January 16, 2017

VIA ELECTRONIC SUBMISSION

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4182-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P)

Dear Administrator Verma,

Boehringer Ingelheim Pharmaceuticals Inc (BI or "the Company") appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS or "the Agency") on the Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule for CY 2019 ("Proposed Rule").[1]

BI is a leading global research organization with extensive expertise developing therapies to treat a variety of chronic and life-threatening diseases. We applaud CMS' ongoing efforts to maintain the quality of the Medicare Advantage (MA) and Part D programs, improve the programs' accessibility and affordability, and enhance the Medicare beneficiary experience. In these efforts, BI asks CMS to ensure that any changes safeguard the programs' existing patient protections, which drive plans and manufacturers to work together to meet individual beneficiaries' healthcare needs. Furthermore, we ask that any changes to the MA and Part D programs be carried out in a clear and transparent manner—this will help to reduce administrative burden for stakeholders and maintain continuity of care for patients.

[1] 82 FR 56336 (November 28, 2017).

We focus our comments and recommendations on the following areas of the proposed rule, emphasizing at the forefront of our comments the importance of considering policy for passing through manufacturer rebates at the point of sale to improve affordability:

- Request for Information (RFI) Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale
- Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing
- Part D Tiering Exceptions
- Changes to the Days' Supply Required by the Part D Transition Process
- Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes
- Eliminating Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences
- Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

We would be happy to discuss these issues further.

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Comments on CMS' Request for Information (RFI) Regarding the Application of

Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

In the proposed rule, CMS includes an RFI on designing a potential policy that would require Part D sponsors to pass through a portion of manufacturer rebates and all pharmacy price concessions at the point of sale. To date, accounting for rebates and price concessions—including discounts, direct or indirect subsidies, and direct or indirect remuneration—in reducing total plan costs has been essential in fostering competition in the Part D program and helping make premiums more affordable for beneficiaries. Looking forward, BI supports continued CMS efforts to ensure Part D beneficiaries receive the full benefit of these manufacturer rebates to reduce their cost sharing at the point of sale.

We ask CMS to reconsider the described methodology for prospectively calculating the applicable average rebate amount. BI is concerned that providing good faith estimates of the point-of-sale rebate amounts for the upcoming payment year (instead of using historical rebate experience) without opportunities to reconcile estimates has the potential to add administrative burden to plans and manufacturers. BI also encourages CMS to consider establishing processes for measuring, monitoring, and updating average class rebate amounts throughout the applicable plan year, rather than relying solely on the previously calculated estimates. The administrative burden and potential for inaccuracies in estimating rebates could ultimately have a limited effect in reducing costs for beneficiaries.

In addition, we request CMS to add clarification on the specific calculation of the minimum percentage for plans. As written, CMS does not offer enough distinction to solidly interpret that the minimum percentage will vary by category or class. BI assumes—for this policy to meet

CMS' intended objective of maintaining fair competition—that the minimum percentage would need to be calculated at the therapeutic category or class level. Calculating at the category or class level has the potential to achieve the balance of accounting for the nuance of different therapeutic areas while preventing competitors from modifying existing proprietary pricing arrangements to gain an unfair advantage. Furthermore, it reflects the variability in the structure of rebates and price concessions for drugs across therapeutic areas.

Assuming the minimum percentage would be calculated at the therapeutic category or class level, CMS should ensure guardrails are in place to safeguard that no drug-specific rebate amounts are ever disclosed. We are also concerned that in categories or classes with a limited number of products, offering a discount that is a portion of a weighted average rebate could quite easily allow industrious entities to calculate or estimate product-specific rebates. For categories or classes with limited brand presence, CMS must determine a percentage of rebate to pass through at the point of sale, potentially by defining a default percentage for these cases.

BI also has concerns about the expected use of the United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) as the method for determining category and class distinctions for this purpose. As currently managed, the USP MMG are updated only every three years and do not necessarily reflect the depth and breadth of therapies required to meet beneficiary needs across the Medicare population. This policy, as considered in the RFI, requires a classification system that subdivides the universe of medications into groupings of similar entities with similar target populations and, theoretically, aligned contracting and rebating approaches. The USP MMG, if used for this purpose, will not yield optimal results for some classes where a broad range of drugs with potentially un-related indications are included. A classification system that includes more granular groupings – and one that it updated on a much more frequent basis – than the MMG, such as the USP Drug Classification system's pharmacotherapeutic groups, could bridge the gap in those categories and classes with distinctive sub-classes.

Comments on Proposals Related to the Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

CMS proposes to revise the definition of a generic drug to include biosimilar products specifically for purposes of maximum non-LIS catastrophic cost sharing and LIS cost sharing. While we commend CMS' efforts to reduce costs to both beneficiaries and the Part D program and to promote biosimilar utilization, we believe that CMS should additionally consider biosimilar policies that would have an even greater impact in achieving these goals.

Consistent with our comments in response to the Medicare Physician Fee Schedule Proposed Rule for CY 2018,[2] BI asks that CMS consider biosimilars as applicable products for the purposes of inclusion in the Coverage Gap Discount Program. Similarly, we ask that CMS apply the treatment of biosimilars as branded products across both the Medicare and Medicaid

[2] 82 FR 33950 (July 21, 2017).

programs. There is significant variation under current policy, as biosimilars are treated as 1) non-applicable products for the Part D Coverage Gap Discount Program (CGDP), 2) branded products under the Medicaid Drug Rebate Program, and 3) as multi-source drugs under the Medicare Part B drug benefit leading up to CY 2018 rulemaking, which provided separate codes for biosimilars. Treating biosimilars as branded products across payment programs would reflect their critical differences from small molecule products.

In considering the impact of treating biosimilars as non-applicable products under the CGDP, Part D enrollees switching to biosimilar products will face increasing out-of-pocket costs. Were biosimilars treated as branded products for purposes of the 50% manufacturer discount in the coverage gap, the additional manufacturer contribution would count to the progression towards the true out-of-pocket (TrOOP) threshold. Therefore, beneficiaries using biosimilar products would reach the catastrophic phase of the Part D benefit sooner than under current policy, which would reduce their out-of-pocket costs. Indeed, such findings were reflected in a recent Medicare Payment Advisory Commission (MedPAC) analysis, which concluded the policy change would better align incentives in the Part D program.[3] Additionally, as it pertains to Part D plans, they will have to cover 75% of the cost of a biosimilar during the coverage gap as compared to 25% of the cost of a reference product in 2020.[4] This is very likely to dissuade Part D plans for pushing utilization of biosimilars in Part D.

BI urges CMS to recognize that biosimilars are in fact not generic medicines as evidenced by the FDA unique 351k pathway that was established specifically because biosimilars did not fit under the generic approval pathways. While BI continues to support the need for Medicare and Medicaid policies that support access to biosimilars, BI also wishes to see CMS further delineate that biosimilars are not in fact generic products and require their own unique considerations.

Absent policy change, beneficiary access to and uptake of biosimilars will continue to be at risk under the Part D program. In addition, manufacturers, Part D plans, and other stakeholders—in assessing these challenges that impede access and uptake of biosimilars—will be less likely to continue investing in these products, which are potentially life-saving therapies for critically ill patients. Overall, BI recommends that CMS continue to explore policies that create a dynamic biosimilar market that decreases costs in the Medicare program, ensures efficient and timely biologic drug approvals, and promotes beneficiary access and utilization of these therapies.

Comments on Proposals Related to Part D Tiering Exceptions

BI supports CMS' efforts to clarify that when a tiering exception is granted for a drug by a Part D plan, the cost sharing for the excepted drug must equal the lowest cost-sharing value for where

[3] Medicare Payment Advisory Commission. Aligning Incentives in the Part D Program. November 2017. http://www.medpac.gov/docs/default-source/default-document-library/biosimilars-in-medicare-part-d_nov-2017_final_print-version.pdf?sfvrsn=0

[4] Medicare Payment Advisory Commission. Biosimilars. November 2017. http://www.medpac.gov/docs/default-source/default-document-library/biosimilars-in-medicare-part-d_nov-2017_final_print-version.pdf?sfvrsn=0

an alternative drug is placed on-formulary. For brand drugs, approved tiering exceptions would be assigned to the lowest cost-sharing value associated with an alternative brand drug. Similarly, generics drugs would be assigned to the lowest cost-sharing value associated with an alternative generic drug. Generally, clarifying this process helps to ensure clear rules and policies related to beneficiary access to drugs in the Part D program across Part D plans.

In principal, this proposed policy aligns with CMS' efforts to lower beneficiary costs in the Part D program. Specifically, the proposal helps to ensure beneficiaries are made eligible for tiering exceptions based definitively on the lowest applicable cost-sharing value of an alternative drug, rather than on tier placement. However, BI encourages CMS to monitor any shifting of covered alternative drugs onto different formulary tiers to potentially decrease opportunities for beneficiaries to request tiering exceptions broadly by plan sponsors. Ensuring that plans do not respond to the policy change in this manner is a critical part of maintaining existing patient protections as outlined under the Part D program.

Separately, BI is particularly concerned that CMS continues to push the bounds of its regulatory authority to exempt drugs and biologics placed on specialty tiers from the exception process. The Medicare Modernization Act clearly articulated that beneficiaries should be able to request more favorable cost sharing for any drug that is considered not preferred when alternative therapies are available at lower cost sharing. Under the policy as interpreted by CMS, beneficiaries whose treatment requires medication placed on the specialty tier are faced with a choice of paying or financing high cost sharing or going without their needed therapy.

Further, we also want to call attention to the fact that Part D plans must choose a single cost-sharing level that applies to one of its existing formulary tiers as the level of cost sharing applied on non-formulary drugs acquired through the exceptions process. As CMS is aware, the vast majority of Part D sponsors currently choose the non-preferred tier for this purpose. Beneficiaries whose drugs are placed on the non-preferred tier face mounting access challenges due to high cost sharing—some of the Part D plans with highest enrollment charge the maximum coinsurance allowed under CMS guidance (50 percent) for non-preferred drugs.[5] In coverage exception situations where beneficiaries have met the clinical criteria to prove they have the medical need to take a particular non-formulary product, it is concerning that these beneficiaries will also most likely face high cost sharing they may struggle to afford.

In an increasingly competitive market where plans continue to narrow their formularies to contain overall premiums, beneficiaries may experience greater challenges in finding an

available plan that covers all of their needed prescription drugs. In these cases, more patients may turn to coverage exceptions to gain access to their medications only to find the cost sharing unaffordable. Permitting these patients to request tiering exceptions for drugs obtained through a

[5] Kaiser Family foundation. Medicare Part D: A First Look at Prescription Drug Plans in 2018. October 13, 2017. https://www.kff.org/report-section/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2018-findings/

coverage exception could help to accomplish the goal of allowing beneficiaries to access the lowest applicable cost-sharing value for needed prescription drugs, improving adherence, and avoiding costly medical expenses over time.

Comments on Proposals Related to Changes to the Days' Supply Required by the Part D Transition Process

CMS proposes two adjustments to the Part D transition process, which would impact the total days' supply required for Part D drugs not on a formulary under a new plan. First, CMS would adjust the current required "30 days" of transition supply in the outpatient setting to "a month's supply" to better reflect the varying number of days in a given month. Second, CMS would adjust the "90 days" of transition supply required in long-term care (LTC) to match the proposed month's supply required in the outpatient setting.

Overall, BI appreciates CMS' clarification to ensure the transition supply in the outpatient setting is for at least a month but has concerns around adjusting the minimum transition days' supply in the LTC setting. Lowering the minimum transitions' day supply may impede access and continuity of care for the LTC population, which comprises some of the most vulnerable patients in the Part D program. Specifically, given the complex needs of many LTC patients, a full 90-day transition period allows for the time to effectively transition these patients onto new regimens, if needed. In addition, maintaining the full transition period will also help to ensure no impediments to access, including unnecessary limits on transition fills. Limitations in access can ultimately lead to delays in acquiring medications, which can lead to unnecessary healthcare expenses, such as emergency room visits, hospitalizations, or readmissions.

Comments on Proposals Related to Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

Under the proposed rule, Part D sponsors could immediately remove a brand drug from its formulary—or make changes in its preferred or tiered cost-sharing—when it is replaced by a therapeutically-equivalent, newly approved generic drug. CMS stipulates that the added generic drug must have the same or lower cost-sharing and the same or less restrictive utilization management criteria than the brand drug it replaces.

Generally, BI supports CMS' attempt to provide Part D sponsors with greater flexibility for generic substitutions at any time of the year—provided advance general and retrospective direct notice is provided to enrollees—that helps maintain patient access and affordability. We do not support negative changes by the sponsor to a plan's formulary during the coverage year that would remove access to covered chemical entities, increase cost sharing, or add utilization management criteria.

However, we want to ensure that in allowing more opportunities for generic substitutions in this circumstance, CMS does not begin to require plan sponsors to implement generic substitution policies moving forward. Plan sponsors—in consultation with providers—should continue to have flexibility as outlined under current law in determining whether to cover brand drugs and/or therapeutically equivalent generics. This flexibility is an essential patient protection that ensures plans can continue to administer brand drugs to patients who may medically require them.

In addition, we ask that CMS acknowledge in the final rule the unique differences complex generic drugs have compared to simple generics—given their unique composition, efficacy, and application—as recognized under existing FDA guidance.

Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

Under the proposed rule, CMS would codify key components of the Medicare Advantage and Part D Star Ratings methodology in an effort to improve plans' ability to develop multi-year initiatives. As a part of these efforts, BI asks CMS to maintain the current weight of Part D medication adherence measures, consider other comprehensive outcomes measures, and add new patient-centered measures to the programs.

Medication Adherence Measures

BI supports keeping the Part D medication adherence measures at a weight of three, which provides a strong incentive for plan sponsors to emphasize medication adherence when determining the quality of coverage. To date, many plans still experience challenges assisting beneficiaries with chronic conditions—and their caregivers and healthcare providers—adhere to their maintenance prescription drugs. Moreover, evidence suggests when these patients are more adherent, Part D plans achieve savings in non-drug spending, less emergency department visits, and fewer inpatient hospital days.[6] It is therefore imperative for CMS to continue to measure adherence across the Medicare Advantage and Part D programs and encourage plan sponsors to improve such measures by giving them an outcome measure weight of three. In addition, BI encourages CMS to consider incorporating existing measures and adding new clinical outcomes measures for medication adherence due to their efficacy in generating savings for the Medicare program.[7]

Address Persistent Measure Gaps

Overall, BI supports CMS' efforts through its new Meaningful Measures Initiative to minimize provider burden and ensure the measures included in its programs are most vital to assessing and improving patient outcomes. However, we are concerned that critical measure gaps, especially those pertaining to high burden conditions among the Medicare population, may continue to persist as a result.

[6] M.C. Roebuck, et al. "Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending." Health Affairs 30 no. 1 (2011): 91-9.
[7] Stuart B, Loh F.E., Roberto P, Miller L. "Incident User Cohorts for Assessing Medication Cost-Offsets." Health Services Research, 49 no. 4 (2014): 1364-1386.

In particular, BI recommends that CMS focus on filling measure gaps for individuals with comorbid diabetes and cardiovascular disease (CVD). CMS has previously reported that for Medicare-Medicaid dual-eligibles, 45% of patients diagnosed with CVD were also diagnosed with diabetes.[8] Furthermore, nearly a third of the costs attributed to treating CVD are tied to the costs of treating diabetes.[9] Currently, CMS' Quality Rating System (QRS) does not report on identification, treatment, and outcomes of patients with these comorbidities in the measure denominator. We also encourage CMS to consider outcomes measures related to cardiovascular mortality for individuals with comorbid diabetes and CVD. Research suggests high mortality rates for patients with these comorbidities. Notably, diabetes patients are eight times more likely to experience a myocardial infarction (MI)—these MI patients are nearly eight times more likely to die from coronary heart disease complications.[10]

Additionally, BI notes ongoing gaps in outcomes measures related to medication use for the long-term management of chronic obstructive pulmonary disease (COPD). CMS has previously noted that patients with comorbidities including COPD incur significantly greater medical costs than the average Medicare beneficiary. Additionally, patients with comorbid chronic conditions including COPD require significantly greater healthcare resources. In 2017, the National Heart, Blood, and Lung Institute (NHLBI), at the request of Congress, developed the first COPD National Action Plan, which focuses on driving actionable results to prevent COPD and to ease the burden for those managing this disease. The Action Plan explicitly notes an aim to focus on ensuring "adoption of [existing and still-developing performance-quality measures that are informed by scientific evidence and input from various COPD stakeholders] to improve COPD detection, care, and treatment in healthcare settings and payer programs."[11] We therefore urge CMS to focus on filling this critical measure gap. For example, one existing measure that CMS should consider adding to the QRS is the Pharmacy Quality Alliance (PQA) measure, Adherence to Long-Acting Inhaled Bronchodilator Agents in COPD Patients.[12] We also encourage CMS to continue to work toward achieving alignment between goals set forth in federal initiatives such as these.

Other Outcomes Measures

Lastly, we urge CMS to consider outcomes measures that better reflect the wide range of conditions Medicare beneficiaries face. In addition to the gaps in outcomes measures highlighted above, we also urge CMS to focus on addressing measure gaps related to cancer treatment and symptom management, pain management, autoimmune disorders, mental illness, dementia/cognitive impairment, and multiple co-morbidities. BI further asks CMS to focus on

[8] Physical and Mental Health Condition Prevalence and Comorbidity among Fee-for-Service Medicare-Medicaid Enrollees. Centers for Medicare & Medicaid Services. Published September, 2014. Accessed January 9, 2017.
[9] Sander S, et al. Poster presented at American Academy of Managed Care Nexus; October 3-6, 2016; National Harbor, MD.
[10] Juutilainen A, Lehto S, Rönnemaa T, Pyörälä K, Laakso M. Type 2 diabetes as a "coronary heart disease equivalent": an 18-year prospective population-based study in Finnish subjects. Diabetes Care. 2005;28(12):2901-7.
[11] National Heart, Lung, and Blood Institute. COPD National Action Plan. 2016. Accessed January 8, 2018. https://www.nhlbi.nih.gov/health/educational/copd/get-involved/town-hall.htm
[12] Pharmacy Quality Alliance. PQA Performance Measures. https://pqaalliance.org/measures/default.asp. Accessed January 12, 2018.

patient-centered measures, which can help ensure that care better reflect and address patient needs. This includes measures such as quality of life, patient-reported outcomes, and functional status. Lack of measures in these areas ultimately hampers CMS' ability to appropriately measure quality of care for these conditions. Ensuring that measures effectively assess patient outcomes and reflect patients' priorities help to reinforce the integrity of the Medicare Advantage and Part D programs, resulting in improved health while mitigating costs. Both patient-reported outcomes and clinical outcomes are important, and BI supports CMS seeking ways to incorporate these types of measures in future Star Ratings.

Conclusion

BI appreciates the opportunity to comment on the Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule for CY 2019. In finalizing the rule, we ask that CMS maintain the integrity of the MA and Part D programs' current patient protections. In addition, we ask that CMS consider our comments around ensuring these programs continue to maintain robust standards for sponsors around beneficiary access and continuity of care. In particular, we emphasize the need for patients with complex medical conditions to be able to access and utilize biosimilars in order to meet their unique healthcare needs. Finally, to ensure continuity of care, we ask that CMS continue to carry out any changes to MA and Part D programs in a transparent manner.

We look forward to working with CMS to improve the quality of the Medicare program, ensure Medicare beneficiary access to potentially life-saving prescription drugs, and to elevate the overall Medicare beneficiary experience.

Sincerely,

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