September 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Attention: CMS-1715-P
200 Independence Ave, SW
Washington, DC 20201

RE: CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS's) CY2020 Revisions to Payment Policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment Policies ("Proposed Rule").

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.

We offer comments on the following areas in the proposed rule, with an emphasis on ensuring that Medicare beneficiaries have access to the full range of items and services necessary to their health:

- BIO appreciates the opportunity to comment on the agency's future consideration of bundled payments under the PFS but urges CMS to prioritize patient access to appropriate therapies and to weigh the results of other demonstrations underway rather than attempting to swiftly implement bundled payments.
- BIO supports the proposal to retain more granular payments for Evaluation and Management (E/M) services, which we think will support access to appropriate care for the sickest patients.

- BIO appreciates the efforts CMS is making to treat patients with opioid addiction and offers comments about the agency's proposals in this area, again with an emphasis on ensuring patient access to appropriate care.

I. Comment Solicitation for Bundled Payments under the Physician Fee Schedule

CMS states it is actively exploring the extent to which the basic principles of bundled payment (e.g., per-beneficiary payments for multiple services or condition-specific episodes of care) can be applied within the statutory framework of the PFS. Specifically, CMS notes, "We believe that the statute, while requiring CMS to pay for physicians' services based on the relative resources involved in furnishing the service, allows considerable flexibility for developing payments under the PFS."

> ***BIO Recommendation:*** We would note that Part B drugs are required, under the Medicare statute, to be separately reimbursed under the Medicare physician fee schedule at ASP+6% (which equates to ASP+4.3% due to the effects of sequestration). In addition, as CMS considers opportunities for bundling payments under the PFS, we would caution that beneficiary access to necessary therapies and services, and the ability of providers to be sufficiently reimbursed for treatments and services they believe a beneficiary needs, should be a primary consideration before moving too swiftly to bundle payments under the PFS. As CMS notes, CMMI has multiple demonstrations underway. It would seem preferable to continue to learn from these demonstrations before expanding bundling within the Medicare program.

II. Evaluation & Management (E/M) Coding Structure

In the 2019 final rule, CMS finalized several policies related to E/M services. Based on ongoing concerns that have been raised since publication of the 2019 final rule, CMS is proposing modifications to its policies that were finalized last year. Specifically, CMS proposes to align with the E&M coding changes established by the CPT Editorial Panel. In doing so, CMS proposes to retain the 5 separate levels of coding for established patients, and 4 levels for new patients. CMS also proposes to adopt the code definitions and other aspects of the CPT recommendations.

> ***BIO Recommendation:*** BIO strongly supports CMS' proposal to adopt the E/M coding structure as revised by the AMA/CPT and accept the RUC-recommended values, including retaining the 5 separate levels of coding for established patients and 4 levels for new patients. As noted in prior comments, BIO is extremely concerned that elimination of the different levels of payment for Levels 2 through 4 E/M services would harm practitioners who are treating the sickest patients. Under a consolidated system, these practitioners would be undercompensated for the complex E/M services they provide as the weighted payment rate that CMS had planned to adopt would be lower than the current payment rates for these services. Eliminating the higher payment rates for Level 4 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 needs. Therefore, we believe that the CMS proposal to adopt the revised AMA/CPT coding structure for E/M services and proposed valuation is an important step in maintaining patient access.

III. Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs

The Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) enacted October 24, 2018 establishes a new Part B benefit for opioid use disorder (OUD) treatment services furnished by an opioid treatment program (OTP) starting January 1, 2020. CMS outlines a range of proposed policies related to the SUPPORT Act, including definition of OUD treatment services and programs and proposed bundled payments.

Patient Cost Sharing. CMS notes that the SUPPORT Act specifies that payment for OUD treatment services furnished by a provider is the amount payable under the statute *less any copayment required as specified by the Secretary.* CMS is proposing to set the copayment at zero for a time-limited duration (for example, for the duration of the national opioid crisis).

> ***BIO Recommendation:*** BIO strongly supports this approach. Any copay expenditure can be a deterrent for a patient attempting to recover. Removing patient cost sharing requirements for these services will eliminate a significant barrier to appropriate patient care and support the recovery efforts of patients with opioid addictions.

Proposed Definition of OUD Treatment Services. CMS proposes that the OUD treatment services that may be furnished by OTPs include those specified in the statute. CMS also proposes to use its statutory discretion to include the use of telecommunications for certain services. CMS seeks comment on any other items and services it should consider adding to this definition.

> ***BIO Recommendation:*** We support a definition of OUD treatment services that is flexible and would allow for coverage of innovative therapies in development that have not yet been approved by the FDA and are not opioid agonist and antagonist medications. Such an approach is critical to ensure that Medicare beneficiaries have access to all FDA-approved therapies that best meet their needs. CMS needs to allow for this flexibility and structure reimbursement to account for new therapies to avoid the uncertainty of seeking future legislation action to resolve. Further, patients suffering from pain or addiction should have knowledge of, access to, and coverage for all available medicines in order to make informed decisions about their treatment. A patient-centric approach to the treatment of pain and addiction will help prevent opioid addiction and provide better care for those who are diagnosed with addiction.
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> To that end, we recommend the following change to the proposed definition at § 410.67 (b) that refers to medications to treat OUD:
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> > *Opioid use disorder treatment service* means one of the following items or services for the treatment of opioid use disorder that is furnished by an opioid treatment program that meets the requirements described in paragraph (c) of this section.
> > (1) Therapies that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug, and Cosmetic Act for use in treatment of opioid use disorder.

BIO Recommendation: BIO recommends that any definition of OUD treatment services recognizes that within these services there may be different levels of time/care required and that reimbursement for such differing levels of care should reflect this.

BIO Recommendation: In order to ensure that individuals suffering with OUD have access to all forms of Medication-Assisted Treatment (MAT), we recommend CMS also include services for detoxification withdrawal/management maintenance, which is required prior to the administration of certain non-opioid, antagonist medications. Current reimbursement limitations associated with detoxifications under Medicare, especially on an outpatient basis, are a serious problem undermining appropriate care. More detail regarding this recommendation is provided below.

There are three types of medications approved by the FDA for the treatment of opioid use disorders: methadone, buprenorphine, and extended-release naltrexone (XR-NTX). XR-NTX differs from methadone and buprenorphine as treatment with XR-NTX for OUD can only begin 7-10 days after the completion of detoxification. Federal law, regulations, and guidelines authorize OTPs to use methadone and other medicines to provide opioid withdrawal management/maintenance for achieving detoxification. Currently, according to the Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Agency (SAMHSA), only about 6% of OTPs provide opioid detoxification. The majority of patients admitted to OTPs today will drop out of treatment in about nine months. Dropping out of treatment, without appropriate detoxification and relapse prevention is a major contributor to relapse and potential overdose. Given this reality, the SAMHSA and U.S. Surgeon General have emphatically argued that opioid detoxification must be followed by induction on to XR-NTX.[1]

> "If medical withdrawal (detoxification) is performed, it must be accompanied by injectable extended-release naltrexone to protect such individuals from opioid overdose in relapse and improve treatment outcomes."

This "detox barrier" has been cited as another important challenge for individuals wishing to end their dependence on opioids. While the prospect of undergoing detoxification in itself is a factor, inadequate coverage for opioid detoxification, especially on an outpatient basis, is another significant barrier. Depending upon the patient and provider, opioid detoxification on an inpatient basis can take one or more weeks, and on an outpatient basis, detoxification can take several weeks.

During the detoxification process the patient's physician and treatment team (e.g., nurses, counselors and case managers) provide several necessary clinical services. These services include a comprehensive medical and psychiatric history and exam, including informed consent treatment discussion; addressing withdrawal questions; writing out prescriptions for ancillary medications; and explaining ancillary medications to patients and family. Other necessary services include daily outpatient assessment and symptom monitoring and medication adjustment for 7-14 days including: nursing support for daily medical assessment; inpatient admission backup option; psychiatrist availability for consultation; counseling support; social services

[1] SAMHSA. Funding Opportunity Announcement, State Opioid Response Grants. No. TI-18-015. (June 2018). Page 6. Available at: https://www.samhsa.gov/sites/default/files/grants/pdf/sorfoafinal.6.14.18.pdf.

support; after hours medical support; and contingency management to encourage compliance.

OUD Treatment Program. The SUPPORT Act defines an opioid treatment program as an entity meeting the definition of an OTP in existing regulations (42 CFR 8.2), specifically that the entity is enrolled in Medicare (and has a provider agreement in place), is certified by SAMHSA, is accredited by an accrediting body approved by SAMHSA, and meets any additional conditions the Secretary finds necessary to ensure the health and safety of individuals being furnished services under such program. CMS seeks comment on whether any additional conditions should be required for OTPs furnishing Medicare-covered OUD treatment services.

> ***BIO Recommendation:*** We support CMS' proposed approach in defining an OUD treatment program, which largely follows the definition outlined in the SUPPORT Act. OTPs are already subject to rigorous licensing, certification and accreditation sufficient to ensure delivery of evidence-based services. Additional requirements would only create barriers to access for Medicare beneficiaries.

Bundled Payments for OUD Treatment Services. CMS proposes to establish a bundled payment for OUD treatment services, which will involve both a drug and a non-drug component. CMS proposes that the duration of an episode of care for OUD treatment services would be 1 week, noting such a policy is similar to the structure of the TRICARE bundled payment as well as the payments by some state Medicaid programs. CMS also proposes an approach for a partial week bundle. CMS does not propose any maximum in the number of weeks covered.

> ***BIO Recommendation:*** We believe CMS' proposed approach for defining an episode of care as a 1-week period (with the possibility of partial week episodes) may be a reasonable approach so long as CMS does not impose any limit on the number of weeks covered for any given Medicare beneficiary. However, since an OTP must maintain base staffing and services regardless of partial week or full week services, a partial week reimbursement model may have a negative impact on the OTP providers, especially if the proposed CMS reimbursement model correlates to either TRICARE or state Medicaid reimbursement rates. Further, the definition of an episode of care should recognize that within these services there may be different levels of time/care required and that the reimbursement reflects this. And, the reimbursement must ensure that the reimbursement matches the episode of care timing so as not to skew care one way or the other due to financial considerations.

Defining the Payment Bundle for Drugs. CMS proposes the following categories of drug bundles based on the medications currently approved by the FDA for use in treatment of OUD: Methadone (oral); Buprenorphine (oral); Buprenorphine (injection); Buprenorphine (implant); and Naltrexone (injection). CMS states that such an approach "would strike a reasonable balance between recognizing the variable costs of these medications and the statutory requirement to make a bundled payment for OTP services."

> ***BIO Recommendation:*** We do not believe that medications should be bundled and are concerned that such an approach will inhibit the ability of a health care provider to choose the best treatment for a patient. If CMS proceeds with a bundling approach as outlined, we have concerns that that the bundling categories identified in the proposed rule are too broad. Specifically, Buprenorphine (injection) assumes that all of the injections last for the same period of time. At a minimum, there should be consideration of separate categories for Buprenorphine (injection) that last

for different periods of time. (e.g., one category for Buprenorphine (injection – weekly) and a separate category for Buprenorphine (injection – monthly). We would also note that keeping drugs outside the bundle and reimbursing them under the pre-existing payment systems available under Part B and Part D would support the statutory mandate to avoid duplicative payments and would focus the bundled payment on treatment services for which coverage was not otherwise provided.

Payment Amount for Bundled Drugs. CMS proposes to use 100% of the volume-weighted ASP for a HCPCS code instead of ASP + 6% to reimburse for the injection and implantation of drugs. CMS proposes to use the typical or average maintenance dose to determine the drug costs for each of the proposed bundles. CMS proposes that the payment amounts for the drug component of the bundles be based on CMS pricing mechanisms currently in place but requests comment on other potential data sources for pricing OUD treatment medications.

BIO Recommendation: Again, we strongly disagree with CMS' proposed approach and recommend continued reimbursement at ASP+6% or under Part D where applicable, as is the case for other drugs. We believe a volume-weighted approach at 100% of ASP will provide a disincentive for the HCP to utilize the most appropriate product for the patient. A fair and reasonable reimbursement of ASP+6% allows the OTP to recoup cost associated with treatment and extra burden of complying with rigorous inventory tracking and storage requirements required by the DEA. Moreover, since the larger OTPs may skew ASP lower than what the smaller clinics could negotiate on their own, CMS needs to consider ASP variances when establishing a rate. Regarding use of the "average maintenance dose," we recommend that CMS better define how it would calculate the average maintenance dose for us to comment on the methodology. Depending on the methodology that is used, it could unintentionally influence treatment patterns. However, it is impossible to say without more transparency from CMS on the methodology.

Payment – Non-drug Component. To price the non-drug component CMS proposes to use a crosswalk to the non-drug component of the TRICARE weekly bundled rate for services furnished when a patient is prescribed methadone. TRICARE's reimbursement for CY 2019 is $133.15 (of which $22.19 is the methadone cost and the remainder, $110.96, is for the non-drug services). Differing amounts would be subtracted from the $133.15 for medications that have a different method of administration. CMS states using the TRICARE weekly bundled rate is a reasonable approach to setting the payment rate for the non-drug component of the bundled payments to OTPs, particularly given the time constraints in developing a payment methodology prior to the January 1, 2020 effective date of this new Medicare benefit category and because the TRICARE methodology was established through notice and comment rulemaking.

BIO Recommendation: We are concerned that such an approach does not recognize the difference in drug services for various therapies, which in turn may disincentivize providers from utilizing the most appropriate therapy. We urge CMS to outline how it would assess potential impacts and allow for a different approach in the future to ensue patient access to the most appropriate treatment. TRICARE is often considered a "bare-bones" rate and may be insufficient to cover the services valued by CMS. CMS may want to consider/evaluate a base bundled rate for basic services but allowing for per diem rates for additional services such as counseling, case management, lab and medical visits.

IV. Bundled Payments under the PFS for Substance Use Disorders

In addition to the new Medicare Part B benefit added by section 2005 of the SUPPORT Act for coverage of certain services furnished by OTPs beginning in CY 2020, CMS is proposing to create an avenue for physicians and other health professionals to bill for a bundle of services that is similar to the new bundled OUD treatment services benefit, but not furnished by an OTP. CMS anticipates that these services would often be billed by addiction specialty practitioners, but that these codes are not limited to any particular physician or non- physician practitioner specialty.

Under this proposal, if a patient's treatment involves MAT, the bundled payment would not include payment for the medication itself. Billing and payment for medications under Medicare Part B or Part D would remain unchanged. Additionally, payment for medically necessary toxicology testing would not be included in the proposed OUD bundle and would continue to be billed separately under the Clinical Lab Fee Schedule. The new proposed codes describe a monthly bundle of services for the treatment of OUD that includes overall management, care coordination, individual and group psychotherapy, and substance use counseling. One code describes the initial month of treatment, which would include administering assessments and developing a treatment plan; another code describes subsequent months of treatment; and an add-on code describes additional counseling.

CMS is proposing that the individual psychotherapy, group psychotherapy, and substance use counseling included in these codes could be furnished as Medicare telehealth services using communication technology as clinically appropriate. CMS is also seeking comment on bundles describing services for other Substance Use Disorders (SUDs) and on the use of MAT in the emergency department setting, including initiation of MAT and the potential for either referral or follow-up care, as well as the potential for administration of long-acting MAT agents in this setting, to help inform whether it should consider proposing to make separate payment for such services in future rulemaking.

> ***BIO Recommendation:*** BIO believes that this proposed new bundle of services, if developed and paid appropriately, would help ensure delivery of the appropriate care for SUD of Medicare beneficiaries, while expanding access to innovations in treatment. Access to such innovations are 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 support CMS's proposed approach that MAT drugs are paid separately from the services in a bundle, to ensure payment policies facilitate access to these critical medicines.
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> 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 medication being delivered (i.e. injectable, oral, long-acting), as well as considering different bundles based on the phase of treatment. 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 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;[2] and The Medicaid Innovation Accelerator Program (IAP) collaboration with Medicaid and behavioral health agencies in development of robust approaches for addressing SUD.[3]

We also note that the CMS proposed model for adjusting rates for intensity of services through the individual clinician's determination of whether a particular patient met 51% of treatment plan services will subject OTPs to heightened audit risk. To avoid this type of subjectivity by the clinician, CMS should consider a single base bundle for the minimum services while add-on services, as could be billed separately as necessarily administered during treatment.

V. Reduction in Practice Expense Relative Value Units for Vaccine Administration

Vaccination is one of the most effective public health tools available to prevent disease. Despite their well-recognized benefit, several persistent barriers to adult immunization rates have contributed to vaccination rates not reaching Healthy People 2020 targets[4]. BIO is concerned that CMS's proposed reduction for payment for the CPT code 96372 will significantly reduce payment for immunization administration and create an additional barrier to immunizing Medicare Beneficiaries.

CMS is proposing to continue a phased-in reduction of the practice expense (PE) component for intramuscular, oral, and nasal immunization CPT codes 90460, 90471, and 90473, respectively. This reduction is in part to a longstanding and outdated policy that ties these codes' payment to CPT code 96372 for subcutaneous or intramuscular therapeutic, prophylactic, or diagnostic injection[5,6]. As a result, reductions to 96372 have and continue to reduce payment for immunization administrations for all payers that rely on the MPFS fee-setting. Reductions of 96372 will reduce payment for immunization administration by 44% between 2017 and 2020.

This approach has inappropriately tied immunization administration codes to non-vaccine injectable products. Providers must devote significant time and resources to vaccine inventory management, vaccine storage, patient counseling, and claims processing[7]. Providers also must manage a spike in patient visits solely for immunization during certain times of year such as the influenza season between October and March. This linkage to 96372 to determine immunization administration fees does not account for these unique

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[2] American Society of Addiction Medicine, American Medical Association. Patient Centered Opioid Addiction Treatment (P-COAT) Alternative Payment Model. 2018.
[3] Medicaid.gov. Technical Resources for States: Medication-Assisted Treatment Bundled Payments.
[4] https://www.healthypeople.gov/2020/data-search/Search-the-Data#objid=4670
[5] https://www.govinfo.gov/content/pkg/FR-2010-11-29/pdf/2010-27969.pdf
[6] https://www.govinfo.gov/content/pkg/FR-2004-11-15/pdf/04-24758.pdf
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594851/

factors and underestimates provider burden when vaccinating adult patients to create an inappropriate reduction in payment.

Financial concerns, including inadequate fees have been cited as a barrier to adult vaccination and a reason why healthcare providers do not stock adult vaccines[8,9]. Further reduction in immunization payment rates will only exacerbate these challenges and create an additional barrier that could undermine vaccine coverage rates. Missed vaccinations will result in increased burden for vaccine preventable diseases with corresponding additional costs to health systems. These payment reductions also have critical public health implications that run counter to our Healthy People goals to further increase vaccination rates, the efforts below by CMS to adopt the adult immunization status measure, and finally the Administration's aim to improve access to influenza vaccination[10].

> ***BIO Recommendation:*** BIO urges CMS to sever the linkage and determine practice expense and associated payment levels for immunization administration codes separate from administration of other injectable products.

VI. Medicare Shared Savings Program (MSSP) and Merit-based Incentive Payment System

We note the proposed rule includes provisions that aim to transition from volume to value-based payment policy, including the MSSP and MIPS programs. BIO believes both offer a key opportunity to encourage both access to, and utilization of, recommended adult immunizations to priority Medicare populations.

The Adult Immunization Status (AIS) measure is a composite of several age-recommended vaccines for adults, comprising influenza, pneumococcal, zoster, and Tdap vaccines. It aims to provide a sound, reliable, and comprehensive means to asses the receipt of routinely recommended adult immunizations while also reducing reporting burden on providers. It will enable robust immunization status monitoring and reporting and inform critical preventive service benchmarks that can account for the value immunization under new payment models.

BIO commends CMS for including the Adult Immunization Status (ACO-47) under the AIM: Better Health for Populations under the MSSP in 2020, with a phase-in to pay-for-performance measure in performance year 2022. BIO also strongly supports CMS's proposal to streamline adult immunization status by broadly adopting the AIS measure for CY 2020 MIPS Specialty Measure Sets. These efforts will increase opportunities to assess immunization status for Medicare beneficiaries by the range of clinicians who care for them, including both primary care and specialty providers.

> ***BIO Recommendation:*** BIO strongly supports the inclusion of the Adult Immunization Status measure in both the MIPS and MSSP and encourages CMS to maintain the measure in the final rule. BIO appreciates CMS' recognition of the need to engage in a focused, concerted effort to and utilization of adult immunizations as a means of improving the overall health of Medicare beneficiaries.

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[8] Primary care physician perspectives on providing adult vaccines; Vaccine; Volume 29, Issue 9, 17 February 2011, Pages 1850-1854

[9] L.P. Hurley, M.C. Lindley, M.A. Allison, L.A. Crane, M. Brtnikova, B.L. Beaty, et al. Primary care physicians' perspective on financial issues and adult immunization in the Era of the Affordable Care Act; Vaccine; Volume 35, Issue 4, 23 January 2017, Pages 647-654

[10] https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-influenza-vaccines-united-states-promote-national-security-public-health/

Building on CMS's work to adopt the AIS for specialty sets, BIO encourages CMS to consider adding the AIS into the Cardiology specialty measure, given the critical role vaccination plays in preventing disease in patients with cardiovascular conditions[11].

BIO also supports the inclusion of the AIS in the Obstetrics/Gynecology specialty measure set. We recommend CMS also consider the adoption of the prenatal immunization status measure, which was created specifically for maternal populations and better reflects the Advisory Committee on Immunization Practices (ACIP) recommendations for pregnant women, specifically Tdap and influenza[12]. Like the AIS, the Prenatal Immunization Status measure will also help to address substantial disparities in prenatal immunization rates.

VII. Transforming the Merit Based Incentive Payment System (MIPS)

CMS is proposing to apply a new MIPS Value Pathways (MVP) framework beginning with the 2021 MIPS performance period/2023 MIPS payment year "to simplify MIPS, improve value, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians." CMS provides examples of potential MVPs in the proposed rule, including preventive health, diabetes prevention and treatment, major surgery and general ophthalmology. Each pathway would have associated quality and cost measures and improvement activities. As part of the MVP, CMS seeks feedback on patient reported measures, specifically which patient experience/satisfaction measurement tools or approaches would be important for inclusion.

BIO Recommendation: In general, we support movement toward MIPS Value Pathways (MVPs) but we urge CMS to a reconsider implementation beginning with the 2021 MIPS Performance Year, as we are concerned that it will not allow sufficient time for development of MVPs prior to 2021. We encourage CMS to allow time to develop and test needed quality/cost measures and improvement activities to support these MVPs prior to implementation. CMS should work closely with stakeholders and measure stewards to identify patient populations or therapeutic areas for which there is greatest need or areas for quality improvement in determining some focus areas for the MVPs, rather than building solely based on currently available measure sets. We look forward to future engagement with CMS on this issue and providing more detailed feedback as CMS provides a specific proposed approach for comment.

VIII. Open Payments Updates

Under the proposed rule, CMS includes updates to the Open Payments program to address provisions of the SUPPORT Act and to make changes solicited in previous comment opportunities. These changes include updates to the definition of covered recipients and changes to the nature of payment categories by consolidating two categories and adding three new categories.

BIO Recommendation: We have concerns regarding the lack of clarity regarding covered recipients that must be reported under the Open Payments System. We welcome collaboration with CMS in finding a solution to identify those who individuals who are true covered recipients under Open Payments.

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[11] https://heart.bmj.com/content/102/24/1953
[12] https://www.ncqa.org/wp-content/uploads/2019/02/NCQA-AIS-PRS-Webinar-Slides-Feb-2019.pdf

Specifically, there are inconsistencies in CMS guidance regarding the definitions of healthcare providers and required reporting. For instance, some definitions reference the "performance" of a certain service as qualifying for reporting, while others only refer to certification or achievement of defined requirements. For example, the existing definition of a physician under the open payments system references the performance of certain functions or actions, but the Agency's FAQ document refers to current licensure as the threshold for reporting under the system.

As another example, regarding the identification of nurse practitioners, based on current definitions it would be a challenge to ascertain who holds a specific degree. We would also note that identification of covered recipients is based on state license boards and what license an individual holds; the majority of licensing boards do not make available what educational degree an individual may hold.

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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