Angela Wasunna
Vice President
Corporate Affairs

VIA ELECTRONIC FILING TO: www.regulations.gov

March 5, 2018

Demetrios Kouzoukas
Principal Deputy Administrator
Director, Center for Medicare

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

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Baltimore, MD 21244-8013

RE: Comments on Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter

Dear Mr. Kouzoukas and Ms. Wuggazer Lazio:

Pfizer Inc. appreciates the opportunity to submit comments on the Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and the 2019 Draft Call Letter dated February 1, 2018.

Comments

Attachment VI, Section I, Enhancements to the 2018 Star Ratings and Future Measurement Concepts

Description of the Issue or Question: The draft Call Letter outlines several proposed ways to improve the Part C and D quality performance measurement system, including additions and proposed changes to current measures, measures to add or retire from the Display Page, and measures to potentially include in future years. The draft Call Letter also describes CMS' proposal to adjust several measures for the effect of dual eligible/LIS and disability status using a categorical adjustment index.

Suggested Revisions/Comments: Pfizer appreciates CMS' continued commitment to improving the MA and Part D quality performance measurement system. In addition to proposed measure changes put forth in this

draft Call Letter, there is a proposal by CMS currently under consideration that would require that additions to the Star Ratings measures for the MA and Part D programs go through a formal rulemaking process.[1] We reiterate the concerns we expressed late last year that 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.

Attachment IV, Section I. Removal of Measures from Star Ratings: Beneficiary Access and Performance Problems (BAPP) (Part C & D). p. 112.

Description of the Issue or Question: Currently, the BAPP measure is based on CMS' sanctions, civil money penalties (CMP) as well as Compliance Activity Module (CAM) data. Every contract begins with a BAPP measure score of 100. A contract's score is then reduced contingent on its sanction status, CAM score, and each CMP related to beneficiary access. For the 2019 Star Ratings, as already signaled in the CY 2018 Call Letter, CMS proposes to retire the current BAPP measure and to modify it in two ways: (1) to only include Compliance Activity Module (CAM) data, and (2) to remove from the BAPP measure all enforcement actions and reductions for plans under sanction due to audit findings. The goal is to separate the BAPP measure from audit results because of the subjective nature of audits, and the absence of audit information for each plan each year. The revised BAPP measure would be on the display page for the 2019 Star Ratings. CMS is soliciting stakeholders' input on the utility of this measure which would now only take into account notices of non-compliance, warning letters, and ad-hoc corrective action plans and their severity.

Suggested Revisions/Comments: Pfizer recommends that CMS retain the current BAPP measure until CMS proposes an alternative approach to addressing the impact of audit results on Star Ratings. Even if enrollment is frozen, the currently enrolled beneficiaries for example may have been denied medically necessary items and services to the extent of a substantial likelihood of adversely affecting them.[2] We are concerned that removing the enforcement actions and reductions applied to plans under sanction due to audit findings will dilute the seriousness of audit findings. The argument against including these actions is that not all plans are audited each year, so that the measure it is not consistent across plans. It is equally true that there is nothing requiring the plans that are audited to have a negative finding from the audit. In fact, the outcome of the audits is the sole consequence of the plans' actions and should have an impact on their ratings. We also encourage CMS to include this issue in the list of topics to be addressed by the Technical Expert Panel (TEP) to be convened by RAND once the 2019 Call Letter is finalized.

2019 Advance Notice, Attachment IV, Section I. Proposed Scaled Reductions for Appeals IRE Data Completeness Issues. p. 114.

[1] Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. [CMS–4182–P].

[2] December 20, 2017; Letter to Riverside Health System; Vikki Ahern Director, Medicare Parts C and Part D Oversight and Enforcement Group, Centers for Medicare and Medicaid Services.

Description of the Issue or Question: CMS is proposing statistical criteria to reduce a contract's Star Ratings for data that are not complete or lack integrity using the Timeliness Monitoring Project (TMP). The reduction would be applied to the measure-level Star Rating for the applicable appeals measures. At present, there are four Star Ratings appeal measures that rely on data submitted to the independent review entity (IRE). Two of the measures are Part C measures (Plan Makes Timely Decisions about Appeals and Reviewing Appeals Decisions), and two are Part D measures (Appeals Auto-Forward and Appeals Upheld).

Suggested Revisions/Comments: Pfizer appreciates that CMS applies scaled reductions to the Star Ratings appeals measures for incomplete data; however, we are concerned that there may be instances where a plan's inappropriate policy regarding denials will not immediately trigger an opportunity for an appeal, and therefore not be counted as an appeal. We recommend that CMS continue to monitor plan policies for triggering appeals to ensure that the data on appeals measures reflect all instances where an appeal could have been made, especially in cases where lack of appeal may impede or endanger beneficiary access to high quality care. Our recommendation is closely tied to our related concerns about the proposed changes to the BAPP measure where CMS proposes to remove enforcement actions and reductions applied to plans under sanction due to audit findings, including audit findings related to the appeals process. We encourage CMS to include this issue in the list of topics to be addressed by the Technical Expert Panel (TEP) to be convened by RAND once the 2019 Call Letter is finalized.

Attachment IV, Section I. Potential New Measures for 2020 and Beyond: Additional PQA Medication Adherence Measures (Part D). p. 154-156.

Description of the Issue or Question: CMS has evaluated two additional PQA endorsed medication adherence measures within the Medicare Part D population using 2016 PDE data, including the measure, "Adherence to Non-Warfarin Oral Anticoagulants (ADH-NWOA)." This measure is defined as the percentage of individuals 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80 percent during the measurement period. Individuals who filled at least two prescriptions for a NWOA on two unique dates of service at least 180 days apart during the treatment period and who received greater than 60 days' supply of the medication during the treatment period were included in the measure. The prescriptions can be for the same or different medications. CMS found that for this measure, 37% of MA-PD and PDP contracts had 30 or fewer member-years in the denominator. Since a low denominator affects the utility of the measure to assess contract performance, CMS is not considering adding this adherence measure to the Patient Safety reports, the display page, or Star Ratings at this time. However, since adherence to these medications is important for achieving positive outcomes, CMS is considering including this measure within the quarterly outlier reports to Part D plans through the Patient Safety Analysis Website in the future, along with the beneficiary-level data so plans can focus adherence improvement efforts for these members.

Suggested Revisions/Comments: Pfizer agrees with CMS that at a minimum, this measure should be included in the quarterly outlier reports through the Patient Safety Analysis Website as soon as possible. Plans can take the information into account and focus adherence improvement efforts for the members that have been identified. We understand that low-denominator member-years (using 2016 PDE data) for this measure may reduce the reliability of the measure to assess contract performance in the Star Ratings program. However, we anticipate the 2017 data will include a larger number of observations, thus improving the low-denominator issue.

Atrial Fibrillation (AF) is a serious, potentially life-threatening condition. Although clinical guidelines recommend oral anticoagulant therapy in patients with AF at moderate or high risk for stroke but not at high risk for bleeding, evidence shows consistent suboptimal use of such therapy, including within the Medicare

population.[3],[4],[5] Gaps in dosing or medication non-adherence leave patients vulnerable to blood clots, often leading to stroke and its complications.[6] Non-Vitamin K antagonists have emerged as an important alternate to warfarin, offering patients convenience with less frequent monitoring, drug- or food-interactions. Given the importance of adherence to anticoagulants for stroke prevention, medication adherence to non-warfarin anticoagulants may be more critical to assess because there is not routine monitoring nor a surrogate lab value, such as the international normalized ratio (INR) that accompanies warfarin and the medicines only reduce the risk of stroke when they are taken by the patient.

Since it is critical that patients adhere to their prescribed new oral anticoagulant therapy, we encourage CMS to reevaluate this measure later in 2018 to check if the number of denominator member-years is large enough to generate reliable measure results appropriate for inclusion as a Star Rating measure.

Attachment IV, Section I. Potential New Measures for 2020 and Beyond: Adult Immunization Measure (Part C). p. 150.

Description of the Issue or Question: For HEDIS 2018, NCQA added the Pneumococcal Vaccination Coverage for Older Adults measure to the ECDS reporting domain. Measures in the HEDIS ECDS domain are calculated using electronic data from administrative claims, electronic medical records, case management systems and registries. For HEDIS 2019, NCQA will build off the pneumococcal measure and evaluate the relevance, scientific soundness, and feasibility of a composite measure for HEDIS that assesses the receipt of routine adult vaccinations. The measure developer is focusing on four specific vaccines: influenza vaccine; tetanus, diphtheria, and pertussis (Tdap) or tetanus and diphtheria (Td) booster vaccine; herpes zoster vaccine; and pneumococcal vaccine. If approved, the new measure would be included in HEDIS 2019. CMS is requesting feedback on the feasibility, value of, and impact on provider/plan burden of this change in data source. Depending on results of implementation, CMS will determine the use of this new composite measure for the display page and Star Ratings for the future.

Suggested Revisions/Comments: Pfizer fully supports the use of the HEDIS composite adult immunization measure in the Star Ratings program. When approved by NCQA for use in HEDIS 2019 we encourage CMS to accelerate the inclusion of the new measure on the display page and timely adoption as a Star Ratings measure. As noted elsewhere in the draft Call Letter (p. 199), CMS raises concerns about low vaccination rates, citing the Center for Disease Control and Prevention's (CDC) 2015 statistics on the low vaccination rates for adults for tetanus and diphtheria with acellular pertussis (Tdap), and the fact that approximately 70% of adults for whom the herpes zoster vaccine is recommended remain unprotected. [7]

---

[3] January, Craig T., et al. "2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society." Journal of the American College of Cardiology 64.21 (2014): e1-e76.

[4] Kimmel, Stephen E., et al. "The influence of patient adherence on anticoagulation control with warfarin: results from the International Normalized Ratio Adherence and Genetics (IN-RANGE) Study." Archives of Internal Medicine 167.3 (2007): 229-235.

[5] Fitch, Kate, et al. "Utilization of anticoagulation therapy in medicare patients with nonvalvular atrial fibrillation." American Health & Drug Benefits. 2012;5(3):157-168.

[6] Noseworthy, Peter A., et al. "Direct comparison of dabigatran, rivaroxaban, and apixaban for effectiveness and safety in nonvalvular atrial fibrillation." Chest 150.6 (2016): 1302-1312.

[7] Williams WW, Lu P, O'Halloran A, et al. Surveillance of Vaccination Coverage among Adult Populations — United States, 2015. MMWR Surveill Summ 2017;66(No. SS-11):1–28. DOI: http://dx.doi.org/10.15585/mmwr.ss6611a1

At the same time, we urge CMS to continue efforts to support the development and use of quality measures that focus on pneumococcal disease and pneumonia vaccination rates. Pneumococcal disease is a very serious infection that causes pneumonia, meningitis and bloodstream infection (sepsis). About one million adults get pneumococcal pneumonia every year and five to seven percent will die from it. Specifically, 18,000 adults age 65 years and older will die from pneumonia and its complications. At its worst, it kills one in every four to five people over the age of 65 years who contract it.[8]

CMS should act -- while the broader composite vaccine measure is under development for the MA and PDP programs—to move the current Pneumonia Vaccine measure (DMC09), which is reported on the Display page and collected through CAHPS, to the list of Star Ratings measures in CY 2019. The national average for this pneumonia vaccine measure in 2017 was only 69%, indicating that plans need to give more attention to ensuring beneficiaries receive this vaccine to prevent the possibility of a very serious infection.[9]

2019 Advance Notice, Attachment IV, Section I. Measurement and Methodological Enhancements: Future Measure Concepts Regarding Use of Non-Pharmacological or Non-Opioid Pain Management Interventions Requiring Use of Non-Claims Data. p. 156.

Description of the Issue or Question: CMS is exploring additional measurement concepts for future work, such as functional status, and use of non-pharmacological or non-opioid pain management interventions, which will require use of non-claims data. CMS is soliciting comments on whether these measure concepts are useful in measuring quality of care and whether these concepts can be measured without adding undue burden on plans or providers.

Suggested Revisions/Comments: Pfizer supports development of these measure concepts related to functional status and non-pharmacological or non-opioid pain management. However, since it typically takes about 5 or more years to develop and implement new measures, we recommend CMS ensure access and utilization of the non-opioid pain management interventions through benefit designs that encourage broad formulary coverage, minimal cost sharing and elimination of prior authorization.

Attachment VI, Section II, Part C Cost Sharing Standards, p. 176-180

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. For CY 2019, CMS will continue the current policy of affording Medicare Advantage greater flexibility in establishing Parts A and B cost-sharing by adopting a lower, voluntary maximum out-of-pocket (MOOP) limit than is available to plans that adopt the higher, mandatory MOOP limit. Medicare Advantage plans that adopt a voluntary MOOP are allowed greater flexibility for individual service category cost-sharing, within limits set by CMS to ensure that cost-sharing is not discriminatory (e.g., Part B prescription cost-sharing is currently limited to 20% or $50/$75). For CY 2020, CMS is considering changes to its policies related to service category cost-sharing limits and is soliciting comment on whether CMS' interpretation of cost-sharing limits is impacting plans' ability to offer more flexible benefit designs that would provide beneficiaries with valuable plan options.

[8] National Foundation for Infectious Diseases, Vaccine-preventable Diseases and Infections/Pneumococcal disease.
[9] CMS. "Medicare 2018 Part C & D Display Measure Technical Notes." December 21, 2017. Table A-1.

Pfizer Comments:
The Part A/B MOOP is a critical feature of the Medicare Advantage program that helps to protect patients against excessive annual cost-sharing and to ensure that Medicare Advantage benefit designs do not discourage sicker Medicare patients from enrolling. The MOOP also helps to improve enrollees' adherence to treatment regimens and, thus, to improve their health, as studies have repeatedly shown that higher cost-sharing leads to reduced or delayed initiation of treatment[10] and lower adherence rates,[11] which, in turn, may result in worse outcomes for patients as well as higher overall Medicare spending.[12]

We urge CMS to maintain the current upper limits for Part B prescription cost-sharing to ensure that cost-sharing is not discriminatory. CMS established the specific cost-sharing limits for individual service categories based on concern for particular beneficiaries who might be impacted by cost-sharing in excess of the amounts established for the original Medicare program. Pfizer believes that the concern for these beneficiaries remains valid, and CMS should not allow additional flexibility for cost-sharing limits for Part B prescription cost-sharing.

Moreover, we urge CMS to apply these same cost-sharing policies to Part D benefits offered by Medicare Advantage plans. 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.

The legal authorities that enabled CMS to establish mandatory MOOPs for local Medicare Advantage plans[13] 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 CMS to add "necessary and appropriate" terms to its contracts with plans and applies to Part D via § 1860D-12(b)(3)(D).[14]

---

[10] See, e.g., 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. *American Journal of Managed Care*.2016;22(4 Suppl):s78-86.

[11] See, e.g., Doshi JA, Takeshita J, Pinto L, et al. Biologic Therapy Adherence, Discontinuation, Switching, and Restarting Among Patients with Psoriasis in the US Medicare Population. *Journal of the American Academy of Dermatology*. 2016;74(6):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 Research*. 2016; 68(11):1624-1630; Gibson T et al., Cost-Sharing Effects on Adherence and Persistence for Second-Generation Antipsychotics in Commercially Insured Patients. *Managed Care*. 2010; 19(40):40-47. Luga AO, McGuire MJ. Adherence and Health Care Costs. *Risk Management and Healthcare Policy*. 2014;7:35-44. doi:10.2147/RMHP.S19801 (literature review finding that "Reducing out-of-pocket costs leads to better medication adherence across many diagnoses. There is a linear relationship between the magnitude of patient cost-sharing and the level of adherence. This relationship persists from low to higher income levels")(citation omitted).

[12] See, e.g., Eaddy MT, Cook CL, O'Day K, Burch SP, Cantrell R. How Patient Cost-Sharing Trends Affect Adherence and Outcomes. *P&T*. 2012;37:45–55. [PubMed] (literature review concluding that "increased patient cost-sharing was associated with declines in in medication adherence, which in turn was associated with poorer outcomes"; the authors found that 85% of the articles that evaluated the relationship between changes in cost-sharing and adherence found that an increasing patient share of medication costs was significantly associated with a decrease in adherence, and that the majority of the articles that investigated the relationship between adherence and outcomes found that increased adherence was associated with a statistically significant improvement in outcomes); MacEwan JP, et al. The Relationship Between Adherence and Total Spending Among Medicare Beneficiaries with Type 2 Diabetes. *American Journal of Managed Care*. 2017; 23(4):248-252. Stuart B, Davidoff A, Lopert R, Shaffer T, Shoemaker JS, Lloyd J. Does Medication Adherence Lower Medicare Spending among Beneficiaries with Diabetes? *Health Services Research*. 2011;46(4):1180-1199. doi:10.1111/j.1475-6773.2011.01250.x.

[13] Regional MA plans have MOOPs by statute.

[14] 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).

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."[15] 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.[16] 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).[17]

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.[18] 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."[19] 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.[20]

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 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.[21]

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.[22] Leaving the cost-sharing on

---

[15] 75 Fed. Reg. at 19714 (final MA and Part D rule for 2011).

[16] SSA § 1860D-2(b)(4)(A).

[17] 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.

[18] 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).

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

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

[21] 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.

[22] 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

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)."[23] 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.[24] 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 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 encourage CMS to include a MOOP on Part D spending in its next MA rulemaking and would welcome the opportunity to work with CMS on further developing this approach in the interim.

Attachment VI, Section II, Medicare Advantage (MA) Uniformity Flexibility, p. 184

Description of the Issue or Question: CMS has determined that it has the authority to permit MA plans to reduce cost-sharing and deductibles and/or offer supplemental benefits for enrollees that meet certain medical criteria (provided all enrollees who meet those criteria are treated the same). In implementing any changes to their benefit designs, MA plans may not deny, limit, or condition the coverage or provision of a service or benefit based on health-status related factors. CMS states that this flexibility will help MA plans better manage healthcare services for particularly vulnerable enrollees. CMS also notes that they will guard against potential discrimination if an MA plan is targeting cost sharing reductions and additional supplemental benefits for a large number of disease conditions, while excluding other conditions, particularly higher-cost conditions. The agency will review benefit designs to make sure that the overall impact is non-discriminatory

---

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").

[23] 74 Fed Reg. at 54657.

[24] 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").

and that higher acuity, higher cost enrollees are not being excluded from these targeted benefits in favor of healthier populations.

Pfizer Comments:
Pfizer supports CMS proposal to expand flexibility under the uniformity requirements. We agree with CMS' new interpretation that the Medicare Advantage uniformity of benefit requirements generally do not preclude offering enrollees who meet specific medical criteria tailored supplemental benefits or reduced deductibles as long as all similarly situated individuals (i.e., all enrollees who meet the specified medical criteria) are treated the same and the Medicare Advantage benefit package does not violate Medicare Advantage nondiscrimination principles by discouraging enrollment by Medicare beneficiaries with higher-cost health conditions (e.g., a plan would not be permitted to offer targeted cost-sharing reductions and supplemental benefits for large number of disease conditions while excluding other, higher-cost conditions). The new flexibility could offer plans the opportunity to better align patient incentives with health care financing and delivery designed to both encourage value-based care and improve patient access to necessary services like medicines used to treat chronic diseases. The new flexibility, with the appropriate safeguards, also complements health plans' interest in exploring value-based arrangements, because value-based arrangements also encourage value-based care and better patient access.

Although CMS cautions that they will be monitoring benefit designs to ensure they are not discriminatory, we strongly urge the agency to develop criteria or principles that can be utilized to safeguard against discrimination.

In addition, we 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 Medicare Advantage 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,"[25] and may not have plan benefit designs that discourage enrollment by certain beneficiaries.[26]

We request that in the preamble to the final Call Letter CMS specifically address the underlying similarities in the Medicare Advantage and Part D uniformity of benefit and non-discrimination rules. This includes identifying any differences in these rules that it sees as calling for less flexibility to offer tailored cost-sharing or supplemental benefits on the Part D side and the specific ways in which CMS thinks that flexibilities might differ in Part D. We hope that CMS ultimately will include a proposal extending its new approach permitting somewhat more flexible benefit designs to Part D in its next rulemaking cycle.

Attachment VI, Section III, Formulary Submissions, p. 193-195

Description of the Issue or Question: The CY 2019 formulary submission window will be open from May 14, 2018 until June 4, 2018. CMS is proposing to move the update window to later in the summer to

[25] 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).
[26] SSA 1860D-11(d)(2)(D)(Part D).

accommodate newly approved brands and generics that occur in July and August. CMS is seeking stakeholder comment on the optimal submission window.

As in past years, the summer formulary update will be limited to: (1) the addition of drugs that are new to the summer release of the FRF (historically posted in July); and (2) the submission of negative changes on brand drugs, only if the equivalent generic is added to the summer FRF and corresponding formulary file.

In an effort to provide more up-to-date information within the Medicare Plan Finder, CMS proposes to add an enhancement-only window in late fall and another one in January 2019. CMS continues to remind Part D sponsors that they can make positive enhancements to their formularies (i.e., add Part D drugs, reduce beneficiary cost-sharing, or remove utilization management edits) between the summer update window and the first HPMS submission of the upcoming year. These enhancements must be included in the Part D sponsor's marketing materials and must be submitted during the next HPMS formulary submission window. Sponsors are encouraged to directly notify beneficiaries of formulary additions in a timely manner.

CMS notes that the Formulary Reference File (FRF) is not intended to be a comprehensive list of Part D drugs – the presence on or absence from the FRF does not indicate whether a particular drug is eligible for Part D coverage. They state that the FRF includes drugs for which utilization under Part D would be extremely rare, and that the inclusion of some of these drugs within the Medicare Plan Finder may lead to beneficiary confusion when the drug is more commonly covered under Medicare Part B. Thus, CMS will identify drugs based on very infrequent utilization under Part D due to their indication, dosage and administration, and usual administration setting and will removed them from the FRF.

Pfizer Comments:
Pfizer supports CMS' intention to delay the summer formulary update window and to add a Medicare Plan Finder update window in the fall and a formulary update window in January of the coverage year. These new, more frequent formulary update windows will help ensure that beneficiaries will have timely knowledge of and access to innovative new therapy options.

However, we continue to object to the limitation on the summer update window to only the addition of drugs new to the summer release of the FRF (new to the market) and negative changes on brand drugs, only if the generic equivalent is added to the FRF and the corresponding formulary file. There are a number of circumstances that could arise during the time between the formulary submission deadline and the summer update window that are beyond the control of both the plan and a manufacturer. For example, an existing product may be approved for a new indication. Prior to receiving that approval, a plan may have decided that an alternative product would meet the needs of their enrollees. However, with the new indication, the value of the product to beneficiaries has increased and now the plan would like to add it to their formulary. We believe the restriction CMS has in place unnecessarily limits the coverage and benefits that could be provided to beneficiaries.

Regarding the proposal to remove certain drugs from the FRF based on low-utilization, we urge CMS not to move forward with this action until stakeholders have had an opportunity to review the implications. We are concerned that, although CMS emphasizes that the presence on or absence from the FRF does not indicate whether a particular drug is eligible for Part D coverage, we are concerned that some plans may still decline to provide coverage for Part D-eligible drugs simply because they are not listed on the FRF.

Attachment VI, Section III, Benefit Review and Tier Composition, p. 198-199

Description of the Issue or Question: CMS reminds sponsors that drug tier labels should be representative of the drugs that largely make up that tier. Sponsors will continue to have the option of selecting a non-preferred drug tier or a non-preferred brand tier, but not both. New for CY 2019, CMS proposes a maximum threshold of 25% generic composition should a plan sponsor use a "brand tier" designation. Sponsors will continue to have flexibility to determine what cost-sharing structure is most appropriate for their benefit design. However, CMS will continue to scrutinize the expected cost-sharing amounts to protect against outliers and to ensure that the resulting coinsurance amount for a drug is not discriminatory. CMS again clarifies that if a non-specialty tier coinsurance is greater than 25%, CMS will compare the expected cost-sharing amounts to the established copay threshold ($100).

Pfizer Comments:
Pfizer continues to strongly disagree with CMS' proposed approach to encourage the use of coinsurance for tiers that include both brand and generic drugs. The high coinsurance rates associated with the non-preferred tiers create cost burdens for patients who need the non-preferred brand drug (and presumably in some cases, the non-preferred generic drug). We believe that CMS' proposal is contradictory to its efforts to guard against and eliminate discriminatory benefit designs.

Pfizer strongly urges CMS to rigorously evaluate cost-sharing levels and beneficiary out-of-pocket exposure for both brand and generic medicines to identify and address potential access barriers that may be created by disproportionately high cost-sharing. Further, we remind CMS of its responsibility to continue enforcing statutory non-discrimination requirements in evaluating plan benefit design for all medicines, both brand and generic. For plans that use coinsurance on what has to date been called the non-preferred brand tier, simply changing the name to "non-preferred" tier and continuing to allow plans to include large numbers of lower-cost generic drugs on that tier (which results in significantly lower average cost sharing across all drugs), implicitly endorses, and in fact encourages, plans to skirt the benefit parameters put in place by CMS intended to ensure that plan benefit designs are not discriminatory.

Based on analysis of the Network and Pharmacy Public Use Files published by CMS, Pfizer has found that the use of high coinsurance tiers (greater than 34% coinsurance) for non-preferred drugs is prevalent in Part D plans, and that this can result in average out-of-pocket costs greater than $100 for brand drugs. More specifically, Pfizer found that for the largest 2016 Medicare Part D plans, the percentage of PDPs with high coinsurance tiers for non-preferred drugs was 90 percent or higher for all but two parent organizations.[27] In addition, according to the Kaiser Family Foundation, virtually all PDPs are using coinsurance for their non-preferred drug tiers in Part D in 2018. The typical coinsurance on this tier is 40% but also can be as high as 50%.[28]

In our analysis, the potential cost impact to beneficiaries associated with products placed on high co-insurance tiers was examined. For each plan, the out-of-pocket costs were calculated using the OOPC calculator cost assumption for the product and the cost sharing requirement for the tier assuming the product was filled at a preferred pharmacy. The out-of-pocket costs on each tier were weighted together using the CMS Part D utilization database to calculate an average out-of-pocket amount for each tier and plan. This analysis showed that in 2015, *average* out-of-pocket amounts for the non-preferred brand coinsurance tier in PDPs were as

[27] Data on file.
[28] Hoadley & Cubanski, "Medicare Part D: A First Look at Prescription Drug Plans in 2018," KFF Issue Brief, October 2017, http://files.kff.org/attachment/Issue-Brief-Medicare-Part-D-A-First-Look-at-Prescription-Drug-Plans-in-2018

high as $124. However, these averages mask considerable variation in the distribution of out-of-pocket costs for both brand and generic drugs. For example:

- For one of the plans with 35% cost-sharing, products with an allowed amount at or above $285 would generate an out-of-pocket cost of $100 or more. Approximately 40% of the brand script volume is above this threshold.
- For one of the plans with 47% cost sharing, products with an allowed amount at or above $212 would generate an out-of-pocket cost of $100 or more. Approximately 47% of the brand script volume is above this threshold.

Further analysis examined the average weighted out-of-pocket costs associated with the high coinsurance tier for the selected (again, the largest) PDP plans stratified between brand and generic products. The findings showed that, in 2015, the *average* weighted average OOP cost for brand drugs was as high as $176; in 2016, the *average* weighted average OOP cost for brand drugs was as high as $151.16.

These findings clearly demonstrate that encouraging the use of coinsurance in non-preferred tiers results in beneficiaries being faced with extraordinarily high cost-sharing amounts for many of their needed medicines.

Attachment VI, Section III, Improving Access to Part D Vaccines, p. 199

Description of the Issue or Question: CMS highlights that the Centers for Disease Control and Prevention has reported that vaccination rates remain low for tetanus and diphtheria with acellular pertussis (Tdap), and that approximately 70% of adults for whom the herpes zoster vaccine is recommended remain unprotected. CMS encourages Part D sponsors to either offer a $0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing in an effort to improve access to these and other Part D vaccines. In the "Benefits and Parameters for CY 2019 Threshold Values" table, CMS illustrates the Vaccine Tier and highlights in a footnote the ability to utilize a lower cost-sharing tier for vaccines.

Pfizer Comments:
Pfizer strongly supports CMS' continued focus on incentivizing $0 or nominal cost-sharing for Part D vaccines through the Call Letter. Pfizer believes that increasing Part D vaccine uptake through $0 or nominal cost-sharing is vital for supporting the overarching goals of the Medicare program, including contributing to a reduction in program spending growth and improving beneficiary health outcomes. We provide the following comments, with recommendations, to assist CMS in its efforts toward achieving these critical goals.

Pfizer recommends that CMS require that Part D plan sponsors offer $0 cost-sharing for vaccines.

While CMS encourages plans to offer $0 or nominal cost-sharing in the CY 2019 Advance Notice and draft Call Letter, Pfizer believes that CMS has the statutory authority to require that Part D plan sponsors offer $0 cost-sharing for vaccines and should do so through the Call Letter.[29] We believe that the disease burden and economic impact of adult vaccine-preventable diseases for current Part D vaccines (e.g., shingles, pertussis) and additional vaccines in development (e.g., C. difficile, staphylococcus aureus) suggest the need for timely action.

[29] Under the Part D statute, the Secretary of the Department of Health & Human Services, in the context of the bid negotiation process, "has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan." 42 U.S.C. § 1395w-111(d)(2)(A) (2016). Consistent with CMS' prior interpretations of the noninterference clause, requiring $0 cost-sharing for vaccines would not directly interfere with negotiations.

Overall, approximately 42,000 adults die each year in the U.S. from vaccine-preventable diseases.[30] As just one example, C. difficile is classified by the Centers for Disease Control and Prevention as an urgent public health threat,[31] with approximately 453,000 cases in the U.S. in 2011,[32] which resulted in nearly as many deaths as car accidents in the U.S. in that same year.[33] Moreover, C. difficile accounts for $6.3 billion in annual healthcare costs in the U.S.[34]

As reflected in the CY 2019 draft Call Letter, CMS is aware that for the herpes zoster, and tetanus and diphtheria with acellular pertussis (Tdap) vaccines, adult vaccination rates remain low. Improving vaccine uptake is a widely recognized public health goal and plays an important role in achieving the Healthy People 2020 goals. The benefits of increasing adult vaccination rates may accrue to other populations as well. For example, a study found that adults and adolescents were responsible for between 76 and 83 percent of transmissions of Bordetella pertussis,[35] which suggests that vaccinating adults against pertussis (included in the Tdap vaccine) can protect infants. Requiring coverage of vaccines with $0 cost-sharing would more effectively raise adult vaccination rates than encouraging plans to do so.

Requiring plan sponsors to offer $0 cost-sharing for vaccines would align the Part D program with other markets, including the commercial and Medicaid expansion markets, where plans are required to provide coverage of Advisory Committee on Immunization Practices-recommended vaccines with $0 cost-sharing. Children in traditional Medicaid are eligible to receive vaccines at no cost under the Vaccines for Children program. The lack of comparable access to vaccines with $0 cost-sharing under Part D creates an unfortunate and disproportionate access burden for older adults.

Pfizer strongly recommends that CMS require Part D plan sponsors to offer $0 cost-sharing for vaccines. However, if CMS elects not to do so, then Pfizer strongly encourages CMS to provide plans with additional information on the disease burden and economic impact of vaccine-preventable diseases and currently low adult vaccination rates in the Call Letter. Additional information could help more strongly encourage plans to offer $0 cost-sharing for vaccines.

Pfizer offers two additional recommendations for improving incentives for Part D plan sponsors to offer $0 or nominal cost-sharing for vaccines.

Pfizer supports CMS' continued efforts to refine the Medicare Advantage (MA) Star Ratings program to ensure that measures provide value and improve the quality of care for Medicare beneficiaries. As an alternative to requiring that plan sponsors eliminate cost-sharing for vaccines, we propose the inclusion of a measure that would evaluate the number of beneficiaries with access to $0 or nominal cost-sharing for vaccines. This access measure would use an analysis of plan contracts as the supporting data source. 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. Alternatively, CMS could include the access measure in a care

---

[30] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Immunization and infectious diseases. Healthy People website. https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases.
[31] Centers for Disease Control and Prevention. Antibiotic resistance threats in the United States, 2013. Washington, DC: Centers for Disease Control and Prevention; 2013.
[32] Lessa FC et al. N Engl J Med. 2015;372:825-834.
[33] US Department of Transportation: National Highway Traffic Safety Administration. A brief statistical summary: early estimate of motor vehicle traffic fatalities in 2011. 2012:1-3.
[34] Zhang et al., BMC Infect Dis. 2016; 16(1): 447.
[35] Wendelboe AM, Njamkepo E, Bourillon A, et al. Transmission of *Bordetella pertussis* to young infants. *Pediatr Infect Dis J*. 2007;26:293–99.

coordination composite measure. A vaccine cost-sharing measure would fit appropriately within a care coordination composite measure because offering $0 cost-sharing would improve access to vaccines and remove a key barrier to increasing vaccine uptake, which could ultimately help reduce avoidable admissions and readmissions.

Pfizer also supports CMS' continued efforts to improve the Medicare Plan Finder. We believe that the Medicare Plan Finder provides a valuable resource for beneficiaries to access easily-identifiable information across multiple categories, such as plan costs, Star ratings, prescription drug coverage, and premiums, in a consumer-friendly manner. To further enhance the Medicare Plan Finder, we recommend changes that would include a visual identifier to denote plans that offer $0 or nominal cost-sharing for vaccines. Inclusion of a visual identifier would help beneficiaries to easily recognize and choose plans that include this meaningful benefit, as well as encourage more plans to offer $0 cost-sharing for vaccines.

Attachment VI, Section III, Specialty Tiers, p. 201-202

Description of the Issue or Question: Similar to past years, an analysis was performed utilizing CY 2017 prescription drug event (PDE) data to identify monthly fills that exceed the current specialty tier threshold of $670. This analysis showed that just around 1% of 30 day-equivalent fills exceeded $670 and as a result, CMS will maintain the $670 threshold for CY 2019.

Pfizer Comments:
Pfizer believes that specialty tiers are a blunt instrument to accomplish the goal of reducing unnecessary spending. Arbitrarily placing high cost-sharing requirements on drugs that meet certain cost threshold limits access without taking into consideration the variable benefits of these therapies and a patient's unique situation. The high cost-sharing allowed on the specialty tier places significant burden on people who need access to these medications, and many studies have linked high rates of coinsurance to non-adherence to medications and prescription abandonment.[36,37,38,39] In particular, we believe the specialty tier policy creates incentives for plan sponsors to create discriminatory formulary structures in which patients with certain conditions have no therapeutic options on lower cost-sharing tiers.

In the past, CMS and others have argued that placing high-cost drugs on specialty tiers helps to keep Part D costs lower for the majority of beneficiaries who do not require drugs on the specialty tier. However, this argument—that sicker beneficiaries should pay significantly more than healthy ones—is directly counter to the purpose of insurance in general, which is to spread risk among a population to protect any one individual from extremely high expenses. Additionally, we question the notion that eliminating specialty tiers would significantly increase costs for most Part D beneficiaries or the Part D program. In 2013, Pfizer commissioned a study by Milliman to examine this question, and found that eliminating the specialty tier would require only very modest increases in cost sharing:[40]

---

[36] Doshi, J. et al. "Impact of Cost Sharing on Specialty Drug Utilization and Outcomes: A Review of the Evidence and Future Directions." Am J Manag Care. March 2016; 22(3):188-197.
[37] Doshi, JA., Li, P, Huo, H, et al. Medicare Part D Cost-sharing And Specialty Drug Initiation In Newly Diagnosed Chronic Myeloid Leukemia Patients. *Value in Health*,19(3):78-86. doi:10.1016/j.jval.2016.03.035.
[38] Doshi, JA. et al. "Biologic Therapy Adherence, Discontinuation, Switching, And Restarting Among Patients With Psoriasis In The US Medicare Population". *Journal of the American Academy of Dermatology.* 2016;74(6):57-1065.e4.
[39] Doshi, JA, Hu, T, Li, P, et al. Specialty Tier-Level Cost-sharing and Biologic Use in the Medicare Part D Initial Coverage Period among Beneficiaries with Rheumatoid Arthritis. *Arthritis Care & Research*. 2016;doi:10.1002/acr.22880.
[40] Dieguez, G., Pyenson, B., and Johnson, R. "Specialty Tiers: Benefit Design Considerations for Medicare Part D." Milliman, June 25, 2013. Available at: http://www.milliman.com/uploadedFiles/insight/2015/specialty-tiers.pdf.

A typical PDP could move all covered specialty-tier drugs to other brand tiers and provide a similar actuarial value through an increase in cost sharing of $7 per non-preferred brand script, or $1 per preferred brand script, or a $5 increase in the deductible, assuming no change in the underlying population or drug utilization patterns.

We believe that it is neither fair nor reasonable to require patients to pay cost-sharing as high as 33% coinsurance when they can demonstrate that they must take a specific medicine and have no reasonable alternative. To impose a very high and un-appealable level of cost-sharing in such circumstances amounts to discrimination based on a particular patient's clinical needs or health status. Patients who have previously undergone step therapy and/or have demonstrated that drugs on lower tiers are not clinically appropriate should pay cost-sharing as if the drug were available on a more favorable tier.

We appreciate that CMS will continue to examine the amount at which specialty tier threshold is set. We believe that CMS is not being aggressive enough in addressing access to specialty drugs for patients that need them. Policies pertaining to the specialty tier, including the relatively low threshold and the exemption from tier exceptions, will continue to place a significant burden on beneficiaries seeking access to medicines placed on the specialty tier.

In addition, 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. 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].[41]

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,

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

as his example when touting the protections offered by the tiering exception provision.[42] We urge CMS to take such action in the next Part D rulemaking.

Attachment VI, Draft CY 2019 Call Letter, Section III, Part D: Improving Drug Utilization Review Controls in Medicare Part D (p. 202-216)

Description of the Issue or Question: In response to the national opioid epidemic, CMS proposes new strategies to further address the issue of opioid overuse in Part D. CMS expects plans to do more to reduce opioid overutilization in the Part D program. Currently, plans are expected to perform retrospective reviews to identify potential opioid over-utilizers and provide case management, as well as prospective implementation of real-time safety alerts at the time of dispensing. Beneficiaries with cancer diagnoses and beneficiaries in hospice are excluded. One of the mechanisms used by CMS to implement its opioid overutilization policies is the CMS Overutilization Management System (OMS), which they developed in 2013. It is used to identify beneficiaries considered to be at significant risk for opioid abuse and helps CMS ensure that plans have established reasonable and appropriate drug utilization management programs.

In October 2016 CMS added a flag to the OMS reports that are distributed to Part D sponsors quarterly, to identify potential opioid over-utilizers who are also receiving benzodiazepines concurrently. Specifically:

- A field was added to the beneficiary current opioid overutilization issue report indicating if the beneficiary concurrently received a benzodiazepine (Yes/No).
- The total number of beneficiaries with a potential opioid overutilization issue concurrently receiving a benzodiazepine was added to the contract summary report.

CMS' expectation was that Part D plans will consider benzodiazepine use within their opioid overutilization review process and include this information within their discussions with prescriber(s).

In the draft 2019 Call Letter, CMS notes that after working with the Office of the Inspector General (OIG) to identify other non-opioid "potentiator" drugs that may pose safety risks when misused with opioids, gabapentin has been identified as an independent risk factor for opioid-related deaths and reported misuse. CMS also states that these safety concerns extend to pregabalin. As a result, CMS proposes to add a concurrent opioid-gabapentin/pregabalin flag to OMS and is requesting feedback from stakeholders about the flags usefulness for Part D sponsors and how case management could help deter gabapentin/pregabalin-opioid misuse.

Pfizer Comments:
Pfizer shares your concerns about the epidemic from the misuse and abuse of opioids and we are committed to supporting public and private sector efforts to prevent and end the cycle of addiction. We are leading a number of important initiatives such as supporting primary prevention through education and community engagement, preventing abuse through partnerships with integrated delivery systems and ensuring access to addiction treatment, rescue and support.

[42] "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).

Ending the opioid epidemic has appropriately been placed as a national priority, and we appreciate the steps taken by CMS to help ensure that Part D plans monitor and seek to prevent inappropriate prescribing and use through drug utilization review (DUR) and quality assurance programs. We support CMS' efforts to monitor various treatments to ensure safe and effective use of these products. We also appreciate CMS' work to assure that efforts aimed at curbing overutilization of prescription drugs do not become unduly restrictive or impede legitimate patient access to medically necessary drugs.

Regarding the concern raised in the draft 2019 Call Letter about drugs that may pose safety risks when misused with opioids, we would like to share important information about pregabalin and gabapentin.

Cumulatively, it is estimated that 35,974 subjects have participated in the pregabalin clinical development program: 24,956 subjects were exposed to pregabalin. Since first approval in 2004 pregabalin has over 40 million years of patient exposure. Pregabalin is an important non-opioid treatment option for patients.

Independent clinical practice guidelines published by the American Association of Neuromuscular and Electrodiagnostic Medicine, the American Academy of Neurology, and the American Academy of Physical Medicine & Rehabilitation recommend pregabalin as a first-line treatment for painful Diabetic Peripheral Neuropathy.[43] The Canadian National Fibromyalgia Guideline Advisory Panel recommends pregabalin as a Level 1, Grade A treatment for Fibromyalgia.[44]

Both pregabalin and gabapentin work in the body by binding to the alpha2-delta location on calcium channel receptors; they do not act at locations associated with drugs of abuse.[45],[46] Preclinical binding studies of pregabalin show it has low liability for abuse when compared with known drugs of abuse such as opioids, benzodiazepines and barbiturates.[47] Pre-approval clinical abuse liability studies show the profile of subjective effects in response to pregabalin was different than diazepam and appears more similar to that of several unscheduled anxiolytics and antidepressants and to over-the-counter medications including antihistamines and nicotine nasal spray, which have proved both in laboratory studies and in the marketplace to be of low abuse potential.[48],[49] Adverse event reports of euphoria were observed in the pregabalin clinical development program, but these were observed relatively infrequently, consistent with the low number of reported abuse-related adverse events reported in the clinical development program.[50]

Since the first regulatory approval of pregabalin, Pfizer has conducted post-marketing surveillance of adverse events reported spontaneously to Pfizer, cases reported by health authorities, cases published in the medical literature, cases from Pfizer sponsored marketing programs, non-interventional studies, and cases of serious adverse events reported from clinical studies. As of January 31, 2017, approximately 2% of these cases reported misuse such as not taking the drug as prescribed, and taking more or less of the medication than

---

[43] Bril V, England JD, Franklin GM, et al. Evidence-based guideline: Treatment of painful diabetic neuropathy—report of the American Association of Neuromuscular and Electrodiagnostic Medicine, the American Academy of Neurology, and the Aerican Academy of Physical Medicine and rehabilitation. Muscle Nerve 2011;43(6):910-7.

[44] Fitzcharles MA, Ste-Marie PA, Goldenberg DL, et al. Canadian guidelines for the diagnosis and management of fibromyalgia syndrome: Executive summary. Pain Res Manag 2012;2013(18):119–26.

[45] Li Z, Taylor CP, Weber M, et al. Pregabalin is a potent and selective ligand for α(2)δ-1 and α(2)δ-2 calcium channel subunits. Eur J Pharmacol 2011;667(1-3):80-90.

[46] Neurontin USPI. New York: Pfizer Pharmaceuticals Inc; 2017.

[47] Lyrica USPI. New York: Pfizer Pharmaceuticals Inc; 2016

[48] Lyrica USPI. New York: Pfizer Pharmaceuticals Inc; 2016.

[49] Data on file. Pfizer Inc.

[50] Data on file. Pfizer Inc.

prescribed. A smaller number of cases reported abuse (approximately 0.5%) or dependence related events (approximately 0.7%).[51]

The limited case reports of abuse in the literature often involve patients with a prior history of substance abuse, including opioids. In this regard, the pregabalin US Package Insert (USPI) recommends that as, with any central nervous system active drug, physicians should carefully evaluate patients for history of drug abuse and observe them for signs of misuse or abuse (e.g., development of tolerance, dose escalation, drug-seeking behavior).[52]

Similarly, Pfizer has conducted post-marketing surveillance for gabapentin. A small number of post-marketing cases report gabapentin misuse and abuse by individuals taking higher than recommended doses of gabapentin for unapproved uses. Most of the individuals described in these reports had a history of poly-substance abuse or used gabapentin to relieve symptoms of withdrawal from other substances. As of February 1, 2016 approximately 1.3 % of spontaneous adverse event reported to Pfizer reported misuse, 0.4 % of cases reported abuse and 0.4% reported dependence.[53] The gabapentin USPI recommends that, when prescribing gabapentin, HCPs should carefully evaluate patients for a history of drug abuse and observe them for signs and symptoms of gabapentin misuse or abuse (e.g., development of tolerance, self-dose escalation, and drug-seeking behavior).[54]

Doctors and patients do not have many non-opioid treatment options available to them today. Access barriers and restrictions have made it difficult for patients to receive a non-opioid medicine like pregabalin. In fact, our research shows that 74 percent of patients with painful diabetic peripheral neuropathy and 65 percent of patients with fibromyalgia are prescribed an opioid first line.[55] Clinical guidelines do not recommend use of opioids first line for either condition.

While only limited evidence exists regarding the misuse of alpha2-delta ligands, Pfizer is committed to partnering with CMS on monitoring and sharing information to ensure patients are receiving safe and appropriate medicines to treat their chronic pain. Many patients suffering from pain rely on non-opioid medicines and it is critical that that they continue to be able to access essential therapies.

****

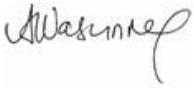
Pfizer appreciates the opportunity to comment on the CY 2019 Advance Notice and draft Call Letter, and hope that our comments will contribute usefully to the preparation of the final guidance. If you have questions or need additional information, please contact Deb Williams (202-368-5875 or deborahkaye.williams@pfizer.com) for the quality-related provisions or Margaret Davis for all other provisions (212-733-3390 or margaret.davis@pfizer.com).

We look forward to continuing our dialogue with CMS on these critically important issues.

Sincerely,

---

[51] Data on file. Pfizer Inc.
[52] Lyrica USPI. New York: Pfizer Pharmaceuticals Inc; 2016.
[53] Data on file. Pfizer Inc.
[54] Neurontin USPI. New York: Pfizer Pharmaceuticals Inc; 2017.
[55] Data on file. Pfizer Inc.



Angela Wasunna
Vice President
Global Policy