By Electronic Delivery

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Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Cc: Demetrios Kouzoukas
Principal Deputy Administrator and Director
Center for Medicare

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

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter [CMS-2017-0163]

Dear Administrator Verma,

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter (Draft Call Letter).[1] 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. Our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, including productivity and quality of life, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO supports CMS's commitment to improving the quality and delivery of care in the MA and Part D programs. We believe it is critically important to ensure that policies in these

[1] Centers for Medicare and Medicaid Services, Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies for 2019 draft Call Letter, February 1, 2018.

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6306 F
bio.org

programs advance patient access to timely and appropriate treatment, particularly for prescription drugs and vaccines. To that end, we provide comments in the following areas:

- The specialty tier eligibility cost threshold should be increased for 2019 and in future years and the exceptions process expanded to ensure that the specialty tier does not discriminate against vulnerable beneficiaries;
- Co-insurance in the Part D non-preferred drug tier can unduly limit access to care for patients with severe and complex diseases;
- Increased enforcement of nondiscrimination should be used when evaluating benefit design in the MA and Part D programs;
- Access to innovative treatment options for pain and addiction should be prioritized as a part of addressing opioid overutilization in MA Part D plans;
- MA and Part D plans should prioritize and increase access to vaccinations for Medicare beneficiaries;
- The timeframes and processes for formulary updates should support the inclusion of new therapies;
- Drug tier labels should be accurately reflective of the tier's composition.
- The inclusion of prescription drug costs in Medicare advantage uniformity flexibility should provide patient access to the most appropriate treatment;
- Additional flexibility in design of maximum out-of-pocket costs should be considered to assist beneficiaries;
- The availability of suitable plan offerings should be increased through removal of the meaningful difference requirements;
- Additions to the Star Ratings are critical to accurate assessment of patient care quality; and
- Efforts to expand coverage for certain subsets of products MA-PD plans should focus across all drugs offered under the Part D program.

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I. The Specialty Tier Eligibility Cost Threshold Should be Increased for 2019 and in Future Years and the Exception Process Expanded to ensure that the Specialty Tier Does Not Discriminate Against Vulnerable Beneficiaries.

Patients prescribed drugs or biologicals on a plan's specialty tier are uniquely at risk for high out-of-pocket costs due to the distinctive cost-sharing structure of the Part D benefit. Patients needing therapies on a plan's specialty tier are more likely to encounter the "donut hole" earlier in the calendar year and incur substantial out-of-pocket expenses all at once. BIO is concerned with insurance design that result in high out-of-pocket costs for vulnerable beneficiaries, which can effectively limit access to therapies. Indeed, BIO believes that the specialty tier may operate in a discriminatory manner by imposing high cost-sharing on Medicare's most vulnerable beneficiaries.

Accordingly, BIO urges CMS to regularly evaluate and appropriately raise the specialty tier cost threshold. CMS has the authority to update the threshold and last did so for 2017—an action we strongly supported and had long recommended. However, we are

concerned that CMS did not update the threshold for 2018, nor has it been proposed for 2019. We strongly urge CMS to revisit the specialty tier threshold amount.

We also believe that CMS should update the threshold on an annual basis. According to a recent analysis by The Moran Company, the threshold for 2017 – if it had been tied to CPI-U for prescription drugs – would have increased from $600 in 2008 to $818. Increasing the threshold in such a manner would reduce the number of drugs subject to the specialty tier, and help ensure beneficiary access to needed medications. Regular updates to the threshold would also be consistent with CMS's process for updating other benefit parameters (e.g., deductibles, cost-sharing and copay limits by tier). Further regular updates to the threshold are consistent with CMS's target of having specialty tier medications remain under 1% of all Part D claims, as it would reduce the number of drugs subject to the cost-sharing requirements at the specialty tier level.

Further, BIO would also like to take this opportunity to re-articulate our concerns with the lack of exceptions processes for drugs and biologicals placed on the specialty tier. For drugs that are not on the specialty tier, the prescribing physician can request a tiering exception for the plan to cover the non-preferred drug at the preferred drug cost if certain conditions are met, including that the preferred drug would not be as effective for the beneficiary or would have adverse effects for the beneficiary.[2] The Part D statute specifically requires Part D sponsors to have a tiering exceptions process consistent with guidelines established by the Secretary.[3] The Part D statute, however, does not include requirements or limitations specific to the specialty tier.[4] When initially implementing the Part D program, CMS did not propose allowing plans with a specialty tier to operate those tiers without an exceptions process.[5] Current regulations, however, allow plans to have a specialty tier for certain drugs and biologicals without allowing beneficiaries to request exceptions.[6] Because the provision regarding specialty tier exceptions was created by regulation and is not required by statute, it – and indeed the entire concept of a specialty tier – can be revisited and revised by CMS.

BIO urges CMS to require plans to allow beneficiaries to seek exceptions for drugs and biologicals on all formulary tiers. Without an exceptions process for specialty tier drugs and biologicals, beneficiaries face the difficult choice between not getting the treatment they and their doctors believe to be the most beneficial or being subjected to significantly higher cost-sharing burdens for that treatment. If CMS applied the same exceptions process requirements for all tiers, beneficiaries and their treating physicians would be able to request coverage on a more favorable cost-sharing tier by demonstrating that the treatment is more effective than the preferred drug or biological or that the preferred drug or biological would have adverse effects for the beneficiary. This would allow patients to obtain the drugs and biologicals they need while still allowing plans to retain flexibility when designing preferred and specialty tiers. We therefore recommend that CMS implement a requirement that Part D sponsors have an exceptions process in which prescribing

[2] 42 C.F.R. § 423.578(a).
[3] SSA § 1860D-4(g)(2).
[4] *Id*.
[5] See 69 Fed. Reg. 46632, 46843 (Aug. 3, 2004). The specialty tier exceptions rule in § 423.578(a)(7) was added by CMS in the final rule, see 70 Fed. Reg. 4194, 4353 (Jan. 28, 2005)
[6] 42 C.F.R. § 423.578(a)(7).

physicians can submit exceptions requests for all drugs and biologicals, including those drugs and biologicals placed on specialty tiers.

II. Coinsurance in the Part D Non-Preferred Drug Tier Can Unduly Limit Access to Care for Patients with Severe and Complex Diseases.

BIO continues to be concerned that Part D sponsors may utilize forms of cost-sharing that impede vulnerable beneficiaries' access to medically necessary therapies. CMS serves a critical role in safeguarding against such practices through its rule-making and issuance of general guidance, among other actions. Coinsurance requirements, compared to copayments, often obligate patients to pay a much higher amount out-of-pocket. Thus, we are concerned that CMS continues to express its belief that "a coinsurance structure is the preferable cost-sharing structure for the non-preferred drug tier."[7] We believe that this type of cost-sharing has the potential to have significant negative consequence for patients with severe and complex disease. Indeed, we are concerned that the use of coinsurance in the non-preferred drug tier may create additional hurdles to access for an already vulnerable population of beneficiaries.

Over the last few years, there has been a significant increase in the use of coinsurance for prescription drugs. In fact, one study found that the average percentage of drugs facing coinsurance has risen sharply from 35 percent in 2014 to 58 percent in 2016 among Part D plans, which could have far reaching effects.[8] There is a demonstrated link between higher out-of-pocket costs and lower patient adherence to therapy.[9] It is critical to minimize reductions in adherence as lower patient adherence can lead to poor health outcomes in the short- and longer-term, as well as higher overall health expenditures (e.g., due to additional hospitalizations, physician office visits, and/or surgical interventions). We urge CMS to ensure that any increase in the use of coinsurance over copayments does not unduly burden certain beneficiaries with unusually high levels of cost-sharing requirements.

III. Increased Enforcement of Nondiscrimination Should be Used When Evaluating Benefit Design in the MA and Part D Programs.

As stated above, coinsurance requirements can often obligate patients to pay a much higher amount out-of-pocket compared to copayments. BIO is particularly concerned that the Agency's encouragement of the use of coinsurance and the application of outlier tests only to plans where copayment is used will undermine efforts to improve patient adherence across the Part D program. Outlier tests must be applied broadly to ensure that plan design does not significantly impede patient access. We urge CMS to help ensure that sponsors do not use cost-sharing in a manner that discriminates against vulnerable beneficiaries, by clarifying its policy positions and conducting tests to ensure value to beneficiaries in instances of both copayment and coinsurance plan design. To the extent possible, CMS should release high level results of its outlier tests and analysis to ensure benefit design is not discriminatory and plans provide meaningful access to all beneficiaries.

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[7] CMS. 2019 Draft Call Letter. February 1, 2018. At 199.
[8] Avalere. Majority of Drugs Now Subject to Coinsurance in Medicare Part D Plans. March 2016.
[9] Eaddy, M. T., C. L. Cook, K. O'Day, S. P. Burch, and C. R. Cantrell. 2012. How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review. *Pharmacy & Therapeutics* 37(1):45-55.

Further, BIO continues to have concerns with CMS's review of Part D prescription drug plan and MA-PD (i.e., MA plans that provide prescription drug coverage) benefit package data to determine whether applicable coinsurance rates are discriminatory. The Part D statute specifically states that the Secretary can only approve a plan if the design of the plan and its benefits are not likely to substantially discourage enrollment by certain Part D-eligible individuals.[10] It is critical that CMS carefully review the specialty tier—which has the greatest potential to be discriminatory, particularly given that patients are barred from appealing cost-sharing decisions of that tier—in examining acceptable cost-sharing thresholds. We recommend that CMS limit the flexibility in specialty tier cost-sharing design so that beneficiaries are not subjected to onerously high out-of-pocket costs.

CMS also discusses its authority to increase the uniformity flexibility by providing MA plans the "ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles" for certain eligible enrollees. As noted in our comments in response to the CY 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—when similar MA uniformity flexibility proposals were raised—BIO believes that any effort to allow additional flexibility in benefit design must be carefully assessed and monitored to prevent discriminatory practices. While BIO supports efforts to implement and increase value-based insurance design (VBID) to help reduce overall costs and improve patient access to those therapies and services that provide the greatest benefit, such changes are only beneficial if they do not discriminate against groups of individuals with certain diseases or medical needs.

IV. Access to Innovative Treatment Options for Pain and Addiction Should be Prioritized as a Part of Addressing Opioid Overutilization in MA and Part D Plans.

In the CY 2019 MA and Part D proposed rule, CMS included policies to implement the Comprehensive Addiction and Recovery Act (CARA) and proposes to build upon these in the Draft Call Letter given the urgency and scope of the continuing national prescription opioid crisis. BIO commends CMS for its efforts to address the opioid epidemic through updates in MA and Part D plan guidance. We believe it is critical that steps taken through Medicare coverage policies to address the crisis prioritize patient access to innovative, novel and safer treatment options for pain and addiction.

BIO and our members are committed to developing solutions to address the opioid crisis. To this end, we have established a working group, composed of representatives from more than 27 of BIO's member companies, in order to identify ways in which the biotechnology industry can assist in mitigation of the opioid epidemic and serve as a strong partner to other stakeholders involved in these efforts. The working group has established priorities that outline how BIO and our members can help mitigate the crisis, focused under three key pillars: (1) advancing the understanding of the biology of pain and addiction to enable the development of innovative treatments for pain and addiction, and ensuring

[10] SSA § 1860D-11(e)(2)(D)(i). See also 42 C.F.R. § 423.272(b)(2)(i).

appropriate and optimal use of existing therapies; (2) ensuring that patients suffering from pain or addiction are able to receive the right treatment at the right time with the right support, without stigma; and (3) stimulating research and development of innovative treatments that effectively treat pain and opioid addiction and prevent abuse. To these ends, we urge CMS as a part of the Agency's broader activities and goals in addressing the opioid crisis to ensure appropriate patient access to novel and safer treatments for pain and to new and current forms of medication assisted treatment (MAT) across care for addiction.

In the Draft Call Letter, CMS proposes several policies aimed at enhancing MA and Part D plan sponsors abilities to combat opioid overutilization. The first includes enhancements to the opioid overutilization monitoring system (OMS) to identify high risk beneficiaries who use "potentiator" drugs (gabapentin and pregabalin) in combination with prescription opioids, and ensuring plans provide appropriate case management. CMS notes that potentiator drugs taken with opioids increase the risk of an adverse event, and that the OMS already flags concurrent benzodiazepine use by beneficiaries. BIO supports CMS efforts to better monitor individuals at risk of opioid overutilization through new flags and measures related to potentiator drugs. We encourage CMS to consider how to incorporate novel and safer therapies into the treatment pathway for beneficiaries who are identified for concurrent use. In instances where a patient needs pain treatment and a therapy exists with reduced or minimal risk of adverse events, such treatments should be accessible to beneficiaries through MA and Part D plans, as appropriate.

In addition, CMS also proposes the addition of a new Pharmacy Quality Alliance (PQA) measure around concurrent use of opioids and benzodiazepines. BIO supports the adoption of such a measure to help mitigate opioid overutilization and concurrent use of therapies that can lead to serious adverse events. Beyond these measures, we encourage CMS to adopt quality measures that prioritize beneficiary access to the highest standard for both novel and safer analgesics for pain and innovative treatments for addiction. While identifying risks is a key component of addressing the opioid crisis, advancing access to treatments that reduce, mitigate, and combat future addiction is also critical. The MA and Part D programs must keep pace with advances in the scientific understanding of and the development of new treatments for pain and addiction in order to help solve this crisis.

Further, CMS proposes point-of-sale (POS) edits as a part of Drug Utilization Review (DUR), a hard edit with a 7 day supply limit for both initial fills of opioids and cumulative daily morphine milligram equivalent (MME) that reaches 90 mg or more, based on Centers for Disease Control and Prevention (CDC) guidelines. CMS also proposes a soft edit, which can be overridden by a pharmacist for duplicative therapy with multiple long-acting opioids, and seeks feedback on concurrent prescription opioid and benzodiazepine soft edits.

These edits are being proposed with exceptions for patients in hospice care, with cancer diagnoses, reasonable overlapping dispensing dates from prescription refills or new prescriptions for continuing fills, and high-dose opioid usage previously determined to be medically necessary through coverage determinations, prior authorization, case management, or appeals processes. CMS specifically states that it is important that sponsors, "implement these edits in a way that beneficiaries' access to MAT is not

impacted."[11] We commend the Agency applaud CMS for highlighting the critical need for access to MAT and noting that it will not approve prior authorization criteria that requires a beneficiary to seek authorization for MAT more than once during a plan year, consistent with the Food and Drug Administration's (FDA's) strengthened labeling requirements. We appreciate the Agency's understanding that opioid use disorder requires continued access to treatment and that expanding access to MAT without burdensome utilization policies is critical to addressing patient need.

BIO appreciates CMS's exceptions to this policy with the aim of ensuring patients with certain conditions are able to access pain and addiction treatment. While we understand the goal of these policies in reducing the number and amount of opioids prescribed to a patient, and subsequently available in their home and the potential for overuse, we are concerned that such hard-and-fast limitations may have the opposite effect. In some instances, they may negatively impact patient access to the appropriate pain treatment and lead to unintended consequences. This concern is compounded by the fact that such policies do not rely on intervention only by the treating physician, but also at the plan level and pharmacy counter. Again, we are encouraged by CMS's aim of addressing overutilization, but caution against policies that interfere with the patient-provider treatment relationship and do not have the ability to consider each individual patient's specific healthcare needs.

We believe that there are a number of other considerations that can be used collectively to both address overutilization and advance access to the most appropriate course of care for pain and addiction treatment. This includes ensuring providers are educated on appropriate use of existing and innovative pain and addiction treatments, ensuring that coverage policies prioritize access to innovative medications that either deter or mitigate addiction potential and represent advances in the treatment of addiction, and assuring that scientific advances in the understanding of the treatment of pain and addiction are incorporated into the continuum of care.

Beyond considering how to best handle overutilization of opioids in the Medicare prescription drug program, BIO believes that novel and safer treatments can play a central role in reducing these risks, while still providing necessary treatment in appropriate cases for Medicare beneficiaries. CMS should consider how novel and safer treatments, including abuse-deterrent formulations and non-opioid analgesics can play a role in the OMS. For instance, CMS could require use of novel and safer treatments for beneficiaries who have been designated as "at risk" under OMS and these additional proposals, where appropriate for their condition.

BIO further asks CMS to look at solutions to advance patient access to treatments that deter or mitigate the risk of addiction, assist in the treatment of addiction, or that represent a significant advance in treatment of pain or addiction for Medicare beneficiaries. Currently, many plan sponsors employ utilization management tools (e.g., step therapy, prior authorization) which can limit provider choice and patient access to timely initiation of appropriate treatment. These policies can be applied to both existing and novel addiction

[11] CMS. 2019 Draft Call Letter. February 1, 2018. At 210.

and pain therapies, inhibiting the provision of patient-centered care. We urge CMS through its efforts focused on the opioid crisis to ensure plan formularies provide adequate access and do not inappropriately apply utilization management techniques.

Additionally, we believe that given CMS's role in setting coverage policy for the MA and Part D programs, the Agency through the Call Letter and other avenues can play a central role in advancing prescriber understanding of available FDA-approved therapies for the treatment of pain and addiction. We encourage the Agency to work with stakeholders to advance education on opioid addiction prevention and treatment options, including novel and safer therapies.

V. MA and Part D plans Should Prioritize and Increase Access to Vaccinations for Medicare Beneficiaries.

Immunizations are central to our country's disease prevention efforts and have a demonstrated track record of success as a means of reducing disease burden and saving lives among all age groups. However, despite the well-known benefits of immunizations, over 50,000 adults die from vaccine-preventable diseases each year, and adult coverage remains below the Healthy People 2020 targets for most commonly recommended adult vaccines. High risk populations, including the elderly, are particularly vulnerable to vaccine preventable diseases. As CMS is committed to maintaining benefit flexibility and efficiency through the MA and Part D programs, the Agency has the power to improve vaccination rates across the Medicare program by improving access to vaccines for beneficiaries and their providers. As such, BIO supports and encourages the following activities to improve vaccination rates:

- *CMS should continue to encourage Medicare Part D plans to cover vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) at first dollar.*

We applaud CMS for recognizing the importance of providing first dollar coverage in Part D plans and strongly support the inclusion of the statement in the Draft Call Letter encouraging Part D sponsors to offer a $0 vaccine tier or to place vaccines on a formulary tier with low cost-sharing.[12] 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 ACIP. While Medicare beneficiaries receive Part B–covered vaccines with no cost sharing, Part D vaccines are typically subject to cost sharing requirements ranging from $14 to $102 per vaccine.[13] The uptake of vaccines covered under Part D within the Medicare population has been historically lower than that of vaccines in Part B. For example, the herpes zoster vaccine is recommended by the ACIP for all adults aged 60 years and older to prevent shingles. Yet, as of 2015, only 30.6% of adults over 60 reported receiving this vaccine, according to CDC

[12] CMS. 2019 Draft Call Letter. February 1, 2018. At199.
[13] Avalere Health. Adult Vaccine Coverage in Medicare Part D Plans, February 2016.

data.[14] By contrast, pneumococcal vaccination coverage that same year was 63.6% among adults 65 and over.

Several studies have shown that one reason vaccination rates are lower for vaccines covered by Part D is the presence of higher cost-sharing obligations. One such study found that, compared with those who had no cost-sharing, Medicare Part D beneficiaries who had a co-pay amount of $26–50, $51–75, or $76– 100, were, respectively, 1.39, 1.66, or 2.07 times more likely to cancel their vaccination when informed at the pharmacy counter of their copay amounts.[15] While the fragmentation of vaccine coverage under Medicare should be addressed in the long-term, in the near-term, BIO supports strengthening Part D coverage by eliminating cost-sharing, which would greatly help expand access to vaccines and thereby increase uptake. Additionally, BIO encourages CMS to further review the implementation of this cost-sharing reduction by Part D plans and analyze opportunities for value-based contracting arrangements with manufacturers that could further help improve vaccination rates in the Medicare population. With many new vaccines in the pipeline, this fix is even more critical, as these vaccines will also be covered under Part D.

- *CMS should move forward with the inclusion of new measures assessing beneficiary receipt of critical vaccinations.*

In the Draft Call Letter, CMS proposes a new Adult Immunization measure for MA plans. For 2019, the National Committee for Quality Assurance (NCQA) will build upon the pneumococcal measure and evaluate the relevance, scientific soundness, and feasibility of composite measures that assess the receipt of routine adult vaccinations. The measure developer is focusing on four specific vaccines: influenza vaccine; tetanus, diphtheria, and pertussis (Tdap) or tetanus and diphtheria (Td) booster vaccine; herpes zoster vaccine; and pneumococcal vaccine. BIO strongly supports the proposal to include such a measure, as this will help encourage uptake across recommended vaccines for the Medicare population.

In previous response to the MA and Part D Call Letter, BIO has supported the use of Star Ratings as a means to ensure beneficiaries are receiving the full suite of ACIP recommended vaccines covered in the Part D program. BIO encourages CMS to move forward with the inclusion of such a measure and consider how it may fit in with our additional feedback below regarding vaccines and the annual wellness visit and to consider additional future measures that will increase vaccination across the Medicare population.

- *CMS should make improvements to the Medicare and You Handbook to ensure that beneficiaries are aware of the vaccine-related components of a wellness visit while reinforcing the Star Rating system to encourage physicians to discuss and administer ACIP-recommended vaccines.*

The *Medicare and You* Handbook provides information on which vaccines are covered under Medicare Part B at no cost-sharing; however, the Handbook does not clarify which

[14] Centers for Disease Control and Prevention. Vaccination Coverage Among Adults in the United States, national Health Interview Survey, 2015
[15] Journal of Managed Care and Specialty Pharmacy. Meeting Abstracts -27th Annual Meeting Expo, Volume 21 Issue (4 Supp A), April 2015.

vaccines are covered under Part D. BIO strongly recommends updating the Handbook to provide clear, concise language around the full set of vaccines that are recommended by the ACIP.[16] The Handbook should also clearly explain to beneficiaries which vaccines are covered under Part B or Part D. Moreover, the Handbook discusses the annual "Wellness" visit and when this visit can be scheduled. It would be helpful for the Handbook to provide information about services covered under the Wellness visit, which includes information-sharing from the physician on which vaccines are recommended for specific age and risk groups. As such, beneficiaries should be knowledgeable of the preventive services that will be covered during the Wellness visit, so they can plan to discuss vaccines with their provider during the visit. This discussion will ultimately lead to the physician providing the recommended vaccine themselves or referring the patient for vaccination to an appropriate community immunizer. Updating the Handbook to include language on vaccine coverage during the annual Wellness visit will also clarify to patients and providers that the visit is a critical time to cover preventive services such as vaccines.

Moreover, CMS could consider how to incorporate such updates for purposes of the Star Ratings and the proposed adult immunization measure for MA plans. The annual Wellness visit is the ideal time to discuss vaccinations with beneficiaries, as this type of visit aims to provide preventive services. The use of the Star Ratings for vaccines affords an opportunity to reinforce the best practices outlined in the Standards for Adult Immunization Practice developed in 2013 by the HHS National Vaccine Advisory Committee (NVAC). These standards, which have been supported by numerous vaccine and medical stakeholders, recommend that all healthcare professionals: 1) assess the immunization status of all of their patients; 2) strongly recommend vaccines that the patient needs; 3) administer needed vaccines or refer the patient for vaccination, and 4) document that the vaccines were received or a discussion took place.[17] BIO encourages CMS to ensure that beneficiaries are getting the most appropriate preventive care through use of these tools.

- *CMS should facilitate Part D billing for physicians for vaccines.*

While some patients do seek vaccinations at many community sites such as pharmacies, physicians' offices remain a critical access point where vaccines can be both recommended and administered to patients during routine visits. Physicians have the ability to bill Medicare for the cost and administration of vaccines under Part B, but are often unable to directly bill Part D plans for vaccines covered under that program. The current challenge physicians face in billing Part D plans translates into an access barrier for Medicare beneficiaries. To increase the number of physicians recommending and administering Part D vaccines and the number of patients receiving them, BIO encourages CMS to improve the ability of physicians to submit vaccine claims directly to Part D plans and receive reimbursement.

The Part D benefit was designed to provide access to self-administered oral drugs obtained in a retail pharmacy setting or through the mail. Physicians typically do not have

[16] Additionally, the National Quality Forum's Draft Report on National Voluntary Consensus Standards for Infectious Disease includes in their "triple aim" of better care a priority around effective prevention and treatment of illness, directly addressing vaccination against the flu or pneumonia to help prevent infection
[17] Centers for Disease Control and Prevention. Standards for Adult Immunization Practice.

billing relationships with prescription drug plans (PDPs) and their offices are not licensed as pharmacies, which is key to billing claims through Medicare Part D. Conversely, PDPs do not have the ready ability to accept current Medicare physician claim forms, and have no administrative relationships with doctors participating in Medicare. One method to improve physician Part D billing is to develop and implement a web-based system to better facilitate physicians' billing of Medicare Part D plans for vaccines. Such a system would: (1) allow physicians to electronically submit claims directly to Part D plans for reimbursement associated with vaccine purchase and administration on behalf of the patient, (2) provide clarity for physicians around plans' reimbursement rates for vaccine cost and administration, which are bundled, and 3) informing beneficiaries what their co-pay will be while they are in the physician's office. Developing and implementing a more efficient process for physician billing specific to vaccines will help reduce one of the most important challenges related to the delivery of vaccines covered under Part D.

VI. The Timeframes and Processes for Formulary Updates Should Support the Inclusion of New Therapies.

Under the Draft Call Letter, CMS proposes updates to the formulary reference file (FRF) process. BIO has previously expressed concern that the timeframes for updating prescription drug formularies could hinder the inclusion of new therapies on formularies. We commend CMS for its efforts to address some of these concerns by pushing back the summary update window to later in the summer in order to allow for "the inclusion of newly approved brands and generics that occur in July and into August."[18] Additionally, the proposed addition of an enhancement-only window in the fall, as well as a January 2019 formulary update window are positive developments. We believe these changes can assist in ensuring that new therapies are added to formularies in a timely fashion, particularly with the addition of a new window in the fall as beneficiaries are making plan selections during open enrollment. However, we continue to express concern around the lack of an updated release of the out-of-pocket cost (OOPC) model tool including drugs that are newly added between the March and May FRF. While BIO appreciates that CMS will allow the addition of new drugs to the summer release of the FRF, we are concerned that these two policies, taken together, may limit plan sponsor addition of new therapies to their formularies.

As CMS notes, Part D sponsors may enhance their formularies at any time, regardless of whether the new drugs have been added to the FRF. Accordingly, we urge CMS to make these proposed formulary submission updates, update the OOPC model (including to reflect newly added drugs from the May FRF), and to ensure/clarify that Part D plan sponsors may easily expand formularies by adding drugs to their formularies, reducing copayments or coinsurance by placing a drug on a lower cost-sharing tier, or removing utilization management requirements at any time during the year. In addition, we urge CMS to continue to reiterate that Part D plans are not required to wait until a new Part D drug appears on the FRF before including the drug on their formularies, and that, in fact, Part D plans cannot deny coverage to new Part D drugs simply because they have not yet been added to the FRF.

[18] CMS. 2019 Draft Call Letter. February 1, 2018. At 195.

Further, BIO would also like to take this opportunity to re-articulate our concerns with respect to the existing OOPC standard. As CMS is aware, a plan-specific, per-member-per-month (PMPM) OOPC estimate is used to determine whether a sponsor is in compliance with the requirement that there is a "meaningful difference" between plans offered in the same geographical area.[19] BIO continues to be concerned that this methodology, as well as the data currently used to calculate OOPC, can incentivize plan sponsors to undermine the inclusiveness of their formulary—and thus risk sufficient patient access to vital prescription medications in order to meet the meaningful difference standard. Accordingly, BIO supported CMS's proposals in the draft CY 2014 Call Letter to update the methodology for calculating OOPC for purposes of CY 2015 so that Medicare Current Beneficiary Survey (MCBS) cohort drugs not on plan formularies would be subject to the cost-sharing of the Part D sponsor's exception tier.[20] BIO also supports the use of the latest available MCBS data in the OOPC calculation (CY 2019 calculations are based on the outdated CY 2012/2013 data set).[21] While not addressed in the draft 2019 Call Letter, BIO urges CMS to follow through with its proposal to update the OOPC methodology, and to do so for 2019 to ensure that the OOPC calculation is an accurate reflection of current patterns of spending and utilization.

VII. Drug Tier Labels Should be Accurately Reflective of the Tier's Composition.

BIO supports CMS's efforts to ensure that drug tiers adequately reflect the types of products available within that tier and the continued evaluation of the non-preferred brand tier as a part of the plan bid review process. For CY 2019, CMS proposes a maximum threshold for generic composition at 25 percent in the non-preferred brand tier, noting that the inclusion of a significant number of generic drugs on a tier that is labeled as brand may lead to confusion for beneficiaries. BIO believes this is an appropriate approach for ensuring that tiers are labeled in such a manner that is not misleading to patients.

Further, CMS notes that they will continue to conduct the outlier analysis of non-preferred tiers related to copay structure. BIO appreciates efforts to ensure beneficiaries are not subject to high out-of-pocket costs in this tier. As detailed at the outset of this letter, we ask the Agency to continue to look to means to address issues of high beneficiary cost-sharing across plans using both copay and coinsurance structures to ensure patients are able to maintain adherence to their most appropriate course of treatment.

VIII. The Inclusion of Prescription Drug Costs in Medicare Advantage Uniformity Flexibility should Provide Patient Access to the Most Appropriate Treatment.

As stated earlier, BIO supports efforts to increase value-based insurance design by increasing MA plans' flexibility to better manage healthcare services. 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

[19] CMS. 2014 Call Letter. February 15, 2013. At 114.
[20] *Id.* at p. 144.
[21] CMS. 2019 Draft Call Letter. February 1, 2018. At 194.

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. As we did in response to the MA Part D Proposed Rule, 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.

Furthermore, CMS may want to consider including Part D in this new flexibility to further enhance value-driven care. A large body of evidence has demonstrated that adherence to prescription drugs can have a significant and positive impact on patient care, while also reducing costs over the long term. The Congressional Budget Office (CBO) has found that every 1 percent increase in the utilization of prescription medicines decreases Medicare spending in Parts A and B by 0.20 percent. Appropriately incorporating Parts B and D into MA flexibility can also positively influence the trajectory of value-based arrangements in the Medicare program—a key priority for CMS, as articled in the Innovation Center (CMMI) New Direction Request for Information (RFI) released on September 20, 2017. VBID can complement health plans' interest in exploring value-based arrangements, because both VBID and value-based arrangements encourage consideration of how the value of a medicine varies between different patients.

IX. Additional Flexibility in Design of Maximum Out-of-Pocket Costs Should be considered to Assist Beneficiaries.

As it relates to the flexibility CMS proposes to give Medicare Advantage plans in the design of their Maximum Out-of-Pocket (MOOP) thresholds, we also ask the agency to consider the benefits of allowing Part D costs to count towards the MOOP. The MOOP provides a critical affordability protection for MA beneficiaries. Data demonstrates that when beneficiary cost-sharing exceeded $250 – a threshold that is not at all uncommon within Medicare Advantage plans –71 percent of new specialty prescriptions were abandoned.[22] Poor medication adherence also forecloses an opportunity for plan sponsors to reap the benefits of lower Part A and B spending brought about by the use of high-value prescription drugs. Although CMS did not speak to this issue directly in the context of flexibility within MA uniformity requirements, applying Part D costs to the MOOP would provide a critical financial safeguard for patients with costly conditions. Accordingly, we encourage CMS to include Part D drugs in the proposed changes to the MA uniformity requirements related to both the VBID and the MOOP provisions.

[22] Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012.

X. The Availability of Suitable Plan Offerings Should Be Increased through Removal of the Meaningful Difference Requirements.

In the recent CY 2019 Medicare Advantage and Part D proposed rule, CMS proposed to eliminate the meaningful difference requirement for MA plan offerings. The Agency notes in the Draft Call Letter that they will provide instructions in the final rule regarding the requirements for 2019. BIO would like to reiterate our support for CMS's efforts to increase the availability of plan offerings for beneficiaries and encourage the agency to do the same across Part D plans.

Rather than solely eliminating the meaningful difference requirements for second enhanced plans, we ask the agency to also eliminate the requirement between the basic and first enhanced plan. BIO believes that eliminating the requirements in both instances will 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.

XI. Additions to the Star Ratings are Critical to Accurate Assessment of Patient Care Quality.

In promoting Medicare beneficiary access to high quality care, CMS uses the Star Ratings system and provides continual updates and enhancements to the Star Ratings and other display measures. BIO supports CMS's continual updates to and consideration of new measures that can enhance quality, patient-centric care and encourages the Agency to continue to consider measures that improve patient access to timely initiation of prescription drug treatment for their given health condition. We provide feedback on proposed measures as well as additional areas for measure consideration below.

- *Addition of the Statin Therapy for Patients with Cardiovascular Disease and Statin Use in Persons with Diabetes (SUPD) Measures*

Under the addition of measures, BIO supports CMS's proposal to add the Statin Therapy for Patients with Cardiovascular Disease and Statin Use in Person with Diabetes (SUPD) measures to the 2019 Star Ratings. This measure is aligned with American College of Cardiology (ACC)/American Heart Association (AHA) guidelines for blood cholesterol. We are encouraged to see the newly proposed SUPD measure being used as an intermediate outcome measure and support movement to a higher weight for this measure in future years to reflect its role in improving patient care and overall health outcomes.

While these measures represent an important step, BIO believes that the retirement of the previous cholesterol screening and control measure for persons with diabetes creates a gap in assessing quality care for beneficiaries. Cholesterol screening and ongoing monitoring of low density lipoprotein levels (LDL-C) for patients receiving treatment continue to be important aspects of care, reflected in current ACC guidelines and treatment

recommendations.[23] We encourage CMS to work with measure developers to enhance their measures that also evaluate screening, monitoring, and recommended treatment goals in accordance with the guidelines and evidence demonstrating the cardiovascular benefits of LDL-C lowering and managing LDL-C to a target goal.

- *Consideration of Measures and Updates Measures to Address Medication Adherence*

In the development and consideration of future measures for the Star Ratings, BIO asks CMS to consider how to best incorporate measures that assess patient adherence with specified medication regimens for certain disease states, where appropriate. The Centers for Disease Control and Prevention (CDC) states that medication non-adherence continues to be a major public health and economic concern. We believe the adoption of additional future measures to address these concerns is central to ensuring the most optimal health outcomes for Medicare beneficiaries.

Currently, adherence quality measures exist for several metabolic related diseases (i.e. cardiovascular, hypertension, hyperlipidemia, and diabetes). However, within the current diabetes measures, gaps exist with respect to insulin adherence as conventional approaches to measure patient adherence are not applicable due to the complexity of developing standardized adherence methodology. In an effort to address this issue, the PQA has convened a series of multi-stakeholder roundtables on insulin adherence measures and is presently examining novel methods to measure insulin treatment persistence, identify its predictors, and evaluate the associated clinical and economic outcomes using health plan claims data and records of patients' actual refill times.[24,25]

BIO encourages the Agency to work with PQA and other measure stewards to identify and translate meaningful methodology for insulin adherence within the Star Ratings system. The development of such a measure would lead to improved glycemic and long-term metabolic control, a reduction in additional comorbidities, and relief from the existing economic burden for the approximately 30% of patients with diabetes currently being treated with insulin.[26] Further, we recommend that CMS continue to work with measure stewards to translate these efforts to identify, and subsequently use in measures, medication adherence methodology for products that may present similar challenges. Ensuring appropriate use of treatments and medications delivered through the MA program is critical to advancing the highest standard of quality, patient-centric care.

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[23] See: Stone, Neil J., et al. "2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines." *Journal of the American College of Cardiology* 63.25 Part B (2014): 2889-2934.; Wadhera, Rishi K., et al. "A review of low-density lipoprotein cholesterol, treatment strategies, and its impact on cardiovascular disease morbidity and mortality." *Journal of clinical lipidology* 10.3 (2016): 472-489.
[24] Wei W, Pan C, Xie L, Baser O. Real-World Insulin Treatment Persistence among Patients with Type 2 Diabetes: Measures, Predictors and Outcomes. Endocr Pract. 2014;20:52-61.
[25] Slaubaugh SL, Bouchard JR, Li Y, Baltz JC, Meah YA, Moretz DC. Characteristics Relating to Adherence and Persistence to Basal Insulin Regimens among Elderly Insulin-Naïve Patients with Type 2 Diabetes: Pre-filled Pens versus Vials/Syringes. Adv Ther. 2015;32:1206-21.
[26] Centers for Disease Control and Prevention. Age-Adjusted Percentage of Adults with Diabetes Using Diabetes Medication, by Type of Medication, United States, 1997–2011.

- *Consideration of PQA and Health Resources and Services Administration (HRSA)-Owned, Human Immunodeficiency Virus (HIV) Core Measures*

Innovative advances in the treatment and prevention of the HIV virus have played a significant role in transforming HIV from what was once considered to be a terminal illness to, in many cases, a manageable, chronic disease.[27] Medicare is an important source of health coverage for many living with HIV, with the number of beneficiaries living with HIV having tripled since the 1990s.[28,29] Evidence-based quality measures assessing HIV care exist, are endorsed by the National Quality Forum (NQF), and used in federal programs, such as the Merit-based Incentive Payment System (MIPS) and the Ryan White HIV/AIDS Program.[30,31] However, currently, the MA Star Ratings program does not address HIV care and treatment.

HIV quality measures are critical to elevating the importance of the care and treatment of patients living with HIV and for reducing the incidence of new HIV infections. The HIV care continuum and measurement framework of diagnosis, treatment, and viral load suppression leading to prevention is aligned with the Institute for Healthcare Improvement's Triple Aim of improving patient experience, reducing cost, and improving population health.[32] A 2011 interim analysis of the National Institutes of Health (NIH) HIV Prevention Trials Network study HPTN 052 found that treating HIV-1-infected patients with antiretroviral therapy (ART) reduced the risk of transmitting the virus to HIV-negative sexual partners by 96%.[33] The final analysis involved over five years of follow up in the full set of HIV-1-infected partners, and found a 93% reduction in transmission risk.[34] These outcomes can only occur, however, if people living with HIV have access to medical care, are diagnosed, receive treatment, and remain adherent to treatment. The use of HIV-related quality measures can help promote standards of health care coverage that support adherence to current HIV clinical guidelines and federal guidelines.[35]

BIO highly recommends the inclusion of PQA and HRSA HIV/AIDS Bureau-owned, HIV quality measures, including: prescription of HIV Antiretroviral Therapy, HIV Medical Visit Frequency, HIV Viral Suppression, and Adherence to Antiretroviral Medications – Proportions of Days Covered (PDC) measure. Adoption of these measures into the MA Star Ratings program presents an opportunity for the expanded use of HIV quality measures

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[27] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. Department of Health and Human Services.
[28] Kaiser Family Foundation. Medicare and HIV. October 2016.
[29] The 1997 estimate is from Gilden DE, Kubisiak JM, Gilden DM. Managing Medicare's HIV Caseload in the Era of Suppressive Therapy, AJPH. Vol. 97, No. 6; June 2007. The 2014 estimate is based on Kaiser Family Foundation's analysis.
4 Kaiser Family Foundation analysis of the 5% sample (see endnote 2) and CDC. (2014) Vital Signs: HIV Diagnosis, Care, and Treatment Among Persons Living with HIV — United States, 2011. MMWR. 63(47);1113-1117.
[30] See: Quality Measures, Quality Payment Program.
[31] Performance Measure Portfolio. HRSA. Accessed February 16, 2018.
[32] The IHI Triple Aim. IHI.
[33] Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2011; 365:493-505. See also http://www.cdc.gov/hiv/prevention/research/art/;
[34]Cohen MS, Chen YQ, McCauley M, et al. Antiretroviral therapy for the prevention of HIV-1 transmission. N Engl J Med 2016; 375:830-839.
[35] HIV Medicine Association. Tools for Monitoring HIV Care: HIV Clinical Quality Measures (Updated) February 2015.

across public quality programs and to promote evidence-based care for Medicare beneficiaries.

- *Measure to assess the receipt of routine adult vaccinations (see "Prioritizing and Increasing Access to Vaccinations for Medicare Beneficiaries" page 7).*

XII. Efforts to expand coverage for certain subsets of products in MA-PD plans should focus across all drugs offered under the Part D program.

Current policy for MA plans allows for coverage free of charge to over-the-counter (OTC) drugs for beneficiaries. CMS notes this is part of utilization management strategies to reduce Part D expenditures and expresses interest in expanding the use of this policy in the Draft Call Letter through additional flexibilities focused on dietary supplements and cough medications. The Agency is also seeking feedback on additional enhancements for the OTC policy.

BIO supports CMS efforts to continue to reduce out-of-pocket costs and deliver needed medications to beneficiaries. While BIO understands the goal of such a policy for OTCs to reduce expenditures, both for the program and beneficiaries, we caution against any application or expansion of the proposal in such a manner that may inappropriately limit patient access to the most timely and appropriate initiation of prescription drugs delivered through the Part D program. This includes through cost-sharing or other utilization management requirements that may inappropriately steer a beneficiary toward an OTC medication when a prescription is necessary.

For certain OTC products, FDA approval is not required and efficacy and value for patients have not been proven. BIO believes that consideration of policies to expand access in the Part D program should be mindful of the original program intent – to improve access to prescription medicines. CMS should provide evidence to support the need of expansion of the OTC policy and review access barriers across all products offered by MA-PD plans. By providing timely and appropriate access to the most appropriate course of prescription drugs, CMS can help reduce overall program costs through avoided additional healthcare interventions and improve beneficiary health outcomes.

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BIO appreciates the opportunity to comment on the 2019 Draft Call Letter. We look forward to continuing to work with CMS on these critical issues in the future. Please feel free to contact us at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/
Crystal Kuntz
Vice President
Healthcare Policy & Research
Biotechnology Innovation Organization

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