments preferred and chosen by patients and their health care professionals. We want to underscore the need for transparent communications by all parties through the transmission of accurate benefit and eligibility information, transparent and timely electronic prior authorization processes, and evidence-based decision support.

We are concerned that misaligned incentives could motivate insurers (and their intermediaries, along with other system suppliers) to guide prescribers toward lower cost alternative therapies without fully considering the potential impact on health outcomes. Furthermore, inaccurate or biased e-prescribing data could prevent patients from receiving the most appropriate medicines.

Outside of these concerns, we recognize the significant benefits of adopting the new standard; for example, allowing the electronic prescribing of compounded medications. The expanded use of electronic prescribing by practitioners may also help Pfizer better understand how our therapies are used and prescribed, thus enabling us to continue developing better medicines, adherence programs, and patient support programs.

Furthermore, we believe that optimal patient care must be at the forefront of any proposed change in the e-prescribing standard. To that end, we recommend that CMS prioritize the following goals for e-prescribing and the new standard:

- Reducing administrative burden to providers and the health care system related to transaction requirements including electronic prior authorization;

- Promoting shared decision-making;

[22] 82 Fed. Reg. at 56439.

- Ensuring that appropriate coverage and clinical information is available for point of care decision making;

- Coordinating care between hospitals, physicians, payers, laboratories, and pharmacies through a secure and effective infrastructure that enhances patient privacy and protection; and

- Providing access to e-prescribing data for research purposes.

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

Description of the Issue or Question:

CMS proposes to revise the definition of a generic drug at 42 C.F.R. §423.4 to include biosimilars approved under section 351(k) of the of the PHS Act solely for purposes of cost-sharing under sections 1860D-2(b)(4) and 1860D-14(a)(1)(D)(ii-iii) of the Act. It would limit inclusion of biosimilars in the definition of generic drug to non-LIS catastrophic cost-sharing and LIS cost-sharing.

Under Part D, the maximum copayments for LIS enrollees, and for non-LIS enrollees in catastrophic coverage, are lower for "generics" and preferred "multiple source drugs" than for other drugs. CMS previously analyzed whether biosimilars were "generics" or "multiple source drugs" and concluded they were not.[23] The Part D regulatory definition of a generic is limited to drugs approved under section 505(j) of the Food, Drug, and Cosmetic Act,[24] and the relevant Part D provisions incorporate a definition of multiple source drugs limited to drugs with therapeutic equivalents listed in FDA's Orange Book.[25] As a result, biosimilars are currently treated as brand name drugs for purposes of the maximum LIS and catastrophic coverage copayments.

Under the proposed rule, CMS would amend the definition of a generic in 42 C.F.R. § 423.4 such that -- solely for purposes of the maximum LIS and catastrophic coverage copays -- biosimilars would be categorized as generics. CMS explained that it would only classify biosimilars as generics for purposes of setting maximum LIS and catastrophic coverage copayments because this classification would be inappropriate for purposes of other Part D policies that distinguish between "generics" and other Part D drugs, and it could cause confusion:

> . . . [W]e want to avoid causing any confusion or misunderstanding that CMS treats follow-on biological products as generic drugs in all situations. We do not believe that would be appropriate because the same FDA requirements for generic drug approval (for example, therapeutic equivalence) do not apply to biosimilar biological products,

[23] March 30, 2015 CMS Memorandum from Amy K. Larrick to Part D Sponsors, "Part D Requirements for Biosimilar Follow-On Biological Products."

[24] 42 C.F.R. § 423.4.

[25] Social Security Act (SSA) § 1860D-14(a)(1)(D)(maximum LIS copayments); SSA § 1860D-2(b)(4). Both of these provisions incorporate the multiple source drug definition in SSA § 1927(k)(7)(A)(i).

currently the only available follow-on biological products. Accordingly, CMS currently considers biosimilar biological products more like brand name drugs for purposes of transition or midyear formulary changes because they are not interchangeable. In these contexts, treating biosimilar biological products the same as generic drugs would incorrectly signal that CMS has deemed biosimilar products (as differentiated from interchangeable biological products) to be therapeutically equivalent. This could jeopardize Part D enrollee safety and may generate confusion . . . due to the many places in the Part D statute and regulation where generic drugs are mentioned.[26]

Suggested Revisions/Comments:

Treating biosimilars as generics for the purposes of LIS cost-sharing and non-LIS catastrophic cost-sharing in Part D would be inconsistent with the approach to biosimilars in other government reimbursement statutes and policies. We are not certain what the rationale would be for classifying biosimilars as generic drugs, even in limited circumstances, as there are no existing CMS or FDA definitions of generics (or even the broader term "multiple source drug") that encompass biosimilars, and the proposed rule does not suggest a rationale. To state the obvious, biosimilars are not generics.

By way of explaining the impetus for the proposal, CMS states that classifying biosimilars as brands for purposes of the maximum LIS and catastrophic coverage copayments has "generated a great deal [of] confusion and concern for plans and advocates alike, and CMS received numerous requests to redefine generic drug at [42 C.F.R.] 423.4."[27] Stakeholders expressed concerns that treating biosimilars as brands for these purposes would discourage enrollees from choosing lower-cost alternatives. CMS agreed with these concerns and stated that "[l]ower cost sharing for lower cost alternatives will improve enrollee incentives to choose follow-on biological products over more expensive reference biological products and will reduce costs to both Part D enrollees and the Part D program."[28]

Pfizer agrees with CMS that encouraging the use of lower-cost biosimilars is an important goal that can reduce costs for Medicare Part D enrollees and for the Part D program. We also support CMS' efforts to foster the growth of a robust, sustainable biosimilar marketplace that promotes greater competition and cost savings over the longer term. Therefore we appreciate and strongly support the intent of this CMS proposal. At the same time, we share the concerns that CMS expressed about classifying biosimilars as generics (even for limited and clearly-defined purposes).[29]

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[26] 82 Fed. Reg. at 56417.

[27] 82 Fed. Reg. at 56417.

[28] 82 Fed. Reg. at 56417.

[29] We also question whether this proposal could significantly reduce copayments for Part D enrollees given the statutory provisions at issue. Under SSA § 1860D-14(a)(1)(D), the maximum copayment for certain LIS enrollees (before catastrophic coverage) is $1 for a generic or preferred multiple source drug and $3 for any other drug, as of 2006; these amounts are annually adjusted and the adjusted amounts for 2018 are $1.25 and $3.70. Under SSA § 1860D-2(b)(4), the maximum catastrophic coverage copayment (for non-LIS enrollees) is the greater of: (1) $2 for a generic or preferred multiple source

Given all these considerations, it may be prudent to proceed systematically in identifying and evaluating options for advancing the vitally important goals underlying this proposal. CMS could survey all the tools it might use to encourage biosimilar utilization in Part D and consider whether alternatives exist that are more logical and offer greater benefits to the Part D program and its enrollees. This is a valuable opportunity for further dialogue between CMS and stakeholders aimed at either refining and clarifying the basis for this proposal or identifying alternative measures with greater potential to stimulate biosimilar utilization and associated cost savings. Like other companies that have already entered the biosimilar marketplace or are considering such a move, at Pfizer we have a number of ideas about CMS policies that might improve the incentives for using biosimilars in Medicare and Medicaid and enable these programs to realize more savings from biosimilars as their utilization expands. Given the importance of supporting a sustainable market for biosimilars, as a starting point we would encourage CMS (in addition to providing a more efficient reimbursement structure where appropriate) to begin actively monitoring biosimilar usage within the Medicare and Medicaid programs by setting up appropriate infrastructure and affirmatively identifying "biosimilar uptake" as a policy priority for the Agency.

IX. Medication Therapy Management (MTM) (§§ 422.2430 and 423.2430)

Description of the Issue or Question:

The Medical Loss Ratio (MLR) regulations applicable to Part D plans currently do not specify whether programs that satisfy the Part D MTM requirements at 42 C.F.R. § 423.153(d) represent Quality Improvement Activities (QIA), the costs of which go into the MLR numerator. CMS now proposes to clarify this issue. In particular, CMS would modify its regulations at §§ 422.2430 and 423.2430 by adding new paragraph (a)(4)(i), which specifies that all Part D plan MTM programs that comply with § 423.153(d) are QIA meeting the requirements of 42 C.F.R. § § 422.2430 and 423.2430 (and thus count in the MLR numerator).[30] CMS believes that treating compliant MTM programs as QIA in the calculation of the Medicare MLR would discourage plans -- particularly standalone PDPs that may currently lack strong incentives to promote MTM -- from adopting restrictive MTM eligibility criteria, and thus improve utilization of MTM.[31]

Suggested Revisions/Comments:

Pfizer strongly supports CMS' proposal to clarify that compliant MTM programs are QIA, and we agree with CMS that this clarification will increase utilization of this important patient care management and safety tool. Strengthening and expanding MTM programs is important to Part D because (among other things) these programs can help to promote adherence and, as CMS notes, "beneficiaries with higher rates of medication adherence have better health outcomes" and

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drug and $5 for any other drug as of 2006 (annually adjusted such that for 2018 these amounts are $3.35 and $8.35); or (2) 5% coinsurance. Because the dollar amounts typically fall below 5% coinsurance, enrollees usually pay 5% coinsurance and classifying biosimilars as generics is thus unlikely to affect enrollee cost-sharing.

[30] 82 Fed. Reg. at 56458.

[31] 82 Fed. Reg. at 56458.

"medication adherence can also produce medical spending offsets, which could lead to government and taxpayer savings in the trust fund, as well as beneficiary savings in the form of reduced premiums."[32] Accordingly, we hope CMS will finalize its proposal to eliminate the current uncertainty about whether MTM activities are classified as QIA.

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

Description of the Issue or Question:

Medicare Advantage plans must cap annual cost-sharing for Part A and B services at a MOOP limit, which may not exceed an annual limit set by CMS.[33] The mandatory MOOP is currently $6700, and represents approximately the 95th percentile of projected out-of-pocket spending for Part A and B services (i.e., only about 5% of Medicare fee-for-service beneficiaries are projected to incur more than $6700 annually in Part A and B deductibles, copayments, and coinsurance).[34] 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."[35]

Suggested Revisions/Comments:

We support this proposal to recognize that CMS has flexibility in establishing annual MOOPs for Part A and B services, and wish to emphasize the importance of extending the MOOP -- which has worked well and provided beneficiaries a critical protection against excessive annual cost-sharing -- to Part D drugs. Extending the MOOP to the full benefit package offered by MA-PD plans would improve adherence to Part D prescribed drug regimens, reduce spending on those Part A and B services the use of which increases with non-adherence to drug regimens, and enable plans to coordinate care better for their enrollees.

Moreover, the legal authorities that enabled CMS to establish mandatory MOOPs for local Medicare Advantage plans[36] are equally applicable to Part D. In initially establishing the MOOPs for these Medicare Advantage plans, CMS relied on: (1) the prohibition on discriminatory benefit designs in Social Security Act (SSA) § 1852(b)(1)(A), which is substantially similar to the Part D non-discrimination provision in SSA § 1860D-11(d)(2)(D); and (2) SSA § 1857(e)(1), which authorizes

[32] 82 Fed. Reg. at 56459.

[33] 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.

[34] 82 Fed. Reg. at 56361.

[35] 82 Fed Reg. at 56495 (proposed 42 C.F.R. §§ 422.100(f)(4), 422.101(d)(2), (3)(ii)).

[36] Regional MA plans have MOOPs by statute.

CMS to add "necessary and appropriate" terms to its contracts with plans and applies to Part D via § 1860D-12(b)(3)(D).[37]

In the past, CMS has raised questions about its ability to establish a MOOP for Part D, stating in the Medicare Advantage and Part D final rule for 2011 that: "We do not believe that a regulatory overall liability limit for Part D would be practical or appropriate given the current design of Part D benefits (such as the coverage gap). We also note that, under the Part D benefit, there is protection afforded to a beneficiary once they enter into the catastrophic phase of the benefit where there is nominal cost-sharing."[38] This passage understates the costs that beneficiaries incur in catastrophic coverage, which is generally the greater of a nominal copay or 5% coinsurance for non-LIS enrollees.[39] The coinsurance charges beneficiaries incur in catastrophic coverage can be very high -- and they occur after a beneficiary has already incurred high out-of-pocket costs on Part D drugs to reach catastrophic coverage (e.g., the catastrophic coverage threshold for 2018 is $5,000 in TROOP for an applicable beneficiary).[40]

For example, a recent Kaiser Family Foundation study analyzed catastrophic spending in 2015 (the most recent year for which data were available) and found that on average non-LIS beneficiaries who reached catastrophic coverage (a total of about one million people) incurred $1215 (40% of their total annual out-of-pocket drug spending) in catastrophic coverage, with 1 in 10 of these beneficiaries having total out-of-pocket spending of at least $5200 in all phases of the Part D benefit.[41] The report observed that "the absence of an annual out-of-pocket spending limit under Part D exposes enrollees to significant costs -- unless their incomes are low enough to qualify for low-income subsidies."[42] In fact, the burden on non-LIS enrollees who reach catastrophic coverage is so significant that MedPAC's June 2016 report recommended eliminating enrollee cost-sharing in catastrophic coverage.[43]

Therefore, non-LIS Part D enrollees who reach catastrophic coverage still face ongoing out-of-pocket costs that are by no means "nominal," and without a cap on their Part D spending a substantial risk of non-adherence and worsened health outcomes exists. It is important to bear in mind that before they even reach the catastrophic phase of the benefit, these enrollees: (1) have

[37] 74 Fed. Reg. 54634, 54657 (Oct. 22, 2009) (proposed MA and Part D rule for 2011, proposing mandatory MOOPs for local Medicare Advantage plans); 75 Fed. Reg. 19678, 19710-11 (April 15, 2010) (final rule for 2011, finalizing MOOP proposal).

[38] 75 Fed. Reg. at 19714 (final MA and Part D rule for 2011).

[39] SSA § 1860D-2(b)(4)(A).

[40] Part D final call letter for 2018 at 48 (Part D benefit design parameters for 2018). The $5,000 for applicable beneficiaries is the TROOP amount, which includes manufacturer coverage gap discounts as well as beneficiary out-of-pocket spending.

[41] Kaiser Family Foundation Issue Brief, "No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending," 1-4 (Nov. 2017).

[42] No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending, supra, at 9.

[43] MedPAC, Report to the Congress: Medicare and the Health Care Delivery System, 156 (June 2016).

already incurred high out-of-pocket costs for Part D drugs; and (2) likely have incurred high out-of-pocket costs for Part A and B services as well.[44]

We understand that Part D has a different benefit design than the Part A and B services covered by Medicare Advantage plans, which raises additional complexities. However, at least for MA-PDs, there is a straightforward legal path for limiting Part D out-of-pocket spending: SSA § 1860D-21(c)(2). This provision states that CMS shall 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.[45] Leaving the cost-sharing on an MA-PD plan's Part D benefits uncapped undercuts the purpose of establishing a Part A/B MOOP in order to ensure that MA plans do not discourage enrollment by any Medicare beneficiaries. As CMS stated in establishing the Part A/B MOOP, "requiring such a limit on plan design is necessary in order 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)."[46] But the absence of any limit on Part D cost-sharing could just as easily discourage individuals who use higher-than-average levels of services from enrolling in an MA-PD. The unlimited cost-sharing on the Part D side thus conflicts with the cap on Part A/B cost-sharing.

Further, the absence of a Part D MOOP also undercuts an MA-PD plan's ability to coordinate Part C and Part D benefits, as less healthy enrollees with high drug utilization may stop taking their Part D drugs or skip doses as their out-of-pocket costs increase without limit on the Part D side, which in turn may increase Part C spending for services such as hospitalizations.[47] In addition, in cases where a particular disease may be treated with Part B or D drugs, the Part A/B MOOP and the absence of a Part D counterpart may create incentives for beneficiaries with high healthcare costs to use the Part B drug even if it may not be the best choice from a clinical perspective.

CMS therefore has ample authority to waive Part D benefit design provisions to the extent they would otherwise impede its ability to limit Part D cost-sharing under MA-PD plans. CMS could either establish a Part D MOOP that would apply in addition to the Part A/B MOOP that applies to

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[44] An instructive contrast is provided by the annual MOOP for non-grandfathered individual and group coverage, which applies to cost-sharing for all essential health benefits (drug and non-drug) and is $7,350 for individual coverage in 2018. 81 Fed. Reg. 94058, 94140 (Dec. 22, 2016). Currently Medicare beneficiaries lack any comparable protection.

[45] SSA § 1860D-21(c)(2) literally 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").

[46] 74 Fed Reg. at 54657.

[47] See, e.g., Congressional Budget Office, Offsetting Effects of Prescription Drugs Use on Medicare's Spending for Medical Services (Nov. 2012) ("policy changes that influence Medicare beneficiaries' use of prescription drugs, such as those altering the cost-sharing structure of the Part D drug benefit, probably affect federal spending on their medical services").

MA-PD plans, or establish a single unified MOOP that applied to all Part A, B, or D services covered by an MA-PD plan. Similar to the MOOP for Part A and B services, CMS could consider a MOOP set at the projected 95th percentile of Part D spending or (if operationally feasible) a total MOOP set at the projected 95th percentile for Part A, B, and D spending. Either of these approaches is within CMS' legal authority and could improve adherence and health outcomes for MA-PD enrollees. We urge CMS to include such a proposal in its next Part D rulemaking.

XI. Cost Sharing Limits for Medicare Parts A and B Services (§§ 417.454 and 422.100)

Description of the Issue or Question:

Under its Medicare Advantage non-discrimination authority (SSA § 1852(b)(1), which prohibits MA benefit designs that discourage enrollment by certain beneficiaries) CMS currently sets annual limits on the cost-sharing that Medicare Advantage plans can impose for certain Part A and B services. CMS determines annually the level at which cost-sharing for certain services becomes discriminatory.[48] The proposed rule states that these annual limits are currently based on Medicare fee-for-service data and reflect a combination of patient utilization scenarios and length of stays for services used by average to sicker patients.[49]

Under the proposed rule, CMS would amend 42 C.F.R. § 422.100(f)(6) "to clarify that it may use Medicare FFS data to establish appropriate cost-sharing limits"; further, CMS "intends to use MA encounter data to inform patient utilization scenarios used to help identify MA plan cost-sharing standards and thresholds that are not discriminatory" and seeks comments on "whether to codify that use of MA encounter data for this purpose in § 422.100(f)(6)."[50] This proposal is designed to allow CMS to use "the most relevant and appropriate information in determining whether specific cost-sharing is discriminatory and to set standards and thresholds above which CMS believes cost-sharing is discriminatory."[51] CMS expects that MA encounter data "will be more accurate and complete in the future."[52]

Suggested Revisions/Comments:

We strongly support CMS setting cost-sharing limits for individual Part A and B services to ensure that cost-sharing amounts for these services do not discourage enrollment by certain beneficiaries,

[48] These amounts differ depending on whether the Medicare Advantage plan adheres to the mandatory MOOP that CMS establishes for all Part A and B services or a lower voluntary MOOP; plans that adhere to the voluntary MOOP have more flexibility in setting the cost-sharing amount for individual services.

[49] 82 Fed. Reg. at 56362.

[50] 82 Fed. Reg. at 56362.

[51] 82 Fed. Reg. at 56362. The proposed regulatory text (proposed 42 CFR § 422.100(f)(6), 82 Fed. Reg. at 56495) provides in part that CMS "may use [FFS] data to evaluate the possibility of discrimination and to establish non-discriminatory out-of-pocket limits and also use MA encounter data to inform patient utilization scenarios used to help identify MA plans cost sharing standards and thresholds that are non-discriminatory."

[52] 82 Fed. Reg. at 56352.

and in setting those limits CMS should use the most relevant and appropriate data. We do encourage CMS to discuss more specifically how it intends to use the MA encounter data; it appears that CMS will compare FFS vs. Medicare Advantage utilization levels for services commonly used by sicker beneficiaries to determine whether MA beneficiaries are using those services less frequently than FFS beneficiaries (and thus may be choosing MA enrollment less frequently than the average beneficiary), but the proposed rule is not specific and we would welcome further explanation in the final rule.[53]

We also hope that CMS will consider extending this approach to Part D benefits. We understand that CMS already specifies cost-sharing limits that apply to certain Part D tiers,[54] but this approach does not guard against discrimination as effectively as the Part A/B approach, where annual cost-sharing limits apply to particular items and services. Because the particular Part D drugs or drug types commonly used by the sickest beneficiaries may all be placed on a tier with high cost-sharing, the approach of limiting Part D cost-sharing by tier is not sufficient to preclude benefit designs that discourage enrollment by certain beneficiaries. Consequently, we are concerned that the absence of cost-sharing limits for particular Part D drugs/drug types creates the opportunity for Part D plans to discourage enrollment by enrollees with the greatest need for Part D coverage. Cost-sharing limits that more closely resemble those that CMS imposes for individual Part A/B services prevent discriminatory benefit designs much more effectively.

Accordingly, we strongly encourage CMS to consider future rulemaking to strengthen the protections against discriminatory cost-sharing for Part D drugs. We note as well that the legal authorities that CMS relied on to establish cost-sharing limits for specific Part A and B items and services (the non-discrimination provision in SSA § 1852(b)(1), and the § 1852(e)(1) authority to add "necessary and appropriate" terms to Medicare Advantage contracts[55]) have counterparts in Part D (i.e., SSA § 1860D-11(d)(2)(D) on non-discrimination, and § 1860D-12(b)(3)(D), applying § 1857(e)(1) to Part D plans). CMS should therefore extend these limits to Part D plans in its next Part D rulemaking.

XII. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§422.254 and 422.256)

Description of the Issue or Question:

CMS proposes to eliminate requirements that approval of an MAO's bid is conditional upon: (1) its plan benefit package being substantially different from those of other plans being offered by the same MAO in the area with respect to key plan characteristics (including premiums, cost sharing or

[53] The proposed rule also is unclear about whether CMS will announce and seek comment on proposed cost-sharing limits via the draft call letter or HPMS memos (82 Fed. Reg. at 56352), and we encourage CMS to specify that it will publicize and seek comment on proposed limits via the annual call letter process, as draft call letters generally are disseminated more widely than HPMS memos and result in comments from a broader group of stakeholders.

[54] 42 C.F.R. § 423.104(d)(2)(iii).

[55] 74 Fed. Reg. at 54657 (final rule for 2011, establishing CMS' authority to set annual limits on cost-sharing for individual Part A and B services).

benefits offered) and (2) if the MAO wants to submit bids for multiple plans in the same area under the same contract, those plans must be substantially different from one another based on CMS' annual meaningful difference standards. CMS would eliminate these rules beginning with the bid submissions for contract year (CY) 2019. This proposal, not related to a statutory change, would not affect the meaningful difference requirements applicable to Part D.

To address potential concerns that the proposed policy would add to beneficiary challenges in making plan choices, CMS points to its tools and materials that focus on key beneficiary purchasing criteria, such as eligibility to enroll in SNPs, need for Part D coverage, Part D formulary and benefit coverage, plan type preference (for example, HMO vs. PPO), network providers, medical benefit coverage, premiums, and the brand or organization offering the plan options. CMS notes too its steps to improve information available through the Medicare Plan Finder. In addition, CMS notes annual guidance and model materials it provides to MAOs to assist them in providing resources, such as the plan's Annual Notice of Change and Evidence of Coverage. Finally, CMS notes its investment in engagement strategies such as 1-800-MEDICARE, Medicare Plan Finder, standard and electronic mail, and social media to continuously communicate with beneficiaries, caregivers, family members, providers, community resources, and other stakeholders.

Suggested Revisions/Comments:

Pfizer support CMS' efforts to continue to refine Plan Finder and agree that it is a critical decision-making tool for beneficiaries. To further enhance the consumer experience and recognize the importance of preventive care, we recommend that CMS feature a symbol on Plan Finder to prominently indicate which plans offer coverage for vaccines without cost-sharing. Addition of such a symbol may incentivize plan sponsors to offer coverage for vaccines without cost-sharing which, in the aggregate, would have positive health benefits for the Medicare population.

XIII. Flexibility in the Medicare Advantage Uniformity Requirements

Description of the Issue or Question:

CMS is proposing to interpret the Medicare Advantage uniformity of benefit requirements in a manner permitting greater flexibility in MA benefit design. CMS has determined that providing access to services (or specific cost sharing for services or items) based on objective criteria tied to a beneficiary's health status or disease state is consistent with the MA uniformity of benefit requirements in 42 C.F.R. § 422.100(d) as long as similarly situated beneficiaries are treated uniformly.[56]

More specifically, CMS is proposing to permit MA plans to offer reduced cost-sharing for certain covered benefits, and specific tailored supplemental benefits, for enrollees who meet specific medical criteria, provided that all similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same. This proposed flexibility would, for example, allow an MA plan to offer diabetic enrollees zero cost sharing for endocrinologist visits, more frequent foot

[56] 82 Fed. Reg. at 56360.

exams as a tailored, supplemental benefit, or a lower deductible.[57] CMS emphasizes that MA plans will not be permitted to use this new flexibility in a manner that violates MA non-discrimination requirements, which prohibit benefit designs that discourage enrollment by Medicare beneficiaries with higher-cost conditions; for example, MA plans would not be permitted to offer targeted cost reductions and supplemental benefits for a large number of diseases but not for higher-cost diseases.[58]

Suggested Revisions/Comments:

Pfizer strongly supports this proposal to allow greater benefit flexibility in Medicare Advantage subject to the safeguards that CMS specifies. We also believe the flexibility to reduce cost-sharing and offer supplemental benefits to individuals with particular conditions like diabetes aligns Medicare Advantage with value-based approaches and other CMS initiatives such as the Diabetes Prevention Program.

However, we would encourage CMS to include Part D drugs in this expanded benefit flexibility. Beneficiaries with conditions that are primarily managed with drugs and biologicals could greatly benefit from creative approaches designed to improve adherence and patient outcomes. Further, Part D's uniformity of benefit and non-discrimination requirements closely parallel those that apply to MA plans. Specifically, Part D sponsors must offer the plan to all Part D eligible beneficiaries in the plan's service area "[a]t a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area,"[59] and may not have plan benefit designs that discourage enrollment by certain beneficiaries.[60]

Given the similarities in the Part D and MA uniformity of benefit and non-discrimination requirements, the key principles set out in the proposed rule (that tailored benefits and cost-sharing for individuals with specified medical conditions is consistent with uniformity of benefit and non-discrimination rules as long the tailored benefits and cost-sharing are available to all similarly-situated enrollees, and are not focused on encouraging enrollment by more healthy beneficiaries and discouraging enrollment by sicker beneficiaries with higher-cost conditions) would seem to apply to Part D benefits as well as MA benefits. Accordingly, CMS' statement that "the benefit and cost-sharing flexibility we have discussed here applies to Part C and not Part D benefits"[61] was puzzling and disappointing, especially as CMS did not identify any reasons for making this distinction. We urge CMS to address this issue in the final rule preamble and to consider expanding this greater benefit flexibility to Part D drugs in future rulemaking.

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[57] 82 Fed. Reg. at 56360.

[58] 82 Fed. Reg. at 56360.

[59] 42 C.F.R. § 423.104(b). See also Medicare Prescription Drug Benefit Manual, Chapter 5, §§ 20.6, 50.5.3 (Part D plans must provide the same negotiated prices to enrollees in all phases of the Part D benefit, and must not have utilization management criteria, DUR rules, or transition policies that differentiate between enrollees for non-medical reasons).

[60] SSA 1860D-11(d)(2)(D)(Part D).

[61] 82 Fed. Reg. at 56360.

XIV. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

Description of the Issue or Question:

CMS proposes to codify in regulation many aspects of the existing Star Ratings System for the MA and Part D programs, given feedback from plans on the need for increased transparency of measurement. Currently, proposed changes to the Star Ratings System are communicated and modified through the annual Advanced Notice and Rate Announcement process.

Suggested Revisions/Comments:

"Codifying" the Star Rating System Generally. Pfizer appreciates CMS' efforts to improve the MA and Part D quality performance measurement system. However, we are concerned that the proposal to require formal rulemaking for the Star Ratings program would lead to new barriers to improving the quality of care in the MA and Part D programs. We believe the proposed codification is duplicative of an already well-developed sub-regulatory process, and adds an unnecessary layer to an already too-lengthy process.

CMS proposes to describe many aspects of the Star Ratings System for the MA and Part D programs in regulations, and thus to make changes via rulemaking. Specifically, CMS states that (beginning with CY 2019 measurement periods) it will "codify the current quality Star Ratings System uses, methodology, measures, and data collection."[62] We think CMS needs the flexibility to make changes relatively quickly, using sub-regulatory action.

Adding New Measures. Pfizer does not support CMS' proposal for adding new measures to the Star Ratings. Specifically, CMS would add new Star Rating measures "based on future rulemaking, but… prior to such a rulemaking CMS would announce new measures . . . and solicit feedback using the [Call Letter process]."[63]

Subjecting new measure additions to rulemaking will exacerbate an already too-lengthy process for current measures to be added to the Star Ratings Program, and we are concerned that this policy would hinder CMS' ability to quickly add measures that promote evidence-based practices and encourage quality care in critical gap areas. Significant programmatic value may be provided through the addition of a new measure that addresses a clinical area gap (such as immunization rates, prevention of thromboembolic disorders) or a new data collection methodology that could reduce Medicare program spending, and/or improve patients' health and safety.

While we agree that it is important to have ample and multiple opportunities for the public to provide input and preview measures as they are being considered for inclusion in any payment program, and that plan sponsors have adequate lead time to know which new measures or adjustments to existing measures are being considered, we are concerned that this proposal would

[62] 82 Fed. Reg. at 56378.

[63] 82 Fed. Reg. at 56383.

delay adoption of new measures without significantly improving transparency or opportunities for stakeholder input. CMS states that "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."[64] CMS provides an example of how long the proposed new process would take, which assumes that the measure in question has already been developed by the National Committee on Quality Assurance or the Pharmacy Quality Alliance and endorsed by NQF (which CMS expects would take 3-5 years).[65] In the example, CMS would start by soliciting comment on the new NQF-endorsed measure in January 2019 (i.e., in the draft 2020 Call Letter) and then ultimately the measure could become part of the Star Ratings on January 1, 2022 and affect plans' quality bonus payments and MA rebate retention allowances in 2025.[66]

There is sufficient and ample opportunity for the public to provide input and preview measures:

- Plans and other stakeholders usually have multiple opportunities to comment during the measure development process at NCQA or PQA.
- Moreover, compared to other quality payment programs, the Star Ratings program is unique in that CMS has historically provided a separate solicitation and comment period regarding the Star Ratings and display measures to review and evaluate comments prior to the Call Letter process. This is done to ensure that the Agency has time to review and consider input from stakeholders on proposed methodology changes for measures, and to provide advanced notice of potential changes to the Star Ratings and display measures.
- Then, there is another opportunity to comment in response to the draft Call Letter each year, and prior to addition to the Star Ratings.
- In addition, measures under consideration for addition are placed on the Display page for two years so that plans gain familiarity with the measure before they it is included in performance ratings. Display measures are not part of the Star Ratings, and they could include measures in transition to or from the Star Ratings or new measures that are tested before inclusion into the Star Ratings. (Actually, we believe that requiring new measures -- that may be revisions of prior measures needed to align with new guidelines (such as pneumococcal vaccine guidelines) – be on display for two years is too long.) CMS provides organizations and plan sponsors with the opportunity to preview their data on the display measures prior to release on CMS' website.

We recommend that CMS continue adding new measures through a subregulatory process, provided that stakeholders have sufficient opportunity to comment prior to new measures being finalized. The measure development and endorsement process involves third parties outside of CMS and this process has a long timeline (3-5 years, as estimated in the proposed rule). Adding to this timeline by starting out with the current call letter process and then following this with notice

[64] 82 Fed. Reg. at 56384.

[65] 82 Fed. Reg. at 56384.

[66] 82 Fed. Reg. at 56384.

and comment rulemaking would make the overall measure development, endorsement, adoption, and implementation process too long.

Quality measurement development and maintenance is a dynamic process that needs to evolve with the science and discovery of new therapeutics, as well as improved technology and data collection capabilities to support measures with a greater focus on patient outcomes. The measure development process itself, when thoughtfully conducted through a patient-centered, clinically-driven and validated process that is transparent and accountable, can take several years, and happens prior to any CMS process beginning. We believe that the current subregulatory process for adding new measures offers a good balance between timeliness and stakeholder engagement and input.[67] As CMS considers changes to enhance the Star Ratings, we encourage CMS to explore way to speed adoption of evidence-based quality measures. We believe the agency will concur that the greatest consideration to any proposal in this area is the opportunity to improve the quality of care for Medicare beneficiaries.

However, should CMS decide to codify the addition of new measures to the Star Ratings, Pfizer strongly urges CMS to consider granting exceptions in circumstances which there are urgent public health and patient safety issues that could be addressed through quality measures.

Star Rating Weighting System. CMS is considering increasing the weight of patient experience measures. We support this proposed change, as we believe that assessments of quality and value by the patient are currently under-valued in Part C and D.

Pfizer also supports maintaining the current medication adherence measures at a weight of 3. Research consistently shows that medication adherence leads to better health outcomes for Medicare beneficiaries, but still remains below optimal levels for many high-priority conditions. Therefore, encouraging plans to improve their enrollees' adherence is important and CMS should maintain the current position of adherence measures in the Star Ratings hierarchy.

Further, Pfizer strongly supports the adoption of additional measures for medication adherence, but as we've previously stated, measure development is a lengthy process. In the interim, it is essential that CMS continue to improve the measurement of adherence in the Part C and D programs at all times, especially in view of the potential impact on adherence from the increased cost sharing for drugs. For example, there is no clinical rationale, especially given the prevalence and cost of stroke, why a PQA measure that would promote better adherence for the multiple Novel Oral Anticoagulants is excluded because generic warfarin doesn't fit in the construct of an adherence measure.

Other areas of comment. CMS is interested in stakeholder feedback on additional opportunities to improve measures so they better reflect the quality of health outcomes under the rated plans, and the potential inclusion of survey measures of physicians' experiences.

[67] As the proposed rule notes, CMS historically has provided an initial comment opportunity on proposed new measures and then subsequently sought additional comments through the annual Call Letter process.

If we can view the health care experience through the patient's eyes, we will become more responsive to patients' needs and provide better patient-centered care. Thus, we ask that CMS provide greater recognition of shared decision-making as the pinnacle of patient-centered care for plans. Both patient-reported outcomes, shared decision-making, and clinical outcomes are important, and Pfizer supports CMS seeking ways to incorporate these types of measures in future Star Ratings.

CMS should also strongly encourage measure developers to focus resources in disease areas and measure types that are "gap" areas, and work to expeditiously include new measures in these areas. Examples of measure gaps (some noted previously) include those related to immunizations/Part D vaccines, prevention of thromboembolic disorders, pain, and the patient value of treating dermatological conditions.

For addressing the gap in measures related to vaccines, CMS should consider the addition of a composite adult vaccination measure to include all adult vaccines.

CMS should also encourage the development of an access measure that measures the number of beneficiaries with access to zero or nominal patient cost-sharing for vaccines. While we acknowledge that structure measures have traditionally been excluded from the Star ratings program, such a measure would consider beneficiary vaccine access rather than features such as plan or provider resources (material or human) or organizational structure. Moreover, if CMS developed a MA care coordination Stars measure, it could include an access component that evaluates beneficiary access to vaccines with zero or nominal cost-sharing. A vaccine cost-sharing measure would fit appropriately within a care coordination composite measure because offering zero cost-sharing improves access to vaccines and encourages vaccination, which ultimately improves a patient's care.

Addressing these gaps is critical to CMS' goals to promote effective communication and coordination of care and:

- Reduce admissions and readmissions
- Embed best practices to enable successful transitions between all settings of care
- Enable effective health care system navigation

Finally, CMS notes that the Agency is considering developing a survey tool for collecting standardized information on physicians' experience with health and drug plans and their services. Data from the ACCC 2017 Trending Now in Cancer Care Survey found a significant increase in prior authorizations for medical drugs. Gathering feedback from providers on their interactions with plan sponsors could provide valuable information that complements patient experience data, particularly given a likely inverse correlation between the time the physician has to spend with the patient on national public health goals such as counseling on smoking, obesity and vaccinations and the time they spend on administrative tasks. (The first two –smoking and obesity--are directly related to cancer incidence, thus counseling is critical.) As CMS further considers this approach, it will be important for the agency to work with providers on the development of the survey so that it

can be seamlessly integrated into their workflow and address their priorities that impede quality cost saving care.

The Categorical Adjustment Index. CMS is proposing to continue the use of the Categorical Adjustment Index (CAI) and codify the calculation of CAI values while it continues to work with stakeholders to consider how to account for social risk factors, including how to account for low income subsidy/dual eligible (LIS/DE) status, disability, and other social risk factors in the Part C and D Star Ratings. Pfizer supports using the CAI as an interim adjustment and believes this is consistent with CMS' goals for addressing the potential impact of LIS/DE and disabled beneficiary enrollment on plans' Star Rating performance. However, we do not believe the CAI should be incorporated into regulations, as it was intended as a temporary adjustment. CMS must be careful not to create a two-tiered standard of care or inappropriately lower standards. We do share CMS' concern about the potential impact of LIS/DE and disabled beneficiary enrollment on Star Rating performance, and we appreciate CMS' commitment to evaluating these issues through an open and deliberative process. We ask that CMS assess, for example, if it is an appropriate adjustment for patient safety and adverse events measures. Finally, we recommend that CMS monitor how adjustments to the Star Ratings affect the quality of care received by LIS/DE and disabled enrollees.

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Pfizer appreciates the opportunity to comment on the 2019 Medicare Advantage and Part D proposed rule, and we hope our comments will contribute to the preparation of the final rule. If you have questions or need additional information, please contact Margaret Davis at 212-733-3390 or margaret.davis@pfizer.com.

Sincerely,

Angela Wasunna
Vice President
Global Policy