Biotechnology Innovation Organization

January 16, 2018

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: 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][1]

Dear Administrator Verma:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) 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 Proposed Rule (proposed rule).

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 supports CMS's efforts to make changes to the Medicare Advantage, Medicare Fee-for-Service and the Part D Prescription Drug Benefit Programs in a manner that improves overall healthcare quality, while not compromising access to the most appropriate course of treatment. Our comments, detailed further in the balance of this letter, focus on the following areas:

- Request for Information to Require Pass through of Manufacturer Rebates at the Point of Sale to the Beneficiary
- Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)
- Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost-Sharing
- Revisions to Part D Tiering Exceptions

[1] 82 Fed. Reg. November 28, 2017.

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- Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes
- Maximum Out-of-Pocket Limit and Cost-Sharing Limits for Medicare Parts A and B Services
- Flexibility in the Medicare Advantage Uniformity Requirements
- Any Willing Pharmacy Standards Terms and Conditions
- Medicare Advantage and Part D Prescription Drug Program Quality Rating System
- MA/Part D Artificial Limits

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I. Request for Information to Require Pass through of Manufacturer Rebates at the Point of Sale to the Beneficiary

In the proposed rule, CMS includes a request for information (RFI) regarding the application of manufacturer rebates and pharmacy price concessions to drug prices at the point of sale. CMS notes the increasing success with which Part D sponsors and their contracted pharmacy benefit managers (PBMs) have been able to negotiate rebates from pharmaceutical manufacturers, network pharmacies, and other entities. As data has found that the negotiated price concessions have not been passed on to consumers at the point of sale (POS), CMS is soliciting comments regarding possible requirements for Part D plans to share minimum percentages of manufacturer rebates and all pharmacy price concessions received in the drug's negotiated price at the POS. BIO strongly supports CMS's efforts to reduce Medicare beneficiary cost burden at the pharmacy counter through implementation of a policy that would ensure beneficiaries see the benefit of manufacturer rebates at the point of sale.

We are encouraged to see the inclusion of this RFI, as 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.[2] 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.[3] 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.

In developing its detailed approach to pass on rebates to beneficiaries, we urge CMS to consider carefully all potential impacts of any methodology, particularly since the effect on beneficiaries may differ depending on their specific circumstances. Further, it may be beneficial for CMS to implement a policy of this nature through a phased, stepwise approach to inform future policymaking and the impact on plan design, contracting, formulary coverage and premiums. This could help ensure that beneficiary access and satisfaction are not negatively impacted. CMS notes the ways in which its potential policy would increase

[2] 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.
[3] Sacks N, Burgess J, Cabral H, McDonnel 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.

price transparency, while also protecting the details of any manufacturer-sponsor pricing relationship. We strongly support such data confidentiality protections and offer some suggestions in that regard.

Specifically, the methodology suggested as part of CMS's proposal would require "that the manufacturer rebate amount applied to the [POS] price for a covered drug be based on the plan's average rebate amount calculated for the rebated drugs in the same category or class." CMS states that its aim is to ensure confidentiality of the manufacturer-sponsor/PBM pricing relationship with regard for any individual drug. We agree that this focus on confidentiality is important, 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. However, we are concerned that this policy as proposed may lead to unintended consequences, including cross-subsidization of competitors in a class. For example, the proposed methodology may create instances in which the average rebate may be higher than what an individual manufacturer is offering for one drug, but lower than what another manufacturer is offering for another drug. In the latter instance, this could create a scenario where one manufacturer's high rebates could subsidize other products across a therapeutic class. Additionally, there may be instances in which there are single drugs in a specific category or class, thereby exposing confidential information. BIO believes that protecting the proprietary nature of rebate information is vital to ensuring pharmaceutical manufacturers and pharmacies/PBMs 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.

BIO encourages CMS to consider alternative methods for implementing its proposed policy. For example, CMS could base POS rebate amounts on manufacturer-specific retrospective rebate data points (i.e. 24 or 36 months prior) which would help to better shield more recent proprietary rebate information. As another example, CMS may also consider reflecting a portion of the expected rebates across a plan's Part D business during bid submission and upon which overall cost-sharing reductions would be based. Ultimately, there are a number of methodological approaches CMS could explore that would address the confidentiality concerns while supporting the overall policy approach – to address high out-of-pocket costs beneficiaries are facing at the pharmacy counter. In continuing to develop this policy, we ask CMS to carefully deliberate all aspects of applying manufacturer rebates at the POS and to make changes in a manner that decreases the overall cost burden for beneficiaries and maintains the competitive nature of the Part D program. We would encourage the Agency to continue to engage with stakeholders to develop and appropriately implement a solution to achieve the shared goal of reducing beneficiary cost-sharing by passing on rebates at the point of sale.

II. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)

CMS proposes implementing the provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA) that require the Agency to establish a regulatory framework that allows Part D plan sponsors to voluntarily implement a drug management program to limit "at risk" beneficiary access to drugs identified as "frequently abused substances" by CMS. Beginning in the 2019 plan year, CMS proposes designating opioids (excluding buprenorphine for medication assisted treatment and injectable) as "frequently abused drugs" and is tying the definition of "at risk" beneficiaries to criteria already used to identify

potential opioid overutilizers through the existing Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS), instituted in 2013. [4] CMS can then limit access to opioids for the beneficiaries identified to a select provider(s) or network pharmacy (or pharmacies).[5]

BIO commends CMS for implementing the provisions of CARA aimed at addressing opioid overutilization in the Medicare program, and we support the parameters of the proposal and use of the existing the DUR and OMS. BIO and our members are committed to developing solutions to address the opioid crisis by: (1) ensuring patients suffering from pain or addiction are able to receive the right treatment at the right time with the right support, without stigma; (2) stimulating research and development of innovative treatments that effectively treat pain and opioid addiction and prevent abuse; and (3) advancing our understanding of the biology of pain and addiction to enable the development of innovative treatments for pain and addiction and ensure appropriate and optimal use of existing therapies.[6] To that end we urge CMS, as a part of the Agency's broader activities and goals in addressing the opioid crisis,[7] to work through its regulatory pathways to expand access to novel and safer treatments, abuse deterrent formulations, and non-opioid analgesics for pain, and to new and current forms of medication assisted treatment across care for addiction.

For instance, CMS estimates under this proposal that more than 319,000 beneficiaries could potentially be at risk for opioid overutilization,[8] and the Health and Human Services (HHS) Office of the Inspector General (OIG) states that although many beneficiaries may receive opioids for legitimate uses, the high number raises concern.[9] BIO believes that novel and safer treatments, abuse deterrent formulations, and non-opioid analgesics can play a central role in reducing these risks, while still providing necessary treatment in appropriate cases for Medicare beneficiaries. Such formulations not only can reduce risk to Medicare beneficiaries themselves, but also for others who may have access to a beneficiary's medication in the home. BIO believes CMS should consider how such innovations in treatment for pain can play a role in the context of the DUR and OMS, and for purposes of implementing the provisions of CARA. We urge CMS, in its discretion to modify and update the list of "frequently abused drugs", to exempt treatments for pain and addiction that combat opioid addiction and illegal diversion. CMS should also consider

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[4] Excludes patients who have cancer or are in long-term care.

[5] Under the OMS sponsors are expected to implement appropriate plan-level claims controls at point-of-sale for opioids, use improved retrospective drug utilization review to identify beneficiaries at high risk for an adverse event due to opioids, and perform case management with the identified beneficiaries' prescribers followed by beneficiary specific point-of-sale edits to prevent opioid overutilization. On a quarterly basis, CMS reports a comprehensive morphine equivalent dose (MED) approach in identifying high risk beneficiaries to plan sponsors, using the following criteria for 2017: "Use of opioids with cumulative daily MED exceeding 120 mg for at least 90 consecutive days with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims, during the most recent 12 months, excluding beneficiaries with cancer diagnoses and beneficiaries in hospice." Beginning in 2018, CMS will be shortening the measurement period from 12 months to 6 months, using average MED rather than a count of 90 consecutive days of high MED, lowering the MED threshold to 90 mg, and grouping providers within the same practice to eliminate false positives – these changes were made based on data analysis following release of additional guidelines. For each beneficiary identified in the OMS, Part D sponsors provide an evaluation response to CMS with the result of their case review.

[6] For more information, see: BIO Releases Plan to Unleash Innovation in Fight against Opioid Abuse and Addiction. November, 2, 2017.

[7] CMS has held a series of meetings with stakeholders seeking ideas and solutions to the opioid crisis.

[8] 82 Fed. Reg., 227, p. 56346. November 28, 2017.

[9] US Department of Health and Human Services, Office of the Inspector General. Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing. July 2017.

requiring use of novel and safer treatments, abuse deterrent formulations, and non-opioid analgesics for beneficiaries who have been identified as "at risk" under the parameters of the DUR and OMS, where appropriate.

Additionally, BIO believes CMS can play a critical role in ensuring access to medications that assist in the treatment of addiction, deter or mitigate the risk of addiction, or represent a significant advance in treatment for pain or addiction for Medicare patients by ensuring appropriate formulary placement within the Part D program. Currently, many plan sponsors do not include these advances in therapies, such as abuse deterrent formulations, non-opioid analgesics, and medication assisted treatments, within their formularies, or if they do, they include a variety of restriction tools (e.g., step therapy, prior authorization) which can limit provider choice and patient access to timely initiation of appropriate treatment. We urge CMS through its efforts focused on the opioid crisis to acknowledge the role novel and safer therapies can play, by assuring plan formularies provide adequate access and do not inappropriately apply utilization management techniques.

Further, we urge CMS to continue to work with the provider community to advance education on all opioid addiction prevention and treatment options, including the utility of novel and safer treatments for pain and addiction. Providers should be armed with the most up-to-date information in combating the opioid crisis, including availability of these medicines, and how they can be appropriately integrated into a patient's overall treatment plan and the broader continuum of care for treatment of pain and addiction. BIO applauds CMS for its commitment to addressing the opioid crisis across programs in the Agency's purview, both in this proposed rule and through the collaborative efforts underway. We appreciate the opportunity to continue to work with CMS as a partner on these efforts, ensuring patient access to the right treatment for pain and addiction, while advancing the development of innovative treatment options and a better understanding of the biology of pain and addiction to inform treatment decisions.

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

As noted in our comments in response to the request for information on point of sale rebates above, BIO commends CMS's efforts to reduce beneficiary out-of-pocket costs. We appreciate CMS's intent to further reduce costs for some of Medicare's most vulnerable beneficiaries – LIS eligible and non-LIS Part D catastrophic beneficiaries – through the proposal to treat follow-on biologics as generics for purposes of cost-sharing. However, consistent with CMS's own considerations, we have concerns with this proposal based on the precedent it may set around treatment of follow-on biologics across the Part D program relative to FDA requirements.

By definition, biosimilars are *not* "generics" but rather biological products approved under section 351(k) of the Public Health Service Act (PHSA) and include both biological products which are biosimilar but not determined to be "interchangeable" with the reference product as well as those which are determined to be both biosimilar and "interchangeable" with the reference product. Congress, in enacting the Biologics Price Competition and Innovation Act (BPCIA) that created the biosimilar approval pathway, recognized that the legal and regulatory construct for generic drugs is inappropriate for biosimilar products due to the scientific differences between biologics and small-molecule drugs. Accordingly, there are considerable differences between the regulatory review pathways for approval and

marketing of generic versus biosimilar drug products, which BIO has previously detailed in our comments.[10,11]

We appreciate CMS's own recognition of these scientific and regulatory distinctions between biosimilars and generics, and the Agency's intention to "avoid causing confusion and misunderstanding that CMS treats follow-on biological products as generic drugs in all situations" in the proposed rule.[12] Indeed, CMS has stated that it would not be suitable for CMS to treat biosimilars as generics for purposes of midyear formulary changes, as it could incorrectly signal product interchangeability.[13] We agree and believe the same policy rationale should apply here as well.

Consequently, BIO does not support CMS's proposal to define follow-on biological products as "generic drugs" for purposes of the Part D benefit. Even a limited application of a proposal that conflicts with FDA regulation has the potential to create confusion that could negatively impact both patient safety, through inappropriate patient switching, and future developments in the biosimilars marketplace. We urge CMS to consider alternative solutions to address cost-sharing obligations for LIS eligible and non-LIS Part D catastrophic beneficiaries that do not have the potential to create such regulatory confusion or be inappropriately applied within the Part D benefit. One potential alternative could be for CMS to work with plans to address such cost-sharing issues through their benefit design and overall tiering structure.

IV. Part D Tiering Exceptions Revisions

CMS proposes updates to the current tiering exceptions policy, including definitively basing eligibility for tiering exceptions on the lowest applicable cost-sharing for the tier containing the preferred alternative drug(s) and not based on tier labels, specifying that plan sponsors would not be required to offer a tiering exception for a brand name drug to a cost-sharing level that applies to a generics only tier.[14]

BIO supports CMS's efforts to lower beneficiary cost-sharing when a preferred treatment is not medically appropriate based on the patient's condition or course of care. However, BIO is concerned that the new framework for consideration of tiering exceptions has the potential to disadvantage certain drugs, in particular biologics. As proposed, the change would limit the exceptions to the lowest tier associated with the biological alternative rather than the brand alternative, in instances where both a biologic and non-biologic treatment for a given condition exist. We ask CMS to update the language of the proposal to ensure patients who rely on biologics that have non-biologic therapeutic

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[10] See: BIO Comments, RE: Docket No. FDA–2013-P-1153: BIO Comments to Generic Pharmaceutical Association Citizen Petition Requesting the Food and Drug Administration to Implement its INN Naming Policy Equally to all Biologics. January 2014.

[11] For instance, in order to receive regulatory marketing approval, Abbreviated New Drug Applications for generic drugs are required to contain information that demonstrates the proposed product is the same as the previously approved drug (see: FFDCA § 505(j), 21 U.S.C. § 355(j)). Biosimilars by definition are not direct copies of the reference product, and instead must be shown to be "highly similar" in structural characteristics with absence of clinically meaningful differences (see: PHSA § 351(i)(2)). As a result, most generics are considered therapeutically equivalent and therefore interchangeable, whereas biosimilars are highly similar, but not clinically identical, to their reference products, and as reflected by the two different standards. FDA has the ability to designate a biosimilar as interchangeable only after certain standards are met (see: PHSA § 351(k)(4)).

[12] 82 Fed. Reg. 227, p.56417. November 28, 2017.

[13] Id.

[14] 82 Fed. Reg. 227, p. 56371. November 28, 2017.

alternatives are not disadvantaged by the details of the new policy. Patients should have the ability to appeal for the cost-sharing level of the lowest applicable product, regardless of whether it is a biologic or not, if their health outcome or treatment considerations require use of a different medication.

BIO maintains concern, as previously detailed in our comments on the Call Letter,[15] with the lack of consistency in updates to the specialty tier threshold for purposes of formulary tiering placement. We remind CMS that the specialty tier threshold is a regulatory creation and CMS has the authority to update the threshold, as was done in 2017 and which we applauded CMS for doing.[16] As a part of this proposed rule, we strongly urge CMS to revisit the specialty tier threshold based on the considerable evolution that has occurred in the Part D program with relation to coverage of specialty drugs, which CMS recognizes in another portion of the proposed rule.[17] BIO urges CMS to take further steps to ensure that specialty tier placement of drugs does not unduly burden or discriminate against particular subsets of patients based on the inability of those who receive medications on the specialty tier to appeal for lower cost-sharing amounts. We encourage CMS to regularly update the specialty tier eligibility cost threshold to ensure it does not unduly discriminate against the most vulnerable beneficiaries and to seek out additional opportunities to allow beneficiaries with medications that fall into the specialty only tier to appeal for and receive lower cost-sharing.

Additionally, in consideration of revisions to the Part D tiering exceptions, we continue to encourage CMS to improve vaccination rates for Medicare beneficiaries in conjunction with plan sponsors by providing first dollar coverage for vaccines covered under the Part D program.[18,19] Vaccines covered under Part D are typically subject to cost sharing requirements ranging from $14 to $102 per vaccine, leading to historically lower uptake of these vaccines than those covered at no beneficiary cost-sharing obligation under Part B.[20] For example, the herpes zoster vaccination, recommended by the Advisory Committee on Immunization Practices (ACIP) to prevent shingles in adults 60 years and older and covered by Part D, only covers 30.6% of the recommended population. In contrast, pneumococcal vaccination, recommended by ACIP for adults 65 and over and covered at $0 cost-sharing under Part B, covers 63.6% of the recommended population.[21] It has been demonstrated that cost-sharing is a barrier that results in lower uptake of vaccinations for beneficiaries in the Part D program. BIO believes that cost-sharing obligations should not serve as a barrier to beneficiary access to appropriate preventive vaccinations.

One option to strengthen Part D coverage and expand patient access to vaccines could be the adoption of an access measure that measures the number of beneficiaries with access to zero or nominal patient cost-sharing for Part D vaccines. Given that CMS is

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[15] Reference to previous years' call letter comments.
[16] Section 1860D(4)(g)(2) of the Social Security Act explicitly permits beneficiaries to appeal tiered cost-sharing of non-preferred drugs.
[17] 82 Fed. Reg. 227, p. 56409. November 28, 2017.
[18] See BIO Comments, RE: Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information. April 2017.
[19] Immunization coverage for Medicare beneficiaries is divided between Medicare Part B, which covers influenza, pneumococcal, and hepatitis B vaccines (for high/medium risk populations), and Medicare Part D, which covers all other commercially available vaccines that are recommended by the Advisory Committee on Immunization Practices.
[20] See: Avalere Health. Adult Vaccine Coverage in Medicare Part D Plans. February 2016.
[21] Centers for Disease Control and Prevention. Vaccination Coverage Among Adults in the United States, national Health Interview Survey, 2015.

currently developing an MA care coordination Star Rating measure, CMS could include an access measure that measures Part D plans' beneficiary access to vaccines with zero or nominal cost-sharing. A vaccine cost-sharing measure would fit appropriately within a care coordination composite measure, as offering zero cost-sharing improves access to vaccines and encourages vaccination, which ultimately improves a patient's care and overall health outcomes.

V. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

BIO supports thoughtful efforts to increase generic competition in the Part D marketplace, provided efforts do not erode important beneficiary protections. Under current policy, Part D sponsors have wide discretion to make substitutions to their formularies – when therapeutically equivalent generics or multi-source brand equivalents become available. We find the current structure of substitutions appropriately balances CMS's goal of reducing beneficiary and government costs, while also protecting patient choice and access to medicines.

As such, BIO does not believe that this proposed change for midyear substitutions would further expand patient choice or access without potentially compromising continuity of treatment for Part D beneficiaries. BIO believes that the beneficiary notification process is a critical component of transparency for understanding of a beneficiary's Medicare Part D plan offering and should not be eliminated for purposes of midyear formulary and expedited substitution policies adopted through this proposed rule or future rulemaking process. CMS should also consider the potential impact of removing branded products from formulary more expeditiously and without the necessary notification process on patient and government costs, particularly when there is limited generic competition on the market.

VI. Maximum Out-of-Pocket (MOOP) Limit and Cost-Sharing Limits for Medicare Parts A and B Services

BIO appreciates CMS's efforts to ensure that cost-sharing is not discriminatory and to establish future MOOP limits using the most appropriate data available. Placing appropriate cost-sharing standards and thresholds is imperative to ensure that beneficiaries are not unduly burdened by their out-of-pocket costs, which can hinder appropriate use of the healthcare system and even deter patients from accessing the care they need. While increasing flexibility for plans who voluntarily offer lower MOOP limits can allow for improved plan design, it will be important to ensure that certain patient populations are not discriminated against. This is especially critical for those patients who need drugs provided under the Part B benefit. CMS has set lower cost-sharing limits for certain services, including for Part B drugs, and we support CMS's continued recognition that cost-sharing for Part B drugs be capped at no more than the fee-for-service amount of 20 percent in order to ensure access for beneficiaries who enrolled in a MA plan. Additionally, any changes must be phased in over time, and appropriately described in an easy to consume manner to minimize the burden on patients who may suddenly be provided with an increased number and type of different plan options.

CMS specifically seeks comment on its proposal to codify that use of MA encounter data be used to help identify MA plan cost-sharing standards that are not discriminatory. Given the operational challenges associated with encounter data thus far, BIO believes that continuing to use Medicare FFS data is more appropriate for now. However, as more

encounter data become available, and as CMS transitions its policy, we suggest that CMS analyze whether using MA versus FFS data would have an impact on the dollar amounts.

Furthermore, we recommend that CMS extend this critical beneficiary protection to Part D benefits offered by a MA plan. Cost-sharing in the Part D program, including among MA-PD plans, continues to rise. Research shows that when beneficiaries encounter significant copayments or coinsurance amounts, a troubling number delay or abandon their treatment regimen. We believe that establishing a MOOP limit for prescription drugs would ensure that beneficiaries have access to the treatments their doctors have prescribed, and is consistent with CMS's approach to Part A and B benefits. We strongly encourage CMS to use its authority to prevent discrimination in the MA program to establish mandatory and voluntary MOOP limits for Part D drugs.

VII. Flexibility in the Medicare Advantage Uniformity Requirements

While BIO supports efforts to implement and increase value-based insurance design into the Medicare Advantage program to help reduce overall costs and improve patient access to those therapies and services that provide the greatest benefit, it is critical that any effort to allow additional flexibility is carefully assessed and monitored to prevent discriminatory practices. In particular, it is critical that any "disease-specific" plans represent enhancements to the base Medicare benefit, both to ensure that disease-specific plans do not offer richer benefits to some beneficiaries at the expense of narrower benefits for others, and to ensure that beneficiaries can confidently select from among "general" and disease-specific plans.

For instance, the proposed language does not specifically exclude or include Part B drugs; however, given that physician administered drugs are included under the Part C benefit, MA applied changes may provide perverse incentives and negatively impede access to these therapies for MA enrollees. It is critical to ensure that any applied changes do not disincentivize use of the appropriate drug or biologic, as determined during the patient-provider decision-making process. We do not believe that it would be consistent with CMS's overall goal in providing this flexibility for a plan to reduce cost-sharing for all Part B drugs except those used to treat certain higher-cost conditions. We ask CMS to provide further detail to ensure MA uniformity flexibilities are not used to inappropriately steer patients to a treatment choice that may not be the most optimal for them given their health condition.

Additionally, CMS notes that the proposed benefit and cost-sharing flexibility applies only to Part C benefits and not to Part D benefits. However, BIO believes that in order to maintain continuity across the Medicare program, the cost-sharing changes should be available for Part D drugs as well.

VIII. Any Willing Pharmacy Standards Terms and Conditions

In the proposed rule, CMS makes clarifications around the "any willing pharmacy" requirements of the Medicare Modernization Act of 2003 (MMA), noting that pharmacy type definitions were not intended for plans to be able to limit the scope of requirements or offer standard terms and conditions for participation that are specific to only one particular type of pharmacy. CMS further clarifies the definition of mail-order pharmacy, revising the definition of retail pharmacy.

BIO supports the efforts by CMS to ensure that definitions of pharmacy type are not used to limit participation to particular types of pharmacies and potentially limit patient access to their preferred set of pharmacy services. We further encourage CMS as a part of these clarifications to advance patient access to specialty pharmacies by ensuring that patients are not inappropriately steered only toward PBM-owned specialty pharmacies in the provision of care.

IX. Medicare Advantage and Part D Prescription Drug Program Quality Rating System

CMS proposes to codify key aspects of the Part C and Part D Star Ratings methodology, including the principles for adding, updating, and retiring measures, and the methodology for calculating and weighting measures. As proposed, BIO is concerned that the discussed efforts to codify measure addition is burdensome and duplicative, and has the potential to add several years to an already multi-year process. There is currently already opportunity for public comment during the measure development process, the annual Part D Call Letter, and the Display Page requirement. For the consideration of additional measures, rulemaking does not increase transparency and instead adds a burdensome regulatory process that delays essential measures which can improve the quality of care for patients. For this reason, BIO asks CMS not to finalize its proposal to codify the measure addition in the Quality Rating System as proposed.

However, if the Agency decides to move forward with this codification, then we believe there needs, at the very least, to be an exception to these rules for measure addition for those measures that address public health issues and patient safety—such as those identified by the HHS ADE Action Plan (e.g., Opioid Addiction, Major Bleeds due to Anticoagulation Use, and Hypoglycemia). These exceptions are essential to ensure that the important issues for patients are able to be addressed in a timely fashion, and not be detained in a lengthy regulatory process.

X. MA/Part D Artificial Limits

CMS is proposing to eliminate the meaningful difference requirements for Medicare Advantage plans beginning in 2019, in an effort to improve benefit offerings and provide beneficiaries with plans that are affordable and tailored to their unique health needs. BIO supports CMS's effort to increase the availability of suitable offerings to beneficiaries in the MA program, and encourages CMS to do the same across Part D plans, where the Agency is proposing to only eliminate the meaningful difference requirements for second enhanced plans but not between the basic and first enhanced plan. BIO believes that eliminating the meaningful difference requirements in both instances for Part D plans would ensure a robust offering of plans to meet a patient's specific health needs. We find that meaningful difference and the out-of-pocket cost values may not be the most accurately reflective resources for determining the value of a Part D plan for a beneficiary, and encourage CMS to use other means to assess the benefits being provided across plans.

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BIO appreciates the opportunity to comment on the 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 Proposed

Rule and we look forward to continuing to work with CMS to address the issues raised in this letter. 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

/s/

Mallory O'Connor
Director, Healthcare Policy & Federal Programs