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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: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model [CMS-1695-P]

Dear Administrator Verma,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (Proposed Rule), including the Request for Information on Leveraging Authority for the Competitive Acquisition program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (the RFI).

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. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we closely monitor changes to Medicare's reimbursement rates and payment policies for their potential impact on innovation and patient access to drugs and biologicals. Our comments on the Proposed Rule are outlined below.

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I. Requests for Information on Leveraging the Authority of the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model.

Building on the comments received in response to the Administration's American Patients First Blueprint for drug pricing (Blueprint), the Agency seeks "additional and more specific feedback on a potential model design that would accelerate the move to a value-based health care system building upon the CAP established under section 1847B of the Act", the RFI includes feedback on items such as the model's design, potential providers and suppliers to be included or excluded, the role of private-sector vendors, beneficiary populations to be addressed in the model, and appropriate patient protections.

BIO appreciates the Agency's continued engagement with stakeholders on items solicited through the Blueprint comment process, and the acknowledgement that this feedback has

been helpful to the Administration. As previously stated in our comments in response to the Blueprint and discussed in more detail below, BIO and our members are committed to continuing to engage with the Agency to meet the Administration's goals of improving competition, supporting better negotiation, and reducing out-of-pocket (OOP) spending for patients in a manner that (1) ensures patient access to the highest standard of treatment is not disrupted; (2) promotes holistic, market-driven solutions; and (3) sustains future biopharmaceutical innovation.

We believe that the questions detailed in this RFI fall into three distinct categories, and we address our thoughts on each of these in turn:

1. Leveraging the existing Competitive Acquisition Program Authority

2. Delivering Value-Driven Care through Value-Based Arrangements

3. Reimbursement of New, High-Cost Therapies

1. Leveraging the existing Competitive Acquisition Program Authority (CAP)

Building on the questions posted in the Blueprint, the Agency seeks additional stakeholder feedback specific to utilizing the CAP authority to foster better negotiation, improve quality of care, and reduce Medicare expenditures and patient OOP costs. BIO supports the goal of creating solutions that reduce patient OOP costs and improve care quality, and we are committed to working with the Agency to meet these goals. However, we have concerns where such proposals to create new methods of delivery and reimbursement for Part B drugs through innovation models, if not carefully designed, can impede patient access to the most appropriate form of treatment for their given condition, and create additional financial or administrative barriers for physicians providing care to these vulnerable beneficiaries.

The previous CAP failed to effectively work for providers, vendors, and patients, or to produce the desired savings and outcomes.[1] The program failed to attract and maintain sufficient participation from both vendors and providers, and payment amounts for drugs were higher than under the standard Average Sales Price (ASP)-based reimbursement structure. Further, we have concern with specific design elements and lack of sufficient detail around the Medicare Payment Advisory Commission's (MedPAC's) proposed Drug Value Program (DVP) as discussed relative to the CAP authority, expressed in our April 2017 letter to MedPAC.[2] This past experience with the CAP demonstrates the complexity of setting up alternative distribution and reimbursement models for the medicines delivered under the Part B program. BIO strongly urges the Agency to take a measured approach that considers and appropriately analyzes the full range of impacts of any models, particularly with regard to patient access to appropriate treatment and the interaction with other ongoing payment and delivery models (e.g., the Oncology Care Model).

An area of particular concern for BIO in the aim of facilitating timely access to the most appropriate care is the implementation of utilization management (UM) tools to govern the

[1] Evaluation of the Competitive Acquisition Program for Part B Drugs, Final Report. Prepared by RTI International for the Centers for Medicare & Medicaid Services, Office of Research Development and Information. December 2009.
[2] BIO Comments, RE: January and March 2017 MedPAC Meeting and Discussed Policy Proposals for the Medicare Part B Program, April 4, 2017.

delivery and coverage of Part B medications. The complex medicines delivered in this component of the benefit are intended for treatment of some of the most serious health conditions, such as cancer, autoimmune disorders, end stage renal disease, and hemophilia. Further, many of these treatments interact dynamically with patients' immune systems or vary based on their individual genetic profiles, which means that an individual patient can fare better or worse on a treatment (in terms of efficacy and side effect profile). In other words, one size does not fit all.

UM can present barriers to accessing timely and appropriate treatment for the vulnerable patient population in Medicare. The program is designed to serve the elderly and disabled – many of whom have complex healthcare needs. Fundamentally, BIO has serious concern with subjecting these beneficiaries to UM processes, such as requiring that patients step through or fail on other therapies, before using the physician's preferred choice in treatment. The use of UM interferes with the patient-physician relationship and decision-making process in determining the most appropriate course of treatment for very serious diseases.

For these reasons, we were extremely concerned to see the use of one such UM tool in Medicare Advantage (MA) as detailed in the August 7th memo permitting step therapy.[3] BIO registered our opposition to this significant change in policy direction for the Medicare benefit in a letter to the Secretary dated September 10th.[4] Of particular concern is the lack of specificity or detail around critical patient protections to ensure use of the most clinically appropriate therapy, how the exceptions and appeals process should be structured, what constitutes a "new" prescription for purposes of applying step therapy, and a lack of requirements to inform and educate beneficiaries on the meaning of step therapy prior to their enrollment. Such tools, especially without appropriate parameters or guardrails, can have the effect of forcing inappropriate treatment choices and affecting patient health outcomes. We urge the Agency to withdraw this memo, or at a minimum implement important patient protections, as outlined in our letter, for beneficiaries accessing Part B drugs in the MA program. Further, we strongly oppose the use of step therapy in any models developed under the CAP authority.

If the Agency is to move forward on the development of innovation models utilizing the CAP authority, it is critical that any such model designed be voluntary, limited in scope, workable for physicians, and not create access barriers for patients. BIO urges CMS to limit any model tests under the authority of the Center for Medicare & Medicaid Innovation (CMMI) to populations and disease states with identified care deficiencies, where a model would both improve outcomes and reduce costs, as required by statute. As we've previously stated in comments to the Agency, CMS should publically share data and assessments of a model before any expansion under the requirements of Section 1115A(c) of the Social Security Act (SSA).

BIO strongly urges CMS to take a thoughtful, measured approach in testing alternatives to the existing structure of buy-and-bill. If the Agency moves forward with one more model tests, these should include design elements that support a competitive, market-driven approach, while ensuring patient access to the most effective form of treatment.

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[3] Memorandum from CMS Administrator Seema Verma to Medicare Advantage Organizations, RE: Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. August 7, 2018.
[4] See: BIO letter to Secretary Azar, RE: Step Therapy for Part B Drugs in Medicare Advantage. September 10, 2018.

Specifically, we urge the Agency to appropriately address the following as it considers development of any potential model:

Adequate protections for patient access to clinically appropriate care and lowering costs to beneficiaries: We encourage the Agency, under any model developed, to ensure that adequate patient protections are in place to avoid any delays in care or use of inappropriate treatment, and to ensure transparency for beneficiaries. As noted, BIO has serious concern with the use of UM tools in Part B, as this can harm patient access to the most appropriate therapy. We encourage the Agency to provide a process by which beneficiaries can better understand the use of delivery models in their care, including the opportunity to opt-out if the model design could negatively influence treatment decisions, and means to provide feedback or highlight concerns to the Agency around the provision of care. Further, in designing models CMS should ensure that new means for reimbursement or delivery of drugs do not increase beneficiary cost-sharing obligations.

Not creating interference that erodes the existing coverage and reimbursement structure: The purpose of innovation models are to test new alternatives for the delivery of care and services to improve care quality while reducing cost. We believe that CMS should not implement simultaneous changes to the current Part B buy-and-bill reimbursement structure, where ASP plus six percent provides adequate reimbursement to deliver these highly specialized medicines to patients, which may force a choice in entering into the model. In addition, it is essential that CMS exclude discounts provided under a CAP program from calculations of ASP, Average Manufacturer Price (AMP), and Best Price (BP) to avoid unintended effects on the buy-and bill system, and that the Agency ensure any price negotiations through such a program remain confidential. CMS should issue guidance clearly detailing how the model's fees and payment structure will be excluded from price reporting. Transformations in the healthcare system require that models are tested for their appropriateness without the influence of external pressures for participation.

Encouraging robust competition and avoiding misaligned incentives: Any models developed should properly address attracting a sufficiently large number of intermediaries, without creating inappropriate incentives that may dictate either participation or choice of treatments delivered through new models. These include ensuring that treatment choice is not limited in a manner that may make participation less attractive to potential providers through UM or other means. Further, vendors should be reimbursed on a fixed fee – that appropriately represents the administrative costs associated with drug and biological products - to avoid creating misaligned incentives for supply chain middlemen under a new competitive acquisition style program.

***Ensuring workability for physicians who may choose to participate*:** As detailed, model participation should be voluntary, and physicians should have flexibility to opt out if the program does not work for them, or change the intermediary/vendor(s) with whom they are working with if they are not satisfied. Further, CMS should acknowledge that practitioners will still need to be reimbursed sufficiently to account for drug management and care requirements. These include,

but are not limited to, storage, handing and administration of drugs and biologicals and establishing new processes necessary to participate in a new model (e.g., new health information and claims processes, maintaining dual inventories for Medicare and non-Medicare patients, and managing returns related to unused drugs). Any new method under a model that shifts from the current buy-and-bill structure to pay physicians for such services should fully capture the scope of services provided, including drug administration and oversight of patient care.

Considering appropriate exemptions for certain drugs and biologicals from such models: In developing models using this authority, CMS should consider exemptions to ensure models are appropriately meeting beneficiary healthcare needs and to avoid potential interference with other ongoing innovation models. In the CAP, certain classes of drugs were excluded from the program.[5] CMS should exclude the same drugs, as well as make additional drug exemptions where significant savings are unlikely and/or there is a potential risk of impeded beneficiary access. The Agency should exempt orphan and rare disease indicated products as they may not be well-suited based on the limited number of options for patients and their role in addressing unmet medical need – where savings potential is limited and could unduly harm access.[6] Further, drugs and biologicals, as well as physicians, currently being included in other ongoing innovations (e.g., Oncology Care Model) should be considered for exemption to avoid interaction of models and confounding results. CMS should also consider that classes with few or no therapeutic alternatives would not be appropriate for such a model. The Agency should further rely on data collection and analysis and stakeholder feedback to make and update potential exemptions throughout the course of the model to ensure it is appropriately meeting patient needs.

Transparency in model design, development, and assessment processes: Consistent with our comments on CMS' new direction for the Innovation Center,[7] we believe all CMMI models should: utilize robust and transparent data assessment in the development and evaluation of CMMI models; delineate a clear stakeholder engagement strategy for collection and incorporation of feedback, both in model development and implementation; assure the demonstration model represents a true test: in size, scope, and design, models should not be used concurrently in a manner that can obscure results; and incorporate appropriate patient guardrails to ensure quality, patient-centric care is being delivered through demonstration models – with a mechanism in place to discontinue the model if it is not producing the desired outcome or has negative impacts for patient access, health outcomes, or OOP costs. Additionally, to ensure any such voluntary model designed through CAP authority is meeting the stated goals, and workable for participating entities, we recommend CMS establish an Advisory Board composed of physicians, manufacturer representatives, patient groups, and distributing entities to address important design

[5] The authorizing statute for the CAP, the Medicare Modernization Act, specifically excluded immune globulins, blood products (other than blood clotting factor), and drugs administered through durable medical equipment. Subsequent regulations extended the exclusions to blood clotting factors and a number of other therapies. CMS should look to these same exclusions for purposes of using the CAP authority. See: SSA § 1847B(a)(1)(D), 70 Fed. Reg. 39022.
[6] CMS should align with the presumptive carve-out for orphan drugs as implemented for the original CAP. See: 42 CFR 414.906(f)(2)(B).
[7] See: BIO Comments RE: Centers for Medicare & Medicaid Services: Innovation Center New Direction. November 20, 2018.

questions and facilitate assessment of outcomes to ensure shared goals of the program are met.

These principles serve as a basis for the development of Innovation Center models using the CAP authority. Further, given the breadth of the feedback still being sought at this point, and with the recent release of significant policy change in the MA program without sufficient detail or comment period, it is critical that CMS use a notice and comment process in proposing any model through CAP or Innovation Center authority. Such feedback is critical for CMS to understand the full range of potential model implications and to consider improvements and modifications. Again, BIO is committed to working with the Administration on market-driven solutions that preserve timely and appropriate patient access to innovations in treatment while better aligning cost of care to the value derived.

2. Delivering Value-Driven Care through Value-Based Arrangements

Specifically, in discussing the CAP authority and development of a potential innovation model, CMS references allowing private-sector model vendors to enter into and administer value-based arrangements (VBAs) with manufacturers of separately payable Part B drugs, and asks if such arrangements can improve beneficiary access and quality of care while reducing Medicare expenditures. As we have expressed in previous comments and our response to the Blueprint, BIO is a strong supporter of facilitating VBAs. To fully realize their potential, however, changes to existing regulatory barriers are necessary. As medical treatments and interventions continue to become more personalized to a patient's need and emphasis is placed on moving from volume to value in providing care, BIO believes that the expansion of the use of VBAs can play a role in achieving these goals.

We believe that the critical first step in facilitating the development of VBAs is to modernize the regulatory structure to create a predictable environment for use of VBAs, particularly around government price (GP) reporting, including best price (BP), and Anti-Kickback Statute (AKS) considerations, which many stakeholders in the healthcare continuum have agreed are regulatory impediments to successful implementation of VBAs.[8,9] Through such modifications, CMS can facilitate development of VBAs for delivery of care in the Medicare and Medicaid programs. To this end, we appreciate the Agency's recent actions to collect information on how to address regulatory provisions that may act as barriers to value-based care, on which BIO will be providing further comment.[10] We urge CMS to continue to work with manufacturers on the development of VBAs, and to make these changes in order to unlock the full potential of VBAs across markets.

In considering the use of innovation models for facilitation of VBAs, we note that CMS must address some of the important hallmarks, as outlined above, for model development, implementation, and assessment – including stakeholder consultation, robust data assessment processes, and ensuring models are selected and implemented that meet the CMMI aims of maintaining or improving patient access, including to new, innovative drugs and biologicals – prior to use of these models. While models designed through CMMI or via the CAP authority may serve as a venue to facilitate certain VBAs, BIO is committed to

[8] Regulatory Barriers Impair Alignment of Biopharmaceutical Price and Value. National Pharmaceutical Council, 2018.
[9] Reward Results: Moving Forward on Value-based Contracting for Biopharmaceuticals. Network for Excellence in Health Innovation, March 2017.
[10] 83 Fed. Reg. 43607 (August 27, 2018).

working with the Agency to address these and other concerns in facilitating the use of VBAs more broadly. We would be concerned if the regulatory barriers are not addressed and the use of CAP model authority is used as the only opportunity for the development of such arrangements. The parameters of an innovation model through CAP authority can vary greatly and impact the ability of participating entities and manufacturers to enter into or participate in VBAs, particularly without associated update s around GP and AKS regulation.

Again, BIO believes that VBAs can play a central role in the future of how healthcare is delivered and reimbursed. New and innovative therapies target the underlying cause of the disease and are often able to substantially mitigate, and in some cases, cure a devastating chronic or life-threatening illness after a single treatment (i.e. transformative therapies). For some of these therapies, VBAs could serve to mitigate payers' short-term risk, promote patient access, and reward innovation, in turn, sustaining the innovation ecosystem. We believe that addressing the regulatory barriers is a critical first step to facilitating VBAs in Medicare, and look forward to continuing to work with the Agency on how innovation models can most appropriately serve as one of many pathways for VBAs.

3. Reimbursement of New, High-Cost Therapies

In discussing implementation of an Innovation Center model, either by leveraging CAP authority or such as through the MedPAC proposed DVP, CMS asks whether testing these approaches may be appropriate for certain drugs and biologics, including high-cost drugs. BIO recognizes that there are a number of considerations to be made for coverage and reimbursement of new, innovative treatments and we would like to continue to work with the Agency on efforts to ensure appropriate reimbursement and access for these "transformative therapies" in both the short- and long-term.

"Transformative therapies" are new, innovative treatments that represent a significant benefit and value for patient health outcomes and overall delivery of care. These therapies generally address very serious diseases with high unmet medical need; serve small patient populations, including rare and orphan diseases; and can provide a substantial, durable health benefit. These therapies include cellular or gene therapies that are truly personalized medicines targeting treatment to specific patient populations or subsets of patient populations.

In addition to the reference to new, high-cost therapies in the Proposed Rule, CMS referenced the RFI in the Medicare Inpatient Prospective Payment System (IPPS) when sharing the Agency's consideration of proposed and requested payment updates for coverage of CAR T-cell therapies in the inpatient setting. Specifically, CMS stated:

> "Given the relative newness of CAR T-cell therapy, the potential model, including the reasons underlying our consideration of a potential model described in greater detail in the Calendar Year (CY) 2019 OPPS/ASC proposed rule, and our request for feedback on this model approach, we believe it would be premature to adopt changes to our existing payment mechanisms, either under the IPPS or for IPPS-excluded cancer hospitals, specifically for CAR T-cell therapy. Therefore, we disagree with commenters who have requested such changes under the IPPS for FY 2019, including, but not limited to, the creation of a pass-through payment; structural changes in new technology add-on payments for the drug therapy; changes in the

> usual cost-to-charge ratios (CCRs) used in rate setting and payment, including those used in determining new technology add-on payments, outlier payments, and payments to IPPS excluded cancer hospitals; and the creation of a new MS–DRG specifically for CAR T-cell therapy prior to gaining more experience with the therapy."[11]

BIO was disappointed to see the Agency take such an approach in the final rule related to the reimbursement of this new innovation in treatment, making only a minor update to the Medicare Severity-Diagnosis Related Group (MS-DRG) reimbursement structure, rather than implementing a number of the more substantial updates considered in the IPPS Proposed Rule that would have significantly improved Medicare beneficiary access for these critical medicines. We believe there was room for the Agency to provide temporary updates to the inpatient payment structure for CAR T, while continuing to work with stakeholders on long-term solutions for these innovations. BIO recommended several short-term solutions to meet these goals in our comments on the IPPS Proposed Rule.[12]

Given the benefit of this therapy in a patient population with limited treatment options, BIO was incredibly concerned to see CMS rely on the potential use of the CAP authority as the pathway for payment and coverage of CAR T, rather than making an appropriate update to the IPPS for 2019 and considering solutions for long-term reimbursement. As explored above, while we agree that VBAs could be appropriate for some treatments and under specific circumstances, we do not believe that a demonstration or new payment model can or should serve as the basis for Medicare reimbursement generally for these therapies and other future therapies with similar health benefit and delivery considerations.

First, we remind CMS that at present, nearly all CAR T therapies are being delivered in the inpatient setting, while this RFI is connected to payment policies for the outpatient setting. Additionally, the CAP authority applies specifically to Part B drugs delivered in the physician office setting. Second, while we acknowledge that there are challenges in creating a long-term solution for CAR T payment in the inpatient structure and that stakeholders had varying views on the most preferable payment pathway, there were a number of short-term solutions present that would have provided appropriate access and payment at least for fiscal year (FY) 2019. The Agency then could have continued to engage with stakeholders to develop an appropriate means to transition to a long-term payment structure for FY 2020.

We strongly urge the Agency to engage in parallel activities—soliciting feedback on the development of novel payment approaches for transformative therapies in the broader context of the Medicare program and providing an adequate payment rate in the inpatient setting for CAR T. Such an approach will allow CMS to benefit from the collection of critical data to inform future updates to the reimbursement structure to account for CAR T and other transformative therapies, while ensuring that patients with serious disease are able to access the highest standard of treatment for their health conditions.

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[11] 83 Fed. Reg. 41144, 41173 (August 17, 2018).

[12] BIO urged CMS to use the proposed cost-to-charge ratio (CCR) of 1.0 alongside payment for CAR T therapies, and noted that the development of a new Medicare Severity Diagnosis Related Group (MS-DRG) was the preferred approach for a long-term solution, providing predictability and stability for physician's delivering these critical medicines and the required associated care. We detailed that while such payment methodologies are being developed, a short-term solution such as separate payment for the drug product, could help in ensuring appropriate and timely uptake of treatment, while generating useful data for CMS in setting a payment rate consistent with the current inpatient reimbursement system.

We encourage CMS to begin an open stakeholder dialogue to consider both how the existing reimbursement system can be updated to account for future "transformative therapies" and for the development of alternative approaches to pay for these medicines that meet the shared goals of reducing healthcare expenditures while improving patient access to treatments that improve health outcomes. It is critical that the Agency work in parallel, providing reimbursement updates when new innovations in treatment become available, while considering alternative reimbursement methods that are appropriate to that therapy and patient population. Further, the Agency must consider how other entities in the Medicaid and commercial markets rely on CMS' decision-making around reimbursement for purposes of development of their own reimbursement policies. CMS, through working with stakeholders, can help ensure patient access to timely and appropriate treatment with "transformative therapies" across the healthcare system.

II. BIO maintains concern with CMS' continued use of packaging policies, as they have the potential to limit patient access to innovations in care and treatment.

CMS continues to promote the Agency's use of packaging policies, stating that "combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves".[13] While BIO believes that efficiency and flexibility are important goals of the Medicare program, packaging policies have the potential to create perverse incentives that could unintentionally limit patient access to certain services and care. Moreover, these potential access issues created by packaging are not necessarily ones that can be identified by a decline in volume of packaged services. Instead, these issues occur when patients do not receive the most clinically appropriate drug, biological, or service that could be provided as one component of a larger package of services because providers and practitioners could be incentivized under packaging policies to make choices that prioritize minimizing costs relative to their expected payment over clinically appropriate care personalized to the patient.

These potential access issues are ever the more important as the healthcare system continues to move toward the delivery of more personalized medicine. BIO urges CMS to consider how to best account for and encourage the use of new innovations, including reconsideration of or updates to packaging policies. We believe CMS should provide continued opportunity for stakeholders to weigh in as new drugs, biologicals, and services come to market to ensure appropriate reimbursement rates in a manner that helps to advance patient access to these innovations.

III. CMS should not finalize the reduction in reimbursement for new drugs when ASP data are not available.

Synonymous with the change in the Physician Fee Schedule (PFS) Proposed Rule, CMS is again proposing to reduce reimbursement for new drugs during the timeframe when ASP data are not available, moving from the existing rate of Wholesale Acquisition Cost (WAC)

[13] 83 Fed. Reg. 37064 (July 31, 2018).

plus 6 percent to WAC plus 3 percent starting in CY 2019.[14] BIO opposes the implementation of such a reduction in payment for new drugs delivered in the Part B program.

As the Agency is aware, drugs delivered through this component of the Medicare benefit include those that require special handling and delivery, and typically administration under a physician's care and supervision (e.g., intravenous infusions, intraocular injections). These therapies, which are generally biologic products, are delivered directly to physicians who then administer them to patients and then bill Medicare. Under the existing reimbursement structure, add-on payments to ASP and WAC are intended to reimburse physicians for these associated care delivery and pharmacy services. Further, we remind CMS that this add-on payment would be 1.35 percent rather than 3 percent given the impacts of the sequester cuts.

Reducing the add-on payment during the timeframe when a drug or biological is newly introduced to the market can have an impact on uptake of new innovations in treatment and ultimately patient access to new medicines that may be the most clinically appropriate for their given condition. Such a reduction is of particular concern in the context of drugs for rare diseases, many of which have few, if any, on-label therapeutic substitutions. Failure to provide a sufficient add-on payment to cover the associated administrative components of delivering Part B drugs and biologicals and not providing parity in payment policy between new and existing medicines will result in diminishing patient access to innovative treatments and potentially chill investment into new innovation. Additionally, while there may be differences between a product's WAC and ASP, the use of WAC is generally limited to the first two quarters while a product's ASP is being determined. The MedPAC data detailed in the proposed rule demonstrates the market-based nature of the ASP payment structure. Following that initial use of WAC-based payment, Medicare is able to benefit from the discounts negotiated in the private marketplace through lower ASP amounts.

Further, we are concerned with the implementation of the proposed policy, which combines Medicare Administrative Contractor (MAC) discretion to determine payment rates for products without a published ASP alongside the Agency's apparent discretion around publication of ASP data reports. While the proposed reduction to WAC-based payment for CY 2019 is only a 3 percent reduction, greater reductions could be proposed and implemented in future years under such a policy. Additionally, new therapies are further impacted by the lack of regulation related to when and how the Not Otherwise Classified Pricing File applies to new therapies. These considerations taken together can have significant impacts on access to new medicines for patients.

The Proposed Rule also discusses the potential concerns raised around revenue generation from the ASP (and WAC) add-on by incentivizing the use of more costly drugs and biologicals. BIO believes there is no evidence to support the assertion that providers may be selecting therapies based on the potential to generate revenue based on the add-on to different products, rather than selecting and delivering the best treatment for each patient's disease state.

[14] CMS notes that the proposal does not include WAC-based payments for single-source drugs where the payment is set in statute.

IV. BIO Supports Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Packaged Drugs and Biologicals at ASP+6%.

For CY 2019, CMS proposes to continue the CY 2013 policy of paying for separately payable drugs and biologicals at ASP+6%, referred to as the "statutory default."[15] The SSA directs CMS to pay for SCODs at either the "average acquisition cost of the drugs for [the] year," as determined by the Agency using survey data,[16] or—if such survey data are not available—based on "the average price for the drug in the year" established under section 1842(o), section 1847A, or section 1847B, as applicable.[17]

BIO supports the Agency's proposal for CY 2019 because it is consistent with the statute and congressional intent. This approach also generates far more predictable payments for drugs and biologicals under the OPPS than the approach previously employed by CMS of adjusting pharmacy overhead costs. In addition, using the statutory default approach ensures that Medicare payment rates for drugs and biologicals are equivalent in both the hospital and physician-office setting, eliminating reimbursement incentives that can drive inappropriate shifts in the site of care and helping to ensure that patients are able to obtain care in the most clinically appropriate setting. CMS should finalize this proposal for CY 2019 to ensure that payments for separately payable drugs and biologicals continue to remain predictable and adequate.

Furthermore, BIO once again recommends that CMS make separate payment for all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes in the OPPS, in the same manner as the Agency does for these therapies when they are administered in a physician's office. We believe that factors such as the methods of administration or type of procedure in which it is used should not determine whether a drug or biological is considered a supply and result in subsequent packaging, as is the case for certain drugs and biologicals when used in a diagnostic or surgical procedure. We believe such policies are harmful to beneficiary access to appropriate treatment.

To the extent that CMS continues to package drugs and biologicals under the OPPS, CMS should require hospitals to report HCPCS codes and revenue code 636 for all billed drugs and biologicals.

V. CMS Should Finalize its Proposed Payment Policy for Therapeutic Radiopharmaceuticals.

For CY 2019, CMS proposed to pay all non-pass-through, separately payable therapeutic radiopharmaceuticals at ASP+6%, based on the statutory default, when ASP information is available.[18] BIO strongly supports this proposal and urges CMS to finalize it.

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[15] *Id* at 37122.
[16] SSA § 1833(t)(14)(A)(iii)(I).
[17] SSA § 1833(t)(14)(A)(iii)(II).
[18] I*d* at 37123.

VI. CMS Should Finalize its Proposed Payment for Blood Clotting Factors.

BIO supports CMS' proposal to pay for blood-clotting factors at ASP+6%,[19] consistent with the Agency's proposed payment policy for other non-pass-through, separately payable drugs and biologicals. We also support CMS' proposal to continue its policy for payment of the furnishing fee using an updated amount, consistent with reimbursement in physician offices and in the hospital inpatient setting. We therefore ask CMS to finalize this proposal.

VII. BIO Supports Payment for Separately Payable Nonpass-through Drugs Acquired with a 340B Discount at ASP-22.5%.

For CY 2019, CMS is proposing to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at ASP-22.5%.[20] BIO appreciates CMS' continued efforts to address the exponential growth of the 340B program, and believe this policy is an important step. Additionally, the modifier finalized in the CY 2018 OPPS Final Rule is a principal aspect of the policy to increase oversight in, and promote integrity of, the 340B program. We appreciate CMS' attempt to address challenges arising from the 340B program within programs under its purview, and we believe the continued utilization of a modifier will help provide much needed transparency into utilization of drugs acquired under the 340B program for Medicare beneficiaries.

However, we are concerned that the interaction of two policies – the 340B payment reduction and the exemption from this reduction for biosimilars with pass-through status - has the potential to create a disparity between federal reimbursement for biosimilars with pass-through status and their reference products. We believe the disparity created by these combined policies could cause an unlevel playing field in the competitive marketplace and lead to inappropriate financial incentives for prescribing in the context of 340B. BIO strongly supports a robust biosimilars market, and we encourage CMS to develop solutions to address this disparity and ensure that biosimilars and their reference product are reimbursed equitably in Medicare.

Further, while these are important steps to managing the continued growth and abuse of the 340B program, additional policy changes are needed to address broader 340B reform. As BIO has expressed in the past, the exponential growth of the program and perverse incentives have led the program to stray from its original intent—to help uninsured and vulnerable patients gain greater access to prescription medicines. BIO urges CMS to continue to work with stakeholders on changes to help refocus the program toward its intended purpose.

VIII. CMS should finalize the update to payment for nonpass-through biosimilars acquired under the 340B program.

For CY 2019, CMS is proposing to pay for nonpass-through biosimilars acquired via the 340B program at ASP-22.5% of the biosimilar's ASP instead of the biosimilar's ASP-22.5%

[19] *Id* at 37124.
[20] *Id* at 37125.

of the reference product's ASP. BIO supports this change to base the biosimilars payment off of its own ASP rather than that of the reference product.

IX. CMS should finalize and seek to expand into the OPPS setting the policy that provides separate payment in the ASC setting for pain management drugs that function as surgical supplies, and consider additional separate payment that facilitates patient access to innovations in treatment and the most appropriate care.

The Proposed Rule states that "it may be appropriate to pay separately for evidence-based non-opioid pain management drugs that function as a supply in surgical procedure in the ASC setting to address the decreased utilization of these drugs and to encourage use of these types of drugs rather than prescription opioids."[21] BIO supports CMS' efforts to appropriately cover and pay for innovation in pain treatment, and encourages continued consideration of additional policies that make separate payment for pain management drugs where they can help reduce use of opioids in appropriate patient populations.

BIO and our members are committed to developing solutions to address the opioid crisis. To this end, we have established a working group, composed of representatives from more than 30 of BIO's member companies, in order to identify ways in which the biotechnology industry can assist in mitigation of the opioid epidemic and serve as a strong partner to other stakeholders involved in these efforts. The working group has established priorities that outline how BIO and our members can help mitigate the crisis, focused under three key pillars: (1) advancing the understanding of the biology of pain and addiction to enable the development of innovative treatments for pain and addiction, and ensuring 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. We therefore urge CMS as a part of the Agency's broader activities and goals in addressing the opioid crisis to ensure appropriate patient access to novel and safer treatments for pain and to new and current forms of medication assisted treatment (MAT) across care for addiction.

For CY 2019, CMS is proposing to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC settings. BIO supports the proposal to separately pay for these therapies in the ASC setting, as we believe this can help advance timely and appropriate patient access to novel pain treatments, reducing the number of opioid prescriptions. In addition, CMS notes that it continues to believe it is appropriate to package payment for postsurgical pain management drugs when furnished in the hospital outpatient setting, but seeks comment on whether separate payment would further incentivize appropriate use of such drugs in the hospital outpatient setting.

We encourage CMS to expand this policy in the ASC setting beyond non-opioid pain treatments to include all those pain treatments that can help improve the treatment of pain while lessening addiction potential. We similarly encourage CMS to examine and alleviate barriers to appropriate treatment options for specific diseases that can help reduce the

[21] *Id* at 37166.

duration or impact of acute pain episodes in certain instances. For example, BIO members have and will continue to advance treatment options for chronic, often rare, diseases (e.g., sickle cell disease) for which severe pain is a hallmark symptom. Similar adjustments around bundled payment for therapies that ameliorate these attacks are critical to reducing incidence of pain for these patient populations and help to reduce unnecessary opioid prescriptions. These patients are not likely to be treated in the ASC setting, but may require care in outpatient and inpatient facilities where barriers to incorporation of drug costs into bundled payments are particularly problematic.

As detailed above, BIO believes that a critical component to addressing the opioid crisis is ensuring patient access to novel and safer treatment options for pain. By facilitating reimbursement for these products in the ASC and other delivery settings (inpatient and outpatient), CMS can help provide patients with appropriate pain treatment based on the procedure they've received and helping to prevent additional abuse or addiction to opioids. BIO urges CMS to apply this new policy beyond the surgical context and ASC setting. Further, we encourage CMS to examine and alleviate barriers to appropriate treatment that may reduce or mitigate acute pain episodes in chronic diseases across care settings.

By providing appropriate reimbursement for innovations in pain treatment, CMS can help facilitate future investment into additional innovations that can help address both acute and chronic pain. Therefore, BIO strongly encourages the Agency to apply this separate payment policy for innovations in pain treatment incident to surgical procedures in the inpatient and outpatient setting as well. Additionally, we encourage the Agency to continue to apply such a policy in these settings for innovations in pain treatment beyond the CY 2019 payment year, as continued appropriate reimbursement will help facilitate uptake of existing and future innovations for pain treatment.

As we have previously discussed with the Agency, we believe there are a number of other policy updates that CMS can make to both advance access to the most appropriate course of care for pain and addiction treatment, while reducing the number of traditional opioids prescribed to beneficiaries. These include: reviewing coverage and reimbursement policies in other areas of the Medicare program to prioritize access to current and innovative medications that either deter, mitigate, or assist in the treatment of addiction (the outpatient setting, in the physician office setting, and Medicare prescription drug benefit and Medicare Advantage programs); ensuring that providers and patients are educated on appropriate use of existing and innovative pain and addiction treatments; and incorporating scientific advances in the understanding of the treatment of pain and addiction into the continuum of care. BIO is committed to continuing to work with the Agency on these broader efforts to address the issues in the pain and addiction treatment space for Medicare beneficiaries.

X. BIO Appreciates CMS' Efforts to Address Financial Incentives that Lead to Shifts in Site of Service.

In the Proposed Rule, CMS is seeking comments on methods to control for unnecessary increases in the volume of outpatient services. CMS notes that it believes the increase in the volume of clinic visits is due to the payment incentive that exists to provide this service in the higher cost setting. In order to address the increase in volume of services as well as the location in which particular services are provided, the proposed rule includes multiple

proposals seeking to eliminate existing financial incentives that are driving healthcare utilization.

As a way to control unnecessary increases in the volume of covered hospital outpatient department services, CMS is proposing to pay under the PFS the adjusted payment amount of ASP minus 22.5% for separately payable drugs and biologicals acquired via the 340B program when they are furnished by nonexcepted off-campus provider-based departments (PBDs) of a hospital. BIO appreciates CMS' interest in addressing the site of service shifts that occur due to existing reimbursement incentives. We believe that patients should be treated in the most appropriate care settings, which should be based on clinical considerations and patients' needs, rather than financial incentives. Additionally, efforts to address these adverse incentives can help reduce patient cost-sharing which is often correlated to the location in which the service is provided as well as the total cost of care.

In addition to higher Medicare reimbursement rates for hospital facilities, the incentives associated with the 340B program are another factor leading to inappropriate shifts in site of service. The availability of deeply discounted 340B pricing allows 340B hospitals to generate higher net revenue which creates perverse incentives for certain practices. We therefore also appreciate CMS' efforts to address the financial incentives that exist within the context of the 340B program.

In the Proposed Rule, CMS proposes to expand the reduced reimbursement rate of ASP minus 22.5% for drugs and biologicals purchased via the 340B program when they are furnished by nonexcepted off-campus PBDs of a hospital. By paying for non-pass through drugs acquired at all off campus PBDs at the same rate, CMS is helping to ensure that higher reimbursement rates at nonexcepted off campus PBDs compared with off campus PBDs does not drive inappropriate utilization to one location versus another. This is critical to help patients obtain care in the most clinically appropriate setting. However, as noted above, we remain concerned that the interaction of the two policies – the 340B payment reduction and the exemption from this reduction for biosimilars with pass-through status - has the potential to create a disparity between federal reimbursement for biosimilars with pass-through status and their reference products. We believe the disparity created by these combined policies could cause an unlevel playing field in the competitive marketplace and lead to inappropriate financial incentives for prescribing in the context of 340B. BIO strongly supports a robust biosimilars market and we encourage CMS to develop solutions to address this disparity and ensure that biosimilars and their reference product are reimbursed equitably in Medicare.

Further, the payment difference between services provided in hospital outpatient departments (HOPDs), physicians' offices, and ASCs is one of the key factors that drives hospitals to purchase freestanding physicians' offices and designate them as HOPDs without changing their location or patient mix. Once acquired, these practices may be treated as HOPDs for purposes of Medicare reimbursement. Another factor contributing to this phenomenon is the interest in enabling acquired practices to participate in the 340B program, which provides substantial benefits for the parent hospital. We urge CMS to continue to study these issues more carefully and address the perverse incentives that shift patients to more costly sites of services—which increases costs for patients and to the healthcare system overall.

XI. Request for Information on Price Transparency and Improving Beneficiary Access to Provider and Supplier Charge Information.

In the Proposed Rule, CMS notes it is considering ways to improve the accessibility and usability of current charge information in order to increase price transparency for patients. BIO supports CMS' efforts to help patients better understand their financial liability for healthcare services. We believe that all cost transparency measures should be grounded in the goal of improving timely access to information that supports informed patient/provider clinical decision-making and that helps ensure smarter healthcare spending. Transparency components should facilitate access to timely initiation of the most appropriate course of treatment for patients.

CMS also seeks feedback on potential activities and actions to further its objective of having providers and suppliers engage in consumer-friendly communication to help patients understand their potential financial expenditures for a given service. While it is critical for patients to have accurate information around out-of-pocket costs in the appropriate context, BIO has concerns around additional information being provided to patients by providers. There are a number of factors that affect patient OOP costs, such as what Medicare pays for particular services and how Medigap affects patient OOP costs. Based on these factors, there is potential for inaccurate information to be delivered which can negatively impact timely and appropriate initiation of care.

Further, sharing such information places an additional burden on providers in accurately reflecting reimbursement details and OOP costs for each individual patient. While we support the Agency's goal of helping beneficiaries better understand the associated costs of their treatment or therapy, providers are not best positioned to provide the appropriate individualized level of detail necessary to ensure the information provided to each patient is accurate. Payers—not the hospital or individual providers—dictate each patient's OOP liability for a given treatment. We encourage the Agency to seek other opportunities to help beneficiaries understand their OOP cost liability for particular services, as well as what other variables impact the amount they may pay.

XII. BIO urges CMS to extend the process of coding drugs separately from their associated professional services and to establish permanent HCPCS codes in the case of transformative therapies.

As noted above, it is critical that CMS work to provide adequate coverage and reimbursement of transformative therapies to ensure timely and appropriate patient access to these innovations in treatment for serious diseases. While the process for delivery of these drugs to patients may vary from other biological products (i.e. require additional steps pre- or post-therapy), BIO urges CMS to ensure they are reimbursed in the same manner as other biologicals, with the drugs and the provider services billed separately.

One such example is the case of the codes for CAR T therapies, where at the May public HCPCS meeting, organizations requested that the ""leukapheresis and dose preparation procedures" be removed from the descriptor in the HCPCS codes – as this process is distinct from the administration of the therapy, and to establish permanent codes (J-codes) for these products. BIO similarly urges the Agency to make these changes to ensure that CAR T, and future transformative therapies, are appropriately treated as drugs for purposes of

reimbursement and facilitating access to these innovations. Further, we urge CMS to clarify through this rule that providers can bill for a Category I Current Procedural Terminology (CPT®)[22] unlisted code or for intravenous infusion chemotherapy and other highly complex drug or highly complex biologic agent administration for the administration of CAR T cell therapies, rather than using any applicable Category III CPT codes until the ongoing National Coverage Analysis process can provide additional clarity to ensure appropriate coverage and reimbursement for these therapies.[23]

XIII. CMS should maintain important measures around vaccination coverage in the Hospital Outpatient Quality Reporting Program (OQR) and Requirements for the Ambulatory Surgical Center Quality Reporting Program (ASCQR).

For the CY 2020 payment determination and subsequent years, CMS is proposing to remove *QP-27: Influenza Vaccination Coverage Among Healthcare Personnel* (NQF #0431) under the proposed measure removal Factor 8 because "[it] has[s] concluded that the costs associated with this measure outweigh the benefit of its continued use in the program."[24]

The Proposed Rule acknowledges that CMS originally adopted the *Influenza Vaccination Coverage Among Healthcare Personnel* (NQF #0431) in the CY2014 OPPS/ASC final rule based on its recognition that influenza was an important healthcare issue, where immunization is a vital component to preventing healthcare associated infections. The measure was also adopted given that healthcare personnel (HCP) can serve as vectors for influenza transmission.

CMS is also proposing to remove a total of 8 measures from the ASCQR Program, including ASC-8 *Influenza Vaccination Coverage Among Healthcare Personnel* (NQF #0431). CMS indicates that it believes "that these benefits are offset by other efforts to reduce influenza infection among ASC patients, such as numerous healthcare employer requirements for healthcare personnel to be vaccinated against influenza."[25]

As CMS notes above, influenza represents a major vaccine preventable illness that takes a heavy toll on adults each season, especially those with chronic or co-morbid conditions. BIO does not agree with CMS' assessment and believes that removal of this measure will result in fewer ASC facility employers requiring health care personnel to be vaccinated. Moreover the risk of HCP transmitted influenza remains a significant for patients. A 2017 commentary *Influenza in long-term care facilities* indicated that in "a study of healthcare workers (HCWs) in an acute hospital during a mild epidemic season, found that 23% had serological evidence of new influenza infection during the season, implying a potential transmission risk to patients as between 28% and 59% of infected workers had subclinical infections and continued to work."[26]

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[22] CPT is a registered trademark of the American Medical Association.
[23] On May 16, 2018 CMS initiated the National Coverage Analysis Process for CAR T-cell therapies with an expected completion date of February 16, 2019. See: National Coverage Analysis (NCA) Tracking Sheet for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N).
[24] *Id* at 37180.
[25] *Id* at 37917
[26] Lansbury, LE, Brown CS, Nguyen-Van-Tam, JS. Influenza in long-term care facilitates. Influenza and other Respiratory Viruses. 2017 Sep; 11(5) 356-366. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5596516/

BIO believes that removal of this measure from the QPR and ASCQR programs will create greater inconsistency across quality reporting programs, add to reporting confusion, and most importantly leave a vulnerable population of Medicare beneficiaries more susceptible to vaccine preventable illness.

BIO strongly urges CMS to maintain the *Influenza Vaccination Coverage Among Healthcare Personnel* (NQF#0431) among healthcare personnel measure from the Hospital OQR and ASCQR programs. This measure plays a critical role in both the CMS Quality Strategy and the National Quality Strategy in supporting influenza immunization efforts.

XIV. CMS should modify measures in the Hospital Inpatient Quality Reporting (IQR) Program in a manner that helps facilitate patient access to the most appropriate form of pain treatment.

CMS is proposing to update the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey by removing the Communication About Pain questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years. CMS notes the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended removal of the HCAHPS Pain Management Survey questions in order to ensure providers are not incentivized to offer opioids to raise their HCAHPS score.

BIO supports the development of meaningful measures of pain management for patients in a manner that helps facilitate patient access to the most appropriate form of treatment. However, we caution the Agency against constructing policies in such a manner that may create undue barriers to access for patients suffering from chronic pain. There are certain instances and disease states for which opioids are the preferred treatment, and measures of patient experience should be modified to better capture patient experience and pain considerations, rather than simply removed. Such modifications can also be made to help advance access to new innovations in pain treatment as they become available. We urge the Agency to continue to work with stakeholders to make pain assessments across treatment, including patient experience measures, more sensitive to understanding beneficiaries' needs given their disease state.

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BIO appreciates the opportunity to comment on the proposals in the Medicare Hospital Outpatient Prospective Payment System Proposed Rule. We look forward to continuing to work with CMS in the future to address the issues raised in this letter. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Sincerely,

/S/

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