March 3, 2017

BY ELECTRONIC DELIVERY

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cc: Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director
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Office of the Actuary

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter

Dear Dr. Tudor:

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) Draft 2018 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 strongly supports CMS's commitment to improving the quality of the Medicare Advantage (MA) and Part D programs. We consider it especially important to focus on policies that impact access to prescription drugs and biologicals for Medicare beneficiaries in MA and Part D plans. To further improve access to crucial therapies and immunizations for these patients, we urge CMS to consider the following comments, discussed in more detail below:

- Cost-sharing in the Part D specialty tier can unduly burden patients with severe, complex diseases and is exacerbated by the fact that the dollar-per-month threshold on the specialty tier allows a broad range of therapies to be included. While we appreciated the effort in 2017 toward increasing the threshold, BIO urges CMS to continue to substantially increase the threshold for 2018 and beyond. BIO also

[1] Centers for Medicare & Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter (February 1, 2017), available at: https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/advance2018.pdf.

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urges CMS to review the specialty tiers to ensure they do not discourage enrollment by certain Part D-eligible individuals.

- CMS should continue to seek information on the Part D tiering exceptions process and ensure that tiering structures do not impede beneficiary access to medically necessary and appropriate treatments.
- CMS should ensure that the timeframe and process for formulary updates reasonably allows for the addition of new therapies.
- CMS should work to make Medicare Plan Finder inclusive of the most up to date formulary information to best inform beneficiary prescription drug coverage choice.
- CMS should finalize the proposal to include a new display measure around the adjudication process and should continue efforts to further increase transparency around this process to provide patients with appropriate access to needed medicines.
- CMS should evaluate access to specialty pharmacies in considering network adequacy and patient access issues.
- CMS should continue to encourage increased beneficiary vaccination rates and ensure MA plans deem vaccinations provided by pharmacists, in accordance with state laws, as in-network providers for these services.
- CMS should finalize the movement of the High Risk Medication (HRM) measure from the Star Ratings to the display measures.
- CMS should ensure that innovative model testing in the Medicare program works to maintain or improve beneficiary access to appropriate care and treatment.
- CMS should look to include display measures consistent with the goals of the National Action Plan for Adverse Drug Event Prevention in future years.
- CMS should finalize the clarification around "reference-based pricing"[2] in Part D beneficiary cost-sharing arrangements.
- CMS should look to further ensure market stabilization for the dually eligible population in Puerto Rico.

I. CMS should increase the specialty tier eligibility cost threshold for 2018 and should continue to do so in future years to ensure that the specialty tier does not discriminate against vulnerable beneficiaries.

Because of the distinctive cost-sharing structure of the Part D benefit, patients prescribed drugs or biologicals on a plan's specialty tier are uniquely at risk for high out-of-pocket costs. Although only a small percentage of Medicare beneficiaries reach the coverage gap or "donut hole" during a plan year, patients needing therapies on a plan's specialty tier are more likely to encounter the donut hole earlier in the calendar year and to incur the donut hole's substantial out-of-pocket expenses all at once. BIO is concerned about insurance designs 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

[2] In the Draft 2018 Call Letter (p. 150) CMS notes a clarification of the Part D "reference-based pricing" policy. For purposes of this Draft 2018 Call Letter, "reference-based pricing" refers to cost sharing designs that require enrollees to pay a differential (i.e. penalty) based upon the difference between the negotiated price of the drug being dispensed and a lower-cost preferred reference drug. This practice of "reference-based pricing" in beneficiary cost sharing was prohibited in the CY 2010 Call Letter. We note that the term "reference-based pricing" is used in broader health policy discussions for payment arrangement thresholds. For purposes of these comments, "reference-based pricing" refers to the CMS definition detailed in the Draft 2018 Call Letter.

operate in a discriminatory manner by imposing high cost-sharing on Medicare's most vulnerable beneficiaries.

Accordingly, BIO commends CMS for increasing the cost threshold for CY 2017 from the $600 threshold established for CY 2008 to $670 by applying the annual percentage increase used in the Part D benefit parameter updates and allowing plans to place a drug or biological on the specialty tier, and thus subject to a higher coinsurance, if the therapy meets that negotiated price threshold.[3] BIO believes that this increase furthered CMS's original intent in creating the specialty tier, which as we understand it, was at least in part to establish more flexibility in plan benefit design. Raising the threshold helps ensure that vulnerable patients can access medically necessary care. In our 2016 response to the solicitation of comments on the CY 2017 Draft Call Letter, BIO urged CMS to regularly evaluate and appropriately raise the specialty tier cost threshold.[4] We noted that applying the annual percentage increase used in the Part D benefit parameter updates to the existing threshold appeared a sound methodology for future updates to the specialty tier threshold and encouraged CMS to continue to evaluate and update the specialty tier cost threshold in each forthcoming year to protect vulnerable patients' access to therapies.[5]

For these reasons, we strongly urge CMS to again update the specialty tier cost threshold above the proposed $670 for CY 2018. In the Draft Call Letter, CMS notes its concern that the percentage of Formulary Reference File drugs eligible for the specialty tier continues to increase and is now near 20%, and states the intent to investigate these trends to shape future analyses involving the specialty tier.[6] CMS should move to again update the specialty tier cost threshold for CY 2018 while concurrently analyzing the specialty tier classification cost threshold to ensure it best supports patient access to appropriate treatment.

II. Co-insurance 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. Thus, we are concerned that the language contained in the Draft 2018 Call Letter encourages the use of coinsurance rather than co-pays for the non-preferred drug tier and may create additional access hurdles for vulnerable beneficiaries. CMS states that "while we continue to believe a coinsurance structure is preferable for the non-preferred drug tier, CMS will continue to afford Part D sponsors the flexibility to determine what cost-sharing structure is most appropriate for their benefit

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[3] Centers for Medicare & Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter (April 4, 2016), pp. 202-203. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf.

[4] Biotechnology Innovation Organization. Comment Letter, Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter. March 4, 2016.

[5] *Id.*

[6] Draft 2018 Call Letter, at p. 144.

design."[7] We note that CMS states the intent to engage in outlier testing for plan sponsors that chose a copay structure for the non-preferred drug tier in order to demonstrate the value of the cost sharing structure to beneficiaries. CMS will ask plan sponsors to submit justification upon request and may ask sponsors to make modifications to their benefit structure or formulary tiering if the submitted justification is not accepted.[8]

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. Coinsurance requirements, compared to copayments, obligate patients to pay a much higher amount out-of-pocket and there is a demonstrated link between higher out-of-pocket costs and lower patient adherence to therapy.[9] 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). 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.[10] 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.

Lastly, 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) prescription drug 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.[11] 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 support CMS's efforts to identify potentially discriminatory and misleading practices, such as the use of decreased or no deductible only for some tiers. We further recommend that CMS limit the flexibility in specialty tier cost-sharing design so that beneficiaries are not subjected to onerously high cost-sharing requirements.

III. The tiering structure and tiering exceptions should ensure beneficiary access to appropriate and necessary therapies.

Under the requirements for the offerings in the Part D prescription drug benefit, plan sponsors are able to use a tiered benefit structure, so long as an established and reasonable exceptions process is in place allowing beneficiaries to obtain a drug in a higher cost-sharing tier at the more favorable cost-sharing amount of a comparable drug on a lower tier when

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[7] Draft 2018 Call Letter, at p. 141.
[8] *Id.*
[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.
[10] Avalere. Majority of Drugs Now Subject to Coinsurance in Medicare Part D Plans. March 2016. Available at: http://avalere.com/expertise/managed-care/insights/majority-of-drugs-now-subject-to-coinsurance-in-medicare-part-d-plans.
[11] SSA § 1860D-11(e)(2)(D)(i). See also 42 C.F.R. § 423.272(b)(2)(i).

the therapy is deemed medically necessary based on supporting documentation from the prescriber.[12] In the Draft 2018 Call Letter, CMS notes that "changes in the prescription drug landscape … have resulted in increasingly complex plan benefit packages and more variation in type and level of cost-sharing," and that the changes CMS has made a to formulary tier models for non-standard plans along with the number of brand and generic drug tiers have resulted in confusion about tiering exceptions for plan sponsors.[13] CMS notes its belief that "plan sponsors are being more restrictive in their application of these exceptions than the statute and regulations contemplate" and that through audits and reviews has "repeatedly seen plan sponsors incorrectly denying tiering exceptions requests," and thus proposes additional policy clarifications.[14]

CMS proposes to first clarify that plan sponsors should not restrict their consideration of a tiering exception based on the alternative drug tier label and should consider multiple lower tiers if available. Second, is the clarification that where the requested drug has alternatives in multiple lower tiers and an exception is made, the lowest of those cost-sharing tiers is the "applicable lower cost-sharing tier" to be applied.[15] BIO supports CMS's clarification of these two components of the exceptions process, by ensuring multiple cost-sharing tiers are considered and the lowest of all cost-sharing amount is applied, beneficiaries will have better access to the most medically appropriate treatments at the lowest costs in situations where an exception is needed.

Further, CMS is soliciting voluntary information on tiering exceptions from plan sponsors, PBMs and other stakeholders based on the fact that they are "consistently associated with significantly lower approval rates than all other types of coverage and exceptions requests."[16] The type of information being requested includes: tiering exception request volume, approval/denial and appeals rates as compared with other cases; data related to the reasons that tiering exception requests are approved or denied; data related to volume of requests for tiering exceptions to a $0 copay tier and rates/rationale for approval and denial; information about enrollee complaints related to tiering exceptions and ways CMS could improve beneficiary experience with the tiering exceptions process; and specific areas of concern or confusion related to CMS policy for tiering exceptions.[17] BIO supports CMS efforts to collect further information in regard to tiering exceptions, particularly around the components aimed at improving beneficiary experience to ensure access to necessary therapies.

IV. The timeframes and processes for formulary updates should support the inclusion of new therapies.

BIO is concerned that the timeframes and processes for updating prescription drug formularies for CY 2018 could hinder the inclusion of new therapies on formularies. CMS notes in the Draft 2018 Call Letter that it will provide the first release of the CY 2018 formulary reference file (FRF) in March and the out-of-pocket cost (OOPC) model tool in

[12] Draft 2018 Call Letter, at p. 136.
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*

April and will provide a second release of the FRF in May to allow plan sponsors to have up-to-date FRF information prior to their formulary submission to CMS. CMS explains, however, that because of the short timeframe between the May FRF release and the formulary submission deadline, the OOPC model will not be updated with any newly added drugs from the May FRF. CMS also proposes to limit the ability of plans to make formulary changes during the summer formulary update window.[18]

While BIO appreciates that CMS will allow the addition of new drugs to the summer release of the FRF, we are concerned that these first two policies, taken together, will limit the ability of plan sponsors to add new therapies to their formularies. We also believe that this policy appears to undermine the longstanding requirement that plans review all new Food and Drug Administration (FDA)-approved drug products (and indications) for inclusion on their formularies on a year-round basis (i.e., within 180 days of their release on the market).[19] Accordingly, we urge CMS to both 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 deleting 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.[20]

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.[21] 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 proposal 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.[22] BIO also supports the use of the latest available MCBS

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[18] Draft 2018 Call Letter, at p. 134-135.
[19] CMS, Prescription Drug Manual, Ch. 6, § 30.1.5 ("[t]he P&T committee will make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days and will make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met.").
[20] An April 8, 2014 CMS Frequently Asked Questions document provided the following guidance: "Q: Can Part D sponsors cover drugs that are not on the FRF? A: Yes. In the event that a sponsor has determined a drug product meets the definition of a Part D drug, the sponsor can cover the drug at point-of-sale and market the addition. However, we expect the sponsor to 1) submit an FRF add request for the missing drug, and 2) add the drug to their HPMS formulary file(s) during the next available submission window." See CMS. 2014 (April 8). *Formulary Reference File Frequently Asked Questions*. Q13, p. 5, available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html.
[21] CMS. 2014 Call Letter. February 15, 2013. At 114. Available at: http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Advance2014.pdf.
[22] *Id.* at p. 144.

data in the OOPC calculation (CY 2017 calculations are based on the outdated CY 2010/2011 data set).[23] While not addressed in the draft 2018 Call Letter, BIO urges CMS to follow through with its proposal to update the OOPC methodology, and to do so for 2018 in order to ensure that the OOPC calculation is an accurate reflection of current patterns of spending and utilization.

V. Timely updates of Part D plan formularies in the Medicare Plan Finder are critical for informing beneficiary prescription drug coverage choice.

In some instances, Part D plan sponsors may enter into contract negotiations with manufacturers for coverage of specific drugs at a later point in the year – and potentially between the closing of the HPMS window for altering the content of Medicare Plan Finder, but prior to or during the annual open enrollment period.[24] This has the potential for beneficiary evaluation and decision making around Part D plans to be based on incomplete information if the formulary in Medicare Plan Finder is not updated accordingly. CMS already prohibits Part D plan sponsors from removing prescription drugs from their formularies during the open enrollment period and in the first sixty days of the plan year,[25] which helps to ensure access to therapy following beneficiary review and selection of Part D plans. BIO urges CMS to take further steps to ensure that Part D plan formularies represent the most up to date resources in Medicare Plan Finder, to inform beneficiary decision making and choice in prescription drug benefit coverage.

I. Timely and appropriate adjudication processes are critical for patient access to necessary therapies.

BIO commends CMS for ongoing efforts to improve clinical decision-making for Part D coverage determinations, including by ensuring effective adjudication processes. Strong adjudication processes are a fundamental component of providing Medicare beneficiaries with meaningful access to healthcare benefits. Where the adjudications process is not providing appropriate access or operating in accordance with required timeframes, this can lead to significant delays in beneficiaries' treatment, result in inappropriate denial of care, and increase beneficiaries' out-of-pocket costs. Each of these consequences can negatively impact patient adherence to therapies and their short- and long-term health outcomes. In the Draft 2018 Call Letter, CMS proposes to adopt a new display measure using the results of the Formulary Administration Analysis (FAA), by which CMS will "evaluate whether Part D sponsors are appropriately adjudicating Part D drug claims consistent with Part D requirements and sponsors' CMS-approved benefits."[26]

CMS proposes a methodology of having Part D sponsors submit all point-of-sale rejected claims relating to non-formulary status, prior authorization, step therapy, and quantity limits for a specified time period; to then review a targeted sample of claims by the Part D sponsor to verify whether the rejection is consistent with the approved formulary

[23] Draft 2018 Call Letter, at p. 141.
[24] The window for CY 2018 would occur in September of 2017 (Draft 2018 Call Letter at p. 73).
[25] Medicare Prescription Drug Benefit Manual, Chapter 6: Part D Drugs and Formulary Requirements, § 30.3.2, January 2016. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.
[26] *Id.* at p. 99.

status; and then CMS will apply a pass or fail rating to each sample claim depending on the appropriateness of the rejection with the percentage of failures displayed for each Part D sponsor.[27] CMS also notes the consideration of including results such as these from the FAA as a part of Star Ratings beneficiary access measures as early as 2020. Given the significant importance of appropriate adjudication of claims, BIO supports CMS's proposal to increase transparency around appropriate adjudication of claims to ensure beneficiary access to timely treatment. As patients face the increased use of specialty tiers and utilization management requirements, the role of these adjudication processes in ensuring patient access to appropriate therapy is more critical than ever. This can be especially true for patients who need specialty therapies to treat some of the most complex, chronic conditions. For example, MedPAC found that "specialty drugs face utilization management restrictions in over one-third of plans – twice as much as other drugs – regardless of whether they are placed by the plan on a specialty tier. They are over five times as likely as other drugs to be subject to prior authorization."[28] BIO encourages CMS to finalize the inclusion of this component of the FAA analysis in the display measures and the movement toward inclusion in the Star Ratings in the future. In conjunction with this effort, we continue to encourage CMS to ensure that adjudication processes are transparent to beneficiaries and to conduct further beneficiary access analysis to understand whether, and how, beneficiaries are able to navigate these processes.

II. CMS should use the process for evaluating Preferred Cost-Sharing Pharmacy network issues to evaluate specialty pharmacy access issues.

BIO appreciates CMS's efforts to increase transparency for Preferred Cost-Sharing Pharmacies (PCSPs) and the continuation of policies initiated in the 2017 plan year and proposed to be carried through to 2018, to work with plans to ensure access in all plan areas to PCSPs.[29] BIO continues to urge CMS to take a similar approach to evaluating whether access to specialty pharmacies is adequate under current plan networks. We are concerned that plans are increasingly limiting the number of specialty pharmacies in their pharmacy networks. In a time when there are a number of specialty drugs and biologics that require unique handling, administration and associated services in delivery to a patient, specialty pharmacies represent a critical access point for beneficiaries. For example, virtually all biologicals must be shipped and stored at particular temperatures and many require other special handling and administration procedures, sometimes the result of FDA requirements. Accordingly, biologicals often are distributed through specialty pharmacies and administered under special conditions. Therefore, inadequate inclusion of specialty pharmacies may result in lack of meaningful access to formulary drugs.

BIO urges CMS to take steps to identify where plan network inclusion of specialty pharmacies is inadequate, resulting in patients having to seek access to formulary drugs on an out-of-network basis, and to ensure that plans include the range of pharmacies necessary to provide beneficiaries with meaningful access to formulary therapies. Further, we would encourage CMS to have plan sponsors make available information on details of in

[27] *Id.*
[28] MedPAC. 2009. *Drugs on Specialty Tiers in Part D*: A study conducted by staff from NORC at the University of Chicago and from Georgetown University for the Medicare Payment Advisory Commission. p. 2, available at:,.
[29] Draft 2018 Call Letter, at p. 139.

network pharmacy providers through Medicare Plan Finder and require sponsors to provide sufficient notice to patients of changes to a plan's specialty pharmacy networks to ensure continuity of access is maintained.

III. CMS should continue to encourage increased beneficiary vaccination rates and ensure MA plans deem pharmacists providing vaccinations, in accordance with state laws, as in-network providers for these services.

In the Draft 2017 Call Letter, CMS highlighted low adult immunization rates related to public health goals and called on plans to improve these vaccination rates by setting a cost-sharing at $0 for dedicated vaccine tiers.[30] BIO supported these efforts to decrease access barriers for beneficiaries in Medicare to appropriate vaccination coverage and expressed our continued concern about MA and Part D plan's policies regarding access to vaccines.[31] It has been demonstrated that MA and Part D plans offer less access to no-cost vaccination than private plans under the Affordable Care Act[32] and in a 2011 GAO report, that nearly 22 million Part D beneficiaries did not receive the routinely recommended vaccinations covered by Part D.[33] BIO is concerned that the Draft 2018 Call Letter does not continue to strongly encourage this important access to vaccines. While the letter does note that CMS "continues to expect cost sharing for the vaccine tier to be $0"[34], there is no specific reference made to bolstering vaccination rates in line with stated public health goals. BIO urges CMS to work with a diverse group of stakeholders to identify mechanisms to overcome patient access challenges in obtaining timely access to vaccinations and to highlight potential efforts in the Final 2018 Call Letter.

Further, we would like to remind CMS that several of the most necessary vaccines for Medicare beneficiaries, including influenza, pneumonia, and hepatitis B (for high/medium risk populations) are covered at no cost-sharing to the Part B beneficiary when administered by a pharmacist. However, many MA plan provider networks may not consider these pharmacists as a part of the network, even though they are typically authorized to administer vaccines under state law and are contracted as a part of the MA plan's pharmacy network. This practice can limit beneficiary access to first-dollar coverage for these vaccines, reducing access to timely vaccination and increasing out-of-pocket costs. To help further the effort for increased vaccination rates among beneficiaries, CMS should require MA plans to deem contracted pharmacy providers as in-network for immunizations provided in accordance with state scope of practice laws.

IV. CMS should finalize the removal of the High Risk Medication (HRM) Measure from the Star Ratings.

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[30] Draft 2017 Call Letter, at p. 189.
[31] Biotechnology Innovation Organization. Comment Letter, Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter. March 4, 2016.
[32] Avalere. Medicare Has the Potential to Avoid Preventable Illnesses by Encouraging Broader Coverage for Adult Vaccines (Feb. 18, 2016).
[33] Government Accountability Office. Report to Congress: Medicare: Many Factors, Including Administrative Challenges, Affect Access to Part D Vaccinations (December 2011). *Available at:* http://www.gao.gov/assets/590/587009.pdf.
[34] Draft 2018 Call Letter, at p. 144.

BIO supports finalization of CMS's proposal to remove the HRM from the Star Ratings and include it in the display measures page beginning in 2018.[35] While we agreed that avoiding utilization of potentially inappropriate medications for Medicare patients is an important aspect of quality of care metrics, we noted in our comments on the Draft 2017 Call Letter –where this movement was initially proposed-- that the HRM measure only addresses this issue tangentially and has the potential to disadvantage plans who enroll a higher proportion of patients reliant on medicines contained in the HRM list.[36] By moving the HRM component to the display measures, CMS will be able to help ensure inform patient safety, while ensuring that the decision to prescribe a therapy is based on the clinical circumstances of the individual patient. For these reasons, BIO supports CMS finalization of the proposal to remove the HRM measure from the Star Ratings and move it to the display measures for 2018.

V. CMS should consider outcomes measures for 2019 and beyond that complement the National Action Plan for Adverse Drug Event Prevention.

The National Action Plan for Adverse Drug Event Prevention[37], established by the Department of Health and Human Services, is aimed at addressing two key objectives: (1) identifying common, preventable, and measurable adverse drug events (ADEs) that may result in significant patient harm; and (2) aligning the efforts of Federal health agencies to reduce patient harms from these specific ADEs nationally. The Action Plan has targeted three priority therapeutic areas: Anticoagulants (with bleeding as the primary ADE of concern), Diabetes agents (with hypoglycemia as a primary ADE concern) and Opioids (with accidental overdoses/over-sedation /respiratory depression as a primary ADE of concern). BIO supports the development of outcomes measures for the Part D program in line with the Action Plan's goals to support safety and the best health outcomes for Medicare beneficiaries. In particular, we recommend that CMS consider the Pharmacy Quality Alliance's (PQA) *"Hospital Admission or Emergency Department Visits for Bleeding Events Associated with Anticoagulant Medications"* metric be included for 2019 and beyond as an outcomes display measure in the Part D program, as we are optimistic this measure will be fully developed by the end of 2017. BIO believes that this measure fits well into The National Quality Forum's Measure Evaluation framework[38] for consideration of this metric as a future tool in evaluation of the Part D program.

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[35] Draft 2018 Call Letter, at p. 100.
[36] Biotechnology Innovation Organization. Comment Letter, Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter. March 4, 2016.
[37] US Department of Health and Human Services, Office of Disease Prevention and Health Promotion (2014). National Action Plan for Adverse Drug Event Prevention. Available at: https://health.gov/hcq/pdfs/ade-action-plan-508c.pdf.
[38] The National Quality Forum's Measure Evaluation Criteria includes four components, we find that the proposed *"Hospital Admission or Emergency Department Visits for Bleeding Events Associated with Anticoagulant Medications" fits in well with these criteria:* (1) *Importance to Measure and Report: t*he Adverse Drug Event Action plan states *"there remains a need for measure concepts that track centrally important markers of anticoagulant safety (e.g., bleeding)"*, (2) *Scientific Acceptability of Measure and Feasibility: c*urrently being tested with plans for Socio-Demographic Status adjustment, (3) *Usability and Use*: plans could perform formulary analyses of relative risk among options or enact policies or procedures to reduce the risk of bleeding events through improved care coordination which is a key component of oral anticoagulant management, (4) *Uniqueness:* this measure fills a current gap in the cardiovascular measure space.

VI. Innovation test models should ensure beneficiaries maintain access to necessary care and treatment and demonstrate true model tests.

BIO closely follows the work of the Center for Medicare and Medicaid Innovation given its potential to impact patient access to needed healthcare interventions. In the Draft 2018 Call Letter, CMS references two innovation models: the MA Value-Based Insurance Design (MA-VBID) and the Part D Enhanced Medication Therapy Management (MTM) models. The MA-VBID model provides an opportunity for plan sponsors to offer supplemental benefits or reduced cost sharing to enrollees with specified chronic conditions, while the Part D Enhanced MTM model is intended to lead to improved therapeutic outcomes, while reducing Medicare expenditures via payment incentives and regulatory flexibility.[39] As a general matter, BIO notes that all innovation models should ensure patient and beneficiary access to timely, appropriate care and treatment, and must rely on robust quality measurement given the CMMI authorizing statute's focus on maintaining or improving patient care.[40]

With the MA-VBID model having begun in 2017, and adding two additional disease states to the list of chronic conditions for which plans can provide flexible benefit design in 2018,[41] BIO urges CMS to ensure robust tracking of the impact of this initiative throughout the 5-year course of the model, through claims data and patient and provider surveys. CMS should assess and ensure flexibility to reduce cost sharing is applied to all therapies that may be clinically appropriate for an individual MA patient, including ensuring access to immunization services and interventions that mitigate, but do not necessarily prevent disease progression, throughout the course of this program. BIO supports efforts that reduce beneficiary cost-sharing, while maintaining or improving access to necessary treatments.

VII. CMS should finalize the clarification of Part D "reference-based pricing" policy for beneficiary cost sharing arrangements.

In the Draft 2018 Call Letter, CMS makes a clarification surrounding "referenced-based pricing" in Part D related to cost-sharing designs. This practice, where an enrollee is required to pay the difference in price between the negotiated price of the drug being delivered and a lower-cost preferred reference drug, was prohibited beginning in 2010.[42] BIO supports the clarification of CMS's policy around "reference-based pricing" as it is defined for beneficiary cost-sharing. As noted in our comments above, it is important that cost-sharing arrangements in the Part D program are not unduly burdensome to beneficiaries and do not create hurdles to timely access to necessary treatment. We further urge CMS to detail how compliance with this prohibition on "reference-based pricing" for beneficiary cost-sharing will be tracked in order to assess potential impacts for patients.

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[39] Draft 2018 Call Letter, at p. 105.
[40] SSA § 1115A(b)(2)(A).
[41] Centers for Medicare and Medicaid Services. Medicare Advantage Value Based Insurance Design Model (February 15, 2016). *Available at:* https://innovation.cms.gov/initiatives/vbid/.
[42] Draft 2018 Call Letter, at p. 150.

VIII. We appreciate CMS's continuation of the risk stabilization measure for Puerto Rico in 2018 and encourage CMS to further ensure access for beneficiaries.

For 2017, CMS implemented a revised risk adjustment model that increased payments made to plans enrolling a large proportion of dually eligible beneficiaries, with significant benefits for Puerto Rico based on their lack of a Medicare Shared Savings Program.[43,44] BIO commends the move by CMS for market stabilization benefitting Puerto Rico, and the continuation of this risk adjustment for 2018,[45] while encouraging the Agency to provide more adjustment to further stabilize the market and best serve this unique subset of Medicare beneficiaries.

IX. Conclusion

BIO appreciates the opportunity to comment on this Draft 2018 Call Letter. We look forward to continuing to work with CMS on these critical issues in the future. Please feel free to contact me 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/

Laurel L. Todd
Vice President
Healthcare Policy & Research

[43] Kaiser Family Foundation. 8 Questions & Answers about Puerto Rico, September 26, 2016. Available at: http://kff.org/disparities-policy/fact-sheet/8-questions-and-answers-about-puerto-rico/.
[44] Centers for Medicare and Medicaid Services. Supporting Medicare in Puerto Rico, April 4, 2016. Available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-04-2.html.
[45] Draft 2018 Call Letter, at p. 95.