



January 29, 2016

**BY ELECTRONIC DELIVERY**

Senator Johnny Isakson  
Senate Committee on Finance  
131 Russell Senate Office Building  
Washington, D.C. 20510

Senator Mark Warner  
Senate Committee on Finance  
475 Russell Senate Office Building  
Washington, D.C. 20510

**RE: U.S. Senate Committee on Finance: Bipartisan Chronic Care Working Group Policy Options Document**

Dear Senators Isakson and Warner:

The Biotechnology Innovation Organization (BIO) is pleased to submit comments in response to the U.S. Senate Committee on Finance's (the "Committee's") Bipartisan Chronic Care Working Group (the "Working Group's") Policy Options Document (the "Policy Options Document") on ways to improve outcomes for Medicare patients with chronic conditions, released on December 18, 2015.<sup>1</sup>

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO appreciates the Committee's focus on chronic conditions as well as the broadly inclusive process in which the Working Group has engaged stakeholders on this issue over the past year. We also note the timeliness of this effort: chronic diseases have a significant impact on the Medicare population as more than two-thirds of Medicare beneficiaries suffer from least two or more chronic conditions.<sup>2</sup> In addition to diseases commonly identified as "chronic,"—like those mentioned in the Working Group letter that accompanied the RFI (i.e., heart disease, diabetes, cancer)—central nervous system diseases—such as Alzheimer's Disease, Parkinson's Disease, and multiple sclerosis—and rare diseases also can require chronic care, and can have a significant impact on this population and on the broader

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<sup>1</sup> U.S. Senate Committee on Finance. 2015 (December). Bipartisan Chronic Care Working Group Policy Options Document, available at: <http://www.aha.org/content/15/chroniccaregroup.pdf>.

<sup>2</sup> Centers for Medicare and Medicaid Services (CMS). 2012. *Chronic Conditions Among Medicare Beneficiaries; Chartbook: 2012 Edition*, p. 6, available at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf>.

healthcare ecosystem.<sup>3</sup> Given the impact of these diseases, BIO shares the Working Group's goal of identifying, developing, and implementing mechanisms to improve the efficiency and effectiveness of care for patients suffering from a myriad of chronic conditions.

Innovative drugs and biologicals are an important component of treatment for many Medicare beneficiaries suffering from chronic conditions. These therapies can improve patient health outcomes and decrease overall Medicare expenditures, as they help to prevent unnecessary hospitalizations, surgical interventions, and physician office visits.<sup>4</sup> Thus, the role of innovative therapies in any mechanism to improve care for this population will be critical.

BIO generally supports the provisions included in the Policy Options Document, and we applaud the Working Group's focus on ensuring that policies considered for inclusion in this initiative improve and expand on existing patient access to clinically appropriate interventions, including prescription drugs. As these efforts progress, we urge the Working Group to continue to consider policies that expand patient access to innovative therapies, including, but not limited to, those that ensure that:

- Cost-sharing requirements and utilization management restrictions do not delay or effectively deny access to clinically appropriate therapies, especially those that are new-to-market;
- Alternative payment models, including Accountable Care Organizations (ACOs), promote individualized patient care and allow patients to obtain items and services from providers with the appropriate expertise and training;
- Quality measures used to assess care provided to chronic disease patients are appropriate for the disease, meaningful to patients, and able to capture the comprehensive benefits and side-effects of a treatment option; and
- Patients have all of the relevant information necessary to make decisions at the point of care and prior to plan enrollment.

While we comment on these issues in our response to the Policy Options Document, we also refer the Working Group to BIO's comments in response to their Request for Information, released in May 2015, for more details about each of these issues (included as an Appendix).

Throughout the balance of this letter, BIO specifically identifies support for several policy options, but also proposes refinements to these options to strengthen their ability to help achieve the Working Group's primary goal: improved care for Medicare patients with chronic disease. For ease of reference, we address the policy options in the same order in which they are considered in the Policy Options Document.

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<sup>3</sup> For example, in 2015, Alzheimer's Disease is estimated to impact 5.1 million individuals over the age of 65, and the estimated costs associated with the disease and similar dementias are \$226 billion (Alzheimer's Association. *2015 Alzheimer's Disease Facts and Figures*, available at: <http://www.alz.org/facts/overview.asp>).

<sup>4</sup> The Congressional Budget Office (CBO) has recognized that increases in the number of prescriptions filled by beneficiaries causes Medicare's spending on medical services to fall overall, see CBO. 2012. *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services*, available at: <http://www.cbo.gov/sites/default/files/43741-MedicalOffsets-11-29-12.pdf>.

**I. Expanding the Independence at Home (IAH) Model of Care: The Working Group should direct the Centers for Medicare and Medicaid Services (CMS) to incorporate an immunization measure in the quality benchmarks included in this IAH model.**

Preliminary data suggest that the IAH model may be making progress toward achieving its goal of providing effective comprehensive care services in the home to improve care for Medicare beneficiaries with chronic conditions. However, more information is necessary to determine whether CMS should consider expanding the program nationally. For example, only nine of the 17 participating practices received a practice incentive payment in the first demonstration year based on their ability to meet established cost and quality benchmarks. Given these data, additional information is necessary to understand the scalability of the program, including, but not limited to, why the other eight practices were not able to meet or exceed their benchmarks as well as a better understanding of individual provider and patient experiences participating in the model.

While additional data are necessary to determine whether the IAH model should be expanded to include additional practices, BIO encourages the Working Group to direct CMMI to expand the scope of the current model to include tracking immunization services as part of the quality measures benchmark. Existing participating IAH practices should be required to collect information about the immunization status of their patients, and, in turn, provide any appropriate vaccines to patients based on the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP). Patients with chronic conditions may be at a higher risk of negative health consequences from contracting a vaccine-preventable disease, including the potential for more frequent and longer duration hospitalizations. Thus, ensuring that patients with complex chronic conditions are up-to-date on recommended vaccines is important to ensuring their overall health and wellbeing. Collecting these data can also inform decisions with regard to whether and how CMS can incorporate immunization measures in other demonstration programs.

**II. Addressing the Need for Behavioral Health among Chronically Ill Beneficiaries: The Working Group should ensure that behavioral health disorders are always defined to include both mental illness and substance abuse disorders, and that beneficiaries suffering from severe mental illnesses are targeted specifically.**

BIO supports the policy options identified with regard to improving the integration of care for individuals with a chronic disease combined with a behavioral health disorder.<sup>5</sup> In fact, we appreciate that the Working Group has defined behavioral health disorders to include both mental illnesses and substance abuse disorders, as both types of disorders can hinder the successful management of other chronic diseases. To reflect the importance of treating these conditions appropriately, we ask the Working Group to clearly state that behavioral health disorders always include both mental illness and substance abuse disorders each time a policy option addresses this population (e.g., in the *Improving Care Management Services for Individuals with Multiple Chronic Conditions* section of the Policy Options Document).

BIO also asks the Working Group to focus, in particular, on beneficiaries with severe (or serious) mental illness (SMI). SMI is defined, among other diagnostic criteria, as "resulting in serious functional impairment, which substantially interferes with or limits one

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<sup>5</sup> Policy Options Document at 12.

or more major life activities,” and includes conditions like schizophrenia, major depression, and bipolar disorder.<sup>6</sup> While the Working Group’s proposals related to behavioral health should be inclusive of beneficiaries with any mental illness, specifically targeting those with severe mental illness may improve the impact of these initiatives because this subpopulation tends to be more seriously affected. For example, in 2010, 53 percent of seniors with severe mental illness (SMI) had three or more chronic conditions, compared to 28 percent of seniors without SMI.<sup>7</sup> In turn, those with a greater number of chronic diseases may be at a higher risk of suffering from poor short- and longer-term health outcomes and have higher overall health care expenditures, and may be in the greatest need of coordinated, integrated care. Thus, as the Working Group finalizes the Policy Options document, we ask that the SMI beneficiary population be identified specifically as a target of behavioral health initiatives.

III. **Adapting Benefits to Meet the Needs of Chronically Ill Medicare Advantage (MA) Enrollees: The Working Group should ensure that adapting benefits does not result in delaying or effectively denying patient access to the most appropriate therapy for them.**

The Working Group is considering allowing MA plans the flexibility to establish a benefit structure that varies based on the chronic conditions of individual enrollees.<sup>8</sup> The purpose of this flexibility would be to allow a MA plan to provide tailored benefits that would reasonably be expected to improve the care and/or prevent the progression of the chronic conditions affecting MA enrollees. BIO strongly supports the four dimensions of flexibility that the Working Group identifies, since each utilizes the flexibility in benefit design to fulfill the underlying goal of expanding and improving patient access to appropriate healthcare interventions, including innovative therapies. As the Working Group continues to build on the Policy Options Document, BIO makes the following recommendations to ensure this flexibility is implemented in a manner that meets this underlying goal.

First, BIO recommends that the Working Group retain the requirement included in the Policy Options Document such that MA plans can only apply this flexibility to *reduce* cost-sharing requirements for items and services that treat the patient’s chronic condition or mitigate and/or prevent the progression of the disease. The evidence base linking higher cost sharing with decreased adherence to therapy is robust, substantiating the potential for reductions in cost sharing for clinically appropriate items and services to improve patient access and adherence to them.<sup>9</sup> BIO also urges the Working Group to ensure that this flexibility to reduce cost sharing is applied to all therapies that may be clinically appropriate for an individual MA patient. Treatment decisions about which therapy, or combination of therapies, a patient may benefit from can be highly individualized, often based on the patient’s characteristics, including his/her clinical presentation, genetic considerations, and his/her treatment preferences. Thus, to maximize the impact of this policy option, this flexibility should be applied broadly across all therapies approved to treat—or with a demonstrated evidence-base for treating (e.g., in nationally-recognized

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<sup>6</sup> National Institute of Mental Health, National Institutes of Health. *Serious Mental Illness (SMI) Among U.S. Adults*, available at: <http://www.nimh.nih.gov/health/statistics/prevalence/serious-mental-illness-smi-among-us-adults.shtml>.

<sup>7</sup> The Scan Foundation. 2013 (February). *DateBrief: Prevalence of Chronic Conditions Among Seniors with Severe Mental Illness*, available at: [http://www.thescanfoundation.org/sites/default/files/1pqdatabrief\\_no35\\_prevalence\\_of\\_chronic\\_conditions\\_among\\_seniors\\_with\\_severe\\_mental\\_illness.pdf](http://www.thescanfoundation.org/sites/default/files/1pqdatabrief_no35_prevalence_of_chronic_conditions_among_seniors_with_severe_mental_illness.pdf).

<sup>8</sup> Policy Options Document at 13-14.

<sup>9</sup> See Eaddy, M. T., C. L. Cook, K. O’Day, S. P. Burch, and C. R. Cantrell. 2012. How patient cost-sharing trends affect adherence and outcomes: a literature review. *Pharmacy & Therapeutics* 37(1):45-55.

guidelines/compendia)—a specific chronic disease. Employing such a protection will help to ensure that patients, in conjunction with their providers, are able to make the most appropriate treatment decision for them individually.

Second, BIO asks the Working Group to clarify that interventions that mitigate, but do not necessarily prevent, disease progression are eligible for inclusion within this policy option. This is important because, in many cases, the underlying clinical and/or medical science has not yet evolved such that prevention of disease progression is possible. Nevertheless, treatments may be available and clinically appropriate to slow the progression of the disease, an outcome which can improve patients' short- and longer-term health outcomes and help decrease total expenditures over time (e.g., due to fewer hospitalizations, surgical interventions, provider office visits).

Third, BIO recommends that the Working Group direct CMS to ensure that flexibility in MA benefit structures includes aligning provider and patient incentives to improve access to immunization services. This focus can help to ensure that patients with chronic conditions are able to obtain ACIP-recommended vaccines in a timely manner and in a care setting that is convenient for the patient, without facing onerous cost-sharing requirements. Improved vaccination rates in this population, in turn, can help reduce the prevalence of vaccine-preventable diseases among beneficiaries who are already at higher risk for poor short- and longer-term health outcomes and higher overall health expenditures.

Fourth, BIO recommends a phased-in approach to changes to MA plan requirements to allow all of the stakeholders involved—including plans, the CMS, providers, and patients—an opportunity to become accustomed to how this increased flexibility can be applied. Moreover, we would suggest that only MA plans with a 5-star rating be allowed to exercise this flexibility in the initial phase of implementation, and that data be collected on exactly what changes are made to the benefit structure and the implications for patient health outcomes. Robust tracking of the impact of this initiative through multiple mechanisms—including the review of claims data and analyses of provider and patient surveys—will be critical to consider whether and how to expand the dimensions of flexibility envisioned by the Working Group. These data analyses will also be critical to ensure that this flexibility is applied to meet the goal of improving and expanding patient access while preserving individual patient/provider clinical decision making.

IV. **Policy Options Related to Telehealth Services: The Working Group should ensure patients continue to have access to in-person services and clarify the roles of the originating and telehealth sites of care.**

Throughout the Policy Options Document, the Working Group solicits input on policy options involving telehealth, including: (1) permitting MA plans to include certain telehealth services in its annual bid amount; and (2) providing Accountable Care Organizations (ACOs) with the ability to expand the use of telehealth. In considering the potential for increased access to telehealth services that these two policies taken together propose, BIO notes our strong support for the Working Group's assertion that "the use of [telehealth] technologies would not be used as a substitute to network adequacy requirements."<sup>10</sup> This addresses our primary concern that, in expanding access to telehealth services, these services are not offered instead of, but rather to augment, in-person services where they are available. We urge the Working Group to retain this provision as this policy option is developed to ensure that patients retain access to in-person care.

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<sup>10</sup> Policy Options Document at 16.

Additionally, in considering expanding the use of telehealth services available to patients enrolled in an ACO, BIO asks the Working Group to ensure that there are processes and policies in place that clearly define the roles of the originating versus the telehealth provider(s) in a patient's care. For example, the Working Group should clarify that the originating site of care is expected to retain meaningful responsibility for a patient's care in instances in which telehealth services are utilized. Establishing policies that codify the responsibilities of each site of care are important both for care coordination purposes, as well as for the purposes of assigning the beneficiary's costs to a particular ACO appropriately. Thus, the Working Group should firmly establish the roles of the originating and telehealth sites of care in developing this proposal further.

**V. Ensure Accurate Payment for Chronically Ill Individuals: The Working Group should further modify the existing risk adjustment methodology to improve its ability to take into account the demographic and health history of patients who actually enroll in individual plans.**

BIO applauds the Working Group's focus on improving the risk-adjustment methodology such that it more accurately captures and accounts for the underlying differences in plans' patient populations.<sup>11</sup> We agree that robust risk adjustment is crucial to combatting the existing perverse incentives to cover patients who are likely to require complex, chronic, and potentially costly care. In the Policy Options Document, the Working Group proposes modifications to the CMS-Hierarchical Condition Category (HCC) methodology so that it would consider: (1) any changes in predicted costs associated with the total number of conditions of an individual beneficiary, including any cumulative impact of a large number of conditions; (2) any changes in predicted costs associated with the interaction between behavioral/mental health conditions with physical health conditions; (3) the differences in costs associated with beneficiaries who are dually eligible for both Medicare and Medicaid through different eligibility pathways; and (4) more than one year of data to establish a beneficiary's risk score. BIO strongly supports the modification of the CMS-HCC in this way, and we also ask the Working Group to consider additional modifications to the methodology to address the following concerns:

1. The HHS-HCC system explicitly gives zero weight to many acute conditions. While these conditions are not always "predictive" of future health spending, they are nonetheless likely to result in a need for potentially expensive services—both in the year they occur, and potentially in subsequent years.
2. The HHS-HCC is a prospective risk-adjustment model; therefore, health problems in the current year are ignored. Consequently, risk scores calculated with the HHS-HCC tend to over- or under-predict scores in the payment year versus the base year used to calculate risk scores.
3. On a related note, the HHS-HCC relies on data from only one year, which limits the ability of the model to take into account prior health conditions that may be predictive of future health costs. For instance, an initial stroke can increase the cumulative risk of recurrence even ten years after it occurs.<sup>12</sup>

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<sup>11</sup> Policy Options Document at 19.

<sup>12</sup> A 2011 meta-analysis of the risk of stroke recurrence found that the cumulative risk of recurrence at five years after initial stroke was 26.4 percent and was 39.2 percent at ten years after initial stroke. See Mohan, K. M., C. D. A. Wolfe, A. G. Rudd, P. U. Heuschmann, P. L. Kolominsky-Rabas, and A. P. Grieve. 2011. Risk and Cumulative Risk of Stroke Recurrence: A Systematic Review and Meta-Analysis. *Stroke* 42:1489-1494.

4. The HHS-HCC relies on historical claims data, and thus inherits the limitations of diagnosis codes recorded on medical claims (e.g., inaccurate or missing coding information). For example, diagnosis codes do not always fully distinguish differences in patient conditions that can significantly influence the nature of services that patients should receive (e.g., stage of cancer). Moreover, claims forms only allow for a limited number of diagnosis codes to be recorded and providers may not report diagnosis codes for conditions that are currently well-controlled (but that could affect future healthcare costs).
5. There may not be standardized definitions of metrics within a given HHS-HCC category, which can impact a practice's risk score. For example, morbid obesity is known to be a predictor of healthcare spending, such that HHS included it in the 2014 HHS-HCC update.<sup>13</sup> However, while the ICD-10 Code Manual defines "morbid obesity" for adults to be a BMI  $\geq$  40, under the Medicare program, HHS covers bariatric surgery for morbid obesity, defined as a BMI of  $\geq$  35 with comorbidity.<sup>14</sup>
6. While HHS-HCC risk scores may be more accurate in predicting risk over large populations (e.g., the 1.4 million enrollees, on average, enrolled in each of the top seven national Medicare Advantage issuers), such risk scores are less likely to average out when applied to smaller patient populations (e.g., of QHPs with smaller patient enrollment) as well as to patients with rare diseases (i.e., inherently small patient populations with potentially significant heterogeneity in the clinical manifestations of disease and disease progression).

Additionally, in response to the question posed in the Policy Options Document, BIO asks the Working Group to consider the potential implications of applying these changes to the CMS-HCC methodology differentially across programs. For example, this could pose concerns given that patient outcomes and total expenditures on the treatment of chronic care conditions are often compared between programs. Thus, applying different risk-adjustment methodologies may make any such comparisons inaccurate or misleading. If the Working Group nonetheless decides to require or allow these changes to apply differentially, the Working Group should similarly require CMS to: (1) clearly state which methodology is applied to which program; and (2) study the impact of these different risk adjustment methodologies on the provision of adequate payment to plans that cover a disproportionate share of patients with chronic diseases.

VI. **Providing Flexibility for Beneficiaries to be Part of an Accountable Care Organization: The Working Group should mitigate perverse incentives to exclude chronic disease patients from ACO participation, and ensure that patients have access to: (1) providers with sufficient expertise and training to treat their disease(s); and (2) the therapies that are most appropriate for them, including new-to-market therapies.**

The Working Group identifies several policy options related to patients' participation in ACOs. While BIO is supportive of policies that seek to streamline care coordination efforts

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<sup>13</sup> Health Alliance. 2014. *2014 CMS—HCC Model Updates*, available at: <http://codingcounts.com/2014/02/28/2014-cms-hcc-model-updates/>.

<sup>14</sup> CMS. 2013 (January 29). Transmittal 2641: Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination, Addition of Laparoscopic Sleeve Gastrectomy (LSG), available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2641CP.pdf>.

and provide better information to patients so that they can more actively participate in their own healthcare, we offer several recommendations in this section to ensure appropriate patient protections are in place to mitigate incentives to discriminate against patients with chronic diseases.

First, BIO supports the underlying intent of the Working Group's policy options related to beneficiary assignment in the Medicare Shared Savings Program (MSSP), which we believe is to improve the ability of an ACO to tailor comprehensive care services to a defined population of patients.<sup>15</sup> We agree that prospective beneficiary assignment can improve an ACO's ability to more definitively identify the beneficiaries for whom they are responsible, and thus, better plan for their specific needs within the context of meeting quality and cost benchmarks. However, as context for continuing to explore this policy option, we urge the Working Group to work with CMS to understand the latter's progress in implementing Track 3 within the MSSP, which employs a prospective beneficiary assignment process and was finalized by CMS through rulemaking in 2015.<sup>16</sup> Data from this existing aspect of the MSSP can and should inform the Working Group's revision of the proposed policy option on beneficiary assignment in ACOs.

In particular, the Working Group should identify what mechanisms the Agency is utilizing to ensure that prospective beneficiary assignment does not encourage ACOs to "game the system" or "cherry-pick" the healthiest patients, and to what extent these mechanisms are effective in preventing these practices. In the absence of such mechanisms, prospective beneficiary assignment may undermine, rather than strengthen, the Working Group's goal of improving care for Medicare's chronic disease population. We also recommend that the Working Group identify whether comparing cost and quality-of-care outcomes among ACOs that elect a prospective versus a retrospective beneficiary assignment methodology creates inherent biases that may disadvantage ACOs utilizing one assignment methodology over the other in such comparisons.

Second, BIO recommends that the Working Group ensure that patients retain the flexibility to see providers outside of the ACO network, if the event that the Working Group moves forward with the specific provision to allow patients to elect to participate in an ACO. Access to providers outside of the ACO is a critical patient protection that helps to ensure that patients have timely access to those with the appropriate expertise and training to treat their condition. This is especially important for patients suffering from rare diseases, for which there may be only a few qualified specialists in the entire country. While we advocate that patients retain this flexibility, we acknowledge that this may have repercussions for the ACO with regard to the total costs of a patient's care that accrue to them and are compared against their benchmark. Thus, we also recommend that the Working Group modify the existing methodology for assigning costs of care to a specific ACO/ACO-participating provider to avoid penalizing providers for the quality and cost of care incurred outside of the sphere of clinical influence.

Third, BIO reiterates our recommendation to the Working Group that innovative medical technologies should be carved out of both the benchmark and performance year expenditures for ACOs. Innovative technologies are increasingly targeting chronic diseases and have the potential to both improve patient outcomes and decrease total expenditures, but only if timely utilization is encouraged. With such a carve-out, an ACO's decision to use a promising new therapy will not affect the calculation of the ACO's expenditures for

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<sup>15</sup> Policy Options Document at 21.

<sup>16</sup> 80 Fed. Reg. 42,425 (June 9, 2015).

purposes of determining whether it generated shared savings. Thus, the ACO will not have an incentive to lower costs by denying patient access to the therapy.

Fourth, we also reiterate our concerns with ACO's use of historical benchmarks to evaluate providers' performance with respect to quality and cost of care. In particular, we are concerned that historical benchmarks: (1) do not take into account the impact of technologies that have come to market since the benchmark was established; (2) may disincentivize the uptake of new-to-market innovations (e.g., because an assessment of providers' quality and cost of care will penalize those who are adhering to a more current standard of care than that established in the historical benchmark); and (3) may disadvantage providers who are already performing well (e.g., to the extent that a certain percent improvement above the historical benchmark is required). These concerns extend to any historically-based performance benchmark, whether in the comparison of providers' quality or costs of care, and we ask the Working Group to take into account these concerns in its recommendations related to structuring ACOs to improve care for patients suffering from chronic diseases.

VII. **Developing Quality Measures for Chronic Conditions: The Working Group should ensure that chronic disease quality-of-care measures are robust and incentivize individualized patient care.**

BIO supports the Working Group's policy option to require CMS to include specific topic areas for measures development related to chronic disease in the Agency's quality measures plan, required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).<sup>17,18</sup> In this section, we identify several general parameters of robust quality measures that the Working Group should consider with regard to its recommendations to CMS. Additionally, BIO recommends including several additional quality measures for inclusion in the Working Group's existing list. Finally, we conclude the section with support for the proposed GAO study, and a recommendation that such a study be more expansive in scope than proposed.

First, BIO asks the Working Group to require CMS to ensure that the quality measures under development meet three minimum criteria, such that all measures are:

- Meaningful to patients and providers;
- Relevant metrics of care for the disease and patient population included in the model; and
- Able to capture the full extent of benefits and side-effects of treatment options available to the population.

Quality measures that meet these criteria will be considered to be robust. This last criterion is particularly important for measures of the quality of chronic disease care since the benefits of treatment interventions may manifest over months or years, rather than hours or days (as may be the case for acute conditions).

Second, BIO recommends that the Working Group include immunization-related quality measures on its topic area list for CMS. Ensuring that the chronic disease population receives ACIP-recommended vaccines in a timely manner and in a care setting that is convenient to them can improve their short- and longer-term health outcomes. For

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<sup>17</sup> Policy Options Document at 22.

<sup>18</sup> 42 U.S.C. § 1395w-4(s)(1)(A) as amended by MACRA § 102.

example, individuals with chronic conditions like diabetes, heart disease, and chronic respiratory conditions can be a higher risk of complications and death from vaccine preventable conditions, such as influenza and pneumonia. In fact, according to the American Diabetes Association, patients with diabetes are three times more likely to die with flu and pneumonia, yet only a third of people with diabetes receive a pneumococcal vaccination.<sup>19</sup> Including immunization-related quality measures on CMS's quality measures plan can help to improve chronic care patients' access to these critical services.

Additionally, among its directions to CMS with regard to the Agency's quality measures plan, the Work Group should consider:

- The potential to encourage CMS to refer to the National Institutes of Health-developed Patient Reported Outcomes Measurement Information System (PROMIS)—which identifies measures of patient-reported health status for physical, mental, and social well-being—to develop disease-specific patient-reported outcome measures to ensure that the individual patient experience is captured in developing and evaluating MIPS;
- Requiring CMS to include disease-specific treatment adherence measures, where possible, based on the link between non-adherence and potentially worse short- and longer-term patient health outcomes, as well as the potential that worse health outcomes increase overall health expenditures (e.g., from increased hospitalizations, physician office visits, and/or the need for surgical interventions); and
- Requiring CMS to include measures that track non-medical switching (NMS)—defined as the substitution of a therapy on which a patient is already stable with another treatment option in the same therapeutic class on the basis of a non-clinical rationale (e.g., cost)—since NMS can impact adherence to treatment, especially in cases in which the new therapy is less effective for the individual patient and/or results in increased negative side-effects.

BIO also recommends that the Working Group direct CMS to develop and utilize measures of shared decision-making that are, where possible, provider specific both to reflect and further encourage the importance of the role of patients in their own care. The Working Group should encourage CMS to work with stakeholders to consider the utility of a national standard for shared decision-making tools to ensure that such tools are appropriately disease-specific, take into account information that is meaningful to the patient and in the context of his/her specific clinical circumstance, and presents information in a manner that clarifies, rather than confuses, patient/provider decision-making.

Third, in the Policy Options document, the Working Group not only proposes CMS include specific topic areas for measures development, but also proposes that the Government Accountability Office (GAO) conduct a study on community-level measures as they relate to chronic care management, which BIO supports. In recommending such a study, the Working Group should charge GAO to consider the extent to which community-level measures are appropriate measures of the care an individual patient receives. This is an important facet of the study implications since in some instances (e.g., immunization services) community-level measures may meaningfully indicate the impact of care on an individual patient, while in the case of chronic disease care, community-level measures have the potential to obscure important information about individualized care. In turn, tying

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<sup>19</sup> American Diabetes Association. 2016. *Flu and Pneumonia Shots*, available at: <http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/other-treatments/flu-and-pneumonia-shots.html?referrer=https://www.google.com/>.

provider reimbursement to the achievement of community-level measures may undermine the Working Group's broader goal of improving chronic disease care for Medicare beneficiaries by incentivizing the provision of "one size fits all" care, rather than targeting care toward the individual complexities and needs of each patient.

VIII. **Eliminating Barriers to Care Coordination under Accountable Care Organizations: The Working Group should move forward with the policy option to allow ACOs to waive cost-sharing requirements for certain items and services, but ensure that the implementation of the policy protects patient/provider decision-making based solely on clinical considerations.**

BIO supports the Working Group's consideration of allowing ACOs in two-sided risk models to waive cost-sharing requirements associated with items and services that treat chronic diseases or mitigate or prevent chronic disease progression.<sup>20</sup> Our support is based on the same rationale provided in response to the Working Group's policy option related to adapting benefits in MA plans (see Section I above). Specifically, given the correlation between high cost sharing and patient nonadherence, waiving cost-sharing requirements for clinically appropriate healthcare interventions, including prescription drugs, can improve patient access and adherence, and in turn, improve patient health outcomes and help to lower overall expenditures (e.g., through fewer hospitalizations, provider office visits, and/or surgical interventions).<sup>21</sup> This is particularly true in the case of chronic diseases, for which patients may need to sustain adherence to therapies for a prolonged period of time to obtain the full benefits of the treatment.

Furthermore, we ask the Working Group to consider allowing ACOs to waive any cost-sharing requirement—inclusive of copayments, coinsurance, and deductibles—that may impose a burden on patients that can result in not initiating or continuing with prescribed treatment. As discussed in more detail in Section I of this letter, it is important that such waivers apply equally to all therapies that are highly effective, may be clinically appropriate for patients suffering from a chronic disease, and are at risk for patient noncompliance based on existing cost-sharing requirements. This will help to ensure that patients, in conjunction with their providers, are able to choose the most appropriate therapy/therapies for them based on their individual clinical circumstances. To implement this policy option, BIO recommends the Working Group require CMS to engage in rulemaking to obtain public feedback on the specific provisions under which an ACO may waive cost-sharing requirements and the patient protections that must be in place to ensure such waivers improve and expand patient access to appropriate care.

IX. **Increasing Transparency at the Center for Medicare and Medicaid Innovation (CMMI): The Working Group should require CMMI to allow opportunities for public comment during the development of models, but balance this requirement with the flexibility to refine the implementation of its demonstration programs.**

BIO strongly supports the policy option that would require CMMI to undertake notice-and-comment rulemaking with respect to the development and implementation of innovative payment and delivery-of-care models.<sup>22</sup> BIO continues to appreciate CMMI's willingness to engage with stakeholders on an ad hoc basis, and we agree that CMMI should

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<sup>20</sup> Policy Options Document at 25.

<sup>21</sup> See Eaddy, M. T., C. L. Cook, K. O'Day, S. P. Burch, and C. R. Cantrell. 2012. How patient cost-sharing trends affect adherence and outcomes: a literature review. *Pharmacy & Therapeutics* 37(1):45-55.

<sup>22</sup> Policy Options Document at 28.

retain a degree of flexibility is refining demonstrations to maintain its ability to be nimble in piloting innovative payment and delivery models. However, we have expressed concern in the past, most recently with regard to the Oncology Care Model, that CMMI lacks a structured, predictable process to obtain input from stakeholders during the development of its demonstrations.

BIO is firmly committed to supporting such a process since it can provide CMMI with information and perspective to which the Agency may not otherwise have access. This information, in turn, can improve the efficiency and effectiveness of demonstrations as well as alert CMMI to operational and logistical hurdles in the implementation of a pilot program that can adversely impact patient access to needed care. Thus, we support the Working Group's proposal to require CMMI to allow at least a 30-day public comment period for all innovation models in advance of their finalization. This public comment period should be compliant with existing requirements governing notice-and-comment rulemaking, including but not limited to, requiring CMMI to: notify stakeholders of the opportunity to provide comments in a predictable manner (e.g., through publishing a notice in the Federal Register); and respond to substantial points raised by the public feedback received, including providing an explanation of how the Agency resolved significant issues raised by stakeholders.<sup>23</sup> However, we also support allowing CMMI to retain flexibility in refining the implementation of these models once finalized, assuming that any intended changes to the model do not substantively or significantly alter its scope or structure.

In considering additional mechanisms to improve the process by which stakeholders interact with CMMI, BIO asks the Working Group to consider requiring the Agency to provide more frequent updates with regard to its ongoing demonstrations and potential future demonstration topics than it does currently (i.e., at least once every other year beginning in 2012).<sup>24</sup> More frequent public updates would not necessarily need to be as detailed as the required Report to Congress in order to provide stakeholders with important information on the progress of the demonstration programs and the Agency's evolving priorities. Stakeholders, in turn, can utilize this information as context to improve the relevance and utility of their feedback to CMMI. Thus, we encourage the Working Group to consider requiring CMMI to provide public updates at least annually to improve the Agency's iterative engagement process with the public.

**X. Study on Obesity Drugs: The Working Group should require a study of the use, and impact, of prescription drugs to treat obesity, and encourage CMS to reconsider Medicare coverage of these therapies, taking into account the study results.**

BIO appreciates the Working Group's focus on therapies that treat obesity, a chronic disease that impacts millions of Medicare beneficiaries and can be a comorbidity for other chronic diseases.<sup>25</sup> The Policy Options Document acknowledges that, despite the impact of obesity on health outcomes and total expenditures, "Medicare Part D has not covered drugs for weight loss or gain."<sup>26</sup> BIO believes this application of the statutory prohibition on Part D coverage of drug agents when used for weight loss can limit patient access to existing therapies that may be effective for them to help treat obesity. Thus, we agree that a study of the use of therapies to treat obesity in the Medicare population can supply the requisite

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<sup>23</sup> Administrative Procedures Act (APA) § 553(b).

<sup>24</sup> ACA § 1115A.

<sup>25</sup> See e.g., Centers for Disease Control and Prevention. 2015. *Adult Obesity Facts*, available at: <http://www.cdc.gov/obesity/data/adult.html>.

<sup>26</sup> Policy Options Document at 30.

data to demonstrate the importance of this class of therapies to Medicare beneficiaries.<sup>27</sup> In addition to requiring such a study, we ask the Working Group to encourage CMS to reconsider its approach to coverage of obesity therapies based on the study results, and to do so in conjunction with stakeholder feedback, including opportunities for stakeholders to provide, and CMS to response to, additional data supporting coverage of these important therapies.

**XI. Conclusion**

BIO appreciates the opportunity to engage with the Working Group as it pursues improvements in chronic disease care for Medicare beneficiaries. We look forward to continuing to engage with the Working Group, the Committee, and other interested partners to ensure that beneficiaries suffering from chronic conditions have access to the most appropriate care for them. Please feel free to contact Jeanne Haggerty 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/

James C. Greenwood  
President and CEO

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<sup>27</sup> Social Security Act (SSA) § 1860D-2(e)(2) referencing SSA § 1927(d)(2).