November 20, 2017

BY ELECTRONIC DELIVERY

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RE: Centers for Medicare & Medicaid Services: Innovation Center New Direction

Dear Acting Director Bassano,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS/the Agency) Innovation Center New Direction Request for Information (new direction/RFI) released on September 20, 2017. [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 represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we have closely monitored the Innovation Center's development and delivery of demonstration models and their potential impact on patient access to treatment and innovation. BIO applauds CMS for engaging in the collection of broad stakeholder feedback through this RFI, and not only for seeking input on the model focus areas, but also on the overarching principles that guide the Innovation Center's activities (guiding principles). We support the Center for Medicare and Medicaid Innovation's (CMMI's) broader goal to improve quality of care and reduce overall healthcare expenditures, and believe appropriate access to, and utilization of, medicines can contribute to both goals. Innovative therapies have the potential to improve patient health outcomes and reduce healthcare spending in the short- and long-term. Thus, a prominent theme of

[1] Centers for Medicare & Medicaid Services: Innovation Center New Direction, available at: https://innovation.cms.gov/Files/x/newdirection-rfi.pdf.

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our comments on this RFI center on the ideal that all demonstrations should not only maintain, but improve access to necessary therapies.

As a threshold matter, we would like to reiterate the tenants of CMMI model design, which we believe are essential to incorporate within the context of the guiding principles and central to the development of models outlined in the focus areas of this new direction. The authorizing statute for CMMI, Section 1115A of the Social Security Act, requires that: (1) innovation models "address a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures"; (2) models reducing cost must do so while also "preserving or enhancing the quality of care received by the individuals served in the model;" (3) evaluation of each model is to be conducted, including an analysis of "the quality of care furnished under the model and measurement of patient-level outcomes and patient-centeredness criteria," and such information should be made publicly available in a timely fashion; and (4) in carrying out development of models, CMMI shall "consult relevant clinical and analytic experts" and "use open door forums to seek input from interested parties."

BIO finds that there are key themes within the context of the authorizing statute that should be clearly defined as a part of the guiding principles and the new direction of the Innovation Center. We strongly urge CMS, in moving forward with this new direction to include and adhere to the following in development, implementation, and assessment of all models (discussed further in this letter):

1. **Utilize robust and transparent data assessments in the development and evaluation of CMMI demonstration models;**
2. **Delineate a clear stakeholder engagement strategy and process for collection and incorporation of feedback when CMMI models are being considered, implemented, and evaluated, and for CMMI generally;**
3. **Assure that CMMI demonstration models represent "true tests" in their size and scope; and**
4. **Develop patient protection guardrails to ensure quality, patient-centric care is being delivered through each CMMI demonstration model.**

Furthermore, within the context of these considerations, CMMI models should prioritize and preserve patient access to innovative therapies, as they serve a critical role in improving patient health outcomes and reducing overall healthcare costs. Models that ensure timely initiation of the most appropriate course of treatment for a patient are aligned with the patient-centric approach of this RFI.

We share these critical considerations in the context of the continued drive toward improving quality of care, patient-centricity, and delivery of innovative treatment options that can reduce overall healthcare expenditures, in accordance with previously stated goals of the Innovation Center:

> "The work of the CMS Innovation Center relies on an understanding – shared by patients, health care providers, and other stakeholders – that our health care system does not consistently reward the quality of care provided, instead rewarding the

quantity of services provided … moving toward delivering high quality care to CMS beneficiaries and by extension, to all Americans, and paying for this care in smarter ways, requires transforming the system as a whole." [2]

BIO believes that well-designed innovation models—those that are built on relevant data insights in conjunction with a broad range of stakeholders and that aim to test small-scale, specified improvements to healthcare delivery and outcomes—are central to positive transformations in the healthcare system. Demonstration models can serve a critical role in generating the evidence and data needed to move in the direction of personalized medicine and delivery of innovative treatment options that transcend the current approach to care, improving quality, health outcomes, and reducing overall healthcare costs. Incorporation of the following themes is critical to achieving these goals.

1. **Utilize robust and transparent data assessments in the development and evaluation of CMMI demonstration models.**

BIO is concerned about the lack of clear, detailed data provided regarding the rationale for creating certain models as well as the data used to evaluate models currently underway. ***It is imperative that CMS articulate the evidence used in the development of a model and generated throughout the model's implementation and assessment process, with appropriate context.***

Specifically, there has been insufficient information made publicly available around both what is driving the development of a specific innovation model and how innovation models are meeting the goals of maintained or improved care at reduced costs to the overall healthcare system. In the example of the previously proposed Part B Demonstration Model, CMS provided no evidence for the basis of the model and stakeholder analysis and feedback revealed the potential pitfalls inherent to a model with the singular goal of reducing healthcare spending.[3]

Moving forward, we believe CMS should detail the analytical basis for the development of a model to the general public as a part of the recommended stakeholder feedback process, discussed further below. This information should be clearly presented and include contextual information such as data limitations, expected outcomes, impacts to patient care and spending, data elements to be collected throughout the course of the model, and the intended use of data generated. Subsequently, once refined, data collected on the model's impacts should be publicly reported, with emphasis on the care and quality improvements and not solely on cost savings. Models designed primarily for cost savings should not be tested unless data demonstrates clearly, unequivocally, and without exception, that patient access, safety, and outcomes will not be compromised. Providing such data is a critical component of ensuring sound model design, outcome measurement, and application for expansion or use in future models.

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[2] Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation Report to Congress, December 2016, available at: https://innovation.cms.gov/Files/reports/rtc-2016.pdf.
[3] See: BIO Comments, RE: Medicare Program; Part B Drug Payment Model [CMS-1670-P], May, 9 2016.

2. Delineate a clear stakeholder engagement strategy and process for collection and incorporation of feedback when CMMI models are being considered, implemented, and evaluated, and for CMMI generally.

BIO believes that broad engagement across the spectrum of stakeholders, as required by the statute and at the earliest stages of model consideration and development, is a cornerstone of the foundation for responsible policy and demonstration model development. ***CMS should take the opportunity under this new direction to set forward a detailed stakeholder engagement strategy, for models being considered and developed, those that are currently underway, and the Innovation Center more broadly***.

We believe this RFI is an important first step in bringing new transparency to CMMI in the development and structure of potential demonstration models. BIO would like to see CMS set forward a predictable, formal process to ensure that interested parties – particularly patients - have the opportunity to participate in model development, implementation, and analysis. A holistic review of multiple perspectives across stakeholder organizations will help the Innovation Center best meet the goals of improved quality of care, patient-centricity, and reduced healthcare costs. Engagement of stakeholders both early and regularly will help inform meaningful outcomes, quality measures, and structural safeguards. In this process, patient engagement must be at the forefront, and extend beyond the more common conditions that tend to drive model design.

Additionally, the Agency should set at least quarterly open door forums to review broader CMMI activities and updates. Further, for each specific model, there should be regular intervals to provide feedback from those with a vested interest in the model. This feedback should be requested at the onset of the model proposal based on data as detailed above, throughout its course and evaluation, and as follow up after the conclusion. Such a process will help inform potential future innovations, model expansion considerations, or the need to discontinue models - as required by statute - if they have negative impacts on patient health outcomes.

3. Assure that CMMI demonstration models represent "true tests" in their size and scope.

As required by statute, models must target specified populations with the aims of maintaining or enhancing care, and require a two-step process for further use of the models design or expansion beyond the initial defined population. BIO believes it is imperative that ***models be voluntary, targeted, and well-defined in scope, and never implemented on a nationwide basis as per the statutory definition of a model***.

These parameters are central to ensuring that a model delivers applicable insights about impacts on care and programmatic spending. BIO has previously addressed concerns with CMMI proposals that aim to make large-scale changes to program delivery, particularly in the case of the proposed Part B Demonstration Project.[4] This model represented a wholesale programmatic change that could have had significant consequences for patient

[4] Id.

access to appropriate care and treatment; did not prioritize patient quality of care, nor provide for evaluation of the model's impacts; and did not align with the statutory provisions for a model. It also delineated a finite Phase I model period after which a scaled-up, and qualitatively different Phase II model would be initiated, potentially before meaningful evaluation as required by statute was conducted. We believe the new direction for the Innovation Center is an opportunity to continue to correct course in the development of future models, and ensure they apply to specified, targeted populations and care deficits. Further, we appreciate the Innovation Center's commitment to the use of voluntary models in the guiding principles as we believe it is imperative for providers to continue to exercise the ability to make the most appropriate treatment choices for their patients.

Further, in appropriate testing of models, CMMI should ensure that concurrent models are not applied within the same patient population or provider base in such a manner that does not allow for accurate assessment of each specific model's impact, to ensure that results are not confounded by members of the identified target patient and provider populations participating in multiple care delivery models. This "layering" of models could inappropriately impact beneficiary access to care or influence the potential for model results to be repeated and applied across a broader populations.

4. Develop patient protection guardrails to ensure quality, patient-centric care is being delivered through CMMI demonstration models.

BIO is concerned that without further details around protecting patient access and proper oversight of innovation models, CMMI's principles may be ineffective or insufficient in impacting true innovative, patient-centric care. ***CMS should incorporate a well-defined structure and set of patient-centered outcomes upon which it will evaluate the quality of care being delivered to patients through innovation models.***

We ask that CMS consider the addition of guardrails to ensure that patient access is maintained or improved throughout the course of the model as is required by statute. Such guardrails should ensure patient access to comprehensive coverage, prioritizing access to evidence-based treatment and preventions. This should include meaningful mechanisms for informing patients of their provider's participation in models, and if the model has the potential to influence treatment decisions, allowing patients to opt-out if desired without having to seek treatment elsewhere.

Further, we encourage CMS to ensure demonstrations do not negatively impact care for patients with complex healthcare needs, or for those who have rare diseases with only one or very few approved therapeutic options. For such high-need patient populations, testing a pilot that may ultimately be unsuccessful might disproportionately subject these patients to significant risk of negative health outcomes. Models should have flexibility to accommodate quality of care for patients who fall outside the "average" patient considerations upon which demonstrations are benchmarked, including accommodating access to innovations in treatment. CMMI should avoid testing pilots that may jeopardize access to care and necessary therapies that are critical for such patients.

BIO believes the development of such guardrails demonstrates an important opportunity for CMS to engage with beneficiary stakeholders, one of the aims outlined in the

RFI, to seek feedback on the care they are receiving and the models in which they are participating. Such information could include, but is not limited to, the development of relevant quality measures, patient reported outcomes, and pathways for patients to share concerns about the care being delivered through specific innovation models.

The key elements outlined above are central to BIO's feedback and comments on the individual components in the RFI, and their incorporation into the broader framework for CMMI activities should be prioritized. In addition, the balance of our comment letter provides feedback on the components of the RFI: (I) comments in response to CMS' guiding principles for the new direction of the Innovation Center and (II) comments in response to the proposed model focus areas:

I. Comments in response to CMS' guiding principles for the new direction of the Innovation Center

II. Comments in response to the proposed model focus areas for the new direction of the Innovation Center

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I. Comments in response to CMS' guiding principles for the new direction of the Innovation Center

BIO appreciates CMS' approach of detailing the specific guiding principles that will direct future model design and implementation. As discussed above, we believe the central themes around application and use of data, regular intervals for broad stakeholder engagement, the notion that demonstration projects should represent "true tests", and patient guardrails should be more broadly incorporated into the guiding principles of CMMI. Further, BIO makes considerations around each of CMS' guiding principles for the new direction of the Innovation Center in turn below. We ask CMS, after incorporating the key themes detailed above, to codify the guiding principles to ensure models moving forward are developed from, and held to, the same set of standards.

1. ***Choice and competition in the market - Promote competition based on quality, outcomes, and cost.***

BIO is encouraged to see the focus on allowing for choice and competition in the healthcare marketplace. It is imperative that model designs ensure patient access to timely and appropriate treatment options, including innovative medicines that may have the potential to offset other healthcare costs and improve health outcomes in both the short- and long-term. However, we have concerns around potential model designs that base healthcare delivery mechanisms solely on financial incentives or cost savings.

We caution CMS against the development of any model that may apply arbitrary limitations, hurdles, or provider disincentives on treatment access in the care setting most appropriate for the patient, as this could negatively interfere with the patient/provider treatment plan and the central ideal of creating patient-centric innovation models. BIO finds that measures of cost often take an overly simplistic view of the value that an individual therapy or treatment may deliver both to the patient and the overall healthcare system. Assessments of cost should take into consideration a number of factors – other healthcare interventions avoided, patient outcomes, time period considered, overall savings to the healthcare system, etc. – which could have serious implications for patient access depending on how each factor is defined.

An additional avenue the Agency should consider as a means for advancing choice and competition that promotes value and quality health outcomes are value-based arrangements (VBAs). Through such arrangements, manufacturers of drugs and biologics can play a central role in advancing value-driven healthcare delivery. The Innovation Center should advance VBAs as a component to this new direction, working to overcome the regulatory challenges for such arrangements, explored further in this letter in our comments on prescription drug models.

2. ***Provider choice and incentives – focus on voluntary models, reduce burdensome requirements and unnecessary regulations to allow for delivery of high-quality care.***

BIO supports flexibility in model design that ensures patients receive the most appropriate, high-quality course of treatment. It is imperative that model design does not place an undue burden on providers in caring for their patients, nor does the design interfere with the patient/provider decision-making process. We strongly agree that participation in models should be decided on a voluntary basis by providers, allowing them the flexibility to assure that a demonstration represents an appropriate means to deliver care for the mix of patients they serve. We also believe that model participation should be voluntary for patients, as they have the right to make informed decisions about the healthcare they are receiving. Further, in scaling of models based on positive data results, participation should continue to be voluntary for both providers and patients. BIO encourages CMMI to further define 'voluntary', including patients and future model expansion considerations, to provide additional clarity around this guiding principle.

Previously, the Agency moved to implement a model that was not consistent with this principle, through the widespread application of the proposed Medicare Part B

Demonstration. As detailed at the outset of this letter, in order for Innovation Center activities to impact the transformation of healthcare delivery and quality, any model developed should represent a "true test", as defined by statute, by identifying a specific patient population and desired health, quality, and cost improvement outcomes that are informed by the stakeholder participation in the model's development.

3. ***Patient-centered care – empower beneficiaries/caregivers to take ownership of their health and ensure that they have the flexibility and information to make choices across the care continuum.***

BIO believes that this guiding principle should not only focus on "ownership of health" from the decision-making perspective, but also in providing feedback on proposed models that may impact a beneficiary's overall care and course of treatment. A critical element of the informed decision-making process for patients is the ability to understand and have the opportunity to provide feedback on the type of care they are going to receive. In conjunction with their providers, patients should have the opportunity to make the decision for the preferred course of care based on their overall treatment goals.

In line with CMMI's stated aim of increasing engagement with beneficiaries for purposes of development of new models or as participants in models, we urge CMMI to undertake a well-defined stakeholder engagement process as detailed above. Through connecting with interested parties, including beneficiaries - before a model is developed, during its implementation, and as follow up to – the Innovation Center can ensure that the model empowers beneficiaries and is relevant in informing future models.

4. ***Benefit design and price transparency – Use data-driven insights to ensure cost-effective care that also leads to improvements in beneficiary outcomes.***

BIO supports delivery of care that prioritizes quality and improved health outcomes. It is BIO's position that any efforts around increasing transparency should apply across the healthcare spectrum and be grounded in the goal of improving timely access to information that supports informed patient/provider clinical decision-making and health insurance enrollment decisions, and that helps ensure smarter healthcare spending, without distorting market dynamics or harming the innovation ecosystem.

When applied to prescription drugs and biologicals, as one element of the broader ecosystem, transparency should facilitate access to medications, while continuing to foster competition and the risk-taking required to deliver on the promise of future treatments and cures. This includes promoting an environment that supports value-based approaches to healthcare delivery and payment that benefit the patient; provides information that is meaningful to healthcare decision makers, and that can be used by patients to improve their clinical and insurance enrollment decision-making; gives information to patients on the models their provider is participating in that could have impacts for their overall course of care; and promotes an understanding of the full spectrum of the healthcare delivery channel and a holistic representation of the marketplace.

As detailed in the beginning of our comments, we find it is imperative to ensure data is used in the appropriate context for the development of demonstration models. The data-

driven insights CMMI references in this principle should not only be aimed at reducing healthcare expenditures, but driving advances in the quality and patient-centricity of care for purposes of the new direction of the Innovation Center. Every demonstration model under development and consideration by the Agency should be presented with the data insights leading to its development, with relevant context for stakeholders to understand the purpose and the aims of the innovation being presented.

5. Transparent model design and evaluation – draw on partnerships and collaboration with broad range of stakeholders.

BIO supports collaboration across a broad range of stakeholders in the design, development, implementation, and assessment of all models. CMS should ensure a robust and inclusive dialogue with stakeholders to identify discreet opportunities for evidence-based model development and work collaboratively in the development of all future demonstration models. BIO finds that such transparency is imperative to ensuring models deliver high-quality, patient-centric care.

As suggested in our comments on a stakeholder engagement process, we urge CMS to solicit feedback from stakeholders across the healthcare spectrum both for individual demonstration models and for CMMI more generally. BIO suggests that CMS use quarterly stakeholder meetings to discuss current model activities and seek feedback from the public on adherence to the stated goals and guiding principles of the Innovation Center. For each model or specific model focus areas, CMMI should convene such meetings when a model is first being considered, as it is designed, during its implementation, and as data is collected, and once a model is complete. Involvement of interested groups, including patients, can help best inform a model's design and evidence generation to support transformations in healthcare.

The recent Summit on Behavioral Health Payment and Care Delivery Innovation[5] held by CMMI represents a positive step in the right direction for this type of appropriate stakeholder engagement. This public summit included discussion of ideas for potential behavioral health models to improve access, quality, and cost of care for beneficiaries with such conditions. We encourage the Innovation Center to continue convening such types of open forum discussions as models are developed in this area and for other models considered in the future.

6. Small-scale testing – test smaller scale models that may be scaled up if they meet the expansion requirements under 1115A(c).

BIO supports this guiding principle for small-scale testing of innovation models and expansion when they meet requirements under Section 1115A(c) of the Affordable Care Act. As detailed in our comments around ensuring innovation models represent "true tests" and as we have previously stated in comments around expansion of models, we ask that CMMI provide additional information around assessment of models before expansion, including collection of stakeholder feedback and release of relevant data and results.

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[5] Summit: Behavioral Health Payment and Care Delivery Innovation, September 8, 2017. Available at: https://innovation.cms.gov/resources/behavioral-health-paymentcare-summit.html.

For purposes of this guiding principle, CMS should define the meaning of "small-scale" in terms of the number of participating providers and patients, geographic range, and duration of the model, and seek stakeholder feedback before moving forward with this definition. This additional detail will help create necessary consistency across future models. Additionally, we believe Congress should play a critical role in expansion of future models. BIO continues to have concerns around use of waivers for expansion of models from Phase I to Phase II.[6]

II. Comments in response to the proposed model focus areas for the new direction of the Innovation Center

The RFI includes a broad range of potential focus areas for future CMMI models and demonstration projects. Below, BIO provides feedback on considerations for some of the outlined focus areas. Throughout these comments, and in CMS' focus areas on which we do not explicitly comment below, the themes described at the beginning of this comment letter - the use of robust and transparent data in innovation models, the development of a broad stakeholder engagement process across CMMI activities, ensuring that models are implemented on a small-scale, voluntary basis, and application of patient guardrails – are critical to implementing high-quality, patient-centric models in all focus areas. Our comments target the following focus areas: (1) prescription drug models, (2) state-based and local innovation, including Medicaid-focused models, (3) physician specialty models, (4) increased participation in advanced Alternative Payment Models (APMs), (5) Medicare Advantage (MA) innovation models, (6) mental and behavioral health models, and (7) program integrity.

1. Prescription Drug Models

CMMI details interest in testing new models for prescription drug payment, in both Medicare Parts B and D and state Medicaid programs that incentivize better health outcomes for beneficiaries at lower costs and align payment with value, referencing innovative value-based purchasing arrangements.

BIO believes it is critical that any demonstration model for prescription drug delivery, whether through Medicare Parts B and D or state Medicaid programs, recognizes the value of drugs and biologicals to patients and the healthcare system, and does not place arbitrary restraints that may limit patient access to appropriate treatment. Such limitations could have detrimental effects for patients who rely on the Medicare and Medicaid programs for their healthcare coverage and interfere with the patient/provider decision-making process. Further, we ask that CMMI ensure, when considering value for purposes of demonstration models, that the measure appropriately account for a number of factors - including but not

[6] See: BIO Comments, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program; Proposed Rule [CMS-1676-P], September 11, 2017 and BIO comments, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model [CMS-1654-P], September 5, 2016.

limited to - other healthcare interventions avoided, patient health outcomes, and overall savings to the healthcare system.

As referenced above, BIO supports VBAs as a novel reimbursement pathway for drugs and biologicals and believes they should be considered central to delivery of care through the new direction of the Innovation Center. However, we note, as we have expressed to CMS previously, the current regulatory paradigm includes a number of hurdles that impact the ability of manufacturers to enter into VBAs. These include Medicaid 'best price' impacts, Medicare Average Sales Price (ASP) considerations, Medicare anti-kickback statute considerations, and Food and Drug Administration (FDA) communication concerns. Despite these hurdles, manufacturers have worked to incorporate value and patient-outcomes considerations into their contractual arrangements, accommodating a patient-centric approach for innovative therapies. In development of VBAs as models through the Innovation Center, CMMI should avoid a one-size-fits-all approach, recognizing the unique circumstances and applications of each therapy in treatment of a specified patient population. VBAs serve as a critical opportunity for manufacturers of drugs and biologics to contribute to transformations in the delivery of healthcare.

BIO cautions CMS against engaging in the development of any demonstration models that place access to critical specialty medicines at risk at the aim of reducing costs, as such proposals do not result in improved care for patients. Over time, there have been proposals raised that would make substantial changes to the delivery of certain therapies for Medicare beneficiaries by shifting drugs and biologicals covered under the Medicare Part B program to the Medicare Part D program, or moving subsets of these drugs. This type of shift has the potential to undermine successful delivery of care to beneficiaries, while increasing beneficiary out-of-pocket costs. CMS should avoid the use of models as a pathway to alter the structure of benefit delivery in this manner, as it is inconsistent with the patient-centered aims of a demonstration project and the significant potential of such models to inappropriately impact patient access.

The Part B program covers drugs generally administered in the physician office setting and that are typically specialty products for treatment of complex diseases (i.e. chemotherapy and other oncology drugs). Physicians receive these therapies directly and bill Medicare and the patient based on a defined cost-sharing structure, with the patient paying no more than 20 percent out-of-pocket. Whereas, Part D typically covers retail prescriptions that a patient picks up and can self-administer, under Part D prescription drug plans patients can be responsible for cost-sharing that can range anywhere from a $0 copayment to a 33 percent coinsurance of the total cost of the product out-of-pocket.[7] By moving even subsets of Part B drugs to Part D, CMMI could risk substantially increasing cost for beneficiaries, leading to deficits in care due to non-adherence and potential increased costs due to hospitalizations, physician office visits, and surgical interventions, and causing confusion for beneficiaries as they navigate their Part D prescription drug plan needs.

[7] Most Part D beneficiaries, half of all PDP enrollees and nearly three quarters of all MA-PD enrollees, are in plans that require them to pay 25%-33% out-of-pocket for certain therapies listed on a specialty tier. See: Kaiser Family Foundation. Medicare Part D at Ten Years: The 2015 Marketplace and Key Trends, 2006-2015. October 2015. Available at: http://kff.org/medicare/report/medicare-part-d-at-ten-years-the-2015-marketplace-and-key-trends-2006-2015/.

Beyond access concerns, models that shift drugs from the Part B to Part D programs present substantial operational and safety challenges. Retail pharmacies that currently deliver Part D drugs are unlikely to be equipped or willing to dispense and deliver Part B drugs that require special handling and storage, presenting safety concerns for patients. BIO believes that these potential access barriers and safety concerns around such a model does not support the new direction of the Innovation Center, do not prioritize quality and patient-centricity, and are inconsistent with statutory requirements for model development. CMMI should not advance demonstration models that may undermine successful delivery of drugs to Medicare beneficiaries. Instead, BIO urges CMS to seek out demonstration pathways that prioritize access to innovative and preventive treatments for which there are current deficits in access.

Additionally, as an aim of this focus area is to "deliver therapies at lower cost", we ask CMS to consider cost not only in terms of overall program spending, but also the implications for beneficiary out-of-pocket costs. BIO encourages the Agency to consider opportunities to improve upon programs that are currently working well, such as Part D, through demonstration models that reduce cost-sharing burden for beneficiaries advancing timely access to appropriate and necessary treatment. CMS could consider, for example, testing improvements in patient access and adherence to a defined subset of drugs for a specific patient population under a Part D benefit design that reduces catastrophic cost-sharing or creates some kind of annual cap on out-of-pocket spending relative to the therapy being delivered. Allowing patients to access critical medicines at reduced cost-sharing levels, particularly for specialty medicines, will improve access, impacting downstream costs by avoiding other healthcare interventions.

An area where CMMI could look to address current deficits in care while delivering therapies at lower cost is through the expansion of access to preventive treatments. BIO urges the Innovation Center to seek out opportunities to improve Medicare beneficiary access to vaccinations by reducing cost-sharing through demonstration models. Currently, there exists a disparity between beneficiary cost-sharing burdens for vaccines covered under Medicare Part B, at no cost-sharing, and those covered under Medicare Part D, where cost-sharing requirements can vary widely.[8] This coverage variance has led to historically lower uptake of those vaccinations covered under Medicare Part D than those covered by Part B.[9] BIO has continued to highlight the importance of reducing cost-sharing barriers to vaccine uptake in our comments on the Part D Call Letter and CMS has encouraged

[8] Cost sharing can range from $14-$102 for Part D covered vaccines, See: Adult Vaccine Coverage in Medicare Part D Plans. Avalere Health. February 2016. Available at: http://go.avalere.com/acton/attachment/12909/f-0297/1/-/-/-/-/20160217_Medicare%20Vaccines%20Coverage%20Paper.pdf.

[9] For example, the herpes zoster vaccine is recommended by the ACIP for all adults aged 60 years and older to prevent shingles. Yet, as of 2015, only 30.6% of adults aged ≥ 60 reported receiving this vaccine, according to CDC data. By contrast, pneumococcal vaccination coverage that same year was 63.6% among adults aged ≥ 65 years. Pneumococcal vaccines are also recommended by the ACIP for the Medicare population but are covered under Part B and are exempt from cost sharing. See: Centers for Disease Control and Prevention. Vaccination Coverage Among Adults in the United States, national Health Interview Survey, 2015. Available at: https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/coverage-estimates/2015.html.

Medicare Part D prescription drug plans to offer vaccines at $0 cost-sharing.[10,11] We believe that Innovation Center models present a distinct opportunity to drive these types of improved cost-sharing arrangements and further demonstrate the value of vaccines as critical preventive services for the Medicare population.

Further, through Innovation Center models, CMS should consider how to improve Medicare Part D vaccination access within the physician office. While some patients seek vaccinations at community sites such as pharmacies, physicians continue to represent a critical access point. As the Part D benefit was designed to provide access to drugs obtained through retail pharmacy, physicians typically do not have billing relationships with Medicare Part D prescription drug plans, nor do these plans have the ability to accept Medicare physician claims. This inability to bill for those vaccines covered under the Part D benefit creates an access barrier for beneficiaries. The Innovation Center should consider opportunities to further demonstrate the public health value of improving vaccination uptake.

2. State-Based and Local Innovation, including Medicaid-focused Model

CMMI notes the central role states play in delivering quality care to their unique populations, and highlights the continued capacity in which the Innovation Center and states have worked in collaboration across several initiatives. BIO believes states represent a critical partner in the delivery of high quality care, particularly to patients served through their Medicaid programs. States provide an opportunity for the testing of models on a small-scale, through more direct coordination, and with the opportunity to make adjustments to fit state- or population-specific needs. BIO supports the development of state-based and local innovations, including Medicaid models where a federal "floor" for model activities is set, to ensure they do not unduly impact patient access to the most appropriate treatment option, and where the key themes outlined at the beginning of this letter – robust and transparent data assessments, stakeholder engagement, scale and scope, and patient protection guardrails – are incorporated.

It is critical that any proposed state innovation model fit the unique local environment(s) of individual states to be effective in decreasing overall healthcare expenditures and improving patient health outcomes. A one-size-fits-all approach to developing and implementing state innovation models would run the risk of ignoring important local circumstances and would prevent the needed flexibility in design to ensure that patient access to care is not compromised. The need for unique models also engenders the need for flexibility with regard to measuring a state's performance under a specific model. Specifically, BIO notes that it would be inappropriate to overlap a standardized set of metrics across all state innovation models. In order to avoid giving the false impression that comparisons are able to be drawn across state innovation models that are developed with a

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[10] BIO Comments 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, March 3, 2017 and BIO Comments RE: Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information, April 24, 2017.
[11] Centers for Medicare & Medicaid Services. 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.

particular state's resources and patient population in mind, we recommend that CMMI establish strict standards for defining the patient populations affected, the interventions employed by the model, and quality of care and overall cost metrics and outcomes that will be measured at the start of each demonstration.

Additionally, in assessing whether a state innovation model is feasible, CMMI should ensure that the state has the data infrastructure to collect the appropriate information and monitor program integrity from participating providers and patients, and the extent to which the participating providers are able to report required metrics in a timely, standardized manner. BIO encourages CMMI to require states participating in innovative models to establish mechanisms to collect provider and patient experience data, in a manner that is appropriately tailored to each State's specific needs.

Further, any model seeking to make changes to the delivery of care within the context of state Medicaid programs must abide by the stated purpose and requirements of Section 1115,[12] such as:

- Expanding eligibility to individuals who are not otherwise Medicaid or CHIP eligible;
- Providing services not typically covered by Medicaid; or
- Using innovative service delivery systems that improve care, increase efficiency, and reduce costs.

These requirements are intended to increase the strength of overall coverage for low-income individuals in the state; increase access to, stabilize, and strengthen provider networks available to serve these populations, improve health outcomes, and increase the efficiency and quality of care through such transformations.[13] BIO supports state flexibility in achieving these aims, but urges CMMI to implement appropriate means to ensure demonstration models through this waiver flexibility prioritize access to appropriate care and treatment, avoiding arbitrary limitations such as through application of formulary restrictions, by setting a federal basis upon which proposed state and Medicaid models will be evaluated.

Finally, as stated above, BIO supports the use of VBAs in delivery of innovative drugs and biologicals, a reimbursement tool that can play a critical role in advancing access in state Medicaid programs. As we note, current regulatory hurdles hinder the development of such models, and we encourage CMS to seek opportunities to address and work through these concerns to advance value-driven access to medicines.

3. Program Integrity

CMS is seeking feedback on ways to reduce fraud, waste, and abuse and improve program integrity through the Innovation Center. One issue that could benefit from creativity under a CMMI demonstration is to find ways to address the duplicate discount prohibition as established by the 340B Drug Discount Program. Although the 340B statute seeks to avoid duplicate discounts by prohibiting covered entities from billing Medicaid for a

[12] About Section 1115 Demonstrations. Available at: https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html.
[13] Id.

unit of a drug purchased at the 340B price, it remains possible for a manufacturer to sell a unit of a drug to a covered entity at the discounted 340B ceiling price, only to subsequently receive a rebate invoice from a state Medicaid program for a Medicaid rebate on that same unit – resulting in a duplicate discount. Covered entities are statutorily required to have mechanisms in place to avoid this; however, it is well documented that states' methods are often inaccurate and incomplete. Although largely under the purview of HRSA, covered entity compliance with the duplicate discount prohibition requires CMS and HRSA to work together to improve accuracy of reporting mechanisms and rebate invoices.

In order to ensure that state Medicaid programs are accurately and appropriately seeking rebates on both Medicaid Fee-for-Service (FFS) and managed care organizations (MCO) utilization – while excluding products purchased at the 340B price – it is necessary that state Medicaid programs report certain summary-level utilization data points to manufacturers, and that these summary-level data are verifiable by both states and manufacturers on the basis of claims-level data. In fact, in a June 2016 report, the Office of Inspector General (OIG) recommended that CMS require states to use claim-level methods to identify 340B claims when collecting Medicaid rebates.[14] Other ways to improve program integrity could involve using a specified 340B identifier for claims and MCOs and their contractors passing that information through to the state in monthly utilization files as well as MCOs using unique BIN/PCNs to clearly identify beneficiaries of Managed Medicaid for pharmacies to flag as potential 340B claims. With this in mind, CMMI should develop a demonstration project through which to test ways to improve program integrity within the 340B program related to the duplicate discount prohibition by encouraging improved state compliance and reporting.

Beyond the considerations for appropriate collection of rebates in interactions with the 340B program, we ask CMMI to consider opportunities to address the uncertainty that exists in accurately forecasting Medicaid rebates for managed care and physician-administered drug utilization. Currently, manufacturers must forecast and hold funds for these rebate payments, and can be placed in situations where they must carry over these reserved funds if a state fails to submit timely or complete rebate invoices, as there is no set time limit for state submissions. This carryover and backdated invoice claims can lead to problematic accounting considerations, particularly when the lack of claims level data from the state makes invoice verification difficult.

Though many states have begun using third-party vendors to manage their Medicaid covered outpatient drug invoicing process, which can improve efficiency and compliance, challenges remain. BIO encourages CMMI to seek improvements to state Medicaid covered outpatient drug invoicing and rebate processes by considering an audit of third-party vendors in use to identify best practices and program improvements; ensuring states are submitting managed care utilization in a timely manner;[15] using mechanisms to ensure accurate invoice submissions and improve claims level data to support utilization on Medicaid covered outpatient drug invoices; and creating pathways for states to enter into innovative arrangements with manufacturers to aid in program integrity and rebate completeness by addressing regulatory hurdles. These potential improvements through the

[14] Office of Inspector General. State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. June 2016. Available at: https://oig.hhs.gov/oei/reports/oei-05-14-00430.asp.
[15] 81 FR 27497: Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability. May 6, 2016.

Innovation Center will help ensure the integrity and accuracy of the Medicaid drug rebate program for both states and manufacturers.

4. Medicare Advantage (MA) Innovation Models

CMMI expresses the desire to "work with Medicare Advantage (MA) plans to drive innovation, better quality and outcomes and lower costs" as a part of the new direction activities, which include considerations around incentivizing plans to compete for beneficiaries through transparency in plan quality and cost.

BIO supports innovation models that improve beneficiary access high-quality, high-value MA plans. However, in the context of potential MA demonstration model design, we caution against increased flexibility for application of utilization management tools for coverage of drugs and biologicals. We find that such tools do not fall within the context of demonstration projects as they do not address a specific deficit in care and instead apply arbitrary limitations on access to medicines. These tools can impede rather than maintain or improve care with the potential to cause serious negative health consequences for patients who cannot access the most appropriate course of treatment for their given condition in a timely manner. In working with MA plans, BIO implores the Innovation Center to take a comprehensive approach to improve the overall benefits and care provided to beneficiaries and avoid singling out drugs and biologicals through plan design that impedes and/or compromises patient access to care.

Additionally, as highlighted above, we believe MA plan models present an additional opportunity for CMMI to increase uptake of vaccinations through providing the full complement of recommended vaccines for the beneficiary population they serve at $0 cost sharing levels. Using MA plans to increase vaccination uptake can help improve quality of care delivered and reduce overall healthcare expenditures through avoided downstream interventions.

5. Expanded Opportunities for Participation in Advanced APMs

In the RFI, CMS references the Innovation Center's central role in the development of operations and policies governing Advanced Alternative Payment Models (APMs) under the Medicare and CHIP Reauthorization Act of 2015 (MACRA). CMS discusses the expectation that APM participation will continue to grow and seeks feedback on increasing opportunities for eligible clinicians to participate.

In assessing how to encourage additional participation, BIO suggests CMMI analyze the ways in which certain providers may be disadvantaged – both in existing Advanced APMs and any proposed models – and therefore, discouraged from participating. For example, certain specialty providers who see patients with greater healthcare needs, and therefore, increased healthcare costs, may have a hard time participating in models whose metrics and quality measures are only applicable to general practitioners. One way to assist these providers is to risk-adjust any included expenditure benchmark in order to ensure that providers are not unduly penalized for aspects of patient care – like underlying health status – which they cannot influence. Moreover, effective risk-adjustment is a necessary

component to developing a model that does not incentivize the underutilization of appropriate care or the "cherry-picking" of the healthiest patients.

As we have detailed, the development and potential expansion of existing or new APMs must be transparent and solicit stakeholder feedback throughout the process. Specifically, BIO urges CMMI to identify, refine, and allow stakeholders to provide feedback on a risk-adjustment methodology that is sufficiently robust to ensure that comparisons between providers, and even between the historical and current expenditures of a single provider practice, accurately account for the care over which the provider has influence. This will ensure providers are able to deliver high-quality care to patients with complex health conditions beyond provider control, without risk of penalty.

6. Physician Specialty Models

In addition to the aims of increasing provider participation in Advanced APMs, CMS specifically seeks feedback on the ability of specialty physicians to participate in APMs and the application of appropriate quality measures. Further, CMS references the potential to test models before the Physician-Focused Payment Model Technical Advisory Committee (PTAC).

BIO supports CMS's aim to increase the ability of specialty physicians to participate in APMs as these providers serve a critical role in caring for patients, who often have above-average healthcare needs and costs. For this reason, any model directed at specialty physicians must take into account the diverse population seen by the array of available specialty providers. As expressed in our comments in response to the 2018 Quality Payment program Proposed Rule,[16] BIO is concerned that comparing different types of providers within the same benchmark has the potential to disadvantage certain provider specialties and sub-specialties who see patients who require more complex care.

Specifically, we believe that any physician specialty models should make peer-to-peer comparisons within provider specialties and sub-specialties in order to more accurately and appropriately capture the quality of care being delivered to patients. In ensuring these appropriate comparisons, we urge CMMI to work directly with measure stewards, provider groups, and patient stakeholders to ensure the quality measures being applied to specific Advanced APMs are relevant in the context of the care delivered by these practitioners. This type of measure development will be a key component of a robust stakeholder engagement process, as outlined at the outset of this comment letter, for models of this type.

Additionally, in the development of physician specialty models, we caution CMMI against prematurely relying on components of existing models in the development of new models until robust data has been collected and assessed, and stakeholder feedback has been incorporated. Specifically, the RFI references "possibly incorporating elements from the existing Oncology Care Model (OCM)." BIO has concerns about outstanding issues in the OCM that should be addressed – both in moving forward with the OCM and as a basis for consideration of future model development. Further, we are concerned by the Innovation

[16] BIO Comments RE: Medicare Program; CY 2018 Updates to the Quality Payment Program [CMS-5522-P]. August 21, 2017.

Center's reference to "models that would test prepayment for Medicare and Medicaid beneficiaries receiving cancer care."

First in considering the development of future models, we caution CMS against the reliance on the OCM as a framework, given the infancy of the model in generation of data on model impacts and the model's reliance on historic data, including the lack of robust patient-reported outcome measures and the inability of the model to capture multiple incidents per patient. Additionally, we find the aggregate novel therapies adjustment to be insufficient, creating potential uncertainty for participating physicians. For these reasons, BIO believes that the OCM does not currently serve as an appropriate basis for future model development, without further data analysis and design refinement. We also believe that the reference to a prepayment approach is problematic, as these payments may not sufficiently or accurately reflect the cost of delivering the most appropriate course of treatment for each cancer patient, particularly as new therapeutic options are developed.

Furthermore, CMS references the potential testing of payment models before the PTAC – whose process for obtaining public feedback also requires further refinement.[17] Broad stakeholder input – at multiple points in the model development process, or at the very least, before CMMI seeks applications for a new model – is as important in the thoughtful development of demonstrations as it is to potentially permanent changes in policy: the more efficiently, and well-developed the model, the more CMMI and stakeholders stand to benefit from the information derived from its implementation. This applies to both innovation models under consideration and the PTAC process.

To that end, BIO recommends a public comment period of at least 30 days for PTAC proposals in order to allow an inclusive process for all interested stakeholders and adherence to a standardized stakeholder comment process, as outlined, should the model be considered for use by the Innovation Center. Models, whether derived from the Innovation Center directly or through PTAC, should be held to the same statutory requirements and data robustness, size and scope considerations, patient guardrails, and stakeholder feedback processes outlined to ensure integrity and equity in model design.

7. Mental and Behavioral Health Models

The RFI references CMMI's interest and intent to explore models in the mental and behavioral health space, including considerations around addressing opioid addiction, substance use disorders and dementia, and related conditions.

CMS has noted the intent of developing models in this area through the previously discussed Summit held on potential behavioral health innovations. BIO believes that in development of models in this space CMS should consider the impact of innovative treatments in improving health outcomes and reducing other healthcare interventions and expenses, the role of early detection for timely initiation of care and treatment, the importance of providing support to caregivers of patients with these conditions, and as expressed throughout the course of this letter, the importance of engaging a broad range of stakeholders in development and delivery of behavioral health models.

[17] See: BIO Comments RE: Oncology Bundled Payment Program Using CNA-Guided Care. April 27, 2017.

In considering models targeted at addressing opioid abuse and addiction, BIO supports efforts that ensure patients suffering from pain or addiction are able to receive the right treatment at the right time with the right support, without stigma. We encourage the Innovation Center to work in partnership with other organizations engaged in addressing America's opioid crisis to advance understanding of the complex diseases of pain and addiction, ensure optimal use of existing therapies, and enable the development of and access to innovative treatment options.

* * *

BIO appreciates the opportunity to comment on this Request for Information for the new direction of the Innovation Center. We support the Agency's efforts to drive improvements in care quality and patient centricity through demonstration models developed from robust and transparent data assessments, that employ broad stakeholder engagement in their development and implementation, are appropriate in size and scope, and ensure that quality of care is maintained or improved through patient guardrails. We look forward to working in partnership with the Agency to address the items raised in this letter. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Sincerely,

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