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BY ELECTRONIC DELIVERY

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

Re: Medicare Program; Medicare Shared Saving Program: Accountable Care Organizations; Proposed Rule [CMS-1345-P]

Dear Dr. Berwick:

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 and Accountable Care Organizations (ACOs) (the "Proposed Rule").[1] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we monitor closely Medicare's payment policies for their potential impact on innovation and patient access to drugs and biologicals. BIO believes that ACOs have great potential to provide better care for individuals, better health for populations, and lower growth in expenditures – a three-part aim that BIO fully supports. At the same time, as CMS recognizes in the Proposed Rule, in any risk-based arrangement "providers of services and suppliers have an increased motivation to control spending and achieve efficiencies [such that] it would be reasonable to anticipate an increase in negative incentives such as incentives to stint on care or undersupply services, [and] shift costs," among other things.[2] BIO supports the steps CMS has taken to minimize these risks, but believes that more must be done to ensure that beneficiaries that are treated by ACO participants have timely access to novel, innovative therapies.

[1] 76 Fed. Reg. 19528 (April 7, 2011).
[2] Id. at 19617.

BIO has a number of comments and recommendations that are aimed at helping to support the important goals of ACOs, while simultaneously ensuring that the risk-based model that CMS is proposing does not negatively affect patient care. Our comments address a few general themes, discussed below.

I. ACO Governance and Operations
- Ensure that ACOs include a role for specialists in leadership and management.
- Include quality measures tied to timely referral to specialists.
- Finalize proposal to share data with ACOs.
- Clarify the proposal with regard to assignment of beneficiaries.
- Provide additional guidance for meaningful inclusion of patients in the ACO governance structure.

II. Quality Measures and Reporting
- Use quality measures that are endorsed by national organizations.
- Establish a process for updating quality measures and removing out-of-date quality measures in a timely manner.
- Include additional transition of care and medical adherence quality measures.
- Continue efforts to align quality measures with existing quality reporting and incentive programs.
- Raise the minimum attainment level for shared savings from the 30th percentile to the 50th percentile.

III. Beneficiary Protections
- Finalize proposed patient protection mechanisms.
- Require ACOs to adopt a bill of rights for both patients and providers.
- Establish a beneficiary appeals mechanism and ombudsman program.
- Collect and publish data regarding ACO performance to ensure transparency and comparability.

IV. Access to Innovative New Technologies
- Implement a range of mechanisms to ensure beneficiary access to new technologies, including:
    - Creating a carve-out for new technologies;
    - Decreasing the proposed outlier threshold;
    - Requiring ACOs to address new technologies in their clinical guidelines and processes and to certify adherence to compendia guidelines.
- Promote ACO participation in clinical trials.
- Protect beneficiary access to transplanted organs.

V. Integrity of the Shared Savings Program
- Ensure the "savings" an ACO generates reflect real quality and efficiency gains by:
    - Requiring ACOs to report on how savings were generated;
    - Monitoring ACOs to identify changes in coding patterns;

  - Ensuring clinical decisions, especially prescribing decisions, are made in the best interest of the beneficiary.
- Ensure that ACOs do not engage in inappropriate drug diversion under the 340B Drug Pricing Program.

These issues are discussed in depth below.

I. ACO GOVERNANCE AND OPERATIONS

A. BIO urges CMS to ensure that ACOs include a role for specialists in leadership and management.

CMS has chosen to implement the Shared Savings Program by emphasizing the role of primary care and primary care providers. For example, with regard to assignment of beneficiaries, CMS has proposed to implement the statutory requirement that beneficiaries be assigned to ACOs based on the primary care services received from an ACO professional by providing for assignment based on the primary care services received from a limited group of primary care physicians.[3] Similarly, CMS's proposal to give ACOs "bonus" points for including Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs) in the ACO is based on the agency's determination that such entities provide "comprehensive, high-quality primary health care to patients."[4]

At the same time, CMS recognizes the important role that specialists serve both with regard to patient care generally, as well as in the coordination of care in an ACO model. In discussing beneficiary assignment, CMS notes that "certain specialists (for example, cardiologists, endocrinologists, neurologists, oncologists) are often the principal primary care provider for elderly and chronically ill patients."[5] CMS also states that "[c]oordination of care involves strategies to promote, improve, and assess integration and consistency of care across primary care physicians, specialist, and acute and post-acute providers and suppliers,"[6] and that primary care physicians can "reduce unnecessary repetition of laboratory testing or imaging" by coordinating with specialists to whom a beneficiary has been referred.[7]

BIO agrees with CMS that it is most appropriate to assign beneficiaries to an ACO based on primary care services received from a primary care physician, and supports that proposal. We are concerned, however, that CMS has not otherwise provided a role for specialists in ACOs and see this as a significant shortfall in the Proposed Rule.

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[3] Id. at 19565.
[4] Id. at 19613.
[5] Id. at 19564.
[6] Id. at 19547.
[7] Id. at 19537.

To ensure that there is an appropriate role for specialists in an ACO, BIO urges CMS to require ACOs to include specialists when developing clinical guidelines and processes. Under the Proposed Rule, ACOs would be required to "develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, and lower growth in expenditures" in order to be eligible to participate in the Shared Savings Program.[8] Similarly, ACOs would be required to define processes to promote evidence-based medicine and to regularly assess and update their guidelines.[9] BIO appreciates that CMS is not being overly proscriptive with regard to either requirement and instead is allowing ACOs "to choose the tools for meeting these requirements that are most appropriate for their practitioners and patient populations."[10] We believe, however, that involving specialists in this process is important to ensure that the care and expertise that specialists provide is not overlooked by the ACO's emphasis on primary care. Such a requirement would not limit the flexibility of ACOs but would ensure that the full continuum of care is appropriately considered.

B. CMS should include quality measures tied to the timely referral to specialists.

BIO appreciates that CMS has taken steps to ensure that patients receive the right care at the right time from the right provider. This includes emphasizing the freedom of choice that beneficiaries retain even when assigned to an ACO or seeing a primary care provider that participates in an ACO. BIO supports this freedom of choice and applauds CMS's efforts to ensure that it is protected. Nevertheless, because there is no specific role for specialists in ACOs and given the inherent incentives in a risk-based model to reduce costs, to be discussed in much greater detail below, BIO is concerned that under the ACO model, beneficiaries may not receive timely referral to specialists.

In a system in which physicians ultimately are accountable for expenditures and potentially liable for losses, however, there is an increased need to ensure that a patient's care is being managed appropriately because of the reliance patients generally place on their physicians' decisions. Therefore, BIO urges CMS to include quality measures that track timely referrals for specialist care. The National Quality forum (NQF) has endorsed several measures that track referrals, including two that measure timely referrals for cardiac rehabilitation and services for certain patients. Additionally, there are several questions relating to access to specialty care that are included in Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys. CMS is proposing to require ACOs to use the CAHPS survey as part of the patient-centeredness criteria, so it would not present an additional burden to ACOs to report this information, and be included as quality performance metrics at the start of the Shared Savings Program on January 1, 2012. Specialty societies also have developed measures relating to referrals. CMS should incorporate some or all of these existing measures into the Shared Savings Program.

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[8] Id. at 19543.
[9] Id. at 19546-47.
[10] See id. at 19546.

C. BIO supports CMS's proposal to share data with ACOs.

CMS is proposing to share both aggregate and beneficiary-identifiable claims data with ACOs.[11] BIO agrees with CMS that sharing this data with ACOs is important to help ACOs "understand the totality of care provided to beneficiaries assigned to them" and to "promote coordinated care."[12] Therefore, BIO supports CMS's proposal to share this data and urges the agency to finalize it. We are concerned, however, about CMS's proposals regarding safeguarding such data. As CMS recognizes in the Proposed Rule, there already are limits on how patient data is shared and used that would, rightfully, continue to apply. We urge CMS to think carefully about the proposed opt-out notice and whether it has the potential to confuse beneficiaries, who may believe that it will limit more than just the claims data that CMS would be sharing with the ACO and also apply to data sharing among ACO participants or other providers that may be permissible under existing laws and regulations. We also question whether it is appropriate to assign beneficiaries who opt-out of this claims sharing to an ACO, given that the lack of access to this data will make it more difficult for an ACO to have the information necessary to promote coordinated care and achieve related quality goals.

To facilitate data sharing, quality measurement, care coordination, and clinical decision making, a health information exchange (HIE) framework and the health information technology (HIT) infrastructure will be key enablers of ACOs. Developing this infrastructure will enable information exchange among affiliated and unaffiliated providers through the use of interoperability standards. Furthermore, an expanded information exchange will improve the value of electronic health records (EHR) for medication management through medication reconciliation, prescription fill notification, and clinical decision support tools. Electronic exchange of pharmacy claims data, as well as other medical data, would automatically facilitate a more accurate picture of the patient's medication history by allowing providers to view a patient's active medication list and history within the EHR, resolve any identified discrepancies, compare any new medications with the list, receive prompts about medication interactions or allergies, and easily share the updated and verified information with the patient and other appropriate providers. In essence, HIEs facilitate enhanced care coordination and comprehensive medication management within an ACO environment and CMS should encourage their adoption by providers.

D. CMS should clarify its proposal with regard to assignment of beneficiaries.

CMS proposes to assign a beneficiary to an ACO if the beneficiary receives a plurality of primary care services from a primary care physician in that ACO.[13] BIO supports this proposal. We note, however, that there seems to be some confusion around the primary care services that will be used to determine whether a beneficiary will be assigned to an ACO. Specifically, based on the proposed regulatory text,[14] it is unclear whether CMS will look at the primary care

[11] Id. at 19554-59.
[12] Id. at 19554.
[13] Id. at 19567.
[14] Id. at 19645 (proposed 42 C.F.R. § 425.6(b)).

services the beneficiary receives from *any provider* or only primary care services received from primary care providers in determining whether the beneficiary received a plurality of primary care services from a primary care physician participating in an ACO. BIO asks CMS to clarify its proposal in this regard.

To the extent that CMS intends to look only at the primary care services a beneficiary receives from primary care physicians to determine whether the beneficiary received a plurality of primary care services from a primary care physician participating in an ACO, BIO is concerned that beneficiaries that receive only minimal care from a primary care physician may nonetheless be assigned to an ACO. That is, a beneficiary with, for example, a cancer diagnosis, could be assigned to an ACO if he or she receives only a single annual wellness visit from a primary care provider but otherwise receives all of his or her care from an oncologist. It seems unfair to make the ACO responsible for the care of such patient when the ACO actually has very little to do with the patient's care. Therefore, if CMS intends to determine the plurality of primary care services based only on the primary care services received from primary care providers, BIO recommends that CMS establish a minimum threshold of services that a beneficiary must receive from the primary care provider before the beneficiary is assigned to the ACO.

E. CMS should provide additional guidance for meaningful inclusion of patients in the ACO governance structure.

BIO strongly supports CMS's goal of creating a patient-centered program for the Medicare beneficiaries assigned to an ACO. To achieve this, it is important that beneficiaries "have a voice in the decision making process" through meaningful participation in the ACO governing body. As CMS discusses, simply inviting a beneficiary to participate in the governing board, even a beneficiary served by the ACO, may not provide a strong enough presence. BIO urges CMS to require that each ACO establish a beneficiary advisory panel to support the beneficiaries serving on the ACO governing body. Participation in these advisory panels should be open to any stakeholder interested in promoting the goal of engaging patients in ACO governance. BIO views these beneficiary advisory panels to operate in support of, but not supplant, the ACO governing body. Additionally, CMS should require ACO governing bodies to include at least two patient representatives, one of whom may be representative of a national patient organization.

II. QUALITY MEASURES AND REPORTING

A. CMS should use quality measures that are endorsed by national organizations.

The statute gives CMS broad authority to determine appropriate measures to assess the quality of care furnished by the ACO. As in the case of its adoption of measures for the Physician Quality Reporting System (PQRS) and Hospital Inpatient and Outpatient Quality Data Reporting Programs [hospital reporting programs], CMS seeks measures that are "nationally

endorsed by a multi-stakeholder organization."[15] Because quality performance plays such an important role in the Shared Savings Program insofar as it is tied to an ACO's eligibility for shared savings and the amount of shared savings to which it may be entitled, BIO believes that it is especially important that the measures used are endorsed by a national organization, such as the NQF, or a disease or provider specialty society.

There are a number of reputable national organizations that have sophisticated processes for developing and endorsing measures. These include the NQF, the National Committee for Quality Assurance (NCQA), the Joint Commission, the Centers for Disease Control and Prevention's Advisory Committee of Immunization Practices (ACIP), and the American Medical Association (AMA). Where there are measurement gaps, there could be two options where CMS could select, for a limited time, one of the following:

1. A measure developed by a national organization that has been submitted for NQF endorsement. This allows for testing the "in process" measure for NQF endorsement. If CMS selects such a measure, the results should not be publicly reported or used for payment calculations until NQF endorsement.
2. A measure endorsed by a disease or provider specialty group has revised its endorsement process to apply established criteria and include multi-stakeholder input, review by external experts and an accessible process to solicit and consider public comments. These entities have specific expertise that enables them to develop appropriate measures relevant to their areas of focus and develop professional consensus for the recommendations found within practice guidelines.

BIO urges CMS to specifically state that it will include only measures endorsed by such organizations.

B. CMS should establish a process for updating measures and removing out-of-date measures, in a timely manner.

In the Proposed Rule, CMS indicates that it expects to "refine and expand the ACO measures" and that ACO measures will "evolve over time."[16] CMS does not, however, specifically indicate how it will update measures based on changes instituted by the organization endorsing the measures or based on other clinical considerations. Nor does CMS address removal of outdated measures. BIO believes that it is crucial for CMS to provide guidance in this regard given the important role that quality performance plays in the Shared Savings Program. If out-of-date or inappropriate measures are left in place, ACOs nonetheless will be compelled to meet the specifications in order to be eligible for shared savings. This could have detrimental effects on patient care.

One example of this is CMS's proposed measure on warfarin therapy. As described in the Proposed Rule, this measure would assess the percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were

[15] Id. at 19569.
[16] Id. at 19592.

prescribed warfarin therapy.[17] This measure already is outdated. There are more advanced therapeutic options available for these patients today as well as additional therapies in development. Leaving the measure in place may force ACOs to use a therapy that is no longer the only clinically-appropriate, or even recommended, choice.

Another example is with regard to CMS's proposed influenza immunization measure.[18] CMS recently released a proposed rule that would require hospitals to establish policies in both the inpatient and outpatient settings to offer and provide the seasonal influenza vaccine to all patients (except those who decline the vaccine or for whom vaccination is contraindicated) as soon as the vaccine becomes available, from September 1 through the end of February each year.[19] In that proposed rule, CMS discusses the health care burden of influenza and the success of vaccination at preventing it.[20] CMS should ensure that its influenza immunization measure is updated to be consistent with the policy on immunizations that the agency ultimately adopts.

In response to CMS's request for comments on whether the list of proposed measures should be narrowed, BIO urges CMS to remove the warfarin measure from the list of proposed measures for 2012. Based on this example, BIO also asks CMS to institute a process for reviewing the existing measures and for updating or removing measures that are outdated on a timely basis, and in no event later than six months after the date at which the measure becomes obsolete. CMS may also consider creating an exception process for providers who follow new guidelines or measures so as to not hinder patient care when quality measures lag behind changes in treatment.

C. CMS should include additional transition of care and medication adherence measures.

BIO applauds CMS's inclusion of quality measures relating to care coordination in the proposed quality measures for ACOs. In particular, BIO supports inclusion of the care transition measures that address medication reconciliation and medication management.[21] BIO urges CMS to include additional measures relating to care transitions.

CMS has not included any quality measures that specifically address medication adherence as part of care transitions or otherwise. BIO views this as a significant oversight given the important role that adherence to a medication protocol can have in reducing unnecessary care and expenditures. NQF has endorsed a number of medication-related measures, including medication possession ratio measures. Examples of these measures include "Adherence to Chronic Medications" (NQF Measure #542), "Coronary Artery Disease &

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[17] Id. at 19586 (Measure Number 51, Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation).
[18] Id. at 19578 (Measure Number 26, Influenza Immunization).
[19] 76 Fed. Reg. 25460 (May 4, 2011).
[20] Id. at 25461.
[21] Id. at 19572 (Measure Number 10, Medication Reconciliation; Measure Number 11, Care Transition Measure).

Medication Possession Ratio for Statin Therapy" (#543), "Diabetes Mellitus & Medication Possession Ratio for Chronic Medications" (#545), and "Pharmacotherapy Management of COPD Exacerbation: 2 rates" (#549). BIO urges CMS to include these and other appropriate medication adherence measures in the quality measure set for ACOs.

D. BIO supports CMS's intent to align quality measures with its existing quality reporting and incentive programs.

In the Proposed Rule, CMS indicates its intent to align the ACO quality measures with other Medicare incentive programs such as the PQRS, Electronic Prescribing Incentive Program, Electronic Health Records (EHR) Incentive Programs, Hospital Inpatient Quality Reporting Program, and also Medicaid and private sector initiatives that align with the aims of the Shared Savings Program.[22] BIO supports this goal as it will minimize the burden on providers. BIO asks CMS to establish processes to ensure that changes made in one of these programs are simultaneously made in the Shared Savings Program to facilitate consistency and to continue the push toward greater alignment as all of the programs evolve.

E. CMS should raise the minimum attainment level for shared savings from the 30th percentile to the 50th percentile.

With regard to quality performance, CMS is proposing that an ACO will receive a performance score on each quality measure. Performance below the minimum attainment level would earn zero points for that measure. Performance equal to or greater than the minimum attainment level would receive points on a sliding scale based on the level of performance, with a maximum of two points available for each measure. CMS is proposing to set the minimum attainment level at 30 percent or the 30th percentile of the Medicare fee-for-service (FFS) or Medicare Advantage (MA) rate, as appropriate.[23]

BIO believes that it is inappropriate to reward ACOs for performance at 30 percent or the 30th percentile. This would enable ACOs that perform far below the average nonetheless to be eligible for shared savings under the Shared Savings Program, thereby distorting the incentives CMS is trying to create to improve quality performance. Although BIO recognizes that not all ACOs will perform equally, and that some may take longer to implement the systems and processes necessary to actually see quality improvements, we nonetheless believe that ACOs should not be rewarded for below average performance on quality measures. We therefore recommend that CMS raise the minimum attainment level to 50 percent or the 50th percentile, and use the proposed sliding scale methodology for scoring only after that minimum attainment level has been obtained.

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[22] Id. at 19569.
[23] Id. at 19595.

III. BENEFICIARY PROTECTIONS

A. CMS should finalize its proposed patient protection mechanisms.

CMS recognizes in the Proposed Rule that "risk-based arrangements require . . . greater beneficiary protections, for example by heightened monitoring to detect inappropriate short-cutting of care and avoidance of at-risk beneficiaries."[24] BIO applauds the steps CMS has taken in the Proposed Rule to ensure that beneficiaries will not be adversely affected by the implementation of the Shared Savings Program. In particular, BIO supports CMS's inclusion of patient and caregiver satisfaction quality measures,[25] which we believe will encourage ACOs to ensure that beneficiaries have access to the right care, at the right time, in the right place, as well as the tough sanctions it is proposing with regard to avoidance of at-risk beneficiaries.[26] Such at-risk beneficiaries often include beneficiaries that are prescribed orphan drugs or who have newly diagnosed cancer. Because the costs associated with treatment of such patients may be high, there is an incentive under the ACO risk-based model to avoid them. BIO appreciates CMS's efforts to ensure that those beneficiaries, as well as others an ACO may seek to avoid in order to reduce the likelihood of increasing costs to the ACO, will not lose access to their providers that are ACO participants.

B. ACOs should be required to adopt a bill of rights for both patients and providers.

Although BIO appreciates the patient protection mechanisms CMS is proposing to implement, including those discussed above, we believe that more should be done, especially to ensure that patients have access to new and innovative medical technologies. In this regard, we recommend that CMS require ACOs to adopt a patient bill of rights, similar to the notification of patient bill of rights that is required under the hospital conditions of participation.[27] This bill of rights would, at a minimum, require providers to inform patients of all of their available treatment options to ensure that the beneficiary is not being steered toward particular treatment protocols by the ACO solely to enable the ACO to meet its expenditure targets. This bill of rights could be provided with the required beneficiary notification regarding ACO participation and data sharing opt-out rights.[28]

Similarly, BIO recommends that CMS require ACOs to adopt a provider bill of rights. We understand that some physicians may be concerned that participating in an ACO somehow will limit their ability to make clinical decisions that they think are most appropriate for the patient. A provider bill of rights would, among other things, ensure that the ACO will not in any way limit the ability of participating providers to order the therapies that they believe to be most appropriate for their patients, or otherwise interfere with the provider's clinical decision-making. This does not mean that the ACO cannot develop and rely on evidence-based clinical guidelines,

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[24] Id. at 19617.
[25] Id. at 19571 (Measure Numbers 1-7).
[26] Id. at 19625.
[27] See 42 C.F.R. § 482.13.
[28] See 76 Fed. Reg. at 19568.

as is proposed, but rather it will ensure that physicians still will be the ultimate arbiters of an individual's care.

C. CMS should establish a beneficiary appeals mechanism and ombudsman program.

Either as part of the patient bill of rights discussed above, or separately, CMS should establish a beneficiary grievance process. This process would provide a mechanism for beneficiaries who believe that they are being denied access to appropriate care as a result of their provider's participation in an ACO to raise those concerns and receive a decision relating thereto. Although BIO recognizes that beneficiaries who are dissatisfied with the care they are receiving have the ability to seek care elsewhere, the grievance process will provide a mechanism for beneficiaries who do not want to change their provider, but who believe that the provider's participation in the ACO is affecting the care that he or she is receiving, to have recourse.

This grievance process could be modeled on either the process for individuals challenging the denial of a claim for FFS benefits,[29] or on the grievance process that is provided for beneficiaries enrolled in MA or Medicare Part D.[30] Under these existing appeal mechanisms, beneficiaries may be assisted by a representative, including a provider. If appropriate, a provider also should be able to assist a beneficiary in the ACO grievance process. In certain circumstances, however, it may be the provider's decision that the beneficiary is challenging. In these cases, the beneficiary should be able to be assisted by other representatives, including manufacturers.

In addition, for patients for whom the grievance process would be inappropriate (e.g., because they are not seeking to have a certain decision reversed, but rather have more generalized complaints), CMS should establish an ACO ombudsman. This ombudsman would receive beneficiary and provider complaints and provide valuable feedback to CMS on how the Shared Saving Program is being operationalized and areas that the agency may need to address in future rulemakings or other guidance.

D. CMS should be the entity that collects and publishes data regarding ACO performance to ensure transparency and comparability.

BIO supports CMS's proposal to require ACOs to publicly report information, including information regarding ACO participants as well as the ACO governance and leadership, the amount of shared savings or losses, and the portion of shared savings invested in infrastructure, redesigned care processes, and other resources, as well as amounts distributed among the ACO participants.[31] BIO believes that such information is essential to ensuring that beneficiaries are able to make informed decisions regarding where to seek and receive care. We think that the only way such information can be used effectively by beneficiaries is if it is provided in a single

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[29] See 42 U.S.C. § 1395ff.
[30] Medicare Managed Care Manual, Ch. 13, §§ 10.1, 10.3.1; Medicare Prescription Drug Benefit Manual, Ch. 18, §§ 10.1, 10.3.1.
[31] 76 Fed. Reg. at 19601.

location in a standardized format that allows for comparability, as is the case with the Hospital Compare and Nursing Home Compare websites. Accordingly, we are recommending that ACOs report information to CMS and that CMS make the information publicly available.

IV. ENCOURAGING INNOVATION, DEVELOPMENT, AND BENEFICAIRY ACCESS TO NEW TECHNOLOGIES

A. CMS should implement a range of mechanisms to ensure that beneficiaries have access to innovative new technologies.

CMS recognizes that a risk-based program, such as the Shared Savings Program as CMS is proposing to implement it, increases the incentives to "stint on care or undersupply services."[32] BIO is sensitive to the fact that one area in which care is stinted and services undersupplied is with regard to new technologies because the savings associated with these technologies often are not realized within the relevant window of time and their costs likely would not be included in the benchmark. The proposed approaches CMS takes to trending the benchmark forward necessarily try to apply national averages to a particular ACO's historical performance. Utilization of new technologies and novel medical breakthroughs is very difficult to predict on a facility level with enough granularity to ensure fair measurement. As a result, simply monitoring an ACO's adoption of new technologies would not be enough to ensure patient access to needed therapies, because of the variations in new technology adoption by providers. BIO's concern is not only that patients continue to have access to the novel therapies that may be the best treatments for their conditions, but also that the incentive to create new therapies is not diminished by the lack of uptake by entities involved in risk-based arrangements, such as ACOs. With these concerns in mind, we offer the following recommendations.

1. CMS should create a carve-out for new technologies.

One way to ensure that patients continue to have access to innovative medical technologies is to carve them out of both the benchmark and performance year expenditures for ACOs. With such a carve-out, the decision to use such a therapy will not affect the calculation of the ACO's expenditures for purposes of determining whether it generated shared savings, and therefore there will be no incentive to lower costs by denying patient access to the therapy.

There are many ways that CMS could implement a carve-out. One way would be to rely on the existing mechanisms for hospital inpatient new technology add-on payments and pass-through payment status under the hospital outpatient prospective payment system. Among other requirements, in order to be eligible for new technology add-on payments in the hospital inpatient prospective payment system, the prospective payment rate otherwise applicable to the new technology must be inadequate.[33] Similarly, when a drug or biological receives pass-through status, CMS necessarily has made a determination that it is a new technology, the costs

[32] Id. at 19617.
[33] Social Security Act (SSA) § 1886(d)(5)(K)(ii)(I).

of which are not insignificant in comparison to the payment for the procedures or services associated with its use.[34] It therefore would be appropriate to exclude all of the expenses related to both of these types of new technologies from the expenditures that are used to determine an ACO's eligibility for shared savings to ensure there is no disincentive for their use in an ACO. Although pass-through status applies only in the hospital outpatient department setting, this carve-out should apply regardless of the care setting, including drugs and biologicals furnished in the physician office setting, which could be identified through the use of the two miscellaneous J-codes. Such congruity is necessary to ensure that the policy does not create an incentive to perform procedures in the hospital rather than in the physician office. By structuring a carve-out in this way, only those ACOs with expenses for new technologies and breakthrough therapies would receive an adjustment to their performance years. These types of policies would not penalize ACOs that incorporate Centers of Excellence and other entities and provider groups that have traditionally been early adopters of novel treatments and therapies, but would still provide these entities with incentives for appropriate utilization of breakthrough therapies.

2. CMS should decrease the proposed outlier threshold.

CMS is proposing to "truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile" for each benchmark and subsequent performance year.[35] The reason the agency is proposing to do so is to "minimize variation from catastrophically large claims."[36] BIO appreciates that CMS has taken this step to take into account outliers that would skew an evaluation of an ACOs with regard to generating savings. We think it also aligns well with the goal of protecting beneficiary access to innovative new technologies. However, BIO believes that the value of the expenditure cut-off in protecting ACOs from the variation associated with catastrophically large claims, as well as protecting beneficiaries from the incentives an ACO may have under the Shared Savings Program to avoid using new medical therapies would be stronger if the threshold were lower. Therefore, BIO recommends that CMS lower the expenditure threshold cut off at the 95th percentile for all ACOs.

3. CMS should require ACOs to address new technologies in their clinical guidelines and processes and to certify adherence to compendia guidelines.

As previously discussed, CMS is proposing to require ACOs to adopt evidence-based clinical guidelines and processes to promote evidence-based medicine.[37] CMS should require ACOs to address how they ensure beneficiary access to new technologies as part of these guidelines and processes. In its review of the documentation an ACO submits as part of its application, CMS must 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.

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[34] SSA § 1833(t)(6)(A)(iv)(II).
[35] 76 Fed. Reg. at 19604-05.
[36] Id. at 19604.
[37] Id. at 19543, 19546.

In conjunction with these requirements, CMS should require ACOs to certify that they will adhere to compendia guidelines for the use of drugs and biologicals within six months of when such guidelines are adopted. BIO is hopeful that these requirements will help focus ACOs on the benefits of new technologies and offset the incentive ACOs may have to limit their use in order to meet the ACO's savings goals.

B. CMS should require ACOs to participate in clinical trials or alternatively be awarded "bonus" points for doing so.

CMS envisions that ACOs will become leaders in health care. BIO believes that this should be true not only for their use of innovative service delivery models, but also with regard to their diffusion of innovative medical technologies. To this end, BIO believes that ACOs should be involved in clinical trials, as they serve as the first step toward bringing new clinical innovations to patients.

CMS could do this one of two ways. First, CMS could require ACOs to participate in clinical trials as a condition of participating in the Shared Savings Program. BIO believes such a requirement would not be overly burdensome on ACOs and would be consistent with the three-part aim of the Shared Savings Program. Alternatively, CMS could award "bonus points" to ACOs that participate in clinical trials. These bonus points would be similar to the increase in the shared savings rate that CMS is proposing to provide to ACOs that include FQHCs or RHCs in the ACO.[38] Requiring or incentivizing participation in clinical trials not only will help to develop new breakthroughs in diagnostics, treatments, and cures for many of the most devastating diseases afflicting millions of Americans, but also will solidify the role of ACOs as leaders in all aspects of health care innovation.

C. Protect beneficiary access to transplanted organs.

BIO notes with concern that the lack of a quality measure or tracking of referrals to transplant coupled with the lack of risk adjustment for diagnoses occurring during the performance period creates a disincentive to provide a transplant. Increasing transplants is an objective of the Department of Health and Human Services (HHS). In fact, each year, HHS recognizes hospitals and health care providers with awards for increasing transplantation.[39] Further, it has been demonstrated in the United States Renal Data System (USRDS) data that after two years, transplants reduce costs, but costs are increased in a year-over-year measure.[40] ACOs will be primarily sensitive to short-run costs and if their expenditures are not

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[38] See id. at 19613.
[39] See HRSA's November 3, 2010 press release, available at: http://www.hrsa.gov/about/news/pressreleases/2010/101103organtransplant.html.
[40] Based on raw USRDS data available at http://www.umm.edu/news/releases/kidcost.htm, overseen by Paul W. Eggers, Program Director for Kidney and Urology Epidemiology National Institute of Diabetes and Digestive and Kidney Diseases

adjusted for new diagnoses, they may avoid transplants, when ultimately those procedures reduce costs for Medicare.

Although BIO understands the use of the CMS-HCC (Hierarchical Condition Categories) risk adjustment model, it is our understanding that there are difficulties with using the HCC model to adjust for risk associated with transplants, particularly for non-kidney transplants. Furthermore, the risk associated with transplants could pose a particular problem for ACOs, given that they will likely treat relatively small populations where a single transplant could cause a significant shift in their per-beneficiary expenditures. If the HCC model does not predict for risk associated with all types of transplants, ACOs will have a very strong incentive to avoid patients in need of transplants or to defer offering a transplant. BIO recommends that CMS remove expenses attributable to organ acquisition, transplants, and drugs provided for purposes of ensuring acceptance of the donor organ when calculating expenditure amounts in both the benchmark and performance years.

V. PROTECTING THE INTEGRITY OF THE SHARED SAVINGS PROGRAM

A. CMS must ensure that the "savings" an ACO generates reflect real quality and efficiency gains and are not a product of gaming or cost-shifting.

In these comments, we have repeatedly emphasized that the incentive to reduce costs inherent in a risk-based arrangement can have negative consequences with regard to, for example, decisions about the care beneficiaries should receive and their access to new technologies. There also is a risk that the need to show reduced costs as compared to a benchmark may lead an ACO to manipulate its expenditures in a performance year so they are not included among those used for purposes of the comparison. CMS has made clear in the Proposed Rule its desire to ensure that the savings ACOs produce and are eligible to share in are the result of its increased coordination of care, and not some other basis.[41] The agency therefore must take steps to ensure that it is not rewarding ACOs that generate "savings" only through such manipulations. As was the case with new technologies, there are a range of things that CMS can do to protect against such behaviors.

1. CMS should require ACOs to report on how savings were generated.

As discussed above, CMS is proposing to require ACOs to report certain information and make that information publicly available in order for the ACO's operation and performance to be

[41] See 76 Fed. Reg., at 19611 (discussing the need to establish a minimum savings rate that will ensure that savings are a result of "coordinating the care for an assigned beneficiary population in a way that controls the growth in Medicare expenditures for that patient population while also meeting the established quality performance standards," and not "a result of normal year-to-year variations in Medicare beneficiaries' claims expenditures in addition to the ACO's activities").

transparent.[42] BIO thinks that an important aspect of such reporting is an understanding of the basis on which an ACO's savings were generated. That is, along with the other required information, ACOs should be required to provide, with specificity, information regarding how they generated shared savings through a qualitative narrative of the steps they have taken that they expected to produce savings. Such a requirement will hold the ACOs publicly accountable and help ensure that they are not motivated to seek "savings" by engaging in gaming or other inappropriate cost-shifting. At the same time, CMS will receive the actual performance data of each ACO and will be able to perform its own quantitative analysis of where the ACO has achieved savings relative to its baseline. Public reporting of both of these statements will allow for CMS and ACOs to identify and share in best practices, while also holding ACOs accountable for producing savings through quality-driven changes.

2. CMS should proactively monitor ACOs to identify changes in coding patterns.

Requiring ACOs to report on shared savings is a necessary but not sufficient protection. As is the case with ensuring that beneficiaries have access to new technologies, CMS has a responsibility to ensure that ACOs are not implementing practices that create the appearance of savings without actually engaging in activities designed to improve the quality and efficiency of the services they deliver. Given the flexibility CMS is proposing to afford ACOs in developing the service delivery models that they believe will be most effective in meeting the requirements of the Shared Savings Program, it is imperative that CMS fully exercise its oversight authority to ensure that the plans and processes outlined in the ACOs' applications are being implemented and used to help the ACO achieve its savings.

BIO urges CMS to use the data available to it to actively monitor ACOs to identify abnormal shifts in coding or service utilization that may be indicative of an attempt by the ACO to inappropriately achieve savings. ACOs that are identified as outliers should be subject to closer scrutiny and placed under a corrective action plan (CAP).

3. CMS must ensure that clinical decisions, especially prescribing decisions, are made in best interest of the beneficiary.

One area of concern to BIO is the potential incentive that the Shared Savings Program creates to change prescribing practices in order to shift drug costs from Part B to Part D. As the Congressional Research Service (CRS) indicated in its report on the ACO Proposed Rule, because the shared savings calculation is based on Medicare Part A and B spending and does not include Part D spending, "there may be instances where there is the appearance of cost savings as a result of providers unduly relying on Part D prescription medicines over other forms of care."[43] CMS neglected to address this issue in the Proposed Rule.

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[42] Id. at 19601.
[43] David Newman, Congressional Research Service, "Accountable Care Organizations and the Medicare Shared Savings Program," at 17 (Apr. 25, 2011).

As CRS notes, this issue may present problems from both the perspective of quality patient care as well as for Medicare program expenditures. From the patients' perspective, they expect and deserve that the choice of treatment would be guided by the best likely outcome for their illness. Financial incentives that inappropriately influence the selection of treatment options is problematic, particularly when patients may incur additional out-of-pocket costs, which in turn may impact prescription drug adherence and ultimately, clinical outcomes. From the perspective of the Medicare program, it is also problematic to reward ACOs for "paper savings" achieved through cost-shifting.

This is an area in which CMS should actively monitor ACOs to ensure that patients continue to receive the most appropriate therapy. If through its monitoring activities CMS determines that there an ACO is systematically denying or prohibiting Medicare beneficiaries access to needed therapies, CMS should evaluate options to remedy the situation through notice and comment rulemaking.

B. CMS must ensure that ACOs do not engage in inappropriate drug diversion under the 340B Drug Pricing Program.

Another area in which BIO believes there is risk to the integrity of the Shared Savings Program is with regard to diversion of drugs and biologicals under the 340B Drug Pricing Program. Pharmaceutical manufacturers that want their products to be reimbursed with federal funds under Medicaid and Medicare Part B are required to participate in the 340B Program and sell their covered outpatient drugs to 340B covered entities at deeply discounted prices.

To safeguard against the potential for diversion of drugs purchased with such discounts, Congress specifically prohibited resale of drugs purchased by covered entities "to a person who is not a patient of the entity."

In 1996, the Health Resources and Services Administration (HRSA) issued final guidance regarding the definition of "patient."[44] This definition is very broad, and in 2007, HRSA issued a notice regarding proposed clarifications to the definition in response to rising concerns that "some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program."[45] That guidance never was finalized, however, and thus covered entities have continued to rely on the 1996 patient definition. In January 2011, HRSA submitted two notices to the Office of Management and Budget (OMB), to issue a new notice on the "patient" definition. OMB has completed its review of this notice, but it has not been published to date.

For years, BIO has expressed its concern about the way in which 340B covered entities have taken advantage of the patient definition, and the complete lack of enforcement, to extend discounted drug pricing to individuals and entities BIO does not believe either Congress or HRSA intended to receive it. In the absence of a new patient definition, BIO is concerned that

[44] 61 Fed. Reg. 55156 (Oct. 24, 1996).
[45] 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007).

ACOs may seek to inappropriately gain access to the discounted pricing available to patients of a 340B covered entity when 340B covered entities are included in the ACO. In particular, we are concerned that the requirement that ACOs coordinate and integrate care will lead the ACO and 340B covered entity to conclude that a patient of the ACO is a patient of the 340B covered entity, even if the patient has no other relationship with the 340B covered entity, for purposes of obtaining discounted drug pricing. The potential for such abuse undermines the integrity of the 340B Program and threatens the goals it is intended to achieve, as well as that of the Shared Savings Program.

In the Proposed Rule, CMS has indicated that it is willing to use its authority under section 1899(a)(1)(A) of the Affordable Care Act to impose program integrity criteria "to protect the Shared Savings Program from fraud and abuse and to ensure that the Shared Saving Program does not become a vehicle for, or increase the potential for, fraud and abuse in other parts of the Medicare program or in other Federal health care programs."[46] BIO urges CMS to use this authority to include specific program integrity provisions to prevent ACOs that affiliate with 340B covered entities from diverting products under the 340B Program. BIO also encourages CMS to work with HRSA to provide the additional guidance necessary to minimize the opportunity for product diversion and to ensure that the 340B covered entities that enable product diversion, including the ACOs in which they may participate, are held accountable.

VI. CONCLUSION

BIO greatly appreciates the opportunity to participate in the development of ACOs by providing these comments on the Proposed Rule. As discussed in detail above, BIO encourages CMS to make several improvements to the Shared Savings Program in the final rule. Specifically, CMS should ensure that patients have timely access to the care of specialists within an ACO. Second, as the quality measures are central to the success of the Shared Savings Program, it is critical that CMS select rigorously evaluated measures and keep them up-to-date and aligned with other reporting and incentive programs. Third, it is critical that beneficiaries remain the focus of the Shared Savings Program through various patient protection mechanisms and the adoption of patient and provider bills of rights. Fourth, continued beneficiary access to innovative new technologies is imperative and CMS should implement mechanisms to ensure beneficiary access to new and innovative therapies. Finally, BIO urges CMS to do more to protect the integrity of ACOs and the Shared Savings Program, including ensuring that prescribing decisions are made in the best interest of the beneficiary and that ACOs do not engage in inappropriate drug diversion under the 340B Drug Pricing Program.

[46] 76 Fed. Reg. 19551-52.

We look forward to working with CMS as it develops new service delivery models to ensure that Medicare beneficiaries continue to have access to innovative drug and biological therapies. Please feel free to contact Laurel Todd at (202) 962-9220 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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