



January 15, 2018

Via Electronic Submission:

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Subject: Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Program, and the PACE Program [CMS-4182-P / RIN 0938-AT08]

Dear Ms. Verma:

Bayer Corporation ("Bayer") appreciates the opportunity to submit comments pertaining to the Centers for Medicare & Medicaid Services ("CMS") proposed rule [CMS-4182-P / RIN 0938-AT08] ("proposed rule") addressing various elements of Medicare drug coverage as published in the *Federal Register* on November 28, 2017.

Bayer has more than 12,000 employees across the United States and is a global life science company with more than 150 years of experience researching and developing new pharmaceuticals and medical devices. We focus our efforts where we can have the most beneficial impact on the lives of those who depend on our innovative products. Our mission is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

On the basis of our experience, we wish to focus our comments on the following elements of the proposed rule:



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- Maximum Out-of-Pocket Limit for Medicare Parts A and B: Bayer strongly supports the maximum out-of-pocket (MOOP) provision of the Medicare Advantage rule, and believes that such protections should be extended to beneficiaries under the Medicare Part D program to help ensure appropriate patient adherence to needed medications.
- Mid-Year Formulary Changes: CMS proposes to reduce the “appropriate notice” requirement for non-generic formulary changes from 60 days to 30 days. However, the NAIC Health Carrier Prescription Drug Benefit Management Model Act maintains that a 60-day period is appropriate. We believe retaining the 60 day provision is important to appropriate patient care.
- Treatment of Follow-On Biologics: CMS’ proposed refinement of the definition of generic drugs to include biosimilars and interchangeable biologics has the potential to support access to these medications and lower patient cost. While we agree with the spirit of the proposal in regards to patient cost, we recommend that CMS reconsider its proposal equating generics with biologics.
- Price Concessions to Drug Prices at the Point of Sale: Bayer applauds CMS for implementing the RFI process regarding the pass through of discounts to patients in order to limit out of pocket costs, but we continue to be concerned about the confidentiality of specific manufacturer pricing concessions. Our recommendations focus on the reasons aggregated discounts are not appropriate, and urge the adoption of a minimum-to-maximum pass-through range to be negotiated between manufacturers and plans.

Our detailed comments follow.

- I. Maximum Out-of-Pocket Limit for Medicare Parts A and B: Bayer strongly supports the maximum out-of-pocket (MOOP) provision of the Medicare Advantage rule protecting beneficiaries against high cost-sharing provisions that may otherwise be applied. We believe that such protections should be extended to beneficiaries under the Medicare Part D program to help ensure appropriate patient adherence to needed medications.

Currently, Medicare Advantage beneficiaries who receive physician administered medications under the Medicare Part B program are protected from significant out-of-pocket costs each year through the MOOP ceiling. Similar protections would be appropriate to patients under the Part D program who may face significant costs under the open-ended cost-sharing provisions once the catastrophic phase of coverage is reached.

As noted in a recent analysis from the Kaiser Family Foundation, patients who are not eligible for low income subsidies (LIS) are confronted with unlimited costs for their medications.¹ The analysis found that in 2015, 3.6 million beneficiaries reached the catastrophic phase of coverage. About 1 million of those beneficiaries were without the LIS. On average, it was found that prescription costs were more than \$3,000 above the catastrophic phase in 2015, with a total of \$1.2 billion in out-of-pocket spending above the catastrophic threshold for this population.²

The benefit of applying such a cap to patients in Part D, beyond protection against high out-of-pocket costs, would be to minimize financial disincentives to adhering to needed medication therapies. This, in turn, can help to prevent or delay hospitalizations and other medical costs related to non-compliance.

- II. **Mid-Year Formulary Changes:** Bayer is deeply concerned with CMS' proposal to reduce the "appropriate notice" requirement for non-generic formulary changes from 60 days to 30 days. The National Association of Insurance Commissioners (NAIC) developed its initial Health Carrier Prescription Drug Benefit Model Act approximately 15 years ago.³ At that time it developed language in the Section addressing "Information to

¹ Kaiser Family Foundation. No limit: Medicare Part D enrollees exposed to high out-of-pocket drug costs without a hard cap on spending. *Issue Brief*. November 2017. Accessed January 8, 2018 at: <https://www.kff.org/medicare/issue-brief/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending/>

² Kaiser Family Foundation. *Ibid*, November 2017.

³ National Association of Insurance Commissioners. Health Carrier Prescription Drug Benefit Management Model Act. Model Regulation Service. July 2003. Accessed December 8, 2017 at: <http://www.naic.org/store/free/MDL-22.pdf>

Prescribers, Pharmacies, Covered Persons and Prospective Covered Persons” with the following requirements:⁴

Whenever the health carrier makes or approves a change in a formulary that causes a particular prescription drug not to be covered, applies a new or revised dose restriction that causes a prescription for a particular prescription drug not to be covered for the number of doses prescribed, or applies a new or revised step therapy or prior authorization requirement that causes a particular prescription drug not to be covered until the requirements of that PBMP⁵ have been met, unless the change is being made for safety reasons or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug’s manufacturer, the health carrier or its designee shall provide notice of that change to:

- (a) Prescribers at least sixty (60) days prior to the effective date of the change, unless the health carrier will provide coverage for up to a 60-day supply of the drug on the same terms as covered previously so long as the drug continues to be prescribed for the covered person...

In addition, the NAIC went on to address appropriate notification of patients:⁶

Whenever a health carrier makes or approves a change in a formulary that causes a particular prescription drug not to be covered, applies a dose restriction that causes a prescription for a particular prescription drug not be covered for the number of doses prescribed, or applies a prior authorization or step therapy requirement that causes a particular drug not be covered until the requirements of that PBMP have been met, the health carrier or its designee shall do one of the following:

⁴ NAIC. Health Carrier Prescription Drug Benefit Management Model Act. Model Regulation Service. July 2003. Section 6.A(2).

⁵ “PBMP” means “Pharmaceutical Benefit Management Procedure.”

⁶ NAIC. Health Carrier Prescription Drug Benefit Management Model Act. Model Regulation Service. July 2003. Section 6.C(1).

- (a) At least sixty (60) days prior to its effective date, the health carrier or its designee shall notify covered persons, who are currently receiving benefits for the drug that is being discontinued from coverage or that is the subject of the new or revised PBMP that results in no coverage until the requirements of the PBMP have been met, of the change, in writing or, if the covered person has agreed to receive information in this manner, by electronic means; or
- (b) Whenever a covered person, who is currently receiving benefits for the drug that is being discontinued from coverage or that is the subject of a new or revised PBMP that results in no coverage until the requirements of the PBMP have been met, requests a refill of the drug, the health carrier or its designee shall cover up to a 60-day supply of the drug on the same terms as covered previously so long as the drug continues to be prescribed for the covered person's authorized representative of the change, unless:
 - (i) The covered person's prescribing provider agrees to a request from the health carrier or pharmacist to change the prescription in accordance with the formulary change or new or revised PBMP; or
 - (ii) For a formulary change or a new or revised PBMP pertaining to generic substitution, the prescription drug order does not prohibit generic substitution, the covered person agrees at the pharmacy to generic substitution, or generic substitution is required by state law.

This past year, the NAIC considered some additional changes to this section that are yet to be finalized, but were recently approved by its Model Subgroup.⁷ The language maintains the requirement for 60 days' notice to prescribers and covered persons impacted by the change. The language further notes that, the change "...does not obviate the requirement that the carrier or its designee provide a minimum 60-day advance notice before the effective date of a formulary change to consumers in order to

⁷ NAIC. Health Carrier Prescription Drug Benefit Management Model Act. Draft: 11/7/17; Model #22. Adopted by Model #22 (B) Subgroup – Nov. 7, 2017. Copyright 2017, National Association of Insurance Commissioners. Accessed January 9, 2018 at: http://www.naic.org/documents/cmte_b_mod_22_sg_exposure_health_carrier_prescription_drug_benefit_proposed_revisions.pdf

provide sufficient time for consumers to discuss alternatives to the prescription drug impacted by the change with their physician or prescriber or file a request for approval of an exception under the health carrier's medical exceptions process."

These provisions are important to appropriate patient care, particularly in the patient populations most benefiting from the Medicare Part D program.

- III. **Treatment of Follow-On Biological Products as Generics for Non-Low-Income Subsidy (LIS) Catastrophic and LIS Cost-Sharing:** CMS proposes to revise the definition of generic drugs to include follow-on biological products solely for purposes of non-LIS catastrophic cost-sharing and LIS cost-sharing. It is suggested that lower cost-sharing for lower cost alternatives will improve enrollee incentives to choose follow-on biological products over more expensive reference biological products, and will reduce costs to both Part D enrollees and the Part D program. Importantly, CMS makes it clear they understand that biological products are, by definition, not interchangeable, and are not substitutable without a new prescription. Specifically, biosimilar and interchangeable biological products do not meet the section 1927(k)(7) definition of a multiple source drug or the CMS definition of a generic drug.

In general, Bayer is supportive of actions which seek to reduce patient cost-sharing while enhancing access to needed medications. However, we are concerned about CMS' proposed refinement of the definition of generic drugs to include biosimilars and interchangeable biologics.

Our primary concern with equating the definitions of biosimilars and generics is that it may further fuel the inconsistencies already apparent with biosimilars and reference products. Given this, we would urge CMS to reconsider its proposal.

- IV. **Price Concessions to Drug Prices at the Point of Sale:** Bayer appreciates the opportunity to offer feedback on the request for information pertaining to the offering of price concessions to drug prices at the patient point of sale. Certainly, we believe that efforts should be taken to ensure that patients are able to afford their medications when faced with cost-sharing provisions by health plans. To that end, we believe there are

several approaches that might be considered, including those that help to better direct the benefits of manufacturer discounts and rebates to patients. The most efficient and effective way to reduce patient cost-sharing is to change the benefit design by reducing patient copay and coinsurance levels. While that may be beyond the scope of this potential initiative and may require further legislation, the options being considered by CMS may help to have a positive impact on patient cost-sharing exposure.

Currently health plans effectively negotiate with manufacturers to reduce prescription drug costs to the health plans which may reduce beneficiary cost-sharing by seeking preferred status. The existing tiered structure allows for negotiation to reduce patient cost-sharing to lower levels in some instances. However, what is being entertained may help to further reduce costs to patients at the pharmacy, even though there may be some commensurate increase in premiums. The benefit of the reduction would be to avoid having those patients with the most significant exposure from bearing the brunt of the program costs. This will likely be most significant for those patients who may be taking medications that would fall into a specialty tier with coinsurance that would be as high as 33 percent. We are also supportive of efforts on the part of CMS to help decrease cost-sharing requirements for patients in the Medicare Part D program that may move to limit total out-of-pocket costs.

We appreciate the discussion CMS has offered for seeking an approach that would ultimately benefit patients. However, a key element of such an approach will need to ensure the confidentiality of specific manufacturer pricing concessions.

With regard to questions that CMS has raised about its proposed approach we offer the following initial recommendations:

- **Aggregated Discounts:** Manufacturers that provide no discounts in a therapeutic class would derive the benefits of other company discounts if such cost-sharing reductions are applied to those medications. Thus, we do not believe it would be appropriate for such reductions to apply to all drugs of the same class. Furthermore, we are opposed to any aggregation of discounts for the purpose a single reduction at the pharmacy. The benefits to be derived for specific patients should be driven by a factor of the discount a manufacturer provides, exclusive of the impact of other manufacturer discounts. For example, even though a manufacturer may only

provide a 2 percent discount, under the proposed methodology, the company would benefit from discounts of other companies that may have offered a 10 percent or 20 percent discount as discussed in the CMS example. This will result in an incentive to manufacturers to provide less discounts and there will be a race to the smallest amount of discount possible. The companies offering a higher discount would likewise realize a diminished positive impact for patients. As a result, there would need to be some adjustment while ensuring confidentiality as intended by CMS.


- ***Portion of Discounts Applied to Total Price:*** As CMS notes for the calculation of the coinsurance for a patient, there would need to be some reduction in the list price of a product for patients to realize any benefits when the coinsurance is calculated. In the example provided by CMS a 50% application of the discount is used to illustrate the calculation, with a sensitivity analysis looking at the potential impact at levels of 33 percent, 66 percent, 90 percent and 100 percent. Our concern with a set percentage pass-through is that it would be easy to back into a calculation of the discount that is actually offered to the health plan, thus breaching the confidentiality concern. Therefore, we recommend a minimum and maximum percent pass-through be set. The minimum pass-through percentage would be the minimum amount of what must be considered in calculating a patient cost-sharing. However, manufacturers and health plans could then negotiate the terms of a higher discount. Thus, without knowledge of the actual pass-through percentage it would limit the ability to determine the actual negotiated price of a medication.

Our recommendation is to consider a minimum pass-through of 50 percent while allowing manufacturers to negotiate with health plans up to a 90 percent pass-through. We believe this level may present an appropriate pass-through minimum. However, in an effort to ensure confidentiality of manufacturer discounts, we recommend the percentage of the pass-through be a confidential point of negotiation between the plan and manufacturer.

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Bayer appreciates the opportunity to comment on the proposed rule and looks forward to working with CMS on efforts to improve access to quality, affordable healthcare.

Sincerely,

A handwritten signature in black ink, appearing to read 'Raymond F. Kerins Jr.', with a stylized, cursive script.

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