

August 21, 2017

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

RE: Medicare Program; CY 2018 Updates to the Quality Payment Program (CMS-5522-P)

Dear Administrator Verma:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) CY 2018 Updates to the Quality Payment Program Proposed Rule ("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 supports the development and implementation of the Quality Payment Program (QPP) tracks: Advanced Alternative Payment Models (APMs) and the Merit Based Incentive Payment System (MIPS), in a manner that improves overall healthcare quality, while not compromising access to the most appropriate care and treatment. Our comments, detailed further in the balance of this letter, focus in the following areas:

- CMS should not finalize its proposal to include Part B drug costs in the MIPS adjustment, as such a policy could severely impact patient access to high quality care and treatment.
- CMS should finalize the proposal to update the low-volume threshold, but look to provide additional transparency around the process for future updates.
- CMS should move forward with the proposal to provide a bonus for complex patients and small practices to protect access to care.
- CMS should not finalize the proposed expansion of the definition of a hospital-based MIPS eligible clinician.

¹ 82 Fed. Reg. 30,010 (June 30, 2017).

- CMS should finalize the proposal of a zero percent weight for cost performance in 2018.
- CMS should continue the process of updating the episode-based payment measures and collect robust stakeholder feedback on inclusion of these measures in MIPS.
- CMS should ensure that any additional feedback provided on the cost performance category is comprehensive and looks at the totality of care, rather than specific subsets of care.
- CMS should ensure the continued strengthening of the quality performance category through use of the most up-to-date, relevant quality measures, working in conjunction with measure stewards and endorsers.
- CMS should refine the quality benchmark proposal for 2018, so as not to disadvantage certain provider specialties.
- CMS should maintain the same five percent APM quality measure bonus cap as was in place for 2017, and not move to a ten percent cap.
- CMS should add further clarity, transparency, and an expanded response timeline in the criteria for Physician-Focused Payment Models (PFPMs) reviewed by the Physician-Focused Technical Advisory Committee (PTAC), particularly if CMS chooses to broaden the definition of PFPMs.
- CMS should include additional meaningful narrative context to help patients understand the MIPS eligible clinician and group performance information available on Physician Compare.
- CMS should finalize the proposed changes around the Immunization Registry Reporting Measure and performance score, and seek out future opportunities to increase provider participation in immunization registries.
- CMS should consider adding vaccine-specific measures to the list of cost-cutting measures in the future.
- CMS should finalize the immunization measures in the APM scoring standard and the proposed new and modified MIPS specialty measure sets for 2018, and identify opportunities to expand immunization measures in future years.
- CMS should develop more sophisticated means to compare providers of the same or similar specialties under MIPS, such as use of CMS-approved healthcare provider taxonomy codes.
- CMS should identify opportunities to incorporate guidelines-driven algorithms into health information technology (HIT) to help better identify and track certain disease states.
- CMS should finalize the proposal to update the process for Qualified Clinical Data Registry annual nominations.
- CMS should consider further expansion of measures around achieving health equity in clinical trials.

I. CMS should not finalize its proposal to include Part B drug costs in the MIPS adjustment, as such a policy could severely impact patient access to high quality care and treatment.

Under the Proposed Rule, CMS includes what it describes as a clarification of policy around MIPS adjustment for Part B “items and services” to include Part B drug purchasing and

administration.² BIO is concerned that this proposal represents a substantial change in policy direction that has the potential to significantly disadvantage those specialists that administer Part B drugs and vaccines in relatively higher volumes, establishing financial incentives that may undermine appropriate care and directly impact patient access to the most timely and appropriate course of treatment.

The proposal to include Part B drug and vaccine costs in the adjustment calculation is inconsistent with the focus of the QPP on improving care quality. As noted in the Proposed Rule, CMS wants to ensure meaningful measurement, enhanced care coordination, and improved patient outcomes, while minimizing physician burden.³ As CMS continues to “go slow and use stakeholder feedback”⁴ to inform development of the QPP, fostering an environment that allows physicians to transition smoothly into the program while making the most appropriate treatment choices for their patients is critical. The introduction of adjustment for Part B drug costs would significantly expand the risk that physicians who administer Part B drugs will face under MIPS. As described in the paragraphs that follow, the proposal has the potential to cause changes in patient treatment patterns and site-of-service, as well as significant economic effects on participating physicians. Given these concerns, BIO would expect CMS would undertake a detailed analysis of the impact of the proposed change—an analysis that does not appear to have occurred. We would urge CMS not to move forward with the change until an analysis which examines the impact on physicians of various specialties (including intra-specialty variation), as well as the impact on patients, can be completed.

BIO is concerned that this proposal could exacerbate the trend of patient care moving from the physician office to the outpatient hospital department. In the Proposed Rule, CMS details “circumstances in which it is not operationally feasible for us to attribute ... items or services to a MIPS eligible clinician.”⁵ The rule does not discuss how this difficulty in attribution could lead to shifts in billing or site-of-service shifting. For example, providers who may be at a performance disadvantage under MIPS could seek to have their patients receive Part B drug treatment from another provider for whom the cost is not attributable. Other physicians could seek to shift particular patients to the hospital. While we believe that it is the intent of providers to put patients’ needs and best course of treatment first, the risks created by this proposal could make continued provision of Part B drugs in the office untenable for some physicians, and in particular for orphan drugs representing the only available treatment option. CMS can mitigate situations that may require patients to seek care in sites not best-suited for their given health condition, delay initiation of appropriate treatment, or receive care at a higher cost by not moving forward with the inclusion of Part B drug costs in the MIPS adjustment.

² “For Part B items and services furnished by a MIPS eligible clinician such as purchasing and administering Part B drugs that are billed by the MIPS eligible clinician, such items and services may be subject to MIPS adjustment based on the MIPS eligible clinicians’ performance during the applicable performance period or included for eligibility determinations. For those billed Medicare Part B allowable charges relating to the purchasing and administration of Part B drugs that we are able to associate with a MIPS eligible clinician at an NPI level, such items and services furnished by the MIPS eligible clinician would be included for purposes of applying the MIPS payment adjustment or making eligibility determinations.” 82 Fed Reg. at 30,019.

³ Quality Payment Program. Proposed Rule for Quality Payment Program Year 2. Available at: https://qpp.cms.gov/docs/QPP_Proposed_Rule_for_QPP_Year_2.pdf.

⁴ Id.

⁵ 82 Fed. Reg. at 30,019.

Moreover, the inclusion of Part B drug and vaccine costs creates inconsistency between the two QPP tracks. Physicians participating in APMs have their bonus payment calculated based on “covered professional services” only.⁶ By including Part B drug costs in the MIPS adjustment, CMS is not providing parity within the program, disadvantaging providers who do not yet have the opportunity or sophistication to participate in APMs. This also runs counter to the structure of programs that have been wrapped into the QPP. For example, neither the Physician Quality Reporting System (PQRS) nor the Electronic Health Records (EHR) Incentive Program included elements related to purchasing of drugs. BIO firmly believes that the proposed policy places an inappropriate emphasis on drug cost that could severely disadvantage providers participating in one track versus another. In addition, CMS should consider how other initiatives, such as those aimed at prevention fit into the payment adjustment, ensuring providers are not adversely impacted for providing core services designed to improve health outcomes.⁷

Furthermore, CMS should not include Part B drug and vaccine costs in the MIPS adjustment to ensure a level playing field for the most appropriate treatment for each patient. BIO urges CMS to not include Part B costs in the adjustment in order to provide parity across covered therapies and to ensure access to the full range of treatment options. This proposal is also problematic when considering its application as more targeted, extended duration, innovative therapies come to market. For example, if a physician administers a therapy with a 24-month extended duration, the cost performance category will be based on costs incurred that year. If purchasing of Part B drugs is included, a physician who is offsetting other healthcare costs (fewer visits, less hospitalization, fewer diagnostic test, etc.) through use of one of these therapies will reflect higher costs in the measurement catchment, though overall costs and quality would improve over time.

Based on these considerations and the significant potential of this proposal to impact patient access, while not providing additional benefit for care quality, it is BIO’s belief that CMS should not finalize the policy to include Part B drug purchasing in the MIPS payment adjustment. The QPP should ensure patients have access to appropriate care and treatment in their preferred service site and ensure consistency across tracks, to achieve the genuine program focus on improving the quality of care delivered.

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

In the Proposed Rule, CMS notes that they heard from many small practices where challenges still exist in their ability to participate in the program, and propose additional flexibilities.⁸ Consistent with our comments on the previous Proposed Rule,⁹ BIO appreciates that CMS is making program updates to meet physician needs. However, we again ask that CMS provide additional transparency in assessment of the threshold and how the threshold

⁶ 42 US Code § 1395I (z)(1)(A).

⁷ One example CMS should consider is treatment of the Welcome to Medicare Visit, to ensure providers are not penalized for providing this high-value, preventive service that sets up opportunities to deliver high quality care to beneficiaries.

⁸ 82 Fed. Reg. at 30,013.

⁹ See: BIO’s comments RE: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models Proposed Rule [CMS-5517-P]. June 27, 2016.

will be updated in the future as the program continues to grow, expand, and produce feedback.

We ask CMS to consider additional flexibilities to meet specific provider need, beyond the current updates to Medicare Part B allowable charges and volume of Medicare Part B patients. 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 - which are necessary as the accuracy of defining 'low volume' will vary depending on the type of patients a provider treats. Given that CMS is collecting feedback from practices to inform the process of updating the low-volume threshold, we would ask that CMS provide further detail as to how the numerical aspects of each prong are chosen and specify how updates will occur in future program years.

III. CMS should move forward with the proposal to provide a bonus for complex patients and small practices to protect access to care.

As detailed in the Proposed Rule, we appreciate CMS's efforts to address the impact of patient complexity and availability of resources on a provider's final MIPS score through use of bonuses. BIO supports CMS's goal of protecting access to care for complex patients and providing them with excellent care, while avoiding placing clinicians who care for complex patients at a disadvantage under the program through the complex patient bonus.¹⁰ Further, we support CMS's effort to accommodate small practices that face unique resource or financial challenges and overcome performance discrepancy due to practice size through the small practice bonus.¹¹ These bonuses 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. BIO urges CMS to continue consideration of means to appropriately account for and provide flexibility to MIPS clinicians serving complex and rare disease patients.

IV. CMS should not finalize the proposed expansion of the definition of a hospital-based MIPS eligible clinician.

CMS is proposing to broaden the definition of a hospital-based MIPS eligible clinician. The current threshold is 75% or more of a MIPS eligible clinician's professional services in sites of service identified as an inpatient hospital, on campus outpatient hospital, or emergency

¹⁰ 82 Fed. Reg. at 30,135.

¹¹ 82 Fed. Reg. at 30,089.

room setting.¹² Under the proposal, the definition of sites of service would be expanded to include off-campus, outpatient departments.¹³ BIO is concerned that this policy could lead to further consolidation of community-based physicians into larger hospital systems, impacting patient care and cost. In line with CMS's goal of creating site neutral payment policies, CMS should (where possible) implement site neutral quality programs. Therefore, we believe that CMS should not move forward with finalization of this policy.

V. CMS should finalize the proposal of a zero percent weight for cost performance in 2018.

From 2017 to 2018, CMS is not proposing any changes to the MIPS performance weights for quality, advancing care information, improvement activities, and cost, with cost performance again being weighted at zero percent. CMS seeks feedback on whether this approach is appropriate or if an alternative is necessary for 2018, based on the change that is set to occur in 2019 for the cost performance weight.¹⁴ While ensuring a smooth transition through MIPS is important, BIO strongly supports the finalization of the cost performance category weight as proposed at zero percent, given that 2018 is still considered a transition year for QPP. We appreciate CMS's consideration of the additional transition year and urge finalization of the proposal for the cost performance weight.

VI. CMS should continue the process of updating the episode-based payment measures and collect robust stakeholder feedback on inclusion of these measures in MIPS.

In the Proposed Rule, CMS notes that they are not planning to use the ten episode-based measures that were adopted for the 2017 MIPS performance period. Instead, CMS is in the process of developing new episode-based measures with significant clinical input and plans to introduce these measures over time. The aim of this approach is to increase clinical familiarity with the concept and episode-based measures, while offering performance feedback prior to the potential inclusion of these measures in MIPS.¹⁵ BIO supports CMS's development of new episode-based measures with significant clinical input and introduction over time. BIO asks that CMS ensure a transparent process with opportunity for broad stakeholder engagement when developing and proposing these episode-based measures.

VII. CMS should ensure that any additional feedback provided on the cost performance category is comprehensive and looks at the totality of care, rather than specific subsets of care.

CMS is seeking comment on whether it would be helpful to provide more frequent feedback, such as on a rolling 12-month basis or in quarterly snapshots of the most recent 12-month period for the cost performance category.¹⁶ CMS wants additional details on the frequency and the format in which this information should be provided to clinicians and group practices. BIO asks that in establishing such a feedback process, CMS consider a holistic

¹² Sites of service are identified by the Place of Service code used in the HIPAA Standard transaction, and percentages are based on claims for a period prior to the performance period as specified.

¹³ 82 Fed. Reg. at 30,076.

¹⁴ 82 Fed. Reg. at 30,015.

¹⁵ 82 Fed. Reg. at 30,016.

¹⁶ Reference FR Version (display copy page 467).

approach to sharing information on cost performance. CMS should present feedback in a manner that does not single out specific categories of care cost, such as drugs and biologicals, or in ways that do not sufficiently reflect the value of care being delivered.

VIII. CMS should ensure the continued strengthening of the quality performance category through use of the most up-to-date, relevant quality measures, working in conjunction with measure stewards and endorsers.

In order to support and correctly evaluate care quality, it is essential that up-to-date measures consistent with clinical guidelines and scientific evidence are used in the QPP. As previously detailed to CMS,¹⁷ BIO asks that CMS continue to ensure the use of appropriate measure specifications by:

- Continuing to refine and further strengthen the quality measure reporting requirements under MIPS over time;
- Ensuring the data on the quality of care furnished by a MIPS eligible provider is reliable, accurate, and comparable;
- Ascertaining that the quality measures used are appropriate to the MIPS eligible providers who will be required to report them;
- Working broadly with stakeholders, including patient advocacy organizations, to identify, address, and improve measure gaps; and
- Continually improving the transparency and the stakeholder engagement process.

In addition, we find that cooperation between the measure stewards, measure endorsers, and CMS is a necessary step to applying most relevant measure specifications within the program. Both measure stewards and the National Quality Forum uphold maintenance policies that include a regular measure maintenance cycle and off-cycle measure update process. The every-three-year regular maintenance cycle allows for measures to be updated based on clinical evidence; the off-cycle process creates a pathway for measures to keep pace with the evolving clinical landscape. As CMS maintains a regular cycle for updates to measures, we ask that the update process include an off-cycle opportunity when measures do not reflect current treatment guidelines. Such updates will help ensure patient care is not impacted by measures that are in conflict with the most up-to-date clinical guidelines. BIO encourages CMS to work closely with measure developers and stewards, via two-way communication,¹⁸ to avoid situations where measures do not reflect clinical guidelines, to further the credibility of the QPP.

Further, we ask CMS to develop alternative means to capture quality metrics and reward clinicians treating patients with rare, chronic, or complex conditions. Practice improvement or advancing care information activities specific to treating these patients could reflect high-value care from diagnosis through treatment and care management. Addressing the needs of these patient populations will have long-term benefits in improving patient access to high-quality care from specialists equipped to address their specific health needs.

¹⁷ See: BIO's comments RE: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models Proposed Rule [CMS-5517-P]. June 27, 2016.

¹⁸ It should be incumbent upon measure stewards to notify CMS at the point that measures in use are updated so these updates can be appropriately reflected in the program. Likewise, it is incumbent upon CMS to make the updates when notified.

IX. CMS should refine the quality benchmark proposal for 2018, so as not to disadvantage certain provider specialties.

CMS is again proposing that the benchmark score for a quality measure be the “benchmark used by the MIPS APM for calculation of the performance based payments within the APM if possible, to align the measure performance and outcomes between the MIPS and APM programs.”¹⁹ If there is no benchmark score, CMS will use the benchmark for the MIPS quality performance category generally for that performance year. BIO urges CMS to reconsider the basis for the benchmark, and the application of a standard benchmark across provider specialties. We are concerned that comparing different types of providers within the same benchmark has the potential to disadvantage certain provider specialties and sub-specialties, where patients require more complex and innovative care. We discuss means by which CMS could consider for comparison of providers of the same or similar specialty later in this letter.

X. CMS should maintain the same five percent APM quality measure bonus cap as was in place for 2017, and not move to a ten percent cap.

In 2018, CMS proposes to move from a five percent bonus threshold of the APM entity’s total available achievement points, to a 10 percent threshold.²⁰ CMS’s previous rationale for the five percent cap, was that in the absence of such a cap or with a cap that is too high, the system may obscure otherwise poor performing providers.²¹ BIO was supportive of this proposal, and encouraged CMS to maintain the threshold at five percent for the first two years of MIPS. We noted that adjustments could be made following evaluation and measurement, to ensure that providers who are unable to significantly report quality measures beyond the minimum required are not disadvantaged. We would ask that CMS not move to a higher bonus point threshold for the second year, and instead maintain the five percent threshold and detail the evaluation process for any updates in subsequent years.

XI. CMS should add further clarity, transparency, and an expanded response timeline in the criteria for Physician-Focused Payment Models (PFPs) reviewed by the Physician-Focused Technical Advisory Committee (PTAC), particularly if CMS chooses to broaden the definition of PFPs.

In regard to the PTAC, CMS is seeking feedback on broadening the definition of PFPs to include payment arrangements that involve Medicaid or the Children’s Health Insurance Program as a payer even if Medicare is not included, believing that this updated definition may be more inclusive in engaging additional stakeholders around PFPs. Further, CMS seeks additional feedback on the Secretary’s criteria and stakeholders’ needs in developing PFP proposals aimed at meeting the criteria.²²

¹⁹ 82 Fed. Reg. at 30,086.

²⁰ Id.

²¹ See: BIO’s comments RE: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models Proposed Rule [CMS-5517-P]. June 27, 2016.

²² 82 Fed. Reg. at 30,207.

As a threshold matter, BIO asks that additional transparency around the model consideration process be afforded to stakeholders, and that timeframes for comments on models before PTAC be expanded, particularly if the definitions of PFPs are broadened beyond the Medicare space. While we understand the need for the PTAC to function efficiently, given the size, scope, and focus areas of models seen to date, a robust process for engagement of stakeholders across the spectrum, including patient communities, requires a longer timeframe.

Additionally, BIO again urges CMS to expand the text of the criteria to capture critical elements for PFPs, we recommend the following edits (underlined text proposed for addition; struck through text for deletion):

- "Flexibility: provide the flexibility needed for practitioners to deliver high-quality health care, including adapting to account for new technologies."
- "Scope: rely on evidence-based information ~~aim~~ to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM entities whose opportunities to participate in APMs have been limited."
- "Care delivery improvements: promote better care coordination, facilitate patient access to high-quality care, provide information on clinical trials (when appropriate), protect patient safety, and encourage patient engagement."

XII. 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 Proposed Rule, CMS references the requirements under statute to make MIPS-eligible clinician and group performance information available on Physician Compare. BIO asks that CMS work to include meaningful narrative context for the information made publicly available under this requirement to best inform patients. Further, we are supportive of CMS's efforts to expand patient experience data collection and urge CMS to provide timely, transparent updates on the beta-testing for the patient experience narrative questions in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) and MIPS survey.

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

For 2017, MIPS eligible clinicians could receive 10 percentage points in the performance score for meeting the Immunization Registry Reporting Measure. However, CMS proposes to modify this policy for 2018 based on its potential to disadvantage providers working in areas of the country where immunization registries are not available. In 2018, CMS is proposing that providers who fulfill the Immunization Registry Reporting Measure will earn 10 percentage points in the performance score. For providers unable to fulfill this measure, 5 percentage points in the performance score could be earned for each public health agency or clinical data registry to which the clinician reports the following measure (up to a

maximum of 10 percentage points): Syndromic Surveillance Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Clinical Data Registry Reporting.²³

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 Immunization Information Systems (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.

XIV. CMS should consider adding vaccine-specific measures to the list of cost-cutting measures in the future.

Cross-cutting measures help focus our efforts on population health improvement. As recognized in Healthy People 2020, prevention of infectious diseases through immunization is a key factor in improving the health of our nation. The 2017 rule eliminated immunization-related cross-cutting measures for influenza and pneumonia. BIO urges CMS to consider adding these measures back to the list of cross-cutting measures in the future.

- NQF#0041/PQRS #110: Preventive Care and Screening: Influenza Immunization, Community/Population Health.
- NQF#043/PQRS#111 Pneumococcal Vaccination Status

BIO believes that all Medicare providers, whether their practice is focused on primary care or specialty care, should be incentivized to offer both immunization as well as screening services in the course of providing care to patients. This will ensure that each individual is counseled and has the opportunity to receive the appropriate immunizations, based on their age and health status. Published literature indicates that fewer providers offering these critical prevention services will result in more 'missed opportunities' for immunization and a greater likelihood of illness and complications from vaccine preventable conditions such as influenza and pneumonia. The National Vaccine Advisory Committee's (NVAC) Adult Immunization Standards call for all providers caring for adult patients to assess, recommend, vaccinate or refer, and document vaccinations.²⁴

²³ 82 Fed. Reg. at 30,058.

²⁴ <http://www.publichealthreports.org/issueopen.cfm?articleID=3145>

XV. CMS should finalize the immunization measures in the APM scoring standard and the proposed new and modified MIPS specialty measure sets for 2018, and identify opportunities to expand immunization measures in future years.

In the Proposed Rule, CMS includes a list of measures introduced for notice and comment that would ultimately serve as the measure set used by participants in identified APMs to create a MIPS score. BIO supports finalization of these measures:

- For the Comprehensive ESRD Care APM:²⁵
 - NQF#0041/PQRS #110: Influenza Immunization in the ESRD Population
 - NQF#0043/PQRS #111: Pneumococcal Vaccination Status
- For the Comprehensive Primary Care Plus (CPC+) APM:²⁶
 - NQF#0041/PQRS #110: Influenza Immunization
 - NQF#0043/PQRS #111: Pneumonia Vaccination Status for Older Adults.

Further, BIO supports the inclusion of a number of specific immunization measures for the 2018 MIPS specialty measures set.²⁷ 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.

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, please 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. We encourage CMS to add the following immunization quality measures into these specialty measure sets:

- Internal Medicine
 - NQF# 0041 Preventive Care and Screening: Influenza Immunization and NQF# 0043 Pneumonia Vaccination Status for Older Adults.
- Endocrinology
 - NQF# 0041 Preventive Care and Screening: Influenza Immunization and NQF# 0043 Pneumonia Vaccination Status for Older Adults.
- Cardiology

²⁵ 82 Fed. Reg. at 30,091.

²⁶ 82 Fed. Reg. at 30,095.

²⁷ Measures include: Allergy/Immunology: Preventive Care and Screening: Influenza Immunization; Family Medicine: Preventive Care and Screening: Influenza Immunization; Family Medicine: Immunization of Adolescents; Ob/Gyn: Preventive Care and Screening: Influenza Immunization; Otolaryngology: Preventive Care and Screening: Influenza Immunization; Pediatrics: Preventive Care and Screening: Influenza Immunization; Pediatrics: Childhood Immunization Status; Pediatrics: Immunization of Adolescents; Preventive Medicine: Preventive Care and Screening: Influenza Immunization; Nephrology: Preventive Care and Screening: Influenza Immunization; Rheumatology: Preventive Care and Screening: Influenza Immunization; Infectious Disease: Preventive Care and Screening: Influenza Immunization; Infectious Disease: Immunization of Adolescents. 82 Fed. Reg. at 30,271.

- NQF# 0041 Preventive Care and Screening: Influenza Immunization and NQF# 0043 Pneumonia Vaccination Status for Older Adults.

XVI. CMS should develop more sophisticated means to compare providers of the same or similar specialties under MIPS, such as use of CMS-approved healthcare provider taxonomy codes.

Under current program structure, MIPS uses the Composite Performance Score to make broad comparisons regardless of provider specialty and sub-specialty for the purpose of applying adjustments to provider payments. BIO believes there is opportunity for further program development in making peer-to-peer comparisons within provider specialties and sub-specialties that would more accurately and appropriately capture the quality of care being delivered to Medicare patients. For example, in the ophthalmology subspecialty space, CMS recently approved new, voluntary healthcare provider taxonomy codes, including retina specialists, oculoplastics, uveitis, and glaucoma categories.²⁸ BIO urges CMS to use taxonomy codes within this and other subspecialties to track physician performance and ensure relevant comparisons are being made between providers in MIPS. BIO encourages CMS to further define “peer” groups of providers, as in the case of ophthalmology, throughout the course of the program and as more specialty specific taxonomy codes become available.

XVII. CMS should identify opportunities to incorporate guidelines-driven algorithms into health information technology (HIT) to help better identify and track certain disease states.

In the Proposed Rule, CMS is seeking feedback on how HIT could support better feedback related to QPP participation, such as HIT functionalities that could contribute to quality improvement, supporting the feedback loop, or informing clinical improvement efforts.²⁹ BIO recommends that CMS seek out opportunities to incorporate guidelines-driven algorithms or advanced tracking and monitoring capabilities for specific disease states to further quality improvement in these areas. For example, in the case of infectious disease and hepatitis C virus (HCV), routine screening across healthcare settings has been proven as scalable and effective to identify, diagnose, and link patients to appropriate care that may mitigate future healthcare costs.

Electronic Health Records (EHRs) and HIT capabilities play a critical role in reducing the number of undiagnosed individuals with HCV, and screening algorithms are currently being developed to help identify eligible patients for testing, consistent with Medicare’s national coverage determination for HCV screening. For instance, EHR algorithms may scan each patient’s medical record for a range of defined criteria³⁰ to automatically determine which patients should be tested for HCV (or other infectious disease). If a patient is determined to be at risk for HCV, the EHR may automatically populate a lab order for the best practice HCV screening or order a confirmatory test if there is a previously documented positive

²⁸ See; CMS Announces New Taxonomy Codes for Retina Subspecialty Ophthalmologists, November 23, 2016, available at: <https://www.corcoranccg.com/news/cms-announces-new-taxonomy-codes-retina-subspecialty-ophthalmologists/>

²⁹ 82 Fed. Reg. at 30,156.

³⁰ Potential criteria could include date of birth, resident of a ZIP code in a high prevalence area, country of origin, chief complaint at visit, history of sexually transmitted infections, and history of injection drug use.

result.³¹ Thereby helping to avoid retesting outside treatment guidelines and unnecessary laboratory costs, and presenting the programming capability to alert clinicians of availability of lab results ensuring that patients are notified of their results and receive care in a timely manner. Another example is in the case of rheumatoid arthritis, where EHRs and HIT presents the opportunity to further assess quality care by incentivizing providers to track and document disease progression.

To enhance patient engagement and increase care coordination between providers treating the same patients, we continue to recommend that CMS work with EHR vendors to ensure interoperability. Improving interoperability and information exchange capabilities of HIT will support practice-level efforts to improve care quality. Without effective liquidity of patient health data and secure information exchange among HIT systems, clinicians will face barriers to improvement of care for patients who access care across multiple settings. Not all practices will be part of the same medical record system; therefore, processes and standards for electronic sharing of information are crucial. BIO finds that HIT can be a useful tool for both clinicians and patients to engage in enhancing care, contributing to the aims of the QPP, and encourages CMS to find pathways to advance these efforts.

XVIII. CMS should finalize the proposal to update the process for Qualified Clinical Data Registry annual nominations.

BIO supports the role that Qualified Clinical Data Registries (QCDRs) play as a reporting mechanism for the quality and clinical practice improvement activities under MIPS, and in particular by including more specific measures for certain patient subsets. We commend CMS for developing a streamlined certification process, beginning with the 2019 performance period, through which existing QCDRs and those in good standing can continue participating in MIPS.

XIX. CMS should consider further expansion of measures around achieving health equity in clinical trials.

Under the proposed new improvement activities for the QPP Year 2 and Future Years, CMS includes efforts to increase health equity and a measure specific to clinical leadership in clinical trials or community-based participatory research.³² BIO supports these efforts focused on minimizing disparities in healthcare access, quality, and outcomes through access to clinical trials. We urge CMS to explore expansion of such a measure to include providers beyond those recognized as leaders who undertake opportunities to make such improvements for their patient-base in providing critical information on clinical trials. This might include, for example, clinical practice improvement activities eligible for the advancing care information bonus related to clinical communications regarding availability of clinical trials and the benefits and risks associated with participation.

³¹ The algorithm can order an antibody screening with reflex confirmatory RNA and an RNA confirmation if there is a previously documented positive result.

³² 82 Fed. Reg. 30,479.

XX. Conclusion

BIO appreciates the opportunity to comment on the CY 2018 Updates to the Quality Payment Program 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 me at 202-962-9200.

Sincerely,

/s/

Mallory O'Connor
Director
Healthcare Policy & Federal Programs