September 10, 2018

By Electronic Delivery

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Attention: CMS-1693-P
200 Independence Ave, SW
Washington, DC 20201

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program Proposed Rule

Dear Administrator Verma,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) Medicare Physician Fee Schedule (PFS) and Other Revisions to Part B for calendar year (CY) 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program ("Proposed Rule"). [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. 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.

As a threshold matter, we raise our concern with the implementation of a policy that can have such impacts in limiting access for beneficiaries in MA via the application of step

[1] 83 Fed. Reg. 35,704 (Jul. 27, 2018).

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6306 F
bio.org

therapy, as detailed in the Administration's August 7th memo.[2] As detailed in our letter to the Administration, we are particularly concerned with the lack of specificity or detail in this memo around critical patient protections and appropriate implementation, including ensuring: sufficient oversight by CMS; clear clinical criteria for step therapy policies; transparency into, and communication of, step therapy policies to beneficiaries and robust beneficiary protections; timely exceptions and appeals processes; sufficient protections for those on existing therapies; and protection for beneficiaries from higher cost-sharing.

Inappropriately applying or implementing stringent utilization management tools, especially without adequate parameters or guardrails, can force inappropriate treatment choices and negatively impacting patient health outcomes. These potential consequences are especially concerning when considering that this new policy is intended to impact those Medicare beneficiaries seeking treatment for the most serious, often life-threatening conditions, such as cancer, autoimmune disorders, ESRD, and hemophilia – conditions that already are complex for providers and patients to manage appropriate and that often can require immediate access to the most effective therapy available in order to avoid life-threatening or irreversible negative complications. Policies such as step therapy that delay access to the most appropriate therapy in an effort to reduce upfront expenditures are not only harmful for patients, but they are short-sighted, as there is substantial potential for increased overall healthcare costs and adverse patient outcomes due to avoidable hospitalizations, doctors' visits, and procedures.

We therefore strongly urge the Agency to reverse course on this new policy, given its potential for serious negative impacts for Medicare beneficiary access to timely and appropriate treatment. However, if CMS insists on proceeding with this new policy, we believe there are a number of critical steps CMS must take to provide further predictability and transparency to Medicare beneficiaries in order to avoid detrimental disruptions in care under this new MA step therapy policy. We caution CMS against future action in rulemaking that may create barriers to patient access to the most timely and appropriate treatment for drugs delivered through Part B.

Our comments on the Proposed Rule are outlined below.

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[2] US Department of Health and Human Services, Centers for Medicare and Medicaid. Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. August 7, 2018.

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I. CMS should provide additional data surrounding the basis for the off-campus outpatient provider based department payment rate and move away from the temporary methodology for payment of these services.

CMS is proposing to maintain the payment rate implemented for the CY 2018 payment year for items and services provided in off-campus outpatient provider based departments (PBDs) paid under the PFS at 40 percent of the Medicare Hospital Outpatient Prospective Payment System (OPPS) rate.[3] For 2019, CMS is proposing to maintain that same 40 percent rate, noting that its analysis supports maintaining this same relativity adjuster.[4] The Agency proposes to maintain this PFS Relativity Adjuster until updated data or other considerations suggest it should be changed.[5]

BIO opposes CMS's proposal to adopt a PFS Payment Adjuster for this year and all future years. The PFS Payment Adjuster was supposed to be a temporary method of paying for services at outpatient PBDs until CMS had time to figure out technical claims processing issues for payment of outpatient PBD services under the PFS. Moreover, it is contrary to the statute to continue to pay for outpatient PBD services by using discounted OPPS payment rates. The statute specifically directs CMS to adopt a system of paying for outpatient PBD items and services outside of the OPPS. CMS needs to develop a means to pay for these claims under another system, instead of continuing to rely on the OPPS contrary to Congressional intent.

At a minimum, CMS must provide more data on why CMS believes this payment rate is valid for CY 2019. In the proposal, CMS explains its general methodology, but does not provide the updated mean weighted average of the top 25 billed codes for outpatient PBDs for CY 2017 nor does it provide a detailed list of these codes or other data used to determine why CMS believes that the 40 percent PFS Relativity Adjuster is still appropriate. The absence of this data makes it impossible for stakeholders to meaningfully evaluate and comment on CMS's methodology for determining the PFS Relativity Adjuster, which is particularly problematic in a year where CMS is not only proposing the PFS Relativity Adjuster for CY 2019 but for future years until the data suggests otherwise.

The PFS Payment Adjuster risks the possibility that the payment rate for an outpatient PBD service does not adequately cover the costs of that service in practice, potentially grossly undercompensating providers. This is particularly problematic for an outpatient PBD that disproportionately provides services billed under codes for which the PFS payment rate relative to the OPPS would be more than 40 percent. This, in turn, could disincentivize outpatient PBDs from providing these more costly services in the first place, or would incentivize health systems to provide these services only through the main hospital campus so that they can be reimbursed at the higher OPPS rate. Both of these scenarios could create patient access concerns if they make it more difficult for a patient to find a clinic that provides a particular service.

Because many drugs and biologicals are paid for as part of a bundled service under the OPPS, the PFS Payment Adjuster effectively slashes payment for these drugs to 40 percent of the existing payment under the OPPS. This reduced reimbursement may force providers

[3] In implementing sections 1833(t)(1)(B)(v) and (t)(21) of the Social Security Act (SSA), which provides that items and services provided in off-campus outpatient PBDs are not considered outpatient department services and therefore need to be paid under a separate payment system, CMS determined that it would pay for these items and services under the PFS.
[4] 83 Fed. Reg. 35,704.
[5] *Id.*

to make difficult decisions about whether they can administer a drug at all, thereby reducing patient access to essential medical treatments.

II. CMS should not move forward with the proposed changes to consolidate payments for office and outpatient evaluation and management services.

In the Proposed Rule, CMS is proposing to make several changes related to outpatient evaluation and management services (E/M) codes, including updates to the visit level payment requirements, documentation requirements, and the establishment of new E/M codes to reflect certain types of visits.

CMS proposes to simplify payment for E/M visit codes by making a single payment for E/M visit levels 2 through 5 for new patients (Current Procedural Terminology (CPT®)[6] codes 99202 through 99205), a single payment for E/M visit levels 2 through 5 for established patients (CPT codes 99212 through 99215), and adopting a single set of relative value units (RVUs) for each of these code sets accordingly.[7] CMS notes they believe these changes will also help streamline documentation requirements.[8] In making these changes, CMS would determine the payment amounts by using existing codes weighted by the frequency in which they were billed in the five most recent years of Medicare claims data[9] (see Appendix 1 for resulting payment rates). Further, the Agency is proposing to adopt a single practice expense per hour (PE/HR) value for E/M visits of approximately $136 applied across these codes.[10]

BIO is extremely concerned that eliminating the different levels of payment for Levels 2 through 5 E/M services may unnecessarily financially harm practitioners who are treating the sickest patients and who may more often bill Level 4 and 5 E/M services. These practitioners would be undercompensated for the complex E/M services they provide as the weighted payment rate that CMS proposes to adopt would be lower than the current payment rates for these services. Eliminating the higher payment rates for Levels 4 and 5 E/M services would be particularly problematic for practitioners engaging in complex discussions over medication therapies for their patients as the sickest patients may have the most complex drug needs.

The work associated with the provision of complex E/M services (e.g. medication management) is critical to improving patient health outcomes and preventing more costly healthcare interventions and hospitalizations. For example, endocrinologists bill Level 4 or 5 E/M visits when working with patients who are insulin dependent. Good glucose control, which is guided by these significant interactions with a patient's physician, prevent additional disease burden related to diabetes – amputations, diabetic foot ulcers, and admissions to the ER for severe acute hypoglycemia and diabetic ketoacidosis. BIO is concerned that these changes to the E/M coding structure may disadvantage providers caring for some of Medicare's sickest and most vulnerable beneficiaries.

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[6] CPT is a registered trademark of the American Medical Association.
[7] 83 Fed. Reg. at 35,839.
[8] *Id*. at 35,839-40.
[9] *Id*. at 35,840.
[10] Payment based on an average of the PE/HR across all specialties that bill these E/M codes, weighted by the volume of those specialties' allowed E/M services. *Id*. at 35,843-44.

In addition to these changes, CMS proposes to separately address payment for certain types of E/M visits that it does not believe are currently reflected in the existing E/M codes. This includes proposals to (1) pay for E/M visits that are separately identifiable from another E/M visit on the same day at 50 percent of the cost,[11] adopting the 50 percent rate for the least costly E/M procedure;[12] (2) adopting a new Healthcare Common Procedure Coding System (HCPCS) code for primary care services intended to capture the additional resources required for these visits compared with regular E/M codes;[13] (3) adopting a new HCPCS code to account for the additional resources costs for some specialty professionals that tend to have the highest ratio of E/M visit codes as part of their overall charges;[14,15] and a new HCPCS code to account for prolonged E/M psychotherapy services.[16] Again, BIO has serious concerns with the Agency moving forward with the proposed changes for E/M visits. We believe that if the Agency does institute the changes as proposed, it will be critical to separately address payment for certain types of visits that are not reflected in the code. However, we find the consolidation of E/M visit levels plus the creation of new HCPCS codes to be more complex and potentially problematic for practitioners, in understanding the changes and when and how to bill, than maintaining the existing structure.

Further, CMS proposes to make changes to the documentation requirements for E/M visits predominantly for office/outpatient visit codes (CPT codes 99201–99215) with the intention of reducing the burden of the E/M documentation guidelines. CMS details that this is part of a stepwise approach that may lead to additional changes to other E/M visit codes in future rulemakings.[17] This documentation streamlining proposal includes: (1) eliminating the requirement that practitioners must document the medical necessity of visiting a patient in the home as opposed to the office;[18] (2) permitting practitioners to choose the existing E/M documentation guidelines framework, medical decision making or the practitioner's time to document the level of E/M visit;[19] (3) adopting further simplifications of the documentation of the history and exam for established patients, such that the billing practitioner need not document information in their note that is already present in the medical record from previous visits;[20] (4) eliminating duplicative documentation requirements in the academic medical center setting.[21] Further, CMS solicits feedback on the elimination of the general prohibition of MACs paying for two E/M visits billed in the same day, unless the physician documents that these were for distinct and unrelated problems.[22]

While BIO appreciates CMS's intentions of reducing the burden on providers when documenting E/M visits with the goal of facilitating their ability to spend more time with their patients. We have serious concerns around the significant other changes to the E/M coding structure that could be extremely troublesome for providers in continuing to deliver

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[11] *Id*. at 35,840-41
[12] *Id*. at 35,841.
[13] *Id*. at 35,841-42.
[14] *Id.* at 35,842-43.
[15] This code, GCG0X, is intended to capture "[v]isit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit).
[16] 83 Fed. Reg. at at 35,844.
[17] *Id*. at 35,835.
[18] *Id*.
[19] *Id*. at 35,835-38.
[20] *Id.* at 35,838.
[21] *Id*. at 35,848-49.
[22] *Id*.

care, and ultimately impact patient access to necessary services. We believe that updates to the E/M documentation guidelines are critical given that they are over 20 years old, however, they should not be made alongside these other more significant changes. BIO instead urges CMS to continue to work with stakeholders, particularly with the physician communities highlighted in this Proposed Rule, to better understand the needs of practitioners providing E/M services and streamlining efforts that can be made while still upholding the delivery of appropriate care.

III. CMS should not move forward with the proposed changes for Wholesale Acquisition Cost-based payment for drugs.

The Proposed Rule includes a change in reimbursement levels for new drugs by reducing the add-on payment from the existing Wholesale Acquisition Cost (WAC) plus six percent to WAC plus three percent during the timeframe in which Average Sales Price (ASP) data is not yet available for these drugs. CMS proposes implementing this policy beginning January 1, 2019, noting that it does not apply to WAC-based payments for single source drugs where the payment add-on is set in statute.

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 biological 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 the associated care delivery and product handling services. Reducing the add-on payment can have an impact on physician ability to deliver these products to patients, particularly given that the payment rates are also subject to the sequester cuts, making the payment add-on 1.35 percent instead of 3 percent.

Reducing the add-on payment during the timeframe when a drug 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 preferred for his/her given condition. By both potentially not providing a sufficient add-on payment to cover the associated administrative components of delivering Part B drugs and not providing parity in payment policy between new and existing products, innovative treatments can be disadvantaged at the outset. 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. Further, 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 in use of when and how the Not Otherwise Classified Pricing File applies to new therapies, these considerations taken together can have significant impacts for 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. We believe it is inappropriate to assert that providers may be selecting products based on the potential to generate revenue based on the add-on to different products, rather than selecting and delivering the best product for each patient's disease state. We are further concerned that a 50 percent reduction in the add-on payment, its logic fails in the context of orphan drugs, many of which have few, if any, viable, on-label therapeutic substitutes.

CMS further notes this policy's impact on lowering patient out-of-pocket spending for Part B drugs. While the 20 percent patient cost-sharing will be based off of a lower amount with a smaller add-on, we remind the Agency that many beneficiaries, and increasingly more, pay much less as a result of their enrollment in Medigap plans, or additional retiree benefits and Medicare Advantage (MA) – where patient out-of-pocket (OOP) spending on medical services is capped. We support efforts to further reduce patient cost burden, but do not believe policies should be applied in such a manner that may impede patient access to new innovations that are the most appropriate form of treatment for their given condition. We urge the Agency not to move forward with the proposed reduction to WAC-based payment.

IV. In developing a bundled episode of care for management and counseling treatment for SUDs, CMS should ensure payment adequately accounts for all phases of care, and that drugs for SUD treatment are paid for separate from the bundle.

CMS is seeking feedback on the creation of a bundled episode of care for management and counseling treatment for substance use disorder (SUD), and references the success of Medication Assisted Treatment (MAT) alongside other coordinated care services as part of a treatment program. CMS is seeking feedback on whether it would be appropriate to develop a separate bundled payment for an episode of care for treatment of SUDs.

In the Proposed Rule, the Agency seeks specific feedback and comments on the development of such a coding and payment system that could include overall treatment management, any necessary counseling, and components of a MAT program that could be included. This includes information on what assumptions should be made in developing a bundle - number of visits and duration related to these services, which types of practitioners could furnish them, and what components of MAT (i.e. medication management, observation of drug dosing) could be included in the bundled episode. CMS invites further comment on suggestions for regulatory and subregulatory changes to help prevent opioid use disorder and improve access to SUD treatment under the Medicare program.

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, 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.

To these ends, we support the Agency's efforts through the Roadmap and the broader Department of Health and Human Services five-point plan to address the opioid crisis and its continued engagement with stakeholders on activities that can help prevent opioid abuse, and help those suffering from addiction receive appropriate treatment. We believe that there are a number of means to collectively address both overutilization of opioids, and expand access to novel and safer treatment options for both pain and addiction. This includes ensuring providers are educated on appropriate use of existing and innovative pain and addiction treatments, ensuring that coverage policies prioritize access to innovative medications that either deter or mitigate addiction potential and represent advances in the treatment of addiction, and assuring that scientific advances in the understanding of the treatment of pain and addiction are incorporated into the continuum of care.
BIO believes that this proposed new bundle of services, if developed and paid appropriately, would help ensure delivery of the appropriate continuum of care for SUD to Medicare beneficiaries, while expanding access to innovations in treatment. Access to such innovations in treatment for SUD is critical to improving patient health outcomes and reducing overall healthcare costs. Through bundled episode of care payments, CMS can ensure that providers of SUD treatment are reimbursed appropriately for the range of services they deliver, including care components associated with MAT, thereby increasing patient access to these services in the Medicare program. We also ask that in considering the development of the SUD treatment bundle, CMS ensure that MAT drugs are paid separately from the services in a bundle, to ensure payment policies facilitate access to these critical medicines.

In developing such bundled episodes, we encourage the Agency to consider not only the elements of MAT that could be included into a bundle, but also the associated care required dependent upon the type of SUD medication being delivered (i.e. injectable, oral, long-acting), as well as considering different bundles based on the phase of SUD treatment a beneficiary is in. For instance, CMS could consider different bundles for induction of MAT treatment, stabilization, and maintenance or follow on treatment, as each of these care phases for SUD treatment require varying services and interventions. It is of the utmost importance that any bundles developed are workable for physicians by providing appropriate reimbursement for the delivery of healthcare services, consider the full range of MAT therapies currently available, are able to be adapted as standards of care evolve and innovations in MAT are developed, and do not include the cost of the MAT therapy in the overall payment rate. In addition, there is a need for bundled payment for detoxification services on an outpatient (and inpatient) basis.

In building bundles for this area of care, we urge the Agency to consider other proposals or activities related to bundled payment for SUD and MAT associated care requirements, and what elements may be translatable for the Medicare population. Examples of such proposals and activities include, but are not limited to:

- The Patient-Centered Opioid Addiction Treatment (P-COAT) Alternative Payment Model as developed by the American Society of Addiction Medicine and American Medical Association;[23] and
- The Medicaid Innovation Accelerator Program (IAP) collaboration with Medicaid and behavioral health agencies in development of robust approaches for addressing SUD.[24]

The P-COAT model seeks to provide appropriate financial support to enable clinicians – including more primary care providers – to deliver successful MAT services through coordinated delivery of the three types of services needed for effective outpatient care of individuals with opioid addiction: medication therapy, psychological and counseling therapies, and social services support.[25] P-COAT includes two new types of payment for separate phases of office-based opioid treatment: (1) initiation of MAT through a one-time payment to support evaluation, diagnosis, and treatment planning for a patient with opioid use disorder and the initial month of outpatient MAT for the patient; and (2) maintenance of MAT via a monthly payment to provide for the coordinated provision of ongoing outpatient medication, psychological treatment, and social services for a patient who has successfully initiated treatment for opioid use disorder, these monthly payments would continue if the patient is determined to be appropriate for continued therapy. Further, in each of the phases of care, P-COAT would provide higher payments to providers caring for patients with complex needs or that require more intensive supervisions or services, and add-on payments would be available for practitioners using technology-based treatment and recovery support tools. Likewise, an adjustment in the payment must be made to support the additional work involved in acquisition, storage, preparation and administration of long-acting, injectable medications used in the treatment of opioid use disorder (OUD) and alcohol use disorder (AUD). Participating practitioners/facilities would be required to meet certain quality standards to receive payments, with relevant quality and outcomes measures in place.

Through the IAP, the Agency seeks to support state Medicaid agency efforts toward system-wide payment reform and delivery system innovations.[26] In one of the models, the Baltimore Buprenorphine Initiative (adapted), which includes a pathway for Buprenorphine and Extended Release Naltrexone, there are five different levels of bundle payments as a patient moves through a course of treatment: (1) clinical assessment and induction, (2) stabilization, (3) transition to primary care, (4) maintenance, and (5) discontinuation and medical withdrawal. In this delivery and payment structure, monthly rates are used for the ongoing services (maintenance and discontinuation - if selected) as average clinical rates can best be defined for these services.

Again, BIO encourages CMS to consider multiple care delivery phases in the context of developing bundled payment for SUD and services associated with the delivery of MAT. It is important that any such payment structure be designed so as to allow for increased access to these services. The payment rates should appropriately reimburse physicians for providing this meaningful and necessary care, with separate payment for MAT drugs

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[23] American Society of Addiction Medicine, American Medical Association. Patient Centered Opioid Addiction Treatment (P-COAT) Alternative Payment Model. 2018.
[24] Medicaid.gov. Technical Resources for States: Medication-Assisted Treatment Bundled Payments.
[25] *Id.*
[26] Medicaid Innovation Accelerator Program. Reducing Substance Use Disorders.

associated with care and treatment, and be able to be updated to account for future innovations both in the MAT medication and SUD care space. We commend the Agency for seeking this feedback and continuing to work with stakeholders through coverage and payment system rules to address the opioid crisis and advance access to the highest standard of care and treatment for SUDs.

V. CMS should finalize the changes to structured assessment, brief intervention and referral to treatment for substance use disorder codes to increase patient access to these services.

In an effort to increase access to SUD treatment and provider payment for such services, CMS is proposing to remove the service-specific documentation requirements associated with the two G-codes for SUD. CMS believes that these requirements are resulting in low utilization of these codes. As detailed above, BIO supports CMS's efforts to increase patient access to SUD treatment and supports the removal of the service-specific documentation requirements associated with these codes to help promote their effective use.

VI. CMS should not finalize cuts to codes related to therapy administration, as these could reduce patient access to drugs administered under such codes.

CMS is proposing further reductions for drug administration CPT codes (96372, 96374, 96375) as a part of the potentially misvalued coding initiative, for which these additional cuts are being phased in over time. BIO continues to oppose these reductions, as noted in our comments on the CY 2018 Proposed Rule, as these revisions result in payment reductions of approximately 19 percent from CY 2018 to CY 2019 and 30 to 40 percent overall.[27]

Further, CMS is also proposing to make reductions to chemotherapy administration codes (96413, 96415, 96417). BIO opposes changes to reimbursement for services associated with providing critical medicines to Medicare beneficiaries with cancer, as they may impact patient access to timely initiation of treatment. Finally, we ask CMS to provide additional clarity around the how they intend to apply the proposed reductions described in the Proposed Rule for multiple procedure payment reductions (MPPR), given the potential changes under this policy to similarly impact chemotherapy administration codes.

VII. CMS should continue its consideration of coverage and payment for mobile stroke units.

We support CMS's proposals to implement the telehealth/telestroke provisions established in the 21st Century Cures Act and Bipartisan Budget Act (BBA) of 2018, including the recognition of mobile stroke units as an originating telehealth site.[28] We encourage continued review of coding and payment for mobile stroke units overall as an innovative approach to improving stroke care for Medicare beneficiaries with the potential for episode-based and longer-term program savings.

[27] The Moran Company conducted analysis of the changes in payment rates under this policy.
[28] 83 Fed. Reg. at 35,730.

VIII. Quality Payment Program and the Merit-based Incentive Payment System

BIO supports the development and implementation of the Quality Payment Program (QPP) tracks, Advanced APMs and MIPS, in a manner that improves overall healthcare quality, while not compromising patient access to the most appropriate care and treatment. In addition, we ask the Agency around considering the potential impacts that the layering on of other changes in the Medicare program, such as the MA step therapy memo, can have on successful use of and implementation of the QPP and APMs. Our comments in response to specific proposals related to QPP outlined in the Proposed Rule are explored in more detail below.

a. CMS should finalize its clarification that MIPS adjustment factors will not apply to Part B drugs.

In accordance with the BBA of 2018, CMS notes the MIPS adjustment factors will not apply to Part B drugs and other items furnished by a MIPS eligible clinician.[29] BIO appreciates this clarification and CMS's efforts to clearly align current regulations to appropriately implement the changes enacted by the BBA of 2018. The exclusion of Part B drugs from the payment adjustment will significantly reduce the risk faced by physicians who provide Part B drugs under MIPS. Additionally, the exclusion of Part B drugs from the MIPS adjustment factors ensure parity within the QPP program since physicians participating in APMS have their bonus payment calculated based on "covered professional services" only.[30] Such a clarification can alleviate incentives that may undermine patient to the most appropriate course of treatment, while promoting parity between the two QPP programs and reducing physician risk. For these reasons, BIO supports the stated clarification and commends CMS for taking such action, and we urge the Agency to finalize this clarification aligning regulations with the statutory changes.

b. CMS should finalize the proposal to update the low-volume threshold, but look to provide additional transparency around the process for future updates.

In accordance with the BBA of 2018, CMS proposes to utilize the minimum number (200 patients) of Part B-enrolled individuals who are furnished covered professional services or the minimum amount ($90,000) of allowed charges for covered professional services to Part B-enrolled individuals by the eligible clinician or group during the low-volume threshold period for the 2020 MIPS payment year. For the 2021 MIPS payment year and future years, CMS is proposing to add one additional criteria to the definition of low-volume threshold. For the 2021 MIPS payment year and future years, eligible clinicians or groups who meet at least one of the following three criteria during the MIPS determination period would not exceed the low-volume threshold: (1) have allowed charges for covered professional services less than or equal to $90,000; (2) provide covered professional services to 200 or fewer Part B-eligible individuals; or (3) provide 200 or fewer covered professional services to Part B-enrolled individuals.[31]

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[29] Id. at 35,890.
[30] 42 US Code § 1395I (z)(1)(A).
[31] 83 Fed. Reg. at 35,886.

BIO appreciates that CMS is making updates to address physician needs. However, as stated in previous comments, we ask that CMS consider additional flexibilities to meet specific provider need, beyond the current updates to Medicare Part B allowable charges, volume of Part B patients, and number of covered professional services to Part B individuals. This includes the potential for different low-volume thresholds specified by provider type—or the requirement that a provider meet a multi-pronged threshold utilizing two or more identified metrics. Such flexibilities are necessary to ensure the definition of low-volume threshold appropriately accounts for the differences in patient populations seen by eligible providers.

Beginning with the 2021 MIPS payment year, CMS also proposes to allow individual eligible clinicians or groups who exceed at least one, but not all, of the low-volume threshold criteria—and would otherwise be excluded from MIPS participation—the option to opt-in to MIPS.[32] CMS notes that individual eligible clinicians and groups who choose to opt-in to participate in MIPS would be considered MIPS eligible clinicians and groups subject to the MIPS payment adjustment factor. BIO supports making updates to MIPS to increase flexibility and reduce burden for providers. CMS notes that in the CY 2018 QPP Final Rule, it proposed the option to opt-in, but did not finalize the proposal due to concerns that such a policy could not be operationalized in a low-burden manner to MIPS eligible clinicians. BIO believes that in order to be effective, any proposal must be implemented in a way that is easy for providers to manage, and does not increase administrative burden.

c. CMS should maintain the weight of the cost performance category at 10 percent for the 2021 MIPS payment year.

CMS proposes to have the cost performance category make up 15 percent of a MIPS eligible clinician's final score for the 2021 MIPS payment year.[33] CMS seeks feedback on whether it should consider an alternative weight for the 2021 MIPS payment year, including maintaining the cost performance category weight at 10 percent. CMS notes that it debated proposing to keep the cost performance category weight at 10 percent since "clinicians are still learning about the cost performance category and being introduced to new measures."[34]

BIO agrees with this assertion and believes that maintaining the weight of the cost performance category at 10 percent for the 2021 MIPS payment year is more appropriate. While ensuring a smooth transition through MIPS is important as CMS works towards its goal of increasing the weight of the cost performance category, BIO strongly supports holding the cost performance category at 10 percent for an additional year to allow clinicians more time to adapt.

Further, as the program advances, it is critical for there to be appropriate transparency into the measures that clinicians are selecting and their performance ratings. CMS should not increase the weight of the cost and quality performance categories before sharing the results from the first year of the program.

[32] *Id.* at 35,887.
[33] *Id.* at 35,900.
[34] *Id.* at 35,901.

d. CMS should finalize its proposal to continue the complex patient bonus for the 2021 MIPS payment year and to transition the small practice bonus to the quality performance category.

CMS notes that the complex patient bonus was intended as a short term solution to protect access to care for complex patients while not disadvantaging MIPS eligible clinicians who care for complex patients. BIO appreciates CMS's efforts to address the impact of patient complexity on a provider's final MIPS score through the use of a bonus, and agree with CMS's assessment that it would be appropriate to continue the complex patient bonus for another year, at minimum, to support providers who treat these patients. We therefore urge CMS to finalize its proposal to continue the complex patient bonus. We also supports CMS's efforts to accommodate small practices that face unique resource or financial challenges and overcome performance discrepancy due to practice size through the small practice bonus.

Both the small practice bonus and complex patient bonus will be particularly helpful to specialists, solo practitioners, and small practices serving patient populations in geographically restricted areas. We support efforts to ensure continued access for complex patients and to encourage providers to take on more complex patients by eliminating concerns around overall impacts to their MIPS performance, including those with rare disease. Program flexibility is critical for provider participation and provision of high quality, patient-centric care.

Under this same focus, we ask CMS to continue to consider how to account for patients with complex health conditions, including rare diseases, and providers who treat a high volume of these patients. For individuals with rare, chronic conditions, attributing cost and capturing quality can be difficult as diagnosis is generally a multi-year process involving a number of providers and clinical visits, and current diagnostic coding systems may lack the precision to capture rare disorders, impacting the ability to benchmark treatment standards. We therefore ask CMS to consider the development and use of quality measures that are appropriate for patients with complex conditions. Currently, many measure in use are based on an average or otherwise "healthy" population, and therefore cannot appropriate account for patients with complex or comorbid conditions. BIO urges CMS continue to consider how to appropriately account for and provide flexibility to MIPS clinicians serving complex and rare disease patients.

e. CMS should finalize the immunization measures proposed for inclusion in the Comprehensive ESRD Care APM and the CPC+ APM, and identify opportunities to expand immunization measures in future years.

CMS is proposing to include several immunization measures in the APM scoring standard and the proposed new and modified MIPS specialty measure sets for 2018. BIO supports the finalization of these immunization measures proposed for inclusion, including:
Comprehensive ESRD Care APM:[35]

- Influenza Immunization for the ESRD Population
- Pneumococcal Vaccination Status (NQF #0043)

[35] 83 Fed. Reg. at 35936.

CPC+ APM[36]:

- Preventive Care and Screening: Influenza Immunization (NQF #0041)
- Pneumococcal Vaccination Status for Older Adults

BIO also supports the inclusion of a number of specific immunization measures for the 2019 MIPS specialty measures set.[37] We ask CMS to continue to add more immunization focused measures to the specialty set for providers who serve as critical access points for vaccination.

The Medicare Shared Savings Program (MSSP) and Accountable Care Organizations (ACOs) present an important opportunity and access point for high quality, and efficient health care for Medicare beneficiaries, including the delivery of critical preventative care through vaccination. As detailed in the Proposed Rule, BIO supports maintaining *Influenza Vaccination* (ACO #14) under the AIM: Better Health for Populations category; however, we are deeply concerned by the proposed removal of the *Pneumonia Vaccination Status for Older Adults* (ACO #15) measure in the MSSP.

Measures that monitor immunization status as well as reporting of immunizations offered and administered for beneficiaries represent critical preventative service benchmarks on the value of immunizations under new payment models. Both the *Annual Influenza Vaccination* (ACO #15) and *Pneumonia Vaccination Status for Older Adults* (ACO #15) ensure baseline measures are in place to determine access to influenza and pneumococcal vaccinations as well as help identify where caps in access remain. BIO strongly encourages CMS to retain *Pneumonia Vaccination Status for Older Adults* (ACO #15) measure in the MSSP.

BIO was disappointed that the Proposed Rule did not include quality measures aimed at patients at greater risk of serious complications from vaccine preventable illness. In particular, we note that the Advisory Committee on Immunization Practices (ACIP) includes age-based as well as condition-specific recommendations for adult vaccination. Patients living with chronic conditions, including heart disease and diabetes are at significantly higher risk of complication and death from influenza and pneumonia. Moreover, patients with diabetes, or those living with HIV/AIDS and chronic kidney disease, are at increased risk for Hepatitis B infection.

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[36] *Id.* at 35,939.

[37] Measures include: Allergy/Immunology: Preventive Care and Screening: Influenza Immunization; Family Medicine: Zoster (Shingles) Vaccination; Family Medicine: Preventive Care and Screening: Influenza Immunization; Family Medicine: Pneumonia Vaccination Status for Older Adults; Family Medicine: Immunization for Adolescents; Internal Medicine: Zoster (Shingles) Vaccination; Internal medicine: Preventive Care and Screening: Influenza Immunization; Internal Medicine: Pneumonia Vaccination Status for Older Adults; Ob/Gyn: Preventive Care and Screening: Influenza Immunization; Ob/Gyn: Pneumonia Vaccination Status for Older Adults; Otolaryngology: Preventive Care and Screening: Influenza Immunization; Otolaryngology: Pneumonia Vaccination Status for Older Adults; Pediatrics: Preventive Care and Screening: Influenza Immunization; Pediatrics: Childhood Immunization Status; Pediatrics: Immunization for Adolescents; Preventive Medicine: Zoster (Shingles) Vaccination; Preventive Medicine: Preventive Care and Screening: Influenza Immunization; Preventive Medicine: Pneumonia Vaccination Status for Older Adults; Nephrology: Zoster (Shingles) Vaccination; Nephrology: Preventive Care and Screening: Influenza Immunization; Nephrology: Pneumonia Vaccination Status for Older Adults; Oncology: Zoster (Shingles) Vaccination; Oncology: Preventive Care and Screening: Influenza Immunization; Oncology: Pneumonia Vaccination Status for Older Adults; Infectious Disease: Zoster (Shingles) Vaccination; Infectious Disease: Preventive Care and Screening: Influenza Immunization; Infectious Disease: Pneumonia Vaccination Status for Older Adults; Rheumatology: Preventive Care and Screening: Influenza Immunization; Rheumatology: Pneumonia Vaccination Status for Older Adults; Geriatrics: Zoster (Shingles) Vaccination; Geriatrics: Preventive Care and Screening: Influenza Immunization; Geriatrics: Pneumonia Vaccination Status for Older Adults; Skilled Nursing Facility: Preventive Care and Screening: Influenza Immunization; Skilled Nursing Facility: Zoster (Shingles) Vaccination. 83 Fed. Reg. at 36,103.

On a related note, the National Committee for Quality Assurance (NCQA) recently released its HEDIS measures for 2019, which includes a new composite adult immunization measure. BIO supports the development, endorsement, and CMS adoption of this composite adult immunization measure, which includes influenza and pneumococcal, going forward. However, eliminating the reporting requirement on these measures prior to CMS adopting the composite measure would insinuate to providers that immunizations are not a priority for the Agency, when there is still much progress to be made in increasing vaccination rates among this population. We urge CMS to add the following immunization quality measures into the specialty measure sets until the composite measure is required for ACO reporting to prevent any additional gaps in care.

- Endocrinology:
    - NQF #0041 Preventive Care and Screening: Influenza Immunization
    - NQF #0043 Pneumonia Vaccination Status for Older Adults
- Cardiology:
    - NQF #0041 Preventive Care and Screening: Influenza Immunization
    - NQF #0043 Pneumonia Vaccination Status for Older Adults
- General Surgery:
    - NQF #0041 Preventive Care and Screening: Influenza Immunization
    - NQF #0043 Pneumonia Vaccination Status for Older Adults
- Skilled Nursing Facility:
    - NQF#0043 Pneumonia Vaccination Status for Older Adults

f. CMS should finalize the proposed changes around the Immunization Registry Reporting Measure, and seek out future opportunities to increase provider participation in immunization registries.

For the MIPS performance period in 2019, MCS proposes awarding 10 points to MIPS eligible clinicians who report two of the following measures within the Public Health and Clinical Data Exchange objective: Immunization Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; Clinical Data Registry Reporting; Syndromic Surveillance Reporting.[38]

According to the Centers for Disease Control and Prevention (CDC), Immunization Information Systems (IIS), or immunization registries currently operate in all 50 states, 5 cities, the District of Columbia (D.C.), and 8 Territories. However, not all systems are able to connect with all providers in a community. Limited resources and staffing as well as legal and policy barriers hinder the ability of all eligible clinicians in a community to report data to their state or local immunization registry. BIO supports the flexibility being afforded to providers who are unable to complete the registry. However, we encourage CMS to work with the CDC and its IIS grantees to achieve a higher level of interoperability and address legal and policy barriers that prevent Medicare clinicians from reporting data to immunization registries as required. BIO encourages CMS to set a goal that Immunization Registry Reporting eventually becomes a required reporting measure under MIPS.

[38] 83 Fed Reg. at 35,916.

g. CMS should finalize the Stroke and Stroke Rehabilitation Thrombolytic Therapy measure proposed for inclusion in the Emergency Medicine and Neurosurgical specialty sets.

BIO supports the proposed inclusion of the Stroke and Stroke Rehabilitation: Thrombolytic Therapy quality measure for MIPS in emergency medicine and neurosurgical specialties. We encourage CMS to continue to consider measurement and payment of high quality, cost-effective stroke care in all settings, including in the hospital inpatient setting.

h. CMS should finalize the inclusion of the new dementia related quality measures in MIPS.

CMS is proposing the inclusion of new dementia related quality measures for MIPS, beginning in 2012. These include measures for cognitive assessment, functional status assessment, associated behavioral and psychiatric symptoms screening and management, safety concern screening and follow up, and caregiver education and support. Given the larger population of Americans with Alzheimer's disease (5.7 million in 2018[39]), BIO appreciates and supports these proposals that will improve care for patients with Alzheimer's disease and related dementias. We encourage the Agency to further support improving access to care by including quality measures for early detection and initial diagnosis.

i. CMS should include additional meaningful narrative context to help patients understand the MIPS eligible clinician and group performance information available on Physician Compare.

In the CY 2018 QPP final rule, CMS finalized a policy to publicly report the final score and the performance for each performance category of each MIPS eligible clinician. In the CY 2019 QPP proposed rule, CMS notes it will "use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel convened by [its] contractor, to determine how and where these data are best reported on Physician Compare."[40] BIO is supportive of CMS's efforts to expand patient experience data collection and ensure the information provided to patients is provided in a coherent manner. To that end, BIO asks that CMS work to include meaningful narrative context for the information made publicly available to best inform patients.

j. CMS should finalize the proposed changes to quality measures aimed at addressing the opioid epidemic and continue to work with stakeholders to develop future quality measures for pain and addiction treatment.

As a part of the Meaningful Measures Framework for the QPP, CMS identifies six overarching quality priorities with 19 meaningful measures, one of which is "Prevention and Treatment of Opioid and Substance Use Disorder". In discussion of measures for MIPS, CMS notes that due to the immense impact of the opioid epidemic, the Agency believes it is imperative to promote the measurement of opioid use and overuse, risks, monitoring, and education

[39] Alzheimer's Association. 2018 Alzheimer's disease Facts and Figures.
[40] 83 Fed. Reg. at 35987

through quality reporting and is amending the definition of a high priority measure to include quality measures that relate to opioids and specifically ask what aspects of opioids should be measured (i.e. should focus solely be on overuse?).

As a threshold matter, BIO appreciates the Agency's focus and emphasis on addressing the opioid epidemic and supports the inclusion of addressing the opioid epidemic as a component of the meaningful measure set. As detailed above, BIO is committed to the development of innovative treatment options for both pain and addiction, and appreciates the Agency seeking feedback on further measures that could be included. In particular, we emphasize that not only should measure sets focus on reducing opioid overuse, but also on ensuring patients are able to access new innovations in treatment options for pain – especially as the scientific understanding of pain evolves, and advances lead to more targeted treatment options for both acute and chronic pain. Further, we believe implementing measures that assess the delivery of SUD treatment are critical as well.

In this same theme, we appreciate the Agency's addition of a new criteria for selection of improvement activities for activities related to addressing public health emergencies (as determined by the Secretary), specifically calling out the opioid epidemic. BIO believes such inclusion criteria is an important to the overall efforts to address the crisis through the activities in the Agency's jurisdiction. Further, we believe this criteria for improvement activities could help to ensure patients receive the most appropriate pain and SUD treatments.

CMS is also proposing two new measures related to the e-Prescribing objective in the QPP as a part of their commitment to combatting the opioid epidemic. BIO supports CMS's efforts to address the opioid epidemic through incorporation of new measures. As noted above, we encourage the Agency to continue to make updates to the program that also facilitate patient access to novel and safer pain treatment options as well as innovations in treatment for SUDs.

k. CMS should move forward with the establishment of a public health priority set across MIPS performance categories.

BIO appreciates the efforts of CMS to provide clinicians with measures that are meaningful to their practice by considering for future rulemaking a proposal that would establish public health priority sets across the four MIPS performance categories. In the rule, CMS states: in developing the first few public health priority sets, we intend to focus on areas that address the opioid epidemic impacting the nation, as well as other patient wellness priorities that are attributable to more complex diseases or clinical conditions. Addressing the opioid epidemic is also incorporated into the National Action Plan for Adverse Drug Event Prevention (ADE Action Plan), which includes additional priorities that CMS should consider for its public health priority sets.[41] Based on that action plan, CMS should consider a public health priority set that focuses on initial target areas of opioids, diabetes and anticoagulants.

These high priority areas would help meet the Agency's goals of focusing on patient wellness priorities that are attributable to more complex diseases. For example, the

[41] U.S. Department of Health and Human Services. National Action Plan for Adverse Drug Event Prevention. 2014.

conditions that necessitate the use of anticoagulants are often clinically complex and require the coordination of care across multiple providers and settings. As the Agency evaluates which public health priority sets to establish, we urge CMS to do so in concert with the ADE Action Plan, as there are likely to be synergies created amongst affected medications and drug classes to better safeguard the interests of patients.

IX. CMS should work to continue to provide updates to the reimbursement system that allow for adoption of newly-FDA approved therapies.

CMS is continuing its policy—finalized in the CY 2018 PFS Final Rule—of creating a unique HCPCS code for each individual biosimilar product. BIO reiterates our support for CMS's finalized policy of creating a separate HCPCS code and separate payment rate for each biosimilar product. This policy maximizes patient safety and access to appropriate therapies, and helps foster a competitive, innovative market for biosimilars.

BIO believes it is critical for current payment and delivery systems to continuously adapt to ensure appropriate and adequate reimbursement for innovative treatments. To that end, we urge CMS to continue to update the system to account for new therapies, many of which do not fit into the current reimbursement paradigm. Rigid timelines and antiquated systems can hinder patient access to the newest available treatments and most updated standard of care. It is critical for there to be flexibility to allow for consistent and appropriate updates so that Medicare beneficiaries have access to the most appropriate therapy available.

* * *

BIO appreciates the opportunity to comment on the proposals in the Medicare PFS 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/

Crystal Kuntz
Vice President, Healthcare Policy & Research
Biotechnology Innovation Organization

/S/

Mallory O'Connor
Director, Healthcare Policy & Federal Programs
Biotechnology Innovation Organization

Appendix 1: Resulting Payment Rates for CMS's Proposed Changes to Simplify E/M Visit Code Payments

Type of Payment	CPT Codes	Payment Rate for CY 2019	Payment Rate for CY 2018
Facility Payments	99202 through 99205	$102.37	$51.48 - $172.08
Nonfacility Payments	99202 through 99205	$134.45	$76.32 - $210.60
Facility Payments	99212 through 99215	$65.60	$25.92 - $113.04
Nonfacility Payments	99212 through 99215	$91.92	$44.64 - $147.00