

January 25, 2019

***By Electronic Delivery***

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Proposed Rule [CMS-4180-P]**

Dear Administrator Verma,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Proposed Rule (Proposed Rule).<sup>1</sup>

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

BIO members represent the entire biotechnology innovation ecosystem devoted to the discovery of new treatments – from universities and research institutes, to start-up biotechnology companies, to the private investors that risk massive amounts of capital to fund these companies, to the larger, established companies that play a critical role in bringing these life-changing innovations through the development and approval process and into the marketplace. Of our approximately 1,000 members, the vast majority are small companies engaged in some of the most challenging, cutting-edge research in the world. They typically have no marketed products and no profits, and thus are heavily reliant on private capital to fund their work. They take enormous risks every day to develop the next

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<sup>1</sup> 83 Fed. Reg., No. 231 (November 30, 2018).

generation of biomedical breakthroughs for the millions of patients suffering from diseases for which there currently are no effective cures or treatments.

BIO is therefore extremely concerned to see the Agency continue to focus on policy changes that erode the value of the Medicare benefit for seniors, placing patient access at risk. This Proposed Rule is yet another in a series of proposals that prioritize cost containment policies over patient healthcare needs. BIO respectfully requests that the Agency and Administration instead focus on holistic solutions that balance the financial sustainability of the Medicare program, while addressing patient out-of-pocket cost and access to appropriate treatment. Our concerns, detailed further in the balance of this letter, focus on the following:

- I. CMS should not allow plans to restrict access in the Medicare Part D six protected classes, as plans already have flexibility to manage these drugs in a clinically appropriate manner.
- II. CMS must go further in protecting beneficiaries enrolled in Medicare Advantage who may be subject to step therapy for their Part B drugs.
- III. CMS should not move forward with the inclusion of drug pricing information in the explanation of benefits, and instead focus on the updates to e-Prescribing standard to appropriately share cost information.
- IV. CMS must continue to work to ensure that patients see the benefit of negotiated prices reflected in their out-of-pocket (OOP) costs.
- V. CMS should move forward with the proposed requirements prohibiting gag clauses.

We recognize that too many patients – even those with insurance – cannot afford the life-saving treatments that are being developed, and we are committed to working to address this serious problem. As we have stated before, to accomplish this, we must harness – not abandon – the free market that has delivered amazing innovations for patients and made America first in the world in biomedical innovation. To this end, we urge the Administration to prioritize policies that ensure patients maintain timely access to necessary medicines, while directly reducing their OOP costs.

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***I. CMS should not allow plans to restrict access in the Medicare Part D six protected classes, as plans already have flexibility to manage these drugs in a clinically appropriate manner.***

Under the Proposed Rule, CMS is proposing to provide plans with greater ability to both impose utilization management (UM) tools on drugs included in the protected classes and to exclude drugs based on certain parameters. BIO strongly opposes these potential changes in policy as they are not aligned with the Congressional intent of the creation of the protected classes and will negatively impact timely and appropriate patient access to critical medicines.

When the Medicare drug benefit was created in 2003, Congress emphasized the role of protecting patients who needed appropriate medicines for their condition. The protected classes were established at the outset of the Part D program because “it was necessary to

ensure that Medicare beneficiaries reliant upon these drugs would not be discouraged from enrolling in certain prescription drug plans (PDPs), as well as to mitigate risks and complications associated with an interruption of therapy for vulnerable populations”.<sup>2</sup> The Agency developed guidance directing Medicare PDPs to cover “all or substantially all” drugs within six classes – anticonvulsants, antiretrovirals, antidepressants, immunosuppressants for the treatment of transplant rejection, antineoplastics, and antipsychotics.<sup>3</sup>

In 2008, Congress codified the classes,<sup>4</sup> and again further codified the importance of the six protected classes in the Affordable Care Act.<sup>5</sup> The protected classes are also linked to the nondiscrimination requirements of the Part D program. While plans are typically required to cover all products available in the protected classes that do not have generic equivalents,<sup>6</sup> CMS allows plans to employ UM tools – through the use of tiered formulary and coinsurance requirements, and use of prior authorization and step therapy for patients who are new starts (with the exception of antiretrovirals).<sup>7</sup>

Instead of maintaining the protections extended to patients taking these medicines and avoiding disruptions in care, the Agency is proposing exceptions to the policy that would allow plan sponsors to: (1) implement broader use of prior authorization (PA) and step therapy across all protected class drugs, extending the policy to patients who are already established on therapy and subjecting patients with HIV/AIDS to these utilization management tools, where they previously were not; (2) exclude a protected class drug from a formulary if the drug represents a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specific lookback period.<sup>8</sup>

For the disease states covered in the protected classes, such as cancer, HIV/AIDS, depression, schizophrenia, and organ transplant recipients, it is critical that patients and their physicians have the ability to make treatment modifications based on associated co-morbidities or changes in clinical needs. BIO is gravely concerned to see the Agency move in a direction that allows plans to restrict access in these classes in a manner that is inconsistent with providing the most appropriate care for Medicare Part D enrollees, as these flexibilities have no basis in clinical evidence or standards of medical practice. We strongly urge the Agency against policies that allow plans to delay or interrupt care for patients for non-clinical reasons.

First, the allowance of additional UM opportunities into the protected classes will harm patient access to appropriate medicines for their given condition – particularly when applied to patients stable on existing therapy. Such a change to the protected class policy seems to assert that there is no or little ability for plans to manage drugs within the protected

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<sup>2</sup> Centers for Medicare and Medicaid Services, Pub. 100-18 – Medicare Prescription Drug Benefit Manual, Ch. 6 § 30.2.5.

<sup>3</sup> *Id.*

<sup>4</sup> Medicare Improvements for Patients and Providers Act, Pub. 110-275.

<sup>5</sup> Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2010).

<sup>6</sup> If there are clinically equivalent drugs, both brand and generic, the plan has the ability choose to cover just one of the drugs.

<sup>7</sup> Centers for Medicare and Medicaid Services, Pub. 100-18 – Medicare Prescription Drug Benefit Manual, Ch. 6 § 30.2.5.

<sup>8</sup> 83 Fed. Reg., No. 231 (November 30, 2018).

classes. This is far from the case given that plans already have the ability to manage patients that are new to therapy outside of the antiretroviral class. Therefore the policy being proposed inappropriately targets patients whose health is being well managed.

In fact, drugs in the protected classes in Part D are subject to similar, and in some cases even more, utilization management as they are in the commercial market and there is significant uptake of generics within the protected classes.<sup>9</sup> A recent study by Avalere in conjunction with the Partnership for Part D Access demonstrates that there is widespread use of UM across the protected classes.<sup>10</sup> Drugs within these classes are placed in a non-preferred or specialty category 73% of the time (for both brand and generic drugs), and 60% of the time beneficiaries are subject to a coinsurance rather than a copay for these products.

Further, the proposal's discussion of allowing plans to require step therapy "without distinguishing between new starts and existing therapy" is extremely troubling. A policy that allows plans to exclude certain drugs from coverage or require patients who have been stable on a medication to undergo step therapy is clinically inappropriate, interferes with patients' overall treatment options and the decision-making process a patient engages in with his/her provider about his/her specific healthcare needs, and discriminates against patients that are affected by these particular disease states. For instance:

- A 2014 study found that patients who take antipsychotics that are subject to formulary restrictions are more likely to be hospitalized, resulting in 23% higher inpatient healthcare costs and 16% higher total healthcare costs.<sup>11</sup>
- For patients with Acute Myeloid Leukemia (AML), speed of initiation of treatment is critical for overall survival and health outcomes. One study demonstrated that delays in chemotherapy over 5 days adversely impacted patients' overall survival.<sup>12</sup>
- Choice of treatment for chronic phase Chronic Myeloid Leukemia (CP-CML) is guided by patient comorbidities, the toxicity profile of treatment, and a risk score that incorporates factors such as a patient's age, spleen size, and peripheral platelet count, among other clinical markers.<sup>13</sup> Imposition of step therapy for stable patients could result in use of a treatment that is not compliant with recommended clinical guidelines or to which the patient has already expressed an intolerance.
- For antiretrovirals, early treatment initiation with the right product for that patient is crucial. The choice of appropriate antiretroviral for a patient living with HIV is complex, as demonstrated by the Department of Health and Human Services (HHS) Guidelines for HIV/AIDS, and includes consideration of many factors including: virologic efficacy, toxicity, pill burden, dosing frequency, drug-drug interaction

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<sup>9</sup> The PEW Charitable Trusts. [Policy Proposals: Revising Medicare's Protected Class Policy](#). March 2018.

<sup>10</sup> Partnership to Protect Part D Access. [Medicare Part D's Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs](#), November 2018.

<sup>11</sup> Seabury, SA et al., Formulary Restrictions on Atypical Antipsychotics: Impact on Costs for Patients with Schizophrenia and Bipolar Disorders in Medicaid. American Journal of Managed Care, February 2014.

<sup>12</sup> Datta, T et al., Time to Treatment Initiation Predicts Overall Survival in Hospitalized Acute Myeloid Leukemia (AML) Patients: A California Population-Based Survey. Blood 2016, 128:3982.

<sup>13</sup> National Comprehensive Cancer Network Guidelines Version 1.2019. Chronic Myeloid Leukemia. Accessed January 15, 2019.

potential, resistance test results, comorbid conditions, access, and cost.<sup>14</sup> These guidelines go on to further demonstrate the need for broad clinical choices for providers in selecting the appropriate antiretroviral therapy for their patient.

In treating HIV, early initiation of choice of therapy – “rapid start” – is critical to overall health outcomes.<sup>15</sup> A growing number of studies have shown that starting HIV treatment on the same day, or within one week, of diagnosis results in better engagement and retention in care, shorter time to viral suppression, increased rates of viral suppression and decreased mortality,<sup>16</sup> as well as improving reduced HIV transmission rates, increasing time to AIDS, and improvement of serious medical conditions including cardiovascular or vascular disease, liver disease, end-stage renal disease, new-onset diabetes mellitus, and non-AIDS malignant disease.<sup>17</sup>

Further for patients with HIV infection, medication adherence increase’s a patient’s chance of achieving viral suppression, which stops HIV infection from progression, helping patients with HIV to live longer, with better health outcomes, and a reduced risk of sexually transmitting the virus to an HIV-negative partner.<sup>18,19</sup> Even established patients may experience or struggle with and face barriers to treatment adherence.<sup>20</sup>

While CMS states that it would be unlikely to approve step therapy requirements that would result in a change of treatment for patients on existing therapy, the Agency does not provide any detail on criteria or guidelines that would be used to assess when a policy that

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<sup>14</sup> US Department of Health and Human Services. [Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV](#) (last updated Oct. 25, 2018) (emphasis added).

<sup>15</sup> See: Lodi, Supra Note 17 (demonstrating that “rapid start”, or immediate initiation of HIV therapy upon diagnosis, has been shown to suppress the virus faster, and to improve retention in care); Highleyman, Liz, *RAPID Program Leads to Faster HIV Suppression*, Beta Blog (July 24, 2015) (stating that participants in San Francisco General Hospital’s “Rapid-start” ART program achieved an undetectable viral load within 56 days of diagnosis, compared with 119 days for those on a standard treatment schedule).

<sup>16</sup> See: Ford, Nathan et al., *Benefits and Risks of Rapid Initiation of Antiretroviral Therapy*, 32 AIDS 17-23 (2018) (finding that that ART started on the day of diagnosis “increased viral suppression at 12 months [and] retention in care at 12 months.”); Highleyman, Liz, *START Trial Shows Benefits of Early Treatment, Supports ART for All*, Beta Blog (July 22, 2015) (finding that participants who started therapy immediately were 57% less likely later to have serious health problems or to die); Cohen MS, Chen YQ, McCauley M, et al., *Prevention of HIV-1 Infection with Early Antiretroviral Therapy*, 365 NEW ENGLAND J MED. 493-505 (2011) (demonstrating that early use of antiretroviral therapy was associated with a 93% lower risk of linked partner infection than was delayed therapy initiation); Ford, N. et al., *Benefits and Risks of Rapid Initiation of Antiretroviral Therapy* 32 AIDS 17-23 (2018) (showing that antiretroviral therapy started on the day of diagnosis “increased viral suppression at 12 months [and] retention in care at 12 months”); Grinsztejn, B., et al., *Effects of Early Versus Delayed Initiation of Antiretroviral Treatment on Clinical Outcomes of HIV-1 Infection: Results from the Phase 3 HPTN 052 Randomised Controlled Trial*, 14 LANCET 281-90 (2014) (finding that earlier rather than later initiation of antiretroviral therapy reduced the risk of HIV transmission, time to AIDS, and serious associated medical conditions, including cardiovascular or vascular disease, liver disease, end-stage renal disease, new-onset diabetes mellitus, and non-AIDS malignant disease).

<sup>17</sup> Grinsztejn B, et al., *Effects of Early Versus Delayed Initiation of Antiretroviral Treatment on Clinical Outcomes of HIV-1 Infection: Results from the Phase 3 HPTN 052 Randomised Controlled Trial*, 14 LANCET INFECT DIS. 181-90 (2014); Cohen MS, Chen YQ, McCauley M, et al., *Prevention of HIV-1 Infection with Early Antiretroviral Therapy*, 365 NEW ENGLAND J MED. 493-505 (2011).

<sup>18</sup> See: National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases. [10 Things to know about HIV Suppression](#), November 14, 2017.

<sup>19</sup> At this time, 86% of people living with HIV have been diagnosed by a healthcare provider, but only 60% of the diagnosed population has achieved viral suppression. Of the diagnosed population, only 57% receive ongoing care. See: Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, Division of HIV/AIDS Prevention. [Understanding the HIV Care Continuum](#), June 2018.

<sup>20</sup> Shubber Z, Mills, EJ, Nachega JB, et al., *Patient-Reported Barriers to Adherence to Antiretroviral Therapy: A Systematic Review and Meta-Analysis*, 13 PLoS MED. E1002183 (2016).

requires switching for existing patients would not be appropriate. BIO urges the Agency not to allow further UM for patients who have been established on therapy given the significant disruptions in care that will be caused by this policy.

Further, the potential proposed exclusion of products within the protected classes - either for new formulations or tying to price increases - can inappropriately harm a patient's ability to access the medicines most appropriate for his/her health condition. Excluding new formulations, particularly when the predecessor product is no longer available, impedes availability of treatment options for patients. Establishing a price benchmark as a condition of coverage for protected class medications has no grounding in statute and can be harmful to patient access, particularly given that plans have wide discretion in formulary tier placement and other utilization management tools.

It is critical that patients and their providers have access to a number of treatment options within the six protected classes, as illustrated above, to ensure optimal care is being provided for a patient's given condition and to improve adherence to medication. Within a class of drugs, patients may respond differently to each product, for instance depending on how the product is metabolized through their system. Similarly, different therapeutic formulations within a class may have varied drug-drug interactions with other treatments used based on each patient's individual care needs. In each case, patients may experience worse health outcomes where on-formulary options within the six protected classes are further limited through application of this policy.

Patients with serious conditions who rely on medications in the six protected classes should not be subject to policies that preference treatment without any clinical basis, and may require them to undergo burdensome and confusing exceptions and appeals processes to gain access to therapies that their provider has determined are appropriate and effective. BIO strongly opposes these changes that would undermine the intent of the creation of these classes and may inappropriately impede patient access or require patients to undergo clinically inappropriate therapy changes.

## ***II. CMS must go further in protecting beneficiaries enrolled in Medicare Advantage who may be subject to step therapy for their Part B drugs.***

In the Proposed Rule, CMS reaffirms and makes additional updates to the policy originally announced via guidance on August 7, 2018 that would allow Medicare Advantage (MA) plans to employ step therapy management for Part B drugs. The Agency proposes changes to the appeals timeline and includes requirements for plans to use their Pharmacy & Therapeutics (P&T) Committees for development of step therapy policies. BIO maintains opposition to the policy of allowing step therapy for Part B drugs, as previously articulated to the Agency in a September 10, 2018 letter.<sup>21</sup> We do not believe step therapy is appropriate for patients taking Part B medicines, and urge CMS to reinstate guidance that prohibits this practice.

However, to the extent CMS moves forward with this policy, we do appreciate the Agency's proposed clarifications around appeals and P&T Committees, as we believe these could work toward ensuring more timely and appropriate patient access under the proposed policy. Although we believe more can be done to strengthen protections to ensure beneficiaries are

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<sup>21</sup> See: BIO Letter, RE: Step Therapy for Part B Drugs in Medicare Advantage, September 10, 2018.

receiving timely and appropriate treatment, these additional steps are critical to limit the harm such policy may do to patients.

First, we were pleased to see CMS recognize the need for an update to the originally stated appeals timeline of 14 days (72 hours expedited) for Part B drugs subject to step therapy in MA. The revised timeline in the Proposed Rule is consistent with the Agency's own views as articulated in the original regulations establishing the Part D program:

*"We agree with the commenters that the proposed adjudication timeframes are too long for making decisions involving an enrollee's access to drugs"; and also states that*

*"... 14 days is not timely for determinations that involve prescription drugs. There is too much risk for an enrollee's health if determinations are not made sooner than 14 days from the date the request is received, since an enrollee often will not be able to pay out-of-pocket for a prescribed medication and thus must forgo necessary therapy until a determination is made."*

This updated appeals timeline is important, particularly as recent findings of the HHS Office of the Inspector General demonstrated that MA plans overturned 75 percent of their own denials from 2014-2016, which raised "concerns that some beneficiaries and providers may not be getting services and payment that MAOs are required to provide."<sup>22</sup> This trend of overturned denials is concerning. Through the alignment of the appeals timeline under the MA Part B step therapy policy with that of Part D, CMS is more appropriately recognizing the time sensitive nature of patients' needs for the products delivered under Part B. If the Agency continues to support the use of step therapy for Part B drugs in MA, we urge the finalization of this proposed update to the appeals timeline.

Further, by requiring the use of P&T Committee processes for plan development of step therapy protocols, the Agency is more closely mirroring activities that take place in other healthcare markets. BIO believes this requirement is a step in the right direction, however, given the vulnerable patients served in the Medicare program, we believe further safeguards and transparency requirements are needed to ensure beneficiaries are adequately protected and that the same standards apply for drugs subject to step therapy across the Part B and Part D components of the benefit. For these reasons, we urge the Agency to do the following if it continues the application of step therapy for Part B Drugs in MA:

1. *Require MA plans to submit all Part B step therapy requirements for review and approval by CMS:* We continue to believe that it is critical for CMS to review and approve a plan's step therapy requirements to ensure beneficiaries are protected from clinically inappropriate policies. As currently detailed, CMS will only review such policies where step therapy is required between Part D and B drugs and we believe the same standard should be applied for all uses of step therapy across the Medicare program. While the use of a plan's P&T Committee is a step in the right direction, there is no guarantee that the plan will adopt the P&T Committee recommendations. We believe it is CMS' role through the annual MA plan review process to ensure these step therapy protocols are applied in a manner that is appropriate, and we

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<sup>22</sup> US Department of Health and Human Services, [Office of the Inspector General. Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials](#) (OEI-09-16-00410), September 2018.



recommend CMS undertake a notice of proposed rulemaking process to determine what clinical guidelines and other evidence should be used to underpin MA plans' step therapy policies.

2. *Extend further protections to beneficiaries who fall outside of the 108-day lookback period, but have had success with previous use of a therapy:* BIO maintains that the 108-day lookback period is inappropriate for patients using Part B drugs. In many instances, there are cases of patients who may be treatment free during that timeframe, either based on dosing that is less frequent than 108-days or those who have a long and established history of successful use of a Part B drug. CMS should adopt a policy that overrides the application of step therapy for patients with prior successful use of a Part B drug, regardless of time frame.
3. *Address concerns with the potential stepping of off-label products before on-label products:* We believe that CMS coverage and reimbursement policies should not undermine the FDA and its role to review and approve investigational uses of approved drugs. We are concerned that sole reliance upon compendia standards as the criteria for coverage would not be wholly consistent with the drug approval process. There is tremendous value in the continued study of on-market products for new indications as well as creating additional competition in the marketplace, while at the same time balancing the clinical need for patients to be treated with available therapies in the judgement of their physician, as acknowledged by the FDA.<sup>23</sup> Compendia are a critical component of delivering care as they can provide rapid updates when new information is understood, but should be consistent with the FDA and its scope and purpose. Accordingly, we believe that CMS needs to strike an appropriate balance between the FDA's drug approval process and the need for physician and patient access to clinically necessary treatment when establishing CMS coverage and reimbursement policies that may be issued under a final rule.
4. *Ensure that patients are not adversely impacted by mid-year changes to Part B step therapy policies:* Another area of concern with the policy as currently detailed is the potential for MA plans to make updates to their step therapy requirements for Part B drugs during the plan year. As detailed further below, we believe patients should have wholly accurate information around what types of drugs will be subject to step therapy when making selections around plan enrollment. Plans should not be allowed to make such changes throughout the course of the plan year.
5. *Update Medicare Plan Finder to allow beneficiaries to determine if their Part B drugs may be subject to step therapy:* As with Part D drugs, beneficiaries should be able to clearly and readily discern when shopping for a plan whether their Part B drugs are impacted by step therapy policies. By reviewing and approving MA step therapy policies as detailed above, CMS can set the same standard for Part B drugs subject to utilization management as Part D drugs and help increase transparency and

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<sup>23</sup> See: e.g., US Food and Drug Administration, ["Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet](#), accessed January 22, 2019 ("Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgement. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects.")



reduce beneficiary confusion. Details on Part B drugs subject to step therapy should also be included on the Medicare Plan Finder website.

6. *Strengthen the requirements around annual notice language for MA plans using step therapy for Part B drugs:* Currently under the MA step therapy policy, plans are required to provide minimal information to beneficiaries on the application of step therapy to their specific Part B drugs. We encourage the Agency to incorporate requirements that would ensure plans communicate each of a beneficiary's drugs that may be subject to step therapy, as well as more detailed information on the plan's overall use of step therapy policies to help better inform healthcare decision-making.

Finally, CMS notes that they believe step therapy will "better enable MA organizations to ensure that ... enrollees pay less overall or per unit for Part B drugs".<sup>24</sup> In fact, this policy can have the opposite impact for beneficiaries in MA. In instances where a beneficiary is required to take a Part D drug instead of a Part B drug, they will be subject to the cost-sharing requirements under the prescription drug benefit and may end up paying more OOP as their Part D drug costs will not accrue toward their MA max OOP for Part A and B services – where the Part B drug would have. Further, we remind the Agency that a significant proportion – over 80 percent – of beneficiaries in Medicare are shielded from the 20% OOP costs on Part B drugs through enrollment in supplemental coverage.<sup>25</sup>

In actuality, the savings generated from such a policy accrue only to the MA plans themselves, who bid on a benchmark of estimated costs for Part A and Part B services to provide coverage for beneficiaries. It is unclear how any savings from step therapy policies are being passed on to beneficiaries if a plan is theoretically spending less on Part B services under a step therapy policy. Again, while we share the Agency's goal of reducing OOP costs for patients, we do not believe step therapy for Part B drugs is an appropriately targeted solution.

BIO strongly urges the Agency to incorporate the additional transparency and patient protections outlined above into the step therapy policy for MA, should the policy move forward. We were pleased to see the Agency recognize the need for a more expeditious appeals timeline for Part B drugs and to review appropriateness of step therapy policies through P&T Committees, but more can be done to ensure Medicare beneficiaries are not harmed under such a policy applied to the critical medicines delivered in Part B.

### ***III. CMS should not move forward with the inclusion of drug pricing information in the explanation of benefits, and instead focus on the updates to e-Prescribing standard to appropriately share cost information.***

Under the Proposed Rule, the Agency is proposing to require the inclusion of drug pricing information in the Explanation of Benefits (EOB). CMS references including information on drug price trends in the form of cumulative percentage change in the negotiated price since the beginning of the benefit year. Additionally, for each prescription drug claim, CMS is

<sup>24</sup> 83 Fed. Reg., No. 231, p. 62169 (November 30, 2018).

<sup>25</sup> See: Kaiser Family Foundation. [Sources of Supplemental Coverage Among Medicare Beneficiaries in 2016](#), November 28, 2018.

proposing to require plan sponsors to provide information to beneficiaries about drugs that are “therapeutic alternatives” with lower cost-sharing on the plan formulary.

BIO is concerned with the context and content of the information being provided as a follow up to a service or receipt of a drug through the EOB. The Agency states that this type of information is intended to further educate beneficiaries and spark dialogue between patients and providers.<sup>26</sup> However, we believe that the information provided through the EOB does not present the full picture of a patient’s health needs, nor is it being presented in an appropriate venue - after a service and not directly with the patient’s provider - to allow for further dialogue. Rather than serving to inform and educate, such EOB information may only create additional confusion and may interfere with the overriding medical rationale for a patient being placed on one drug versus another based on comorbidities and overall health status.

For instance, CMS does not define the term “therapeutic alternative” which could lead to significant variability in the information presented by plans, including clinically inappropriate or inaccurate information as the proposal would allow plans to reference drugs in other categories or classes. Further, the proposal speaks to drugs with a “lower negotiated price” and drugs that have “lower cost sharing” – two completely different concepts with very different impacts for patients. Use of information relative to negotiated price can be particularly confusing for patients, as this does not present clear information about their OOP cost obligations. If the true intent of the policy is to reduce patients’ OOP costs, then only the “lower cost sharing factor” should be the emphasis of such a proposal. Further, the requirements do nothing to ensure plans would be required to detail to beneficiaries how any changes in negotiated price are passed along to beneficiaries.

BIO believes the EOB proposal is not an effective means for increasing transparency and patient understanding of healthcare costs. Instead, we believe the Agency’s proposal to update the standards of e-Prescribing to include a real time benefit tool (RTBT) requirement for Part D sponsors is a more appropriate step toward providing healthcare cost transparency. Through conveying patient-specific, real-time cost or coverage information at the point of prescribing, patients are realistically able to have a conversation with their providers around potential OOP cost savings based on formulary parameters, and understand if their product may be subject to utilization management requirements.

We believe it may be ambitious to institute these requirements in an appropriate manner by 2020 as proposed, based on technical and operational concerns. However, we urge the Agency to work with stakeholders to refine the information being delivered through an RTBT and to continue to make updates consistent with feedback as the Agency moves toward implementation.

#### ***IV. CMS must continue to work to ensure that patients see the benefit of negotiated prices reflected in their OOP costs.***

As we have previously expressed,<sup>27</sup> BIO is supportive of efforts to reduce Medicare beneficiary cost burden at the pharmacy counter through implementation of policies that

<sup>26</sup> 83 Fed. Reg., No. 231, p. 62168 (November 30, 2018).

<sup>27</sup> See: BIO Comments RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, July 13, 2018; BIO Comments RE: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare

ensure beneficiaries see the benefit of manufacturer rebates at the point-of-sale (POS). However, we believe that this rule presents a missed opportunity to also require plan sponsors to pass through a portion of manufacturer rebates at the POS to further reduce the negotiated price. CMS instead considers changing the definition of “negotiated price” to ensure that all pharmacy discounts are reflected in the drug prices beneficiaries pay at POS, but does not address any potential requirements for Part D sponsors to pass through a share of manufacturer rebates to further reduce the negotiated price. Doing so would help patient’s realize the benefit of lower negotiated prices through reduced OOP costs.

It is BIO’s longstanding position that patients should see direct benefit from the rebates negotiated by health plans and PBMs in the form of reduced cost-sharing. Numerous studies have shown that patient cost-sharing is an important factor in medication adherence, with patients less adherent when their cost-sharing requirements increase. One study that specifically looked at patient adherence to diabetes medications found that a \$10 increase in the patient cost-sharing index resulted in a reduction in adherence between 5.4 and 6.2 percent.<sup>28</sup> Nonadherence is associated with poorer health outcomes and higher overall healthcare expenditures, with a recent estimate of \$100 billion in annual avoidable nonadherence costs in the United States.<sup>29</sup> Reducing patient cost-sharing not only benefits the beneficiary by increasing access, but also decreases overall costs to the healthcare system by improving health outcomes through increased medication adherence. We therefore urge CMS to take action to share these savings with patients in the Part D program.

We support a policy that would pass through the benefit of these rebates to patients. In developing such a policy, BIO believes that it is critical for any methodology implementing such policies to pass along savings to patients to maintain manufacturer pricing confidentiality, as it is a critical element in maintaining the competitive nature of the Part D program—whereby robust negotiations between entities help bring costs down for beneficiaries. Protecting the proprietary nature of rebate information is vital to ensuring pharmaceutical manufacturers and pharmacies/pharmacy benefit managers are able to engage in rigorous negotiation to bring down costs and drive competition in the Part D marketplace while helping to ensure that patients benefit from a policy that passes on rebates at the POS.

Further, in the discussion outlined in the Proposed Rule, we believe the definition of negotiated price should remain the same across all phases of the Part D benefit. The approach described in the rule could result in higher cost-sharing and confusion for beneficiaries. BIO encourages the Department to work with stakeholders on possible routes for implementation of such a policy in a manner that has meaningful impact for reducing patient OOP costs while maintaining the competitive nature and confidentiality of rebates in the Part D program.

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Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit and the PACE Program.

<sup>28</sup> Gibson TB, Song X, Alemayehu B, Wang SS, Waddell JL, Bouchard JR, Forma F. Cost sharing, adherence, and health outcomes in patients with diabetes. *Am J Manag Care*. 2010;16(8):589-600.

<sup>29</sup> Sacks N, Burgess J, Cabral H, McDonnell M, Pizer S. The effects of cost sharing on adherence to medications prescribed for concurrent use: do definitions matter? *J Manag Care Spec Pharm*. 2015;21(8):678-87.

**V. *CMS should move forward with the proposed requirements prohibiting gag clauses.***

In the Proposed Rule, CMS outlines a proposal to incorporate new requirements into the Part D regulations that provides that a plan sponsor may not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D enrollee of the cash price of a drug at the pharmacy counter that is below the price of the drug obtained through the plan. As we have previously articulated in other comment opportunities,<sup>30</sup> BIO supports the proposal to update the regulations governing Part D in a manner that allows beneficiaries to know if their drug is available at a lower cost at the pharmacy counter.

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BIO reiterates our concern with CMS' actions that fail to meet the goals of ensuring timely and appropriate beneficiary access to therapy while reducing patient OOP costs. The continued issuance of Medicare policies that allow greater plan flexibility to restrict access, particularly without adequate oversight or patient protections, impact the value of Medicare for the vulnerable beneficiaries the program serves. We urge the Agency to move away from such actions, and instead come together with stakeholders on policies that are patient-centric, prioritize access to innovations in treatment, and address cost issues across healthcare sectors. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Sincerely,

/S/

Crystal Kuntz  
Vice President, Healthcare Policy & Research  
Biotechnology Innovation Organization

/S/

Mallory O'Connor  
Director, Healthcare Policy & Federal Programs  
Biotechnology Innovation Organization

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<sup>30</sup> See: BIO Comments RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, July 13, 2018.