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By Electronic Delivery

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

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and D Payment Policies and 2020 Draft Call Letter

Dear Administrator Verma,

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS') Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 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' 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 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- The specialty tier is an outdated approach that presents risks for vulnerable beneficiaries and should be re-evaluated;
- Coinsurance 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;

¹ Centers for Medicare and Medicaid Services, [Advance Notice of Methodological Changes for Calendar Year \(CY\) 2020 for Medicare Advantage \(MA\) Capitation Rates, Part C and Part D Payment Policies for 2020 draft Call Letter](#), January 30, 2019.

- 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;
- CMS must go further in protecting beneficiaries enrolled in Medicare Advantage who may be subject to step therapy;
- CMS should mitigate the impact of the increase in the out-of-pocket (OOP) threshold for CY 2020;
- MA plans should have the flexibility to determine what constitutes a chronic condition for purposes of providing special supplemental benefits for the chronically ill;
- Additional flexibility in design of maximum OOP costs should be considered to assist beneficiaries;
- Drug tier labels should accurately reflect the tier's composition;
- Inclusion of additional measures in the Star Ratings are critical to accurate assessment of patient care and quality;
- 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.

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I. The specialty tier is an outdated approach that presents risks for vulnerable beneficiaries and should be re-evaluated.

For CY 2020, CMS is proposing to maintain the specialty tier threshold in an effort to balance plan flexibility with beneficiary access, noting that its analysis found that the percentage of 30-day equivalent fills that exceeded the \$670 threshold was slightly greater than 1%.² BIO has consistently raised concerns with CMS' lack of updates to the specialty tier threshold in previous comments in response to the Draft Call Letter. Given the continued discussions around addressing patient out-of-pocket (OOP) costs, and efforts to ensure patients have access to high value Part D medicines, we urge the Agency to move away from the use of a specialty tier threshold.

We maintain concern that the continued use of a specialty tier prioritizes plan flexibility over beneficiary access, and advocate that considering alternatives to the specialty tier is critical in an era of personalized medicine, where access to the most appropriate therapy can reduce or negate the need for other healthcare services. The specialty tier construct forces beneficiaries to 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. These high cost-sharing requirements may deter patients from seeking appropriate treatment altogether. Additionally, as the Agency considers how to pass along rebates in the Part D program to beneficiaries at the point-of-sale – a policy which BIO has supported – maintaining the specialty tier may further complicate such calculations.

² Id. at page 179.

Accordingly, BIO urges CMS to eliminate the specialty tier as the Agency develops policies to ensure patients pay less for their medicines. 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 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 operate in a discriminatory manner by imposing high cost-sharing on Medicare's most vulnerable beneficiaries.

For drugs on the specialty tier, plans are permitted to require patients to pay up to 33% co-insurance, rather than a fixed copay amount. What is more, patients cannot seek a tier cost-sharing exception for therapies on the specialty tier. It has been widely documented that high OOP costs are associated with higher rates of prescription abandonment, delays between refills or treatment interruptions, and worse health outcomes. In fact, one study that looked at rates of medication abandonment for oral anticancer agents among individuals with differing cost-sharing requirements found that only 10 percent of patients in the lower OOP cost category abandoned their prescription, while almost half (49%) of patients in the highest OOP cost category did. Further, abandonment rates double as cost-sharing requirements increase from less than \$100 to \$100-\$500.³

We note that studies indicate that failure to take medications as prescribed causes an estimated 125,000 unnecessary deaths per year. What is more, poor adherence accounts for up to 10 percent of all hospitalizations annually.⁴ Non-adherence has been estimated to cost the US healthcare system between \$100 billion and \$298 billion annually in direct costs.⁵ The evidence shows clearly that increasing patient adherence will result in significant improvements in clinical outcomes and thus a reduction in healthcare spending.⁶

As Part D sponsors are able to charge co-insurance over copayments for therapies placed on other formulary tiers, the specialty tier simply adds an additional access restriction by prohibiting patients from seeking a tiering exception for these medicines.

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.⁷ The Part D statute specifically requires Part D sponsors to have a tiering exceptions process consistent with

³ Doshi, J. et al. Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. *Journal of Clinical Oncology*. 2017.

⁴ Meera Viswanathan, et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review, *ANN INTERN MED*. 2012;157(11):785-795

⁵ Viswanathan M, et al., Medication Adherence Interventions: Comparative Effectiveness. Closing the Quality Gap: Revisiting the State of the Science, Evidence Report/Technology Assessment prepared for the Agency for Healthcare Research and Quality (Sept., 2012) at 3.

⁶ The CBO estimates that a 1% increase in the number of prescriptions filled by Medicare beneficiaries causes Medicare spending on medical services to fall by roughly one-fifth of 1%. Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services (November 2012).

⁷ 42 C.F.R. § 423.578(a).

guidelines established by the Secretary.⁸ The Part D statute, however, does not include requirements or limitations specific to the specialty tier.⁹ 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.¹⁰ Current regulations, however, allow plans to have a specialty tier for certain drugs and biologicals without allowing beneficiaries to request exceptions.¹¹ Exempting specific treatments from tiering exceptions – based on cost alone – unnecessarily discriminates against beneficiaries who need these therapies.

CMS also seeks feedback on whether generics and biosimilars should be eligible for specialty tier placement if their cost exceeds the specialty tier threshold. As noted above, we believe CMS should eliminate the specialty tier. However, if CMS continues to allow plans to utilize a specialty tier, we believe that any drug or biologic that meets the specialty tier cost threshold should be eligible for specialty tier placement regardless of its FDA approval pathway (i.e., new drug application; abbreviated new drug application; biologics license application; abbreviated biologics license application). It is critical that patients are able to access the therapy that is most appropriate for their given condition—as determined during the patient-provider decision-making process—and that patients requiring certain drugs and biologicals are not unfairly disadvantaged from accessing these products. Accordingly, if CMS continues to allow plans to utilize a specialty tier, we also urge the Agency to regularly evaluate and appropriately raise the specialty tier cost threshold. We encourage CMS to increase beneficiary access to the most beneficial treatment by reducing barriers such as high cost-sharing, and/or discriminatory benefit design.

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. We believe that this type of cost-sharing has the potential to have significant negative consequences for patients with severe and complex diseases. 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.¹² There is a demonstrated link between higher out-of-pocket costs and lower patient adherence to therapy.¹³ It is critical to

⁸ SSA § 1860D-4(g)(2).

⁹ *Id.*

¹⁰ 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)

¹¹ 42 C.F.R. § 423.578(a)(7).

¹² Avalere. [Majority of Drugs Now Subject to Coinsurance in Medicare Part D Plans](#). March 2016.

¹³ 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.

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.

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.¹⁴ 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.

In the CY 2020 Draft Call Letter, CMS also highlights the new interventions that MA plans participating in the value-based insurance design (VBID) model for CY 2020 may test including providing “non-uniform benefit design to provide reducing cost-sharing or additional supplemental benefits for enrollees based on condition and/or certain socioeconomic (i.e., low-income subsidy eligibility or dual-eligible) status,” as well as “meaningful and focused Medicare Advantage and Part D Rewards and Incentives (RI) Programs.”¹⁵ CMS notes that “participating MA plans that offer a Prescription Drug Plan (MA-PDs) may also offer RI programs for enrollees who take covered Part D prescription drugs and who participate in disease state management programs, engage in medication therapy management with pharmacists or providers, receive preventive health services, and actively engage in understanding their medications, including clinically-equivalent alternatives that may be more cost-accessible.” While BIO supports efforts to implement and increase VBID to help reduce overall costs and improve patient access to those therapies and services that

¹⁴ SSA § 1860D-11(e)(2)(D)(i). See also 42 C.F.R. § 423.272(b)(2)(i).

¹⁵ Centers for Medicare & Medicaid Services, Value-Based Insurance Design Model (VBID) Fact Sheet CY 2020. January 18, 2019.

provide the greatest benefit, such changes are only beneficial if they do not discriminate against groups of individuals with certain diseases or medical needs. It is critical that any effort to allow additional flexibility in plan design be carefully evaluated and monitored to prevent discriminatory practices, and to ensure that any applied changes do not disincentive the use of the most appropriate treatment, as determined during the patient-provider decision-making process. We urge CMS to provide further detail on the appropriate use of these new VBID tests to ensure that any increased flexibility is not used to inappropriately steer patients to a treatment choice that may not be the most optimal given their health condition.

IV. 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. A study published in *The Journal of Primary Prevention* found the estimated annual cost of just four major vaccine-preventable diseases among US adults aged 65 years and older was more than \$15 billion in 2013.¹⁶ High risk populations, including the elderly, are particularly vulnerable to vaccine preventable diseases.

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.¹⁷ 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.¹⁸ 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 percent of adults over 60 reported receiving this vaccine, according to CDC data.¹⁹ By contrast, pneumococcal vaccination coverage that same year was 63.6 percent 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

¹⁶ Estimated Human and Economic Burden of Four Major Adult Vaccine-Preventable Diseases in the United States, 2013. *J Prim Prev.* 2015; 36(4): 259-273.

¹⁷ CMS. 20120 Draft Call Letter. January 30, 2019. At180.

¹⁸ Avalere Health. [Adult Vaccine Coverage in Medicare Part D Plans](#), February 2016.

¹⁹ Centers for Disease Control and Prevention. [Vaccination Coverage Among Adults in the United States](#), national Health Interview Survey, 2015

times more likely to cancel their vaccination when informed at the pharmacy counter of their copay amounts.²⁰ 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.

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

In the Draft Call Letter, CMS proposes to include a limited update window in August 2019, following the close of the formulary submission window on June 3, 2019. CMS notes that during this limited update window, Part D sponsors may add drugs that are new to the Formulary Reference File (FRF), and may also make negative changes to existing formulary drugs – only if the affected drug is replaced by an equivalent generic or therapeutically similar drug. BIO has previously expressed concern that the timeframes for updating prescription drug formularies could hinder the inclusion of new therapies on formularies. We appreciate CMS' efforts to address some of these concerns by including an update window in August to allow for the inclusion of new drugs to the formulary. 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.

²⁰ Journal of Managed Care and Specialty Pharmacy. [Meeting Abstracts -27th Annual Meeting Expo](#), Volume 21 Issue (4 Supp A), April 2015.

VI. CMS Must Go Further in Protecting Beneficiaries Enrolled in Medicare Advantage who may be Subject to Step Therapy.

While not specifically addressed in the Draft Call Letter, we wanted to take this opportunity to reiterate our concerns regarding the lack of transparency and adequate patient protections with the newly implemented policy to allow step therapy for Part B drugs, including among Part B and Part D drugs. Although—as stated before in multiple letters to the Agency²¹—we do not believe step therapy is appropriate for patients taking Part B medicines. To the extent that CMS moves forward with this policy, we urge CMS to strengthen protections to ensure beneficiaries receive timely access to the most appropriate treatment.

While CMS proposed several important updates in the MA and Part D Proposed Rule, including updating the appeals timeline to align with the requirements established in the Part D program, as well as requiring the use of P&T Committee processes for plan development of step therapy protocols, we urge the Agency to take additional action to protect beneficiaries. Specifically, we strongly recommend the Agency do the following if it continues the application of step therapy for Part B drugs in MA:

1. *Require MA plans to submit all Part B step therapy requirements for review and approval by CMS:* As currently detailed, CMS will only review such policies where step therapy is required between Part D and B drugs, and we believe the same standard should be applied for all uses of step therapy across the Medicare program. We believe it is CMS' role through the annual MA plan review process to ensure these step therapy protocols are applied in a manner that is clinically appropriate, and we recommend CMS undertake a notice-and-comment rulemaking process to determine what clinical guidelines and other evidence should be used to underpin MA plans' step therapy policies.
2. *Extend further protections to beneficiaries who fall outside the 108-day lookback period, but have had success with previous use of a therapy:* CMS should adopt a policy that overrides the application of step therapy for patients with prior successful use of a Part B drug, regardless of time frame.
3. *Address concerns with the potential stepping of off-label products before on-label products:* We believe that CMS coverage and reimbursement policies should not undermine the FDA and its role to review and approve investigational uses of approved drugs. There is tremendous value in the continued study of on-market products for new indications as well as creating additional competition in the marketplace, while at the same time balancing the clinical need for patients to be treated with available therapies in the judgement of their physician, as acknowledged by the FDA.²² Accordingly, we believe that CMS needs to strike an

²¹ See: BIO Comments RE: Contract Year 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule. January 25, 2019.

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

appropriate balance between the FDA's drug approval process and the need for physician and patient access to clinically necessary treatment when established CMS coverage and reimbursement policies that may be issued under a final rule.

4. *Ensure that patients are not adversely impacted by mid-year changes to Part B step therapy policies:* We do not believe plans should be allowed to make updates to their step therapy requirements for Part B drugs during the plan year. Patients should have wholly accurate information around what types of drugs will be subject to step therapy when making selections around plan enrollment.
5. *Update Medicare Plan Finder to allow beneficiaries to determine if their Part B drugs may be subject to step therapy:* As with Part D drugs, beneficiaries should be able to clearly and readily discern when shopping for a plan whether their Part B drugs are impacted by step therapy policies. By reviewing and approving MA step therapy policies as detailed above, CMS can set the same standard for Part B drugs subject to utilization management as Part D drugs and help increase transparency and reduce beneficiary confusion. Details on Part B drugs subject to step therapy should also be included on the Medicare Plan Finder website.
6. *Strengthen the requirements around annual notice language for MA plans using step therapy for Part B drugs:* We encourage the Agency to incorporate requirements that would ensure plans communicate clearly each of a beneficiary's drugs that may be subject to step therapy, as well as more detailed information on the plan's overall use of step therapy policies to help better inform healthcare decision-making.

Should CMS continue to move forward to permitting the use of step therapy in MA for Part B drugs, BIO urges the Agency to incorporate the additional transparency and patient protections outlined above into the step therapy policy. It is critical that appropriate guardrails are implemented to ensure that Medicare beneficiaries are not harmed under such a policy.

VII. CMS Should Mitigate the Impact of the Increase in the OOP Threshold for CY 2020.

Under a provision of the Affordable Care Act (ACA), growth in the OOP threshold had been slowed for the past several years. However, the provision requires CMS to set the OOP threshold for 2020 and future years assuming that no limitation had been in place – causing a significant jump in the OOP threshold from \$5100 to \$6350 for CY 2020. While we recognize the significant jump in the OOP threshold between 2019 and 2020 is a statutory consequence of the ACA, we encourage CMS to consider ways to mitigate the impact of this increase.

Beneficiaries enrolled in Part D can face significant cost-sharing requirements which can lead to affordability challenges for needed prescription medications. While in the coverage gap, patients are responsible for a much larger share of their total drug costs, leaving them exposed to higher OOP costs. This disproportionately affects high-cost enrollees whose spending pushes them into the catastrophic phase each year. Approximately 1.1 million beneficiaries—with non-low-income subsidies—enter the

catastrophic phase each year.²³ These affordability issues for the most vulnerable enrollees will only be exacerbated by the sudden and significant increase in the OOP threshold.

VIII. MA Plans Should Have the Flexibility to Determine what Constitutes a Chronic Condition for Purposes of Providing Special Supplemental Benefits for the Chronically Ill.

In the CY 2019 Final Call Letter, CMS expanded its interpretation of how a benefit may be a “health care benefit” that is approvable as a supplemental benefit offered by an MA plan. Specifically, CMS expanded its definition to consider items or services used to “diagnose, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization.”²⁴ Further, the Bipartisan Budget Act of 2018 expanded the supplemental benefits that may be provided by MA plans, which CMS notes will be known as Special Supplemental Benefits for the Chronically Ill (SSBCI).

For CY 2020, CMS states that it will consider any enrollee with a condition identified as a chronic condition in the Medicare Managed Care Manual as meeting the statutory definition of: (1) having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee; (2) has a high risk of hospitalization or other adverse health outcomes; and (3) requires intensive care coordination. CMS is soliciting comments on whether plans should have flexibility in determining what chronic conditions meet the statutory definition. BIO is supportive of providing MA plans this flexibility, in order to allow plans to make the best determination to meet the needs of its enrollees.

Several chronic conditions not included in the Medicare Managed Care Manual meet the statutory definition of chronically ill, and MA plans should be able to determine which of patients diagnosed with these conditions would benefit from access to SSBCI. In order to provide comprehensive care to its beneficiaries—and reduce unnecessary expenditures due to utilization of additional emergency or healthcare—MA plans should be able to tailor its supplemental benefits to those individuals it deems would most benefit. Providing MA plans with the flexibility to determine what a chronic condition is that meets the statutory definition is an important step in CMS’ efforts to expand access to supplemental benefits.

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

²³ The Medicare Prescription Drug Program (Part D): Status Report. MedPAC. 17 January 2019.

²⁴ Centers for Medicare & Medicaid Services, [Announcement of Calendar Year \(CY\) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter](#). April 2, 2018.

abandoned.²⁵ 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.

X. Drug Tier Labels Should Accurately Reflect the Tier’s Composition.

BIO supports CMS’ efforts to ensure that drug tiers accurately reflect the types of products available within that tier and the continued evaluation of the non-preferred brand tier as part of the plan bid review process. For CY 2020, 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.

CMS also notes it is considering, as an alternative to the tier composition policy, discouraging or prohibiting plan sponsors from placing generics on brand formulary tiers and brand drugs on generic formulary tier, and eliminating the non-preferred drug tier. CMS would expect that FDA-approved, therapeutically equivalent generics would be automatically included on a generic formulary tier immediately after launch. CMS is also interested in whether biosimilars should be treated the same as generic medications for purposes of this policy. BIO raises concerns with the potential for such a new tiering policy to treat biosimilars the same as generic medications. By definition, biosimilars are not “generics” but rather biological products approved under section 351(k) of the Public Health Service Act (PHSA) and include both biological products which are biosimilar but not determined to be “interchangeable” with the reference product as well as those which are determined to be both biosimilar and “interchangeable” with the reference product. Congress, in enacting the Biologics Price Competition and Innovation Act (BPCIA) that created the biosimilar approval pathway, recognized that the legal and regulatory construct for generic drugs is inappropriate for biosimilar products due to the scientific differences between biologics and small-molecule drugs. Accordingly, there are considerable differences between the regulatory review pathways for approval and marketing of generic versus biosimilar products, which BIO has previously detailed in our comments.^{26,27} We therefore do not believe that biosimilars should be treated the same as generic medications for purposes of this policy.

²⁵ Congressional Budget Office. [Offsetting Effects of Prescription Drug Use on Medicare’s Spending for Medical Services](#). November 2012.

²⁶ See: BIO Comments, RE: Docket No. FDA–2013-P-1153: BIO Comments to Generic Pharmaceutical Association Citizen Petition Requesting the Food and Drug Administration to Implement its INN Naming Policy Equally to all Biologics. January 2014

²⁷ For instance, in order to receive regulatory marketing approval, Abbreviated New Drug Applications for generic drugs are required to contain information that demonstrates the proposed product is the same as the previously approved drug (see: FDCA § 505(j), 21 U.S.C. § 355(j)). Biosimilars by definition are not direct copies of the reference product, and instead must be shown to be “highly similar” in structural characteristics with absence of clinically meaningful differences (see: PHSA § 351(i)(2)). As a result, most generics are considered therapeutically equivalent and therefore interchangeable, whereas biosimilars are highly similar, but not clinically identical, to their reference products, and as reflected by the two different standards. FDA has the ability to designate a biosimilar as interchangeable only after certain standards are met (see: PHSA § 351(k)(4)).

As CMS considers a possible change in policy to allow only generic drugs be part of generic formulary tiers and brand drugs be part of brand formulary tiers, it would be important for CMS to continue to reference allowing Part D plan flexibility for the placement of vaccines and brand drugs on lower cost-sharing tiers to reduce beneficiary out-of-pocket costs. CMS encourages Part D sponsors to either offer a \$0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing in an effort to improve access to these and other Part D vaccines.²⁸ CMS also discusses that the CDC has reported that vaccination rates remain low for tetanus and diphtheria with acellular pertussis (Tdap) for adults age 65 and older, at 58 percent and 20 percent, respectively, and that although the Healthy People 2020 herpes zoster target vaccination rate has been achieved, approximately 70 percent of adults for whom the vaccine is recommended remain unprotected.²⁹ An aging population increases the need to focus on adult immunizations. The projected annual number of cases of influenza, pertussis, and herpes zoster are expected to show substantial growth over the coming 30-year period (36.4% influenza; 31.8% pertussis; and 30.6% herpes zoster), driven primarily by those 65 and older.³⁰ Changing demographics will likely add to the already significant disease burden in the absence of increased vaccination rates.³¹

It is important that CMS continue to reaffirm the ability for plans to include vaccines and brand drugs on formulary tiers with lower cost-sharing tiers. CMS should continue to include the footnote to the "Benefit Parameters for Threshold Values" table that states: "The Select Care Drug and Select Diabetic Drug Tiers must provide a meaningful benefit offering with low or \$0 beneficiary cost-sharing for drugs targeting specific conditions (e.g., \$0 tier for drugs related to diabetes and/or smoking cessation). We continue to expect cost-sharing for the Vaccine tier or Select Care/Select Diabetes tiers that contain vaccines, to be \$0."³²

XI. Inclusion of Additional Measures in the Star Ratings are Critical to Accurate Assessment of Patient Care and 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.

- *Removal of the Part D Appeals Auto-Forward, Appeals Upheld Measures*

²⁸ Centers for Medicare & Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter (January 30, 2019), Page 179-180.

²⁹ *Id.* page 179.

³⁰ Talbird, S.E., La, E.M., Carico, J., et al. (2018). Projected Burden of Vaccine-Preventable Diseases in Older Adults in the United States: Impact of Population Aging. ISPOR Europe 2018, Pin 25. Retrieved from <https://tools.ispor.org/ScientificPresentationsDatabase/Presentation/87007?pdfid=56772>

³¹ *Id.*

³² Centers for Medicare & Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter (January 30, 2019), Page 182 - 183.

CMS is proposing to remove the “Appeals Auto-Forward (Part D)” and “Appeals Upheld (Part D)” Measures beginning with the 2020 measurement year and 2022 Star Ratings, due to low reliability with these measures. CMS is seeking feedback on whether these measures should be retained as display measures or retired entirely. BIO urges CMS not to finalize its proposal to remove the Part D appeals measures. While we recognize CMS’ concerns regarding measures with low reliability, CMS also notes it is considering replacing measures to ensure Part D access issues are captured in the Star Ratings measures. We believe it is premature to remove the existing measures prior to identifying and implementing new measures that address potential access to care issues.

These measures monitor key elements of PBM behavior that lead to patient satisfaction with their plan. Examining the rate of appeals—and subsequent outcomes—is critical to ensuring plans are providing the most appropriate care to their patients. Delaying access to vital care can also lead to an increase in overall healthcare expenditures through worse health outcomes and avoidable side effects caused by using a less appropriate treatment option. Further, the importance of monitoring appeals rates in Part D was underscored in a recent report released by the Office of Inspector General (OIG) which looked at appeals rates in Medicare Advantage plans. The OIG found that Medicare Advantage Organizations (MAOs) overturned 75 percent of their own denials during 2014-2016. During the same period, independent reviewers overturned even more denials in favor of beneficiaries and providers. These results show how frequently patients are denied services or payments that should have been provided. CMS must carefully monitor the rate of denials, appeals, and overturned appeals to protect beneficiaries and ensure adequate and appropriate care is provided. Removing the Part D appeals measures from the Star Ratings is a step in the wrong direction toward improving beneficiary access to needed care.

- *Potential Changes to Existing Star Ratings and Display Measures*

CMS has proposed that the Plan All-Cause Readmissions measure (Part C) be moved to the display page for 2021 and 2022, with a possible return with a weight of one to the 2023 Star Ratings based on 2021 measurement year data. While BIO supports the goal of ensuring that the data underlying performance measurement can capture meaningful changes in quality performance, we have some concerns about the proposed changes to this measure. BIO is concerned that the proposed changes to the measure may inadvertently exclude patients with chronic conditions, such as chronic obstructive pulmonary disease (COPD), who could benefit from care management programs that reduce readmissions. CMS should undertake additional assessments to better understand which patient populations are being removed from the measure with the proposed changes. In addition, CMS should further study how keeping the measure, as is, (i.e. allowing individuals with high frequency hospitalizations to remain in the measure) will skew readmission rates. We request that CMS consider our comments before finalizing the measure changes in the MA Star Ratings for calendar years 2020 and 2021. We support CMS’ decision to move the measure to the display page until further verification of the implications of the changes is better understood.

NCQA believes removing individuals with high frequency hospitalizations from the measure calculation allows the readmissions rates not to be skewed by this population. BIO is concerned with the removal of any patient population from the measure, as it may unintentionally remove patients with chronic conditions in need of hospital readmission

prevention programs, care coordination for discharged patients, and post-discharge home medication reconciliation assistance or medication therapy management (MTM). Upon further research, we've noted that NCQA defines frequent hospitalizations as "Medicare and Medicaid members with four or more index hospital stays during the measurement year and commercial members with three or more index hospital stays during the measurement year."³³ We request further information from NCQA as to the diagnoses to be removed from the measure, as using quantity to define outliers may capture patients in need of greater care coordination and management. Additionally, we encourage CMS to place this measure on the display page until NCQA is better able to clarify impacted populations, as we believe this information is critical to properly managing patients with chronic conditions.

- *Potential New Measure Concepts*

CMS has continued its value-driven quality efforts to incorporate the patient voice into care decisions and improve patient outcomes. Tenets of value-based delivery are optimal outcomes, affordability, appropriate incentivization, and transparency. Yet, despite the availability of human immunodeficiency virus (HIV) quality measures since 2008, very few payers have used them to measure the quality of care delivered to people living with HIV (PLWH). As CMS seeks new measure concepts to evolve the MA Star Ratings program, BIO recommends the adoption of HIV quality measures to encourage the advancement of high quality care through adherence to clinical guidelines, improvements to care coordination and care transitions, patient engagement, and a focus on achieving outcomes. Specifically, we encourage the adoption of HIV quality measures that focus on the diagnosis, treatment and suppression of viral load in all quality reporting programs and when possible, strongly encourage the use of existing viral load suppression outcome measure (NQF #2082).

Viral load suppression is the gold standard in HIV treatment and means that the virus has been reduced to an undetectable level in the body with standard tests.³⁴ The National Institute of Allergy and Infectious Diseases (NIAID) recently supported research that demonstrated that achieving and maintaining a "durably undetectable" viral load not only preserves the health of the person living with HIV, but also prevents sexual transmission of the virus to an HIV-negative partner.³⁵ This builds a strong case for the implementation of process and outcome quality measures to encourage testing, linkage to care, and ongoing treatment so that PLWH can achieve viral load suppression to the "undetectable" level and ultimately improve their health outcomes. Moreover, pursuit of this "undetectable" measure on an individual scale may lead to huge population health successes to curtail and prevent the spread of HIV.

Innovative advances in the treatment and prevention of HIV have played a significant role in transforming HIV from what was once considered to be a terminal illness

³³ National Committee for Quality Assurance. "HEDIS®1 2019 Volume 2: Technical Update."2018. <https://www.ncqa.org/wp-content/uploads/2018/10/HEDIS-2019-Volume-2-Technical-Update.pdf>. Accessed December 20, 2018.

³⁴ National Institutes of Health (NIH) "Ten things to Know about HIV Suppression" <https://www.niaid.nih.gov/news-events/10-things-know-about-hiv-suppression>.

³⁵ Science Validates Undetectable = Untransmittable HIV Prevention Message. NIAID. 22 July 2018. Available at: <https://www.niaid.nih.gov/news-events/undetectable-equals-untransmittable>,

to, in many cases, a manageable, chronic disease.³⁶ Medicare is an important source of health coverage for people living with HIV. As the size of U.S. HIV positive population has grown over time, so too have the number of Medicare beneficiaries with HIV. The number of Medicare beneficiaries with HIV have tripled since the 1990s, rising from 42,520 in 1997 to 120,000 in 2014.^{37,38} Many Medicare beneficiaries with HIV are dually-eligible for Medicare and Medicaid, and receive low-income subsidies under Part D.³⁹ Medicare spending for HIV has also increased over time, and the program is now the single largest source of federal financing for HIV care and treatment.

Evidence-based quality measures assessing HIV care exist, are endorsed by National Quality Forum (NQF), and used in federal programs, such as the MIPS and the Ryan White HIV/AIDS Program.^{40,41} However, the MA Star Ratings program does not include any HIV-related quality measures. 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 are aligned with the Institute for Healthcare Improvement's Triple Aim for improving patient experience, reducing cost and improving population health.⁴² Additionally, the implementation of HIV quality measures across federal programs will help realize HHS' plan of ending the HIV Epidemic: A Plan for America in the next 10 years.⁴³ We applaud the Agency for this effort and believe that utilizing HIV quality measures will help make this goal possible. BIO highly recommends the inclusion of the following Pharmacy Quality Alliance (PQA) and Health Resources and Services Administration (HRSA) HIV/AIDS Bureau-owned, HIV quality measures:

N/A	HIV Screening
NQF #2079/NQF #3290E	HIV Medical Visit Frequency
NQF #2083/NQF #3211E	Prescription of HIV Antiretroviral Therapy
NQF #2080	Gap in HIV Medical Visits
N/A	Adherence to Antiretroviral Medications – Proportions of Days Covered (PDC) Measure
NQF #2082/ NQF #3210e	HIV Viral Load Suppression

Optimal outcomes for PLWH can only occur if providers and plans are measured along the HIV care continuum. The use of HIV-related quality measures will promote

³⁶ 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. Accessible at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed 26 Feb 2018.

³⁷ Medicare and HIV. Kaiser Family Foundation. 14 October 2016. Available at: <https://www.kff.org/hiv/aids/fact-sheet/medicare-and-hiv/#footnote-200104-3>.

³⁸ 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; 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. Accessible at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6347a5.htm?s_cid=mm6347a5_w

³⁹ U.S. Federal Funding for HIV/AIDS: Trends Over Time. Kaiser Family Foundation. 9 November 2017. Available at: <https://www.kff.org/global-health-policy/fact-sheet/u-s-federal-funding-for-hiv/aids-trends-over-time/#footnote-242359-3>.

⁴⁰ Quality Measures. Quality Payment Program. Available at: <https://qpp.cms.gov/mips/quality-measures>.

⁴¹ Performance Measure Portfolio. HRSA. Available at: <https://hab.hrsa.gov/clinical-quality-management/performance-measure-portfolio>. Accessed February 16, 2018.

⁴² The IHI Triple Aim. IHI. <http://www.ihio.org/Engage/Initiatives/TripleAim/Pages/default.aspx>.

⁴³ Department of Health and Human Services. 2019. "Ending the HIV Epidemic: A Plan for America." <https://www.hhs.gov/sites/default/files/ending-the-hiv-epidemic-fact-sheet.pdf>.

standards of health care coverage that support adherence to current HIV clinical guidelines and federal guidelines.⁴⁴

- *Annual Flu Vaccine and Adult Immunization Stats Composite Measure*

BIO supports the addition of the annual flu vaccine as a candidate for the Star Ratings Categorical Adjustment Index (CAI). Quality measurement, particularly when tied to reporting and payment, serves as a mechanism to incentivize plans, providers, health systems, and other stakeholders to improve immunization rates.

Influenza is a potentially serious disease that can lead to hospitalization and sometimes even death. Millions of people get flu every year, hundreds of thousands of people are hospitalized and thousands or tens of thousands of people die from flu-related causes every year. The 2017-2018 Flu season resulted in 959,000 hospitalizations and 70,400 deaths.⁴⁵ Vaccination has been shown to have many benefits including reducing the risk of flu illnesses, hospitalizations and even the risk of flu-related death in children.

While BIO is encouraged by the addition of the flu measure, we ask that CMS consider the inclusion of the Adult Immunization Status (AIS) composite measure, which includes four specific vaccines in one (influenza vaccine; tetanus, diphtheria, and pertussis (Tdap) or tetanus and diphtheria (Td) booster vaccines; herpes zoster vaccine; and pneumococcal vaccine). The composite was developed by the HHS National Vaccine Program Office (NVPO) and the Centers for Disease Control and Prevention (CDC) in collaboration with the National Adult Immunization and Influenza Summit. It provides a reliable and comprehensive means to assess the receipt of routine adult vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP).

The National Committee for Quality Assurance (NCQA) added the adult composite measure to their 2019 Healthcare Effectiveness Data Information Set (HEDIS) using the Electronic Clinical Data System (ECDS) reporting domain data from administrative claims, electronic medical records, case management systems and registries. Prior to HEDIS, the composite was successfully piloted by the Indian Health Service. In the CY 2019 Call Letter, section "Potential New Measures for 2020 and Beyond (page 150-151)" CMS stated it would add NCQA's Adult Immunization Status (AIS) composite measure to the display for 2020. BIO strongly supports an adult immunization composite measure and asks that CMS introduce an Adult Immunization Composite Measure on the Star Ratings Display page. Application of the composite measure will provide the foundation for Medicare quality reporting programs and reflect the National Quality Strategy (NQS) "triple aim" of better care, affordable care, and health people/communities and serve as an overarching framework for guiding and aligning public and private efforts to improve quality healthcare. At the same time, the composite will help to streamline the patchwork of existing adult immunization measures and help to reduce the reporting burden on providers.

⁴⁴ HIV Medicine Association. Tools for Monitoring HIV Care: HIV Clinical Quality Measures (Updated) February 2015. Available at:

http://www.hivma.org/uploadedFiles/HIVMA/Policy_and_Advocacy/Policy_Priorities/Increased_Federal_Funding/Comments/Tools_for_Monitoring_Issue_Brief_update%20Jan%202015.pdf.

⁴⁵ Estimated Influenza Illness, Medical visits, Hospitalizations, and Deaths in the United States—2017-2018 influenza season. Centers for Disease Control and Prevention. 18 December 2018.

This measure is a part of NCQA's measure digitalization process and its rapid adoption will encourage plans and providers to invest in infrastructure and interoperability improvements needed to report on this new generation of measurement. NCQA demonstrated through its field-testing of the AIS measure that not only can health plans collect and report on electronic clinical data sets (ECDS) across commercial, Medicaid and Medicare product lines, but that rates were higher in plans that used data from multiple electronic data sources, compared to only claims data.⁴⁶ BIO encourages CMS to include this measure as a display measure for 2020 and eventually as a Star Rating measure.

- *Improving Diabetes Star Ratings and Quality Provisions*

We urges CMS to play a lead role in ensuring that Medicare Advantage and Part D plans, as well as Medicare providers, are aware of critical updates to national treatment guidelines and cost-benefit analyses regarding diabetes and cardiovascular management.

Diabetes is a highly prevalent and costly chronic disease, the cost of which is largely supported by government payers.⁴⁷ In 2013, the prevalence of type 2 diabetes (T2DM) among Medicare beneficiaries 65 and older was nearly 20 percent.⁴⁸ Medicare beneficiaries with T2DM may face barriers to accessing healthcare and more negative health outcomes than those without diabetes. Beneficiaries with T2DM average significantly more inpatient admissions per 1,000 beneficiaries (349.5) than those without diabetes (215.3).⁴⁹ Additionally, individuals with T2DM are disproportionately affected by cardiovascular disease (CVD) and have an elevated risk of CVD morbidity and mortality.⁵⁰ Accordingly, the median annual costs per patient for CVD among those with T2DM are 112% greater than those without CVD.⁵¹ Treating patients with T2DM and CVD increases cost of care by between \$3,418 to \$9,705 compared with treating patients with T2DM alone.⁵²

Recently, the Food and Drug Administration (FDA) has approved innovative dual-indication medicines for the management of T2DM and CVD. As such, several key stakeholders, including the ADA, the ACC, and the European Association for the Study of Diabetes have revised clinical practice guidelines to reflect evidence demonstrating the improved outcomes of these medications. For example, in 2017 the ADA updated guidelines

⁴⁶ The National Committee for Quality Assurance. Draft Document for HEDIS Public Comment. NCQA Website. Available at: <http://www.ncqa.org/Portals/0/PublicComment/HEDIS-2018/05.%20Adult%20Immunization%20Status.pdf?ver=2018-02-12-095720-750>. Accessed February 16, 2019.

⁴⁷ Wanya, Yang, Dall, Timothy M, Beronija, Kaleigh et al. "Economic Costs of Diabetes in the U.S. in 2017" *Diabetes Care*, 41 (2018) 917-928. Available at: <https://doi.org/10.2337/dci18-0007>

⁴⁸ Hasche, Jennifer, Ward, Christopher, and Schullerman, Nicholas. "Diabetes Occurrence, Costs, and Access to Care among Medicare Beneficiaries Aged 65 Years and Over" Medicare Current Beneficiary Survey (MCBS), 2017. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Downloads/Diabetes_DataBrief_2017.pdf

⁴⁹ Hasche, Jennifer, Ward, Christopher, and Schullerman, Nicholas. "Diabetes Occurrence, Costs, and Access to Care among Medicare Beneficiaries Aged 65 Years and Over" Medicare Current Beneficiary Survey (MCBS), 2017. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Downloads/Diabetes_DataBrief_2017.pdf

⁵⁰ Martin-Timon, Iciar, Sevillano-Collantes, Cristina, Segura-Gallindo, Amparo, et al. "Type 2 diabetes and cardiovascular disease: Have all risk factors the same strength?" *World Journal of Diabetes*, 5(2014) 444-470. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4127581/>

⁵¹ Einarson, TR, Acs, A, Ludwig, C, and Pantou, UH. "Economic Burden of Cardiovascular Disease in Type 2 Diabetes: A Systematic Review" *Value Health* 21(2018)881-890. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30005761>

⁵² Einarson, TR, Acs, A, Ludwig, C, and Pantou, UH. "Economic Burden of Cardiovascular Disease in Type 2 Diabetes: A Systematic Review" *Value Health* 21(2018)881-890. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30005761>

for patients with T2DM and established CVD to incorporate these treatments.⁵³ These guidelines were reaffirmed in 2018, wherein the ADA recommended that providers “incorporate an agent proven to reduce major adverse cardiovascular events and cardiovascular mortality,” as supported by Level A evidence.⁵⁴

Cardiovascular providers have also become more engaged in diabetes management due to new agents that have indications related to cardiovascular care. The American College of Cardiology (ACC) stated: *In analogy to the “heart team” approach used for those with other forms of heart disease, collaboration between cardiologists, primary care physicians, and diabetologists will be necessary to achieve the goal of more optimal treatment of vulnerable patients with type 2 diabetes.* Clearly there is a paradigm shift occurring in the treatment of T2DM and CVD. However, health care providers and plans have more capacity to adhere to the new guidelines. As the nation’s largest payer, CMS should encourage, via the ANCL or another regulatory tool, Medicare Advantage and Part D plans to acknowledge the significant change in this large, expensive, and chronic population and provide sufficient guidance to ensure best practices are reflected in health plan coverage decisions.

XII. 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.

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 any changes to Medicare coverage policies intended 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 of more than 27 of BIO’s member companies, in order to identify ways in which the biotechnology industry can assist in mitigating the opioid epidemic and serve as a strong partner to other stakeholders involved in these efforts. The working group has established priorities that outline the role that BIO and our members can play, 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 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 part of the Agency’s broader activities and goals in addressing the opioid crisis to ensure appropriate patient access to novel and safer FDA-approved treatments for pain, and to new and current forms of medication assisted treatment (MAT) across care for addiction.

⁵³ American Diabetes Association “Standards of Medical Care in Diabetes – 2017” *Diabetes Care*, 40 (2017) 1-142. Available at:

http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf

⁵⁴ American Diabetes Association “Standards of Medical Care in Diabetes – 2018” *Diabetes Care*, 41 (2018) 1-172. Available at:

http://care.diabetesjournals.org/content/diacare/suppl/2017/12/08/41.Supplement_1.DC1/DC_41_S1_Combined.pdf

In the CY 2019 Draft Call Letter, CMS proposed several policies aimed at enhancing MA and Part D plan sponsors abilities to combat opioid overutilization. BIO supported these efforts to help monitor individuals at risk of opioid overutilization through new flags and measures related to potentiator drugs. In the CY 2020 Draft Call Letter, CMS notes it is “continuing to explore other initiatives to prevent new cases of opioid misuse, overdose and death, and support beneficiaries who are already at risk.”

Specifically, CMS is proposing to implement the Pharmacy Quality Alliance (PQA) opioid overuse measures that were finalized for the 2019 measurement year in the 2019 PQA Measurement Manual. CMS notes it will implement these revisions in the Patient Safety reports for the 2019 measurement year and proposes to include all three revised measures on the 2021 display page and is considering these measures for the 2023 Star Ratings. As noted in our comments in response to the CY 2019 Draft Call Letter, BIO supports the adoption of measures to help mitigate opioid overutilization and concurrent use of therapies that can lead to serious adverse events. We encourage CMS to also consider how to incorporate novel FDA-approved therapies into the treatment pathway, and 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 risk is a key component of addressing the opioid crisis, advancing access to treatments that reduce, mitigate, and combat future addiction is also critical.

In addition, CMS is proposing ways to increase access to naloxone, by encouraging Part D sponsors to make changes to formulary benefit design to ensure that cost-sharing requirements do not inappropriately restrict access to naloxone products for beneficiaries for which the drug is clinically appropriate. BIO supports efforts to increase access to naloxone. As CMS notes, high out-of-pocket costs can be a barrier to access opioid-reversal agents, which when delivered timely, can prevent most opioid overdoses. BIO encourages CMS to also consider additional policies that would provide access to all available options for addiction treatments, including those that represent a significant advance in treatment of pain or addiction. We urge CMS to ensure plan formularies do not inappropriately apply utilization management techniques in order to provide adequate access to novel and safer FDA-approved treatments, including abuse-deterrent formulations and non-opioid analgesics.

Further, while no new policies are raised in the CY 2020 Draft Call Letter, CMS previously finalized a hard point-of-sale (POS) 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. As noted in our comments in response to the CY 2019 Draft Call Letter, while we understand the goal of such a policy, we are concerned that such hard-and-fast limitations may negatively impact patient access to the appropriate pain treatment. 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. We are encouraged by CMS’ 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 healthcare needs.

In addition to implementing the opioid overutilization policies outlined in the Draft Call Letter, BIO believes that CMS 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.

* * *

BIO appreciates the opportunity to comment on the CY 2020 Draft Call Letter. We look forward to working 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