Biotechnology Industry Organization

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BY ELECTRONIC DELIVERY

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding the Medicare Shared Savings Program (MSSP) and Accountable Care Organizations (ACOs) (the "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 members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products.

BIO represents an industry that is committed to improving health care through the discovery of novel therapies and ensuring patient access to them. We support Medicare payment policies that foster innovation and protect patient access to drugs and biologicals. Thus, we generally support growth and development of delivery of care and payment paradigms that have the potential to achieve the triple aim: provide better care for individuals, better health for populations, and lower growth in overall expenditures.

According to CMS, the goals of the Medicare Shared Savings Program include "promot[ing] accountability for a patient population, foster[ing] coordination of items and services under parts A and B, and encourag[ing] investment infrastructure and redesigned care processes for high quality and efficient health care service delivery."[2] BIO has previously commented on CMS proposals and requests for information regarding ACOs, and we have a number of comments and recommendations for the program that we believe will help CMS to better achieve its goals. Our comments address the following subjects:

[1] 79 Fed. Reg. 72,759 (December 8, 2014).
[2] *Id.* at 72762.

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I. Structure of the MSSP within Department of Health and Human Services' (HHS's) Delivery Reform Initiatives

- Provide more detail around how the structure and implementation of changes to the MSSP is intended to align with the broad Medicare payment goals recently established by the Department of Health and Human Services (HHS)

II. Access to Innovative Technologies

- Take additional steps to ensure that patients have access to innovative technologies

III. Quality Measures

- Ensure the appropriateness and validity of quality measures used

IV. Leadership and Management Structure

- Permit an ACO to request CMS approval to designate as their medical director a physician who is not an ACO provider/supplier but satisfies certain other requirements

V. Consideration of Physician Specialties and Non-Physician Practitioners in the Assignment Process

- Implement with modifications proposed changes to the beneficiary assignment methodology
- Provide additional information about the possibility of transitioning to a one-step assignment process

VI. Proposals Related to Transition From the One-Sided to Two-Sided Model

- Finalize the proposal to allow ACOs to enter into one additional 3-year agreement period under Track 1

VII. Proposals for Assignment of Beneficiaries under Track 3

- Put in place mechanisms to identify and prevent efforts by ACOs to game the system to avoid taking on certain types of beneficiaries
- Limit an ACO's shared losses or gains in certain circumstances

VIII. Payment Requirements and Other Program Requirements That May Need to Be Waived in Order to Carry Out the Shared Savings Program

- Identify standards for any telemedicine or telehealth services and ensure that such services supplement, rather than replace, in-person care

IX. Step-Wise Progression for ACOs to Take on Performance-Based Risk

- Require each segment of a risk-split ACO to meet all eligibility requirements to participate in the program and ensure appropriate risk-adjustment
- Permit groups of ACO providers/suppliers to participate in separate risk tracks

- Permit each half of the segmented list of ACO providers/suppliers to have its own benchmark and list of assigned beneficiaries
- Prohibit individual ACO providers/suppliers participating in a split ACO from changing risk tracks in the middle of a performance year

X. Methodology for Establishing, Updating, and Resetting the Benchmark

- Transition to a benchmark methodology that takes into account an ACO's shared savings from a prior agreement period in establishing a benchmark for a subsequent agreement period
- Use regional factors to establish and update benchmarks but continue to base benchmarks on an individual ACO's historical fee-for-service costs rather than on regional fee-for-service costs
- Implement additional mechanisms to prevent against "gaming of the system"

XI. Public Reporting and Transparency

- Require ACOs to publicly report additional information as proposed by CMS and make ACO-specific information available online
- Add public reporting requirements for ACOs specific to health information technology (HIT) interoperability to improve accountability in this space and speed adoption of interoperable HIT platforms
- Perform a more thorough assessment of ACOs' performance with regard to amount of risk borne and underlying patient population, and consider how best to make such analyses publicly available

XII. Risk-Adjustment Methodology

- Improve risk-adjustment methodology to address several shortcomings in the current methodology

Additional details regarding each of these items are provided below.

I. <u>Structure of the MSSP within HHS's Delivery Reform Initiatives</u>: CMS should provide more detail around how the structure and implementation of changes to the MSSP is intended to align with the payment goals recently established by HHS.

On January 27, 2015, HHS announced the establishment of two specific goals around payment reform in the Medicare program broadly: (1) by 2016, 30 percent of all Medicare provider payments will be in alternative payment models that assess the quality of provider care rather than the volume of care; and (2) by 2016, at least 85 percent of all Medicare fee-for-service payments will be tied to quality and value—and by 2018, at least 90 percent.[3] The HHS announcement specifically mentioned accountable care models as an example of an alternative payment model that may be used to fulfill the first goal. In light of

[3] HHS Press Release. 2015 (January 26*). Progress Towards Achieving Better Care, Smarter Spending, Healthier People*, available at: http://www.hhs.gov/blog/2015/01/26/progress-towards-better-care-smarter-spending-healthier-people.html.

these goals, BIO urges the Department, in partnership with CMS, to provide more details around how these goals will be achieved, what role the MSSP (and other existing demonstration projects) will play, and what impact the goals may have on proposed changes to the MSSP in this, or other, rulemaking activities. Stakeholders also will benefit from a more thorough understanding of the potential role of the proposed Health Care Payment Learning and Action Network (HCPLAN) and plans for its development and implementation.

While BIO shares HHS's goal of improving patient-centered, quality care, we caution the Department to ensure that plans to meet the established payment reform goals: allow for meaningful public comment; rely on the collection and analysis of robust quality measures that are sufficiently specific to reflect the care provided to individual beneficiaries; and prioritize patient access to the most appropriate providers and treatments for them individually. These elements are a crucial bulwark against a sole focus on the cost of care, which can incentivize underutilization of appropriate care, and, in turn, result in higher overall expenditures (e.g., from increased hospitalizations and physician office visits) and negatively impact patient health outcomes. Specifically, as CMS considers evolutions in the MSSP, the Agency must take into account how changes to reimbursement for innovative technologies can directly impact patients' timely access to the best available treatment. This is particularly true in the case of complex, chronic conditions and rare diseases: patients with these conditions may respond better to one therapy (or have fewer side-effects) than another or, in the case of rare conditions, there may be few—or sometimes no other—therapies available at all. Thus, CMS must work to incorporate mechanisms that maintain adequate reimbursement for these technologies within ACOs moving forward.

II. <u>Access to Innovative Technologies</u>: CMS should take additional steps to ensure that patients have access to innovative technologies.

As evidenced by the Food and Drug Administration's (FDA's) new focus on breakthrough therapies, we are in an era of new and important discoveries for the treatment of human diseases. Unfortunately, risk-based programs such as the MSSP can increase incentives to stint on care or undersupply services in areas such as new technologies because the savings associated with these technologies frequently are not realized within the relevant window of time, and their costs likely are not included in the benchmark. As a result, under the MSSP, patient access to innovative new technologies may be limited, and incentives to develop new technologies may be diminished. The purpose of the MSSP is to achieve savings through improvements in the coordination and quality of care, and not through avoiding certain beneficiaries or placing limits on beneficiary access to needed care.

To ensure that patients continue to have access to innovative medical technologies, including drugs and biologicals, BIO strongly urges CMS to incorporate protections similar to those added by Congress to the Medicare program (i.e., outpatient pass-through payments, and inpatient new technology add-on payments, exceptions to the inpatient packaged-

reimbursement policy[4]) by creating a carve-out for new, innovative medical technologies from ACOs' shared-savings calculations. Innovative medical technologies should be carved out of both the benchmark and performance year expenditures for ACOs. With such a carve-out, an ACO's decision to use a promising new therapy will not affect the calculation of ACOs' expenditures for purposes of determining whether they generated shared savings. Thus, the ACO will not have an incentive to lower costs by denying patient access to the therapy.

There are a number of existing mechanisms, including hospital inpatient new technology add-on payments and pass-through payment status under the hospital outpatient system, that may be used by CMS to implement such a carve-out. Under the hospital inpatient prospective payment system, CMS provides new technology add-on payments for new technologies that meet certain requirements, including a requirement that the prospective payment rate otherwise applicable to the technology would be inadequate. Similarly, under the hospital outpatient prospective payment system, when CMS grants pass-through status for a drug or biological, CMS makes a determination that the drug or biological is a new technology, the costs of which are not insignificant in comparison to the payment for the procedures or services associated with its use.

Thus, when expenditures used to determine an ACO's eligibility for shared savings are calculated, it would be appropriate to exclude all of the expenses related to both of these types of new technologies from the expenditures that are used in an ACO. Such a carve-out would ensure that there is no disincentive related to the use of new technology by an ACO. Further, we believe that this carve-out should apply across all care settings, including drugs and biologicals furnished in the physician office setting, and that such drugs and biological could be identified through the use of two miscellaneous J-codes. Implementing this policy in a consistent manner across care settings will help to ensure that the MSSP does not create an incentive to perform procedures in one setting over another.

In addition, CMS should require ACOs to address how they ensure beneficiary access to new technologies as part of the clinical guidelines and evidence-based practices ACOs must establish in applying to the MSSP. In its review of the documentation an ACO submits as part of its application, CMS should ensure that those evidence-based medicine materials provide for appropriate access to new medical technologies and do not impose barriers with regard to their timely adoption.

To further foster the development of innovative new therapies, CMS also should consider incentivizing ACOs to participate in clinical trials by either requiring ACOs to participate in clinical trials or by adjusting an ACO's shared savings to reflect participation in clinical trials. Under the former option, CMS would require ACOs to participate in clinical trials as a condition of participating in the MSSP. Under the latter option, CMS could award "bonus points" to ACOs that participate in clinical trials to increase their shared savings rate.

[4] *E.g.*, Congress, through the Omnibus Budget Reconciliation Act and the Balanced Budget Act of 1995, requires CMS to pay separately for hemophilia factor products within the Medicare Inpatient Prospective Payment System, *see* 42 U.S.C. § 1395ww(a)(4).

Incentivizing such participation in clinical trials will help to not only facilitate the development of novel therapies but also to ensure that ACOs remain at the forefront of health care innovation and development.

III. Quality Measures: CMS should ensure the appropriateness and validity of quality measures used.

Under a risk-sharing reimbursement system, an ACO may be disincentivized to provide appropriate care that may cost more, but the use of robust, evidence-based quality metrics can help to mitigate such incentives. The MSSP employs a variety of measures to assess the quality of care that an ACO provides. In the Proposed Rule, CMS does not address these specific measures. However, BIO believes it is important to reiterate the concerns we have expressed previously to CMS about the measures used to evaluate ACO performance.

Under the MSSP, an ACO's eligibility for shared savings and the amount of shared savings to which the ACO may be entitled is based on, in part, quality performance. Quality measures are used not only to measure care provided by primary care providers, but also to assess care provided by specialty care providers. Yet existing quality measures are not always appropriate for specialty care providers. For example, whether A1C levels in diabetes patients are appropriate is determined by comparing the A1C levels of diabetes patients with the estimated mean of the entire population. However, patients that receive care from an endocrinologist, rather than their primary care physician, generally do so because they are sicker, and their diabetes is less well controlled than the average population. Thus, using the A1C metric, which is benchmarked to a patient population that does not uniformly receive specialty care, unduly penalizes endocrinologists based on the underlying disease severity of their patients, rather than the quality of the care they provide. CMS should take additional steps to ensure that appropriate measures are used to assess the performance of specialty care providers, and that use of quality measures doesn't penalize specialists.

In addition, even where quality measures appropriate for specialty care do exist, not all measures are created equal. We urge CMS to ensure that the measures used to assess ACO quality have been endorsed by national, consensus-based organizations such as the National Quality Forum (NQF), or a disease or provider specialty society. Consensus-based organizations use sophisticated processes to develop and endorse measures, and these processes help to ensure the validity of those measures that are endorsed. In addition to NQF, other reputable national organizations that develop and endorse measures include the National Commission for Quality Assurance, the Joint Commission, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices, and the American Medical Association. CMS should also continue to engage with patients, providers, and stakeholders through a formal rulemaking process to ensure measures used to assess ACO performance are scientifically and clinically relevant.

CMS must also ensure that measures used to assess ACO performance capture the long-term impact of interventions on patient outcomes and total costs of care. Many patient interventions have an impact that may not be realized immediately after the intervention

occurs. In some cases, the benefits may not be apparent for weeks, months, or even years. In order to avoid incentivizing short-sightedness in the provision of care, BIO recommends that the quality and cost of health care administered by Medicare providers be monitored over a period of time sufficient to account for the full effect of longer-term treatments and therapies. To effectively sustain improvements in quality of care and decrease overall costs, it is critical to consider the long-term impact of innovative drugs and biologicals.

Additionally, BIO would like to encourage CMS to employ quality measures that are outcomes-focused as much as possible, instead of those that are process-focused. BIO acknowledges that process-related measures play an important role in helping to ensure that an ACO is adhering to a given standard of care. However, outcomes measures more directly link the care provided with a specific health outcome. Thus, outcomes-based measures best reflect the impact that an ACO has on a patient's care, and we therefore believe the MSSP should utilize such outcomes-based measures as much as possible to assess the quality of care provided by ACOs.

IV. <u>Leadership and Management Structure</u>: CMS should permit an ACO to request approval to designate as their medical director a physician who is not an ACO provider/supplier but satisfies other specific requirements.

Eligible ACOs are required to satisfy certain leadership and management requirements in order to participate in the MSSP. [5] These requirements include that an ACO's clinical management and oversight must be provided by a senior-level medical director who is one of the ACO providers/suppliers, physically present on a regular basis in an established ACO location, and a board-certified physician licensed in a state in which the ACO operates. CMS is proposing to eliminate the requirement that the medical director be an ACO provider/supplier or, alternatively, to retain this requirement but permit an ACO to request CMS approval to designate as its medical director a physician who is not an ACO provider/supplier but who is closely associated with the ACO and satisfies all of the other medical director requirements.

Under the current structure, ACOs may request an exception to the leadership and management requirements. This exception was created to foster innovation in leadership and management structures. However, according to CMS, although over 330 organizations are now participating in the MSSP, to date, CMS has granted only one narrow exception for an ACO that sought to allow a physician who had retired after a long tenure with the organization, but remained closely associated with the clinical operations of the ACO, to serve as the medical director of the ACO.

BIO supports CMS's proposal to maintain the current standard but to allow exceptions that resemble the one described in the preamble (and referenced above). As the individuals responsible for clinical management and oversight at the ACO, medical directors must have the appropriate perspective and experience to serve in this crucial role. To this end, we agree with CMS that the medical director of the ACO should be directly associated with the

[5] 79 Fed. Reg. at 72777-78.

ACO's clinical operations and familiar with the ACO's organizational culture. However, we acknowledge that limited circumstances may exist where a medical director can satisfy these requirements without being an ACO provider/supplier.

As such, we believe that retaining the general standard but carving out the proposed exception will best help to achieve CMS's goals for the program while simultaneously affording ACOs additional flexibility.

CMS also proposes to eliminate regulatory language that permits CMS to approve applications from innovative ACOs that do not satisfy the leadership and management requirements related to operations management and clinical management and oversight. Although CMS believes that the proposed change to the medical director requirement renders this language unnecessary, we believe that CMS should retain this language nonetheless. Although the exception offered by this language has been rarely employed, it affords an additional protection for the governance of ACOs that seek to structure themselves in innovative ways.

V. Consideration of Physician Specialties and Non-Physician Practitioners in the Assignment Process.

A. CMS should implement, with certain modifications, its proposed changes to the beneficiary assignment methodology.

CMS proposes to make the following changes to the beneficiary assignment methodology including that:

- Primary care services furnished by nurse practitioners, physician assistants, and clinical nurse specialists will be included in Step 1 of the assignment process;
- Specific physician specialty designations would continue to be included in Step 2 of the beneficiary assignment process; and
- Services provided by certain CMS physician specialties would be excluded in Step 2 from the beneficiary assignment process. [6]

BIO supports the proposed change to the assignment methodology to include primary care services furnished by nurse practitioners, physician assistants, and clinical nurse specialists in Step 1 of the assignment process. Non-physician practitioners play a critical role in managing and coordinating the care of Medicare beneficiaries. As CMS acknowledges in the Proposed Rule, non-physician practitioners frequently serve as a beneficiary's sole primary care provider, particularly in areas where there are shortages of primary care physicians. As a result, we believe these proposed changes will more accurately capture where beneficiaries are receiving their primary care services. Further, we support this change because, as CMS indicates, it would better align the assignment methodology under the MSSP with the primary care provisions of the Patient Protection and Affordable Care Act.

[6] *Id.* at 72794-97.

Although CMS is proposing to exclude services provided by certain CMS physician specialties from the beneficiary assignment process in Step 2, CMS proposes to continue including certain physician specialties in Step 2. While BIO appreciates that some patients may receive their primary care services from certain specialties, we believe these patients are likely to have different characteristics than patients who are attributed to the ACO based on their interactions with primary care providers. We are concerned that the risk-adjustment methodology that CMS employs may not accurately account for the underlying health of a provider's patient population. By virtue of the type of medicine they practice, specialists are often responsible for sicker patients or those in need of more complex care. Thus, appropriate risk-adjustment is particularly crucial for ensuring an accurate assessment of how these providers are performing in the MSSP (see section XII on risk adjustment below for more detail).

In addition, the measures used to assess whether patients are receiving high-quality care are not sufficiently targeted at specialty care. As a result, they may not meaningfully represent whether patients receive the standard of care and may not serve as a robust point of comparison between participating providers. Given the complexity of certain types of specialty care and the heterogeneity of the underlying patient population of many specialists, we believe these concerns are amplified in the specialist population. BIO cannot overstate the importance of robust quality measures as they serve as a bulwark against incentives to meet cost targets by underutilizing medically necessary care, which, in turn, can increase overall expenditures in the longer-term (e.g., through the need for increased hospitalizations, surgical interventions, and provider office visits) and negatively impact patient health outcomes (see section III above for more detail on quality measures).

BIO also has a more general concern regarding the structure of the MSSP assignment methodology. Specifically, the current beneficiary assignment methodology makes providers responsible for aspects of patient care outside of their control. This situation is particularly concerning with respect to specialty care providers, who tend to be responsible for sicker patients, who, in turn, often require most intensive, costly care. Thus, specialty providers are at increased risk of being unduly penalized based on the underlying health of their population. While we appreciate CMS's effort to improve the benchmarking methodology that compares provider groups to like-groups in assessing shared savings or losses, we believe that, in the case of specialists, the benchmarking methodology does not sufficiently account for the vast heterogeneity within patient populations treated by specialists. Thus, we encourage CMS to seek stakeholder feedback on mechanisms that could be used to identify and exclude from assessments of the ACO's performance certain aspects of patient care beyond the control of a given ACO.

B. CMS should provide additional information about the possibility of transitioning to a one-step beneficiary assignment process.

In the Proposed Rule, CMS requests feedback on whether to replace the current two-step beneficiary assignment methodology with a new one-step assignment process in which the plurality of primary care services provided by the physicians currently included in

assignment steps 1 and 2 and the non-physician practitioners proposed for inclusion in assignment step 1 would all be considered in a single step. [7] Although CMS believes that this approach could simplify the current assignment process and partially address certain stakeholder comments about the current assignment methodology, CMS is not proposing to combine the two steps pursuant to this Proposed Rule due a number of concerns about a one-step assignment methodology. These include that a one-step assignment methodology may assign some beneficiaries to an ACO inappropriately based on specialty care over true primary care, and could introduce instability into the assignment process. CMS seeks comment on this.

To best facilitate careful consideration by stakeholders of the advantages and disadvantages of transitioning to a single-step methodology, BIO urges CMS to model the impact of transitioning to a single-step assignment methodology based on the characteristics of the assigned population for several "model" ACOs. Such ACOs would have patient populations of greater than 10,000 to ensure statistical significance and would incorporate a significant percentage of specialty care providers that would be affected by this proposal. Stakeholders need such data before they can offer well-informed comments on this proposal.

VI. Proposals Related to Transition from the One-Sided to Two-Sided Model: CMS should finalize the proposal to allow ACOs to enter into one additional 3-year agreement period under Track 1.

In the Proposed Rule, CMS states the intention to permit ACOs that have completed a 3-year agreement under Track 1 to enter into one additional 3-year agreement under Track 1.[8] This would replace the existing requirement that ACOs transition to Track 2 after one agreement period. The rationale the Agency provides in the preamble is that this change will allow ACOs that demonstrate they have been compliant with program requirements to remain participants, even if they are not yet ready to transition to a two-sided risk model. First and foremost, BIO expresses support for the retention of Track 1 generally, as we believe it is an important aspect of the program that incentivizes potential ACO participants to join the program. Moreover, BIO believes that this specific proposal will allow such ACOs time to develop the foundation that will be necessary to be successful in bearing risk in the future. Additionally, insofar as the new structure of Track 2 creates a more gradual transition to the two-sided risk model, we also believe that this proposal will allow ACOs the time needed to focus on accurately measuring quality of care and refining quality metrics to the benefit of individualized patient care.

[7] *Id.* at 72797.
[8] *Id*. at 72804.

VII. Proposals for Assignment of Beneficiaries under Track 3

A. BIO recognizes CMS's rationale for creating Track 3 with prospective assignment of beneficiaries, but urges CMS to put in place mechanisms to identify and prevent efforts by ACOs to game the system to avoid taking on certain types of beneficiaries.

In order to provide more options for participation in the MSSP, and with the hope of encouraging more ACOs to accept increased performance-based risk, CMS has proposed to add a Track 3 option for ACO participation. Under this option, beneficiaries would be prospectively assigned to the ACO, and unlike the current Track 1 and Track 2 models, CMS would perform only a limited reconciliation during the year. Beneficiaries would not be added, and would only be removed from the prospective assignment list at the end of the year if they were not eligible for assignment at that time under limited criteria set forth in proposed regulations.

In considering this proposal, we remind CMS that Medicare fee-for-service (FFS) beneficiaries retain all the rights and benefits afforded them under traditional Medicare in the MSSP. This includes the right to see any physician of their choosing, as beneficiaries do not "enroll" in the MSSP in the same way they would in, for example, a Medicare Advantage plan. In fact, unlike managed care settings, the MSSP ''assignment'' methodology in no way implies a lock-in or enrollment process. To the contrary, it is a process based exclusively on an assessment of where and from whom FFS beneficiaries have chosen to receive care during the course of each performance period.

Keeping this in mind, with regard to the newly proposed Track 3, BIO recognizes CMS's rationale in proposing to offer an ACO model in which beneficiaries are assigned prospectively. We agree with CMS's comment that this will allow ACOs to more definitively identify the beneficiaries for whom they are responsible and thus better plan for their specific needs within the context of meeting quality and cost benchmarks. We also appreciate that CMS is sensitive to concerns that prospective assignment of beneficiaries could increase the risk that an ACO might attempt to game the incentives structure of the program and focus on a subset of beneficiaries assigned to the ACO, rather than broadly redesigning care processes to better serve all beneficiaries.

In addition to the steps that CMS has taken to address these concerns, such as retaining policies and procedures to risk-adjust expenditures and monitor ACOs to ensure they are not engaging in gaming or avoidance of at-risk beneficiaries, BIO notes that ACOs may use other mechanisms, including utilization management techniques, that can negatively impact the provision of the most appropriate patient care. We request that CMS continue to give careful consideration to the various ways that prospective assignment of beneficiaries might result in ACOs "cherry-picking" or "gaming the system," and to put in place mechanisms to identify any such practices, both during CMS's review of ACO applicants and during their participation the MSSP.

B. Under the proposed methodology for assignment of beneficiaries under Track 3, CMS should limit an ACO's shared losses or gains in certain circumstances.

Under the proposal for a new Track 3, beneficiaries would not be added to an ACOs assignment list after the start of the year, and would only be removed during the limited reconciliation process at the end of the year if they were not eligible for assignment at that time under limited criteria set forth in a newly proposed section 425.401(b). This differs from the retrospective reconciliation process under Tracks 1 and 2. CMS believes this process, which would hold ACOs accountable for all beneficiaries prospectively assigned to them, with very narrow exceptions, would reduce the risk of ACOs attempting to avoid caring for high-risk beneficiaries, because the ACO would continue to be held accountable for the quality and cost of care provided to these beneficiaries, even if they sought care elsewhere, outside the ACO. However, CMS also acknowledges that this may mean that ACOs will be held accountable for beneficiaries with whom the ACO providers had little contact during the year, and therefore limited opportunity to affect, through no fault of the ACO.

BIO shares CMS's concern that holding ACOs responsible for beneficiaries with whom the ACO had little contact could have negative impacts on the ACO if a not-insignificant percentage of the ACO's assigned beneficiaries fall into this category. This could happen, for example, if a high percentage of an ACO's providers/suppliers were specialists, or if a high percentage of patients required care not available through the ACO to which they were "assigned" for the purposes of the MSSP. We ask CMS to consider establishing a mechanism to limit an ACO's shared losses (or shared gains) if the percentage of an ACO's assigned beneficiaries with whom it had little or no contact, but who do not meet the limited criteria for exclusion, exceeds a certain threshold. CMS should seek ACO and other stakeholders' input on an appropriate threshold.

VIII. Payment Requirements and Other Program Requirements That May Need to Be Waived in Order to Carry Out the Shared Savings Program:

CMS should identify standards for any telemedicine or telehealth services and ensure that such services supplement, rather than replace, in-person care, and monitor the quality of care provided.

In order to increase ACOs' willingness to participate under two-sided performance-based risk arrangements, CMS acknowledges that it may be necessary and advisable to provide for additional flexibility, including the establishment of waivers of certain Medicare program rules. In particular, CMS seeks comment on the use of telehealth technologies to provide beneficiaries with improved quality and access to care, and better care coordination, and asks whether a waiver of certain existing Medicare telehealth requirements would be necessary to achieve these goals.

BIO supports the increased use of telehealth services and agrees that they have the potential to expand access to care and to supplement the services being provided directly

by ACO participating physicians and other clinicians, in that such services may provide opportunities to better coordinate health care services, particularly for beneficiaries with complex care needs, and for whom frequent in-person visits with their health care providers are challenging, or are not necessary to best address their care needs. But we caution CMS to carefully monitor the use of telehealth services and the quality of care provided to beneficiaries receiving these services, particularly when existing program requirements are waived. It is essential that all beneficiaries continue to have access to the full breadth and depth of diagnostic and treatment services. It will be important to ensure that telehealth technologies do not create delays in accessing care or to substitute for necessary in-person care, and BIO urges CMS to consider identifying standards for the provision of telehealth services to ensure they supplement, rather than replace, in-person care.

We also caution the Agency to consider the potential that the expansion of the use of telehealth services within the MSSP may lead to inappropriate utilization through the 340B drug discount program without more detailed guidance on the interaction of the two initiatives. Originally intended to improve access to prescription drugs for indigent, uninsured patients, the 340B program allows covered entities to purchase covered outpatient drugs at a significantly discounted rate. However, the current implementation of the program leaves BIO with significant concerns that the use of telehealth services in the MSSP through the waiver process—particularly in non-rural areas—may implicate the 340B program in ways that do not accrue benefit to the neediest patients. While there is specific guidance on the issue of 340B covered entities participating in ACOs, no such guidance exists to govern the potential interaction of ACOs and telehealth services.[9] Thus, we recommend that CMS not implement the non-rural waiver for telehealth services until a more specific definition of a patient, for purposes of the 340B program, is implemented. In considering how to expand the use of these services over the longer term, CMS should work with the Health Resources and Services Administration (HRSA)—which administers the 340B program—to affirm that it is not the Agency's intention for the receipt of telehealth services within the context of the MSSP to, in and of itself, qualify a beneficiary as a patient of 340B covered entity. BIO is concerned that without such a clarification—and necessary oversight—in place, patients may be unduly encouraged to seek telehealth services even when in-person services are available and more appropriate.

In addition to the potential to expand telehealth services, CMS also requested comments related to expanded use of remote monitoring among ACOs. CMS currently offers limited reimbursement of remote monitoring services such as for cardiac trans-telephonic monitoring of pacemakers. In addition, CMS recently established separate payments for non-face-to-face services, including remote monitoring, for Medicare beneficiaries who have multiple, significant chronic conditions (two or more). We are supportive of this step by CMS to the extent that CMS requires such remote monitoring to exist within bona fide

[9] HRSA. 2012 (May 23). *Clarification of covered entity eligibility within accountable care organizations: Release no. 2012-2*, available at: http://www.hrsa.gov/opa/programrequirements/policyreleases/accountablecare05232012.pdf.

provider/patient relationship situations to help existing patients adhere to their medication and treatment plan.[10]

IX. Step-Wise Progression for ACOs to Take on Performance-Based Risk

Although not proposing to change the regulations to allow providers and suppliers participating through the same ACO to participate in different tracks at this time, CMS is soliciting comments on possible ways of doing so in the future. CMS has put forth various options it is considering, and BIO provides the following feedback.

A. CMS should require each segment of a risk-split ACO to meet all eligibility requirements to participate in the program, and CMS should ensure appropriate risk adjustment.

CMS states its expectation that if ACOs were permitted to split their participant list into different risk tracks, the ACO as a whole would be required to meet the eligibility requirements to participate in the program, including the requirement that the ACO have at least 5000 assigned beneficiaries, and the governance requirement. BIO recommends that if CMS were to allow ACOs to split their participants into different risk tracks, each segment of the risk-split ACO should be required to meet all eligibility requirements to participate in the program, although we note that some of these requirements will be fulfilled by the same mechanism for each segment of the entity (e.g., only one governance body would be required as long as it maintained governance over all ACO professionals in each segment).

We are concerned about the implications of small segments of ACO professionals (i.e., those responsible for fewer than 5,000 assigned beneficiaries) participating in different risk segments because the current risk-adjustment methodology used by CMS—the CMS-HCC prospective risk scoring methodology—less accurately accounts for the underlying risk of a patient population the smaller its size. Risk adjustment is crucial in the MSSP in order to ensure that providers aren't unduly penalized for treating patients with more acute medical needs. Requiring each segment to meet the eligibility criteria also would clarify the Minimum Savings Rate (MSR) each segment must meet to achieve shared savings, and allow for a more accurate assessment of the success of each segment.

B. CMS should consider using different quality measures for different risk tracks.

CMS solicits comment on whether the ACO as a whole would be responsible for submitting quality data, and notes certain advantages and disadvantages of this versus each segment reporting separately. BIO notes that not all quality measures are appropriately applied to

[10] In this instance, a bone fide provider/patient relationship is characterized as—at least—one in which the provider: ensures that a medical history is obtained; (ii) provides information to the patient about the benefits and risks of a treatment course given their individual prognosis and personal characteristics; (iii) performs or has performed an appropriate examination of the patient, either physically or via diagnostic equipment (e.g., imaging) him/herself—except for medical emergencies—or such examination has been performed within the group in which he/she practices; and (iv) is able to initiate additional interventions and follow-up care, if necessary.

all types of providers, and that allowing groups of ACO providers/suppliers to participate in separate risk tracks may be an opportunity to apply relevant quality measures in a more focused and meaningful way, either by provider specialty or patient population characteristics.

C. CMS should require that each segment of an ACO with participants in more than one risk track have its own list of assigned beneficiaries and its own benchmark, and the segmented ACOs should be limited to participation in Tracks 1 and 2.

If CMS permits segments of ACO providers/suppliers to participate in different risk tracks, BIO recommends that each segment have its own assigned beneficiaries and its own benchmark rather than a common benchmark across the ACO. Otherwise, it would be difficult to assess each segment's success or shortcomings in affecting patient care and health expenditures. BIO also recommends that an ACO's participation in multiple risk tracks be limited to those participating in Tracks 1 and 2 because of the similarities in their assignment methodology and how their MSRs are set.

D. CMS should not permit individual ACO providers/suppliers in an ACO with a segmented list of participants to change risk tracks in the middle of a performance year.

As part of the Proposed Rule preamble's discussion on the potential to allow ACOs to segment groups of providers/suppliers into different risk tracks, CMS identifies potential requirements for such a proposal, such as those discussed in the previous two sections around the number of total beneficiaries and use of quality metrics. To this list, BIO asks CMS to consider adding a requirement such that an ACO that undertakes this approach will not allow individual providers/suppliers to switch risk tracks in the middle of a performance year. We believe that such a requirement will allow for more predictable assessments of each segment and help to ensure more consistent treatment of beneficiaries cared for by these participants.

X. <u>Methodology for Establishing, Updating, and Resetting the Benchmark</u>

A. CMS should transition to a benchmark methodology that takes into account an ACO's shared savings from a prior agreement period in establishing a benchmark for a subsequent agreement period.

As CMS notes, the current methodology for resetting an ACO's benchmark may provide disincentives for long-term participation in the MSSP because as ACOs perform more efficiently their benchmarks for subsequent agreement periods will be set lower, and over time they will exhaust the extent to which natural efficiencies in care management and coordination can continue to decrease health expenditures. BIO also is concerned that the lower an ACO's benchmark is set, the greater the incentive it may have to stint on necessary care or use strict utilization management techniques in order to meet that

benchmark. The purpose of the Shared Savings Program is to achieve savings through improvements in the coordination and quality of care, and not through avoiding certain beneficiaries or placing limits on beneficiary access to needed care.

BIO urges CMS to carefully consider the comments it receives regarding methods for resetting the benchmark, and to then describe in detail the methodology(ies) being considered, and solicit stakeholder feedback prior to finalizing any change. Nonetheless, based on the description in the preamble of the proposed rule, BIO generally supports transitioning to a benchmark methodology that takes into account an ACO's shared savings from a prior agreement period in establishing a benchmark for a subsequent period. We believe this approach would better reflect the ACO's performance in the previous period than simply weighting each of the three benchmark years equally in order to determine the benchmark for a subsequent period.

However, we also are sensitive to the fact that an ACO can make good progress in reducing expenditures while maintaining or improving quality, but not do so by enough to achieve shared savings in a given performance year. Such an ACO would then not benefit from the alternative methodology for resetting its benchmark if it chose to renew its participation in the MSSP. To avoid discouraging participation by such an ACO, we would recommend that CMS employ the equal weight methodology for setting an ACO's benchmark for a subsequent period for all ACOs that did not receive shared savings in any of the performance years of the previous agreement period.

Additionally, we believe that the potential to reflect an ACO's progress in meeting the goals of improved patient care and reduced overall expenditures more accurately in resetting its benchmark outweighs the reality that relying on performance data to do so necessarily means that the finalization of an ACO's historical benchmark will be delayed until mid-way through its first performance year during its subsequent agreement period.

B. CMS should use regional factors, rather than national factors, to establish and update benchmarks but should continue to base benchmarks on an individual ACO's historical fee-for-service costs rather than on regional fee-for-service costs.

As CMS notes, some stakeholders have expressed concern that the current benchmarking methodology doesn't take into account the influence of cost trends in the surrounding region or local market on the ACO's financial performance. Taking these concerns into account, and based on experience with the Physician Group Practice (PGP) demonstration, CMS is considering the use of regional factors in establishing and updating benchmarks.

BIO agrees that the benefits of taking into account regional, rather than national, fee-for-service costs outweigh some of the administrative and statistical challenges of doing so, as this would better reflect the local realities in which ACOs operate. In doing so, we also support CMS's proposal to establish a comparison group of at least 25,000 to address any concerns of insufficient statistical power. However, we urge CMS to continue to set

benchmarks individually for ACOs to ensure such benchmarks can be feasibly attained based on the individual circumstances of an MSSP participant.

C. CMS must take additional steps to guard against "gaming of the system."

BIO continues to urge CMS to take additional steps to prevent ACOs from engaging in cost shifting and taking other steps to game the system, in light of the fact that ACOs are not responsible for all costs incurred by beneficiaries in the Medicare system. Since ACOs are accountable for Part B but not Part D spending, there is the potential for providers to, for example, direct patients towards an oral drug covered under Part D rather than a physician-administered innovative product that would be covered under Part B, which may be more appropriate for some patients. From the perspective of Medicare policy, it is problematic to reward "paper savings" achieved through cost shifting from one part of the program to another. These concerns are exacerbated by the recently proposed changes to narrow and even eliminate crucial protections under the current Part D protected class policy, which ensures that some of the most vulnerable patients continue to have timely access to the drugs they need in the setting that is most appropriate for them. This "gaming" can significantly affect patients' ability to receive the most appropriate care in the most appropriate and convenient setting, which may also impact adherence to treatment plans, and both short and long-term health outcomes.

We also urge CMS to ensure that if ACOs are put at full risk for additional categories of patients and/or costs (e.g., dual-eligibles, Medicaid recipients), they are adequately reimbursed to avoid disincentivizing the use of new technologies and those treatments that may be more expensive in the short term but yield significant patient benefits and/or savings in the longer term.

Further, for years, BIO has expressed concern about the expansion of the 340B program beyond its original Congressional intent: to improve access to prescription drugs for uninsured, indigent patients. In the absence of a robust definition of a patient under the 340B program, BIO remains concerned that requirements that ACOs coordinate and integrate care may lead an ACO participant, of which one component is a 340B covered entity, to inappropriately expand access to 340B-discounted prescription drugs to ACO beneficiaries that do not independently meet the definition of an eligible patient of the 340B covered entity. While we appreciate HRSA's 2012 guidance expressly stating that "[t]he inclusion of a covered entity in an ACO does not automatically make all of the individuals receiving services from an ACO patients of the covered entity for 340B Program,"[11] we believe there is increased need for CMS and HRSA to work together to ensure ACO participants are aware of and adhere to this guidance. Without more specific oversight by both Agencies with regard to ACO participants, the integrity of each program and ability of each program to meet its Congressionally-identified goals, respectively, will be undermined.

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[11] HRSA. 2012 (May 23). *Clarification of covered entity eligibility within accountable care organizations: Release no. 2012-2*, available at: http://www.hrsa.gov/opa/programrequirements/policyreleases/accountablecare05232012.pdf.

XI. Public Reporting and Transparency

A. CMS should require ACOs to publicly report additional information as proposed by CMS and make ACO-specific information available online.

In addition to existing reporting requirements, CMS proposes to require that ACOs publicly report the following information:

- The key clinical and administrative leaders within the ACO;
- The types of ACO participants or combinations of ACO participants that have joined to form the ACO; and
- ACO performance on all quality measures used to assess the quality of care furnished by the ACO (not just performance on claims-based measures, which is the current requirement).

CMS also proposes to post online ACO-specific information, including information the ACO is required to publicly report, in addition to what CMS already makes available on its website and the Physician Compare website.

BIO strongly supports these additional transparency requirements. ACOs must demonstrate that they meet certain patient-centeredness criteria, and we agree with CMS that patient engagement and transparency are important cornerstones of patient-centeredness. As CMS recognizes, transparency empowers patients to make informed decision about where to seek care, facilitates oversight, and helps to ensure program integrity and accountability. It can also spur innovation and improvement in both quality and efficiency.

We agree that requiring an ACO to publicly report this information would afford the public additional insights into the ACO's composition and performance. We applaud CMS for continuing to improve the transparency of the MSSP, and we urge CMS to finalize this proposal.[12]

B. CMS should add public reporting requirements for ACOs specific to health information technology (HIT) interoperability to improve accountability in this space and speed adoption of interoperable HIT platforms.

Throughout the Proposed Rule, it is clear that the availability of data—related to delivery and cost of care—is crucial to assessing the progress of ACO participants. BIO also notes that the availability of the most relevant, up-to-date data is crucial to assessing the quality of care patients receive and patient outcomes. However, data collection and analysis can be fragments, especially for ACOs newer to the MSSP and smaller ACOs. While CMS has put into place initiatives to boost the use and utility of HIT, such as Electronic Health Records

[12] 79 Fed. Reg. at 72846.

(EHR) and incentives provided by the newly proposed Precision Medicine Initiative,[13] it is still unclear to what extent this technology is interoperable at all of the facilities within a larger network or across facilities in different provider networks. Since the MSSP is meant to provide incentives for ACO participants to move toward more integrated care, and interoperable HIT is a key component of such integration, we encourage CMS to establish public reporting requirements for ACO specific to the degree of interoperability an ACO has achieved. Such requirements also could take into account whether an ACO has a detailed plan to achieve, and is able to make steady progress toward, fully interoperable HIT platforms. This especially is important as CMS states in the preamble several times that patients of ACO providers/suppliers do not necessarily seek the entirety of their care from the ACO participant. The ability to ingrate all of the data from a patient's interaction with the healthcare system can improve the ability of ACO providers/suppliers to tailor an individualized care plan that is better informed. Thus, public reporting requirements for HIT interoperability can improve accountability in this space and serve to speed adoption of these important platforms to support integrated patient care.

C. CMS should perform a more thorough assessment of ACOs' performance with regard to amount of risk borne and underlying patient population, and consider how best to make such analyses publicly available.

Throughout the preamble of the Proposed Rule, CMS expresses interest in ensuring the structure of the MSSP appropriately incentivizes not only participation by ACOs but increased assumption of risk over time. To better support this interest, CMS should consider how it assesses the impact of participation in the MSSP on ACOs and whether the data currently available are sufficiently robust to conduct such assessments. To this end, CMS should consider either conducting, or making publicly available the data needed to conduct, performance analyses to identify how different types of ACOs are performing, the characteristics of ACOs that allow them to successfully participate in two-sided risk models, and trends in underlying patient populations, among other research questions. These analyses can not only be instructive to current and potential ACO participants, but they also can potentially help CMS identify the causes of, and thus prevent, adverse patient selection within specific risk tracks. We encourage CMS to work with stakeholders to develop and execute such analyses with Track 1 and Track 2 participants first, including Track 3 if CMS finalizes its creation, and consider how to make the data used and the results available to the public.

[13] *See* CMS. 2015. *EHR Incentive Program*, available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms/; The White House. 2015. *FACT SHEET: President Obama's Precision Medicine Initiative*, available at: http://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative.

XII. Risk-Adjustment Methodology: CMS should improve its risk-adjustment methodology to address several shortcomings in the current methodology.

The CMS-Hierarchical Condition Categories (HHC) risk methodology plays an important role in determining whether an ACO will meet cost and quality metrics. Unfortunately, we believe that the risk-adjustment methodology still suffers from a number of shortcomings. Though CMS does not address specific use of the CMS-HCC risk adjustment methodology in the Proposed Rule, we would like to reiterate concerns that we have expressed previously regarding this methodology.

Because the CMS-HCC methodology is prospective, rather than concurrent, the methodology is designed to predict future spending rather than measure current patient needs or capture current patient health problems. In addition, the CMS-HCC methodology health condition weights are based on factors that affect regression-based predictions of actual spending, including increased utilization unrelated to health status, but the methodology does not account for changes in clinical evidence regarding patient care. We also disagree with the manner in which the current CMS-HCC methodology explicitly assigns zero weight to many acute conditions. These conditions are likely to result in a need for expensive services – both in the year in which they occurred and potentially in subsequent years. Consequently, risk scores generated under the current CMS-HCC methodology tend to over- or under-predict costs in the payment year versus the base year used to calculate risk scores. Additionally, we are concerned about the ability of the CMS-HCC to accurately translate underlying health risk to potential costs of care in a beneficiary's final year of life. Providers with large percentages of their patient population that fit into this category risk being unduly penalized, since it is well document that 25 percent of all Medicare payments are toward beneficiaries in their last year of life. [14]

CMS must continue to refine its risk-adjustment methodology so that it will better measure current patient needs and better capture current patient health problems. In addition, refinements should be made to account for changes in standards of care and the increased costs associated with many acute conditions. We believe that such refinements will help to ensure that risk scores generated under the CMS-HCC methodology more accurately predict costs in the payment year versus the base year used to calculate risk scores.

[14] For example, *see* Riley, G.F., and J. D. Lutz. 2010. Long-Term Trends in Medicare Payments in the Last Year of Life. *Health Services Research Journal* 45(2): 565-576, available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2838161/.

XIII. Conclusion

Thank you for this opportunity to provide our feedback as CMS continues to develop and improve the ACOs. Please contact me at 202.962.9220 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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