Biotechnology Industry Organization

VIA ELECTRONIC SUBMISSION

March 1, 2014

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RE: Request for Information: Evolution of ACO Initiatives at CMS

Dear Dr. Conway:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments regarding the Request for Information (RFI) on the "Evolution of ACO Initiatives at CMS" released by the Center for Medicare and Medicaid Innovation (CMMI) on December 20, 2013.[1] BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we closely monitor 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 overall expenditures—a three-part aim that BIO fully supports. That said, risk-based models, particularly those involving capitated payment rates, create incentives to undersupply services to control spending, to the potential detriment of patients. BIO is particularly 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 are not included in the benchmark. Moreover, while BIO applauds CMMI for seeking public input with respect to the Pioneer ACO program, BIO is concerned that CMMI aims to expand the program after obtaining only limited savings in the first two years, particularly after nine ACOs recently left the Pioneer demonstration.

[1] Center for Medicare and Medicaid Innovation, Request for Information: Evolution of ACO Initiatives at CMS (Dec. 20, 2013), available at: http://innovation.cms.gov/Files/x/Pioneer-RFI.pdf.

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To address these and other concerns, we believe that CMMI should take steps to ensure that the Pioneer ACO demonstration incentivizes participants to reap savings through the provision of better, more coordinated care, rather than by restricting patient access to care covered under Medicare or avoiding high-risk beneficiaries. BIO's concern is not only that patients 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, including Pioneer ACOs. While the majority of our comments respond specifically to CMMI-posed questions, BIO makes additional recommendations in line with CMMI's overarching goal of improving quality, efficient patient care, including that ACOs should serve as the first step toward bringing new clinical innovations to patients by actively participating in clinical trials.

I. What are the Potential Benefits/Risks of Paying ACOs on a Capitated Basis akin to the Medicare Advantage (MA) Program? (Section II(A), Question 1)

As CMS has recognized in the context of the Medicare Shared Savings Program (MSSP), in any risk-based arrangement, providers of services and suppliers have a stronger incentive to control spending and achieve efficiencies, including to "stint on care and undersupply services."[2] This risk would only be exacerbated by moving from the double-sided risk model currently employed under the Pioneer ACO demonstration to payment on a capitated basis. Accordingly, CMMI would need to address how a fully capitated model would integrate existing cost-sharing requirements and whether a capitated model would maintain incentives put in place to provide certain types of care (e.g., preventive services) or to provide care to certain at-risk populations (e.g., influenza vaccines for the Medicare-age population). While the establishment of robust, evidence-based quality metrics can mitigate this risk, CMMI has yet to comprehensively address the concerns that the current quality outcomes metrics are flawed, as discussed in greater detail in Section X, below.

II. What Categories of Spending Should ACOs at Full Insurance Risk be Responsible For? (Section II(A), Question 2)

BIO believes that, to the extent ACOs have only partial responsibility for the care of beneficiaries, they may have incentives to shift patient care towards those areas for which they are not responsible. For instance, when the ACO is not responsible for both Part B and Part D spending, there is the potential that providers will unduly rely on prescription medications reimbursed through the non-included Medicare program, namely Medicare Part D, over other forms of care. These concerns are exacerbated by the recently proposed changes to narrow and even eliminate crucial protections under the current Medicare Part D protected class policy, which afford the most vulnerable patients more robust and timely access to the drugs they need in the settings most appropriate for them.

This "gaming of the system" can also cause a shift in the site of care that significantly impacts patients' ability to receive care in the most appropriate or convenient setting, which

[2] 76 Fed. Reg. 19,528, 19,617 (April 7, 2011).

in turn can impact adherence to treatment and short- and longer-term health outcomes.[3] Any financial incentives that inappropriately influence the selection of treatment options are problematic, not only because of the access to quality care issues they may create, but also because they may cause patients to incur additional out-of-pocket costs, which in turn can also 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. Therefore, CMS should actively monitor ACOs to ensure that patients continue to receive the most appropriate therapy from these ACOs. Such measurement should be ongoing, and the need for any changes to the program to improve patient access to the most appropriate therapies should be identified, and remedies evaluated, through notice-and-comment rulemaking. Moreover, to the extent that ACOs are at full insurance risk for additional categories of spending (e.g., Part D, Medicare/Medicaid dual-eligibles, Medicaid), the agency must ensure that ACOs are adequately reimbursed for these costs to avoid disincentivizing the use of new technologies and those treatments that may be more expensive over a short timeframe but yield significant benefits to the patient over the longer-term.

III. Are there Services that Should be Carved out of ACO Capitation? (Section II(A), Question 3)

As noted above, a risk-based program, such as the Pioneer ACO demonstration, increases the incentives to "stint on care or undersupply services." BIO is sensitive to the fact that one area in which care is stinted and services undersupplied is with regard to new technologies. This is 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. In fact, recent research illustrates that ACOs are not currently able to demonstrate the value of appropriate medication use to decrease overall costs and increase care quality, raising questions of the appropriateness of including prescription drugs within any capitation demonstration before these capabilities are improved.[4] Additionally, to the extent that ACOs are paid on a capitated rate based on a prior trend, innovative technologies specifically are highly unlikely to be adequately captured by that capitated fee, as utilization of new technologies and novel medical breakthroughs is very difficult to predict on a facility level with enough granularity to ensure fair measurement. Consequently, ACOs would effectively not be reimbursed to the extent their patients obtain these items and services.

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. To ensure that patients continue to have access to innovative medical technologies, including drugs and biologicals, BIO strongly urges CMMI to incorporate protections added by Congress to the Medicare program more broadly by creating a carve-

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[3] As recently as February 2014, the Department of Health and Human Services (HHS) Office of Inspector General identified evidence of site-of-care shifts due to financial incentives, *see* HHS OIG. 2014 (February 20). *Medicare and Beneficiares Could Realize Substantial Savings if the DRG Window Were Expanded*. OEI-05-12-00480. Washington, DC: HHS OIG, Available at: http://oig.hhs.gov/oei/reports/oei-05-12-00480.pdf.

[4] Dubois, R.W., M. Feldman, A. Lustig, G. Kotzbauer, J. Penso, S. D. Pope, and K. D. Westrich. 2014. Are ACOs Ready to be Accountable for Medication Use? *Journal of Managed Care Pharmacy* 20(1):17-21a.

out for new, innovative medical technologies from both the shared savings calculations and capitated payment rates for Pioneer ACOs. With such a carve-out, the decision to use promising new therapies will not affect the calculation of ACOs' expenditures for purposes of determining whether they generated shared savings. Moreover, ACOs would not be penalized when a new technology is approved mid-year that was not contemplated in the calculation of its capitation rate.

There are a number of ways that CMMI could implement this carve-out. One way would be to rely on the existing mechanisms for pass-through status under the hospital Outpatient Prospective Payment System (OPPS). When a drug or biological receives pass-through status, CMS necessarily has made a determination that it 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.[5] 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.[6]

By structuring the carve-out in this way, only those ACOs with expenses for new technologies and innovative 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 important advances in therapy.

In addition to important advances in therapies, BIO also encourages CMMI to consider carving-out certain existing therapies, namely those that may be particularly vulnerable within a full insurance risk model based on the small number of patients who may need it, disease severity, and the cost of providing such care. For instance, hemophilia factor products—used to treat rare bleeding disorders such as Hemophilia A, Hemophilia B, and Acquired Hemophilia—are used by a relatively small population but to significant, life-sustaining effect. Patients with severe hemophilia produce less than one percent of the normal amount of the affected clotting factor and are dependent on factor from infusions to treat or prevent bleeding episodes. Including hemophilia factor products in an ACO's capitated rate may significantly disadvantage access to these products because of the impact it could have on an ACO's shared savings calculation, especially for smaller ACOs. This, in turn, would further exacerbate the perverse incentives already in play to stint on or undersupply care, or otherwise discriminate against these patients. Therefore, to further ensure some of the most vulnerable patients have access to the most appropriate care, we encourage CMMI to consider carving-out, or otherwise providing equivalent protections for, existing therapies such as these.

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[5] SSA § 1883(t)(6)(A)(iv)(II).

[6] 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 physician office.

IV. What Key Elements of the Regulatory and Compliance Framework for MA Should be Adopted for ACOs Assuming Full Insurance Risk? (Section II(A), Question 5)

As noted above, BIO is very concerned that the transition to full insurance risk may further incentivize providers to restrict or limit patient access to the most appropriate care, or for ACOs to cherry-pick the healthiest patient populations. To mitigate these incentives, we strongly urge CMMI to incorporate into any future phase of the Pioneer ACO model—whether it includes the assumption of full insurance risk or another structure for risk-based reimbursement—several of the patient protections that have helped counteract these pressures under the MA program for decades. Specifically, we believe that the Pioneer ACO model should incorporate each of the following protections:

- **Anti-Discrimination Protections:** In light of the potential for adverse selection in the Pioneer ACO program, particularly under a capitated fee arrangement, BIO urges CMMI to incorporate the MA requirements aimed at preventing patient discrimination. For instance, CMMI should adopt the beneficiary protections outlined at 42 C.F.R. § 422.110(a), under which ACOs would be prohibited from denying, limiting, or conditioning benefits to beneficiaries on the basis of factors such as medical condition, claims experience, medical history, and genetic information. Relatedly, we also urge CMMI to consider incorporating the MSSP's tough sanctions for avoidance of at-risk beneficiaries.[7]
- **Ensure Access to Medically Necessary Care:** Because capitated payments raise the risk of ACOs restricting patient access to medically necessary care, we believe that CMMI should incorporate certain MA protections aimed at ensuring access to these services, including access to a diverse provider network, discussed in more detail below. For instance, CMMI should establish a review process under which the agency ensures that beneficiaries receiving care from Pioneer ACOs continue to have access to the basic Medicare benefits. CMMI may look to the process outlined at 42 C.F.R. §§ 422.100-101 as a model for this review.
- **Establish a Robust Appeals and Grievance Process:** To ensure that beneficiaries are not adversely affected by the ongoing demonstration, CMMI should establish a robust beneficiary appeals process available to beneficiaries whose providers are participating in Pioneer ACOs. This process, which could be modeled on the process that is provided for beneficiaries enrolled in the MA program,[8] would provide a mechanism for beneficiaries who believe 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 their care are not bound to the ACO, this grievance process will provide recourse 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. In implementing this recommendation, BIO urges CMMI to consider approaches to improve upon existing challenges with delays in the MA and traditional Medicare appeals processes. In addition, for

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7 See 42 C.F.R. § 425.316(b).

8 See Medicare Managed Care Manual, Ch. 13, §§ 10.1, 10.3.1.

patients for whom the appeals process would be inappropriate (e.g., because they are not seeking to have a certain decision reversed, but rather have more generalized complaints), CMMI should establish a grievance mechanism, such as an ACO ombudsman. This ombudsman would receive beneficiary and provider complaints and provide valuable feedback to CMMI on how the Pioneer ACO program is being operationalized and areas that the agency may need to address in future rulemakings or other guidance. Relatedly, CMMI should require ACOs to provide meaningful inclusion of patients in the ACO governance structure.

- **Prevent Interference with the Practice of Medicine:** BIO is also very concerned that efforts to obtain shared savings (and avoid shared losses) within the Pioneer ACO demonstration may cause ACOs to exercise undue influence over the practices of their participating providers (e.g., in attempts to better regulate utilization of services). Similarly, moving to a full insurance risk model may introduce financial incentives into the clinical decision-making process, including prescribing decisions, that may negatively impact patients' access to the therapies and services that are most appropriate for them individually as expressly covered by Medicare. Accordingly, we urge CMMI to prohibit ACOs from interfering in health care professionals' advice to beneficiaries (42 C.F.R. § 422.206), or from making shared savings payments to physicians as an inducement to reduce or limit medically necessary services (42 C.F.R. § 422.208(c)). We also believe that affording participating providers with a key role in the development of ACO policies and procedures will ensure that their medical decision-making is not unduly restricted, and thus urge CMMI to adopt protections akin to 42 C.F.R. § 422.202, under which ACOs would be required to create a formal mechanism to consult with providers regarding the organization's medical policy, quality improvement programs, and medical management procedures. Finally, a robust process must be in place for providers to quickly appeal the coverage decisions of the ACO on the basis of clinical appropriateness for an individual patient. CMMI should therefore consider setting minimum standards and timelines for participants' review processes and give stakeholders the opportunity to provide meaningful input into those minimum standards.
- **Prohibit Excessive Beneficiary Cost-Sharing:** It is not clear from publicly available documentation regarding the current operation of the Pioneer ACO demonstration how beneficiary cost-sharing will be calculated for services for which Pioneer ACOs are paid on a capitated basis. To the extent that ACOs are given flexibility in this regard, we urge CMMI to ensure that such cost-sharing conform to MA cost-sharing protections outlined under 42 C.F.R. §§ 422.100 and 422.105. Otherwise, we are concerned that aligned beneficiaries will end up paying more out-of-pocket than beneficiaries receiving care outside the Pioneer ACO demonstration.
- **Protect Beneficiary Confidentiality:** Given the need for data sharing within the Pioneer ACO demonstration, BIO is concerned that patients' personal information, including medical history, may not be adequately protected. Therefore, we urge CMMI to require ACOs to ensure the privacy and confidentiality of patient records (42 C.F.R. § 422.118).
- **Encourage Participation by a Wide Range of Providers:** In order to ensure that patient care is adequately coordinated by the ACOs, it is essential that the ACOs include a wide array of participating providers, including medical specialists. In a full

insurance risk model, there is a specific concern that providers may be assessed for inclusion in an ACO based on economic criteria rather than on their ability to provide vital, quality services to a patient population. Therefore, BIO urges CMMI to require ACOs to provide access to appropriate providers and services (42 C.F.R. §§ 422.112-114), to meet certain requirements with respect to provider selection and credentialing (42 C.F.R. § 422.204), and to require ACOs to include a role for specialists in leadership and management. CMMI should also require ACOs to make certain disclosures to "aligned" beneficiaries, including with respect to the number, mix, and distribution of participating providers (42 C.F.R. § 422.111).

In addition to the need for patient protections, BIO is concerned that changes in policy or the arrival of a new innovative therapy would impose costs on Pioneer ACOs not included in their capitated rates, incentivizing the ACOs to restrict patient access to this care based on financial, rather than clinical, considerations. Accordingly, we urge CMMI to adopt a policy akin to that outlined at 42 C.F.R. § 422.109, under which ACOs would not be required to assume risk for the costs associated with a mid-year National Coverage Determination (NCD) or legislative change that imposes costs not included in that year's capitated rate. We believe that this policy should also be expanded to account for newly approved technologies that are not yet included in the capitated rate.

V. What are the Advantages and Disadvantages of Different Strategies for Risk Adjustment? (Section II(A), Question 9)

As you are aware, risk adjustment serves to correct for market imbalances that occur if an insurer (or, in this case, ACO) differentially attracts pools of beneficiaries whose medical costs diverge from the market-wide average. The need for this adjustment arises from the skewed nature of health risk: the top 20 percent of the population accounts for about 80 percent of total spending, and the very highest medical costs are concentrated in the top one percent.[9] In the absence of risk adjustment, those ACOs that attract more than their share of these high-cost beneficiaries will be penalized—both in terms of their shared savings calculation and capitated rate—particularly to the extent ACOs are prohibited from avoiding high-risk beneficiaries, as we recommend in Section IV, above.

There are two basic measures to assess health risk for purposes of risk adjustment: demographic and medical. BIO strongly urges CMMI to adopt a risk-adjustment methodology that is based on medical factors, as risk adjustment based on demographic factors alone is insufficient. Indeed, a study conducted by Jonathan Weiner of the Johns Hopkins University found that the best diagnosis-based adjuster is about five times more accurate than demographic adjustment.[10] Moreover, using encounter-based diagnostic information for this purpose is generally feasible for all types of health plans. For instance, risk adjustment based on medical factors is used for all Medicare Advantage and many

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[9] Conwell LJ, Cohen JW. Characteristics of people with high medical expenses in the U.S. civilian noninstitutionalized population, 2002. Statistical Brief #73. March 2005. Agency for Healthcare Research and Quality, Rockville, MD. Web site: http://meps.ahrq.gov/mepsweb/data_files/publications/st73/stat73.pdf.

[10] This study randomly assigned 50,000 members to 25 hypothetical health plans to determine which risk-adjuster (medical v. demographic) would overpay the lowest-risk plan or underpay the highest-risk plan). See J.P. Weiner, A. Dobson, S.L. Maxwell et al., "Risk-Adjusted Medicare Capitation Rates Using Ambulatory and Inpatient Diagnoses," *Health Care Financing Review*, Spring 1996 17(3):77-99.

Medicaid patients nationwide.[11] Not to mention that collecting these data may assist ACOs in performing other necessary tasks, to include care coordination and performance on quality measures.

One strategy that CMMI may consider for this purpose is adopting the diagnosis-based risk-adjustment methodologies employed in the MA and Part D programs. For instance, CMMI could make retrospective adjustments to capitated payment rates made to ACOs based on health status, akin to the procedure used for Medicare Part D plans pursuant to 42 C.F.R. § 423.343(b).

On a related note, BIO is concerned that two strategies used to calculate shared savings under the Pioneer ACO demonstration do not adequately take into account risk. First, BIO is concerned that 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 healthcare providers with awards for increasing transplantation. Although BIO understands the use of the CMS-HCC (Hierarchical Conditional 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 therefore recommends that CMMI remove expenses attributable to organ acquisition, transplants, and drugs provided for ensuring acceptance of the donor organ when calculating expenditure amounts in both the benchmark and performance years.

Second, BIO is concerned that the outlier threshold used for this purpose is too high, requiring ACOs to potentially bear the risk of extraordinarily high-cost beneficiaries. As you are aware, as with the MSSP, for purposes of calculating shared savings under the Pioneer ACO demonstration, ACOs have the option to truncate an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile for each benchmark and subsequent performance year.[12] BIO appreciates that CMMI has taken this step to take into account outliers that would skew an evaluation of an ACO with regard to generated savings. We think it also aligns well with the goal of protecting beneficiary access to innovative new therapies. However, BIO believes that the value of the expenditure cut-off—both for protecting ACOs from the variation associated with

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[11] See, e.g., G.C. Pope, J. Kautter, R.P. Ellis et al., "Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model," *Health Care Financing Review*, Summer 2004 25(4):119-41, available at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/04Summerpg119.pdf; R. Winkelman and R. Damler, *Risk Adjustment in State Medicaid Programs* (Jan. 2008), available at: http://www.soa.org/library/newsletters/health-watch-newsletter/2008/january/hsn-2008-iss57-damler-winkelman.pdf.

[12] CMMI. 2011. *Pioneer ACO Alignment and Financial Reconciliation Methods v.7.1*. pp.12-13. Baltimore, MD, CMS, Available at: http://innovation.cms.gov/Files/x/Pioneer-ACO-Model-Benchmark-Methodology-document.pdf.

catastrophically large claims and for protecting beneficiaries from the incentives an ACO may have under the Pioneer ACO program to avoid using new medical therapies—would be stronger if the threshold were lower. Therefore, BIO recommends that CMS lower the expenditures threshold cut-off to the 95th (rather than 99th) percentile for all ACOs.

VI. What are Potential Program Integrity Issues that ACOs Transitioning to Full Insurance Risk May Encounter and what are Appropriate Preventive Safeguards? (Section II(A), Question 11)

The principal area in which BIO believes that the transition to full insurance risk under the Pioneer ACO demonstration poses a program integrity risk relates to the diversion of drugs and biologicals under the 340B Drug Pricing Program. As you are likely aware, pharmaceutical manufacturers that want their products to be reimbursed with federal funds under Medicaid 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 the resale of drugs purchased by these covered entities "to a person who is not a patient of the entity."[13]

In 1996, the Health Resources and Services Administration (HRSA)—the agency charged with administering the 340B Program—issued final guidance regarding the definition of "patient" for this purpose.[14] 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 under the 340B Program."[15] That guidance was never finalized, and in fact it was later rescinded, effectively compelling covered entities to return to relying 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 the lack of a robust patient definition has led to significant enforcement challenges and the extension of discounted drug pricing to individuals and entities that BIO does not believe either Congress or HRSA intended to receive it. In the absence of a new patient definition, BIO is concerned that ACOs may seek to inappropriately gain access to the discounted drug 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 does not otherwise meet the definition of a 340B patient, 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 Pioneer ACO demonstration.

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13 42 U.S.C. § 256b(a)(5)(B).
14 61 Fed. Reg. 55,156 (Oct. 24, 1996).
15 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007).

To address this issue, BIO urges CMMI to use its authority under section 1899(a)(1)(A) of the Social Security Act to impose program integrity criteria to protect the Pioneer ACO program from fraud and abuse related to the 340B Program. Specifically, CMMI should prevent ACOs that affiliate with 340B covered entities from diverting products under the 340B Program. This aligns with 2012 HRSA guidance that states that "inclusion of a covered entity within an ACO does not make the entire ACO eligible for receiving discounted drugs under the 340B Program and does not permit ACO associated entities, which do not satisfy the eligibility requirements of section 340B(a)(4), to access 340B Program discounted drugs."[16] BIO also encourages CMMI 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 participate, are held accountable. This is especially important given the concerns recently raised by the HHS Office of Inspector General that: a lack of clarity on HRSA's definition of a 340B-eligbile "patient" has led to the inconsistent assessment of eligibility at the contract pharmacy level; and that most covered entities do not employ oversight activities in compliance with HRSA's recommendations.[17] With the rise in the number of covered entities that employ contract pharmacies, and the sheer number of contract pharmacies emerging, coordination between CMMI and HRSA will be crucial to ensure the integrity of the interaction between ACOs and the 340B program.

On a related note, BIO urges CMMI to ensure that ACOs are not unjustly enriched for products purchased through the 340B program. Specifically, we believe that CMMI should adjust the capitated rate paid to ACOs that include 340B "covered entities" downward to account for the discounted drugs obtained under the 340B program. Otherwise, these entities would obtain an unfair advantage over ACOs that do not include such covered entities, potentially causing perverse incentives with respect to the 340B program and participation in the Pioneer ACO demonstration.

VII. Integration of Medicare Part D (Section II(B))

As we have previously noted, BIO believes that the shared savings calculation should incentivize ACOs to generate "savings" that reflect real quality and efficiency gains and are not the result of gaming or cost-shifting. If CMMI includes Part D expenditures in the calculation to achieve this aim, we urge that all Part D beneficiary protections similarly convey, including, but not limited to:

- **Protecting patients' access to appropriate therapies through minimum formulary requirements**: CMMI should include the statutory formulary review and transparency requirements included in the Part D regulations at 42 C.F.R. § 423.124. Pioneer ACOs should adhere to all requirements associated with pharmacy and therapeutic committee review, composition, and decision-making. While Pioneer ACOs should also be required to meet the Part D minimum inclusion standard for drugs and biologicals, the number and type of covered therapies should not be

[16] HRSA. 2012 (May 23). 340B Drug Pricing Program Notice Release No. 2012-2.
[17] HHS Office of Inspector General (OIG). 2014. *Contract Pharmacy Agreements in the 340B Program*. Washington, DC: HHS OIG, Available at: https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp.

allowed to be revised downward from those currently included when meeting this minimum standard. CMMI should also review the beneficiary transition process to ensure patients will be able to access appropriate therapies during and after any inclusion of Part D expenditures in the shared savings and benchmark calculations.

- **Ensuring out-of-network-access to appropriate therapies**: Though beneficiaries are able to opt-out of receiving care from a Pioneer ACO entirely, protections must be in place for those who want to remain a part of this primary care collective but may need to obtain some portion of their therapies outside of it (e.g., based on where they live or work). To ensure these patients are able to retain this option, CMMI should require Pioneer ACOs adhere to the same standards as Part D sponsors in providing out-of-network pharmacy access to covered drugs without excessive cost-sharing (42 CFR § 423.124).
- **Patients must be able to access covered drugs conveniently**: To ensure equal accessibility of Part D-covered drugs by Pioneer ACO patients, CMMI should require Pioneer ACOs to meet the same requirements as Part D sponsors in securing sufficiently broad participation in their pharmacy networks (excluding mail-order pharmacies) to ensure convenient access to covered drugs.[18]

BIO believes that including these beneficiary protections is crucial to any effort to incorporate Part D expenditures into the sharing savings calculations of Pioneer ACOs.

In considering the integration of Part D expenditures in the ACO model, CMMI must address issues around cost-sharing and utilization-management techniques already employed by Part D prescription drug plans. Under a full insurance risk model—without adequate out-of-pocket cost restrictions and cost-sharing limits built into benefit design requirements—ACOs may be incentivized to shift more and more costs to patients through higher copays and coinsurance to drive down their recorded contribution to the entities' spend. This would directly and significantly increase the burden on patients, negatively impacting patient access to the treatments most appropriate for them and patient adherence to those treatments, especially with respect to those treatments that require a longer course. ACOs may also be incentivized to increase their use of utilization-management techniques, like fail-first protocols and step therapy, to deter patients from higher-cost therapies regardless of their clinical benefits. Thus, if CMMI decides to pursue the integration of Part D expenditures in the ACO model, it must simultaneously include all current out-of-pocket cost limits, require robust exceptions and appeals processes, and actively monitor for increased use of discriminatory utilization management practices. These protections are necessary to ensure that an institution's financial incentives are not impacting patients' timely access to the therapies most appropriate for them.

Finally, CMMI should not alter the current market-based process by which the Part D program operates, as doing so risks perverting the incentives in the Part D program that have made it successful to-date in providing seniors with affordable prescription drug plans. Any effort by CMMI to incorporate Part D into the Pioneer ACOs' demonstration project must therefore protect the robust private competition that has kept the Part D program working well to generate lower costs for seniors, while providing broader choice for enrollees. The

[18] Medicare Prescription Drug Benefit Manual (MPDBM), Ch. 5 v.09.20.11, 50.

success of this market-oriented program is evidenced by the stability of the average beneficiary premium (which has remained at approximately $31 for the last four years) [19] and overwhelming support—as high as 90 percent—by seniors.[20] Accordingly, we strongly urge CMMI to continue to rely on the current Part D bidding process, instead of creating a unified expenditure target, as it represents a successful market-oriented approach to ensuring timely patient access to innovative therapies.

VIII. Integration of Medicaid (Section II(C))

As noted above, BIO is concerned about CMMI expanding the scope of the Pioneer ACO program to include additional ACOs, given that the program has not uniformly shown cost savings and that many ACOs recently left the program. This same concern applies to the inclusion of additional covered lives, particularly Medicaid beneficiaries.

The Medicaid program is quite complicated and Medicaid beneficiaries, including dual-eligibles, tend to be sicker and more vulnerable than individuals covered by Medicare or private insurance. With this in mind, CMMI is also operating duals demonstrations in a handful of states, through which states are experimenting with ways to better coordinate care for this population. CMMI and the states have not yet demonstrated an ability to launch these programs successfully, so further incorporating these populations seems premature. Rather, CMMI should wait to obtain results from the duals demonstrations before incorporating duals into the Pioneer ACO program.

If CMMI nonetheless moves forward with this suggestion, the agency should take care to limit the participation of Medicaid beneficiaries in the demonstration to a small sub-population. Otherwise, CMMI runs the risk that, between the duals and Pioneer ACO demonstrations, so many dual-eligibles will be involved in some type of demonstration initiative, such that there will essentially be no "control" population against which to compare the results of these programs. We would also urge CMMI to take care to address the myriad of administrative issues associated with incorporating Medicaid beneficiaries into the Pioneer ACO demonstration, including ensuring that Medicaid drug rebates are not collected for non-Medicaid utilization within the ACOs.

IX. Other Approaches for Increasing Accountability (Section II(D))

CMMI identifies the potential to explore a "provider-led community ACO" model that would hold an ACO accountable for total Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) expenditures and quality outcomes for all Medicare, Medicaid, and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. BIO recommends that, in the development of such a model, CMMI closely coordinate with the House Committee on Ways and Means and Senate Committee on Finance, which identified the same model as a potential alternative to current policy in its

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[19] Department of Health and Human Services (HHS). 2013 (July 30). *Medicare drug premiums remain stable four years in a row*. Washington, DC: HHS, Available at: http://www.hhs.gov/news/press/2013pres/07/20130730c.html.

[20] Freeman, M. 2012. Survey: U.S. Seniors Overwhelmingly Satisfied with Medicare Part D Coverage. Medicare Today, Available at: http://www.krcresearch.com/pdfs/PART-D-R.pdf.

October 2013 Discussion Draft on SGR Repeal and Medicare Physician Payment Reform. We reiterate here the themes expressed in our comments in response to the high-level framework put forward by the Committees to CMMI: (1) any such model must improve patient access to high-quality care and require robust assessment and improvement efforts on a continuous basis; (2) the outcomes of current demonstration projects should be thoroughly evaluated before new models are attempted; (3) there must be in place mechanisms to support adoption of, and patient access to, newer tests and treatments that are recognized by providers and patients as important and promising advances; and (4) patients must retain the flexibility to choose providers and make treatment decisions that are most appropriate for them individually.

X. Multi-Payer ACOs (Section II(E)): Harmonizing Quality Measures and Interactions with Private ACOs

A. Harmonizing Quality Measures

As we noted in the first section of this comment letter, the establishment of robust, evidence-based quality metrics can mitigate the inherent disincentives to provide appropriate care caused by a risk-sharing reimbursement system. However, BIO believes that the quality metrics employed in the current Pioneer ACO demonstration project do not yet meet this standard.

For example, we are very concerned that CMMI has yet to comprehensively address the concerns that current quality outcomes metrics are flawed, voiced by then-Pioneer ACO participants in a February 25, 2013 letter to CMMI.[21] This letter expresses that there remains a need for "metric standards [that] support a level playing field", are precise, and shoot "for a uniform benchmark" that is realistic and fair; rely only on metrics that have a robust evidence-base for specific subpopulations (e.g., segregated by demographics); and that aggregation methodologies for composite metrics are logical and "carefully constructed". BIO supports these requests but remains unsure how they have been addressed in the time since the letter was sent. Accordingly, before expanding the current Pioneer ACO demonstration or establishing demonstrations of new ACO models, CMMI should meet the requests of current participants and release additional information on the performance and assessment of current metrics along with the input of current participants.

Because quality performance determines an ACO's eligibility for shared savings and the amount of shared savings to which it may be entitled, BIO also believes that it is especially important that the measures against which ACOs are measured are endorsed by a national organization, such as the National Quality Forum (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. In addition to the NQF, these include 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).

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[21] Letter from Pioneer ACOs to Rick Gilfillan, Hoangmai Pham. 2013 (February 25). Available at: http://www.washingtonpost.com/blogs/wonkblog/files/2013/03/2013-Quality-Benchmarks.pdf.

Furthermore, to ensure that Pioneer ACOs are not required to adhere to outdated standards, we urge CMMI 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. CMMI may also consider creating an exception process for providers who follow new guidelines or measures to avoiding hindering patient care when quality measures lag behind changes in treatment.

Once robust quality measures are defined, and a process for updating them has been put in place, BIO generally supports CMMI's aim to align these measures across initiatives and demonstrations—such as the Physician Quality Reporting System, Electronic Health Records Incentive Program, Hospital Inpatient Quality Reporting System, the Value-Based Payment Modifier, Medicaid, and even private sector initiatives—to decrease redundancy as well as the measurement and reporting burden on providers. In doing so, however, CMMI must take into account whether and how the current measures are able to sufficiently capture the benefits of appropriate use of drugs and biologicals with different populations. CMMI also should take into consideration that the impact of certain healthcare services may not be fully apparent even over a period of six months to a year. Accordingly, BIO recommends that the quality and cost of health care given by Medicare providers should be studied over a period of time sufficient to account for the full effect of longer-term treatments and therapies. Considering the longer-term impact of innovative drugs and biologicals, for example, is crucial to sustaining improvements in quality of care and decreasing overall costs.

Finally, BIO recommends that, to decrease the redundancy and burden of reporting multiple sets of measures, CMMI undertake more general efforts to consider what can be learned from the challenges and lessons obtained from different private ACO models, especially from the perspectives of providers and patients participating in those models. Additionally, BIO cautions that, while coordination is encouraged between all payers to minimize duplicative and burdensome requirements, a one-size-fits-all approach is not the answer to appropriately provide for the needs of such diverse provider and patient communities as those served by private insurance, Medicaid, and Medicare. To better ensure that robust quality measurement is leading to improved patient care and patient access to necessary and innovative therapies, CMMI should therefore engage with patients, providers, and other stakeholders through a formal rulemaking process to ensure included measures are scientifically and clinically relevant.

B. Improving the Regulatory Environment for Innovative ACO Models

BIO urges CMMI to take steps to give manufacturers and Pioneer ACOs greater flexibility to allow for innovative contracting models that better support integrated care. Such flexibility is also necessary to allow better harmonization of contract arrangements across federal integrated care models, which may currently present a barrier to participation.

From the point of view of manufacturers, certain contracting arrangements may not be pursued due to the financial risk and/or penalties they may generate, including in the context of operating these arrangements in compliance with existing federal price reporting requirements. For example, adding to the inherent uncertainty of entering into risk-sharing

arrangements in general, it is an open question how such arrangements between manufacturers and ACOs, or the component entities of ACOs, should be factored into the various price reporting requirements with which manufacturers must comply (e.g., Medicare Average Sales Price, Medicaid Best Price). To improve the regulatory environment for these innovative arrangements, BIO therefore recommends that CMMI engage with stakeholders to identify a process that allows manufacturers to exempt some or all of these arrangements from their price reporting obligations.

In the same vein, to improve the consistency of legal requirements across integrated care arrangements, we ask CMMI, in collaboration with the HHS Office of Inspector General (OIG), to use the authority under section 3021 of the ACA to issue waivers of the federal anti-kickback statute that cover participants in the Pioneer ACO demonstration, similar to the waivers that CMS and OIG issued for participants in the MSSP.[22] We also strongly urge CMMI to work with OIG and other stakeholders to explore the flexibility of extending such waivers to manufacturers that contract with ACOs and ACO provider/suppliers in the context of this demonstration on a case-by-case basis.[23]

XI. CMMI Should Require ACOs to Participate in Clinical Trials

While much of the RFI asks specific questions about the next phase of ACO models, it is clear that CMMI envisions that ACOs will become leaders in health care over the longer-term through improving on the current models to increase quality care and decrease overall costs. BIO believes that a third tenet of this goal should be improving access to care, which was one of the primary goals of CMMI's authorizing legislation, the ACA. This should be true not only for their use of innovative service delivery models, but also with regard to their diffusion of innovative 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.

CMMI could do this in one of two ways. First, CMMI could require ACOs to participate in clinical trials as a condition of participating in the Pioneer ACO program. BIO believes that such a requirement would not be overly burdensome on ACOs—particularly the sophisticated ACOs participating in the Pioneer demonstration—and would be consistent with the "three part aim." Alternatively, CMMI 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 CMMI is proposing to provide to ACOs that include Federally Qualified Health Centers or Rural Health Clinics in the ACO. 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 affecting millions of

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[22] ACA § 3021 (codified as SSA § 1115A(d)(1)) (permitting CMMI to waive provisions of title XI of the Social Security Act). See also 76 Fed. Reg. 67,992, 68,007 (November 2, 2011) ("[s]everal commenters inquired about the application of these waivers to ACO demonstration programs sponsored by the Innovation Center, including application to the Pioneer ACOs. The waivers in this IFC are promulgated under section 1899(f) of the Act and, as set forth in the statute, are limited to the Shared Savings Program. Section 3021 of the Affordable Care Act includes a similar waiver authority that may be exercised for Innovation Center demonstration programs, including the Pioneer ACOs. We will address the exercise of that waiver authority in guidance relevant to those programs. As noted previously in this IFC, the waivers in this IFC will apply to ACOs participating in the Advance Payment Initiative because those ACOs also participate in the Shared Savings Program.").

[23] 76 Fed. Reg. at 68,001.

Americans, but also will solidify the role of ACOs as leaders in all aspects of health care innovation.

XII. CMMI Must Ensure that Each ACO's "Savings" Reflect Real Quality and Efficiency Gains

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. CMMI must therefore take steps to ensure that it is not rewarding ACOs that generate "savings" only through such manipulations. CMMI has several options in this regard:

- **CMMI Should Require ACOs to Report on How Savings Were Generated:** As you are aware, Pioneer ACOs must report certain information to CMMI as part of the demonstration program. 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, CMMI 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 CMMI and the ACOs to identify and share in best practices—one of the aims of the Pioneer ACO demonstration—while also holding ACOs accountable for producing savings through quality-driven changes.
- **CMMI 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, CMMI 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 ACOs have in developing their service delivery models, it is imperative that CMMI 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 CMMI 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.

XIII. Conclusion

BIO appreciates the opportunity to comment on the RFI for new ACO models. We look forward to continuing to work with CMMI to address these critical issues in the future. Please feel free to contact me at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy