From: David Bishai <dbishai1@jhu.edu>
Sent: Monday, July 24, 2017 3:05 PM
To: PTAC (OS/ASPE)
Subject: Medicare 3vbpp

Dear Ms. Tejeda,
I would like to comment as a physician on the 3VBPP Medicare plan. This plan includes a valuable feature in the form of wellness payments. If there is ever a trial of this plan the wellness payments should be accompanied by strategic communication that helps practicing physicians bring the existence of the payments to the patient's attention. Many of the "nudge" experiments show that it does not take large amounts of money as much to frequent reminders and social cues about how socially attractive the person would be if they meet the payment conditions. It would be a shame to put the majority of the nudge designs of the plan into the cash amount. It would be better to use some of the dollars to make the patient aware of their progress towards the reward.

Sincerely,
David Bishai, MD, PhD

July 31, 2017

Jeffrey Bailet, MD
Committee Chairperson
Physician-Focused Payment Model Technical Advisory Committee

Assistant Secretary for Planning and Evaluation, Room 415F
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP) Proposal

Dear Chairperson Bailet:

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP) Proposal (Proposed Model)[1] that has been submitted to the Physician-Focused Technical Advisory Committee (PTAC). 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 recognizes the need to ensure that the PTAC functions efficiently; however, as with our previous comment letter submitted on April 27, 2017,[2] we raise threshold concern with the short timeframe for public comment and transparency elements for this and future proposed models. Given that the Medicare 3VBPP Proposed Model represents a "first of its kind" model, we intend to use this opportunity to identify the hallmarks of value-based payment arrangements. Additionally, we will address concerns specific to the Medicare 3VBPP Proposed Model parameters and design. While innovation in the payment and delivery of care has great potential to achieve these aims, it requires robust patient protections and a focus on appropriate quality-of-care measures to guard against incentives to underutilize appropriate care. Specifically, BIO's members have identified the following as critical to sustaining patient access to necessary care and treatment in value-based payment design:

- The need to ensure patient access to critical, appropriate prescription medicines and providers with necessary expertise in treating a patient's given condition; and

[1] Zhou, Yang. Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP), June 29, 2017. Available at: https://aspe.hhs.gov/system/files/pdf/255731/Medicare3YearValueBasedPaymentPlan.pdf.
[2] BIO Comment Letter: Oncology Bundled Payment Program Using CAN-Guided Care, April 27, 2017.

- The importance of establishing robust, meaningful, and specific quality metrics and program parameters to ensure appropriate access and that the most vulnerable patients are not adversely impacted by the proposed value-based design.

It is important for the PTAC to consider these critical themes when evaluating the Medicare 3VBPP Proposed Model and future proposed models that include value-based payment arrangements.

In addition to the overarching themes around value-based models, BIO has specific concerns with the Proposed Model's capitation design, discussion of limitations on Part D drug expenditures, lack of sufficient quality metrics and patient protections, and the potential undue burden on providers, all which could have serious consequences for patient access to care and appropriate treatment. Our concerns are detailed further in the balance of this letter.

I. Value-Based Payment Design: Ensuring Patient Access to Critical, Appropriate Prescription Medicines and Providers with Necessary Expertise

Innovative drugs and biologics serve a crucial role in comprehensive treatment for many patients, and particularly for those served by Medicare and who have complex, chronic, and rare diseases. We ask that the PTAC consider how the Proposed Model, and future models before the Committee, account for innovative therapies. It is of the utmost importance that patients have reliable access to the most appropriate therapies for their given condition, irrespective of the management tools in place for a chosen value-based payment arrangement.

BIO urges the PTAC to ensure that proposals related to value-based payment are structured in a manner that allows patients and their providers to choose the most appropriate therapy at each stage of care, as well as to allow for, but not require, the successive trial of multiple drugs before a final regimen is selected, if this approach is appropriate for the patient's given condition based on patient and provider decision-making. For example, BIO finds that models reliant on "average" cost of care provided are problematic as they do not address the individualized treatment needs of a patient or take into account each provider's unique patient population makeup, and may therefore fail to appropriately address access to innovative medicines as a key component of delivering high-value care.

Equally important to ensuring patient access to timely and appropriate care and treatment in value-based payment arrangements is the need to establish an appropriate pathway for the consideration of new technologies and treatments. Failing to allow for new technologies may limit patients' access to the evolving standard of care. It is important that any value based approach maintain a dual focus on improving the quality of care patients receive and decreasing overall health expenditures. Additionally, in development and consideration of value-based models, it should be considered that drugs and biologicals are a small percentage of overall spending and have the potential to actually decrease spending on otherwise costly services such as hospitalization and surgical intervention. We ask that PTAC take a patient-centered, quality-focused approach in evaluating such models.

II. Value-Based Payment Design: Establishing Robust Patient Protections and Meaningful Quality Measures

BIO supports and appreciates the importance of affording flexibility to develop arrangements to fit the specific healthcare needs of the patient population or sub-populations being served. Development of value-based payment arrangements should consider an extensive set of measures to ensure that both quality in patient care and savings, without detriment to patient access to necessary care and treatment, are being achieved. Measures used in value-based payment should appropriately account for the patient population being served. Additionally, any quality measure should be used for program adjustments to achieve better health outcomes, and be designed to ensure that they do not deter the provider from selecting the most appropriate treatment pathway for each individual patient. In considering the appropriateness and robustness of quality measures for value-based payment, PTAC should consider whether for a given patient population:

1. The quality measures are sufficiently specific to measure the type of care received and provide actionable assessments;
2. The available quality measures selected for inclusion meet certain criteria, such as endorsement by the National Quality Forum (NQF), to ensure their validity and appropriateness for the condition in question;
3. Such measures adequately take into account how specialty care may be affected by factors outside the specialty providers' control (e.g., care rendered by other providers); and
4. The quality measures themselves do not inappropriately incentivize providers to focus on cost.

Emphasis should be placed on adopting quality metrics that are not solely aimed at driving down cost. For example, quality measures that focus on drug adherence, medication management, and care coordination should be prioritized. Careful evaluation of these measures and their appropriateness for inclusion is crucial to ensuring that quality measures serve as an effective check against the incentive to shift cost, while working to deliver high-value care to patients.

In addition to these considerations around quality measures, value-based payment should include standard patient protections across models to ensure patients are afforded robust and timely access to the most appropriate treatment, including drugs and biologicals and new-to-market therapies. In development of protections for patients and quality metrics, value-based payment models should provide a pathway for collection of stakeholder feedback, including the patient community, to ensure that these measures and protections are working in practice to achieve the stated goals of improved health outcomes and healthcare cost savings.

III. The Medicare 3VBPP Model Design Could Have Serious Impacts on Patient Access to Appropriate Care and Treatment

Based on the hallmark elements detailed above for value-based payment models to help improve patient health outcomes while reducing overall health expenditures, BIO finds that the Medicare 3VBPP Proposed Model lacks these critical elements and relies on both measures and arrangements that could be detrimental to beneficiary access to appropriate medical care and treatment.

First, the payment design described in the model creates perverse incentives to appropriate care, particularly for patients who suffer from rare and/or chronic diseases and conditions. The Proposed Model design includes providing each participant with a "Medicare Account" with a starting balance equal to three times the average annual Medicare expenditures of FFS patients.[3] This type of capitation payment based on the "average" patient could have severe adverse consequences for Medicare's most vulnerable patients by not providing adequate funding for coverage of necessary services and treatment. The Proposed Model notes risk adjustment for existing conditions. However, given the lack of sufficient detail around the risk adjustment methodology, the adjustment presented in this model could be insufficient to meet the high healthcare needs of patients with rare or chronic conditions, and is set for three years, which does not provide the opportunity to account for additional costs based on advances in treatment protocol or new-to-market innovation medicines for specific conditions. Without further transparency around the risk adjustment methodology, it is difficult to ascertain what the potential impact to patient access may be. BIO believes that transparency in Proposed Model design and evidence to support proposed structure are critical details for inclusion and consideration of models before PTAC.

The structural design of this model includes catastrophic coverage over the three-year period, as opposed to on an annualized basis.[4] While this type of catastrophic coverage is important to ensuring patient access and has the potential to lower cost-sharing for patients, PTAC should consider how this and other proposals that may rely on a value-based arrangement for delivery of Medicare services treat patients with serious diseases. Without additional detail or elaboration of patient protection considerations, the Proposed Model has the potential to treat vulnerable patients differently, dependent upon the time of their diagnosis. For example, a patient diagnosed with cancer before entering the model as compared with a patient diagnosed during participation in the three-year model will be subject to different cost-sharing obligations. BIO recommends that in evaluation of this and future models, PTAC ensure appropriate patient protections are in place to avoid disadvantaging certain patients on the sole basis of their diagnosis or time of diagnosis. Overall, the Proposed Model lacks sufficient detail or qualitative evidence to demonstrate how the benefits will be implemented and what their impacts will be to patient access and health outcomes. In considering this and future value-based proposals, the PTAC should ensure appropriate detail and examples are included for purposes of developing models aimed at transforming care delivery for the Medicare population.[5]

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[3] Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP), page 2.
[4] Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP), page 3.
[5] Models before the PTAC focused on value-based care should include appropriate evaluation and consideration as to how patient access will be impacted from the provider, beneficiary, plan and CMS perspectives. Additional

The Proposed Model could also have further and more direct negative impacts for beneficiary access to the most appropriate medicines by allowing plans to place greater limitations on coverage for prescription drugs. The Proposed Model includes the notion that participating plans could either provide integrated Part D coverage in addition to the Part A and Part B services, or participating beneficiaries could select their own separate Part D plan. Under the integrated Part D services component, the Proposed Model states, "For the plans that provide integrated Part D coverage, they should be granted not only more power to negotiate reimbursement rate, formulas etc. than the stand-alone Part D plans, but also the freedom to determine the annual limit of prescription drug expenditures."[6] From the perspective of the Proposed Model, this design will allow for "innovative care coordination models for patients … in, particular those with multiple chronic diseases and complex demand for prescription drugs".[7]

However, it is BIO's belief that this integrated plan design fails to take into account a number of factors and could ultimately be detrimental to patient access. By placing annual limitations on expenditures for prescription drugs, providers may be forced to make inappropriate determinations around treatment pathways to stay within the bound of the limitations on annual expenditures. This type of proposed plan design also does not appropriately reflect the contribution that prescription drugs, particularly for patients with multiple chronic conditions or rare conditions, may have in reducing other healthcare expenditures such as hospitalization or surgical intervention.[8] The three year design of the plan also does not appropriately account for the rapid evolvement and introduction of innovative treatment, which BIO finds is an important hallmark of value-based designs.

Further, the Proposed Model's evaluation metrics are purely cost and utilization driven, and only include one "health outcome measure", which is annual mortality rate.[9] These evaluation criteria fail to be specifically sufficient to provide actionable assessments; do not include any quality assessment measures recognized for their validity and appropriateness; do not adequately take into account how varying types of care for specified patient populations may be affected under the Proposed Model; and do not ensure that cost is not the only driver of care decision processes. Moreover, the Proposed Model does not include any patient protections or pathways for beneficiaries to provide feedback on participation in the value-based arrangement and simply relies on the Center for Medicare and Medicaid Services to "ensure patients' safety is not protected and not abused", doing nothing to ensure access pathways are maintained.

Finally, the Proposed Model would place an undue burden on Medicare providers and beneficiaries for management of their healthcare services within the bounds of the "Medicare Account" described, ultimately impacting access to appropriate care and

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analysis to inform these models should include health economic assessments of impacts, in particular for this model, how CMS funding to a carrier implementing the benefit design outlined would be represented across the Medicare population.

[6] Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP), page 8.

[7] Id.

[8] For example, the use of curative therapies may be impacted in a plan of this nature that does not take into account the overall healthcare value and cost avoidance of such treatments.

[9] Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP), page 7.

treatment.[10] The proposal states that Medicare 3VBPP, "aims to encourage both providers and beneficiaries to be aware of the patients' budget and health trajectory when making choices of Medicare covered services to maintain their physical health as well as a healthy balance of their Medicare account."[11] This statement suggests that providers are responsible

for making care determinations based on the bounds and balance of their patients' "Medicare Account", at any point during the three-year period of the value-based program. Additionally, this places an enormous responsibility, and potentially unrealistic burden, on the Medicare beneficiary population to manage their health in ways they are either not conditioned or accustomed to, and that may negatively impact their healthcare decisions. This element could have the direct impact of influencing provider or patient decision-making on the sole basis of cost, either by not selecting the standard protocol in care or choosing less-costly and less-effective treatment options, potentially having detrimental impacts for patient health outcomes.

For these reasons, BIO believes that the Medicare 3VBPP proposal does not represent a robust path for providing value-based care to Medicare beneficiaries, instead, this proposal is insufficient in ensuring that beneficiary health and access is improved while delivering cost savings.

IV. Conclusion

BIO reiterates our appreciation for the opportunity to comment on the Proposed Model, and we look forward to working with PTAC to improve the efficiency and effectiveness of its process to promote the development and testing of value-based payment models that meet the shared goals detailed above. 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 these very important considerations.

Sincerely,

/s/

Laurel L. Todd
Vice President, Healthcare Policy & Research

[10] Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP), page 2.
[11] Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP), page 4.