

June 22, 2015

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: Request for Information (RFI) on Ways to Improve Outcomes for Medicare Patients with Chronic Conditions

Dear Senators Isakson and Warner:

The Biotechnology Industry Organization (BIO) is pleased to submit comments in response to the Request for Information (the "RFI") on ways to improve outcomes for Medicare patients with chronic conditions, as an input into the efforts of the bipartisan Working Group on Chronic Care (the "Working Group"), established by the Senate Committee on Finance (the "Committee") on May 15.¹

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

BIO appreciates the Committee's focus on chronic conditions, and we recognize the timeliness of the efforts of the Working Group. The Centers for Disease Control and Prevention (CDC) estimated that, in 2012, about half of all adults—117 million people—had one or more chronic health conditions, and seven of the top 10 causes of death in 2010 were chronic diseases.² These diseases have a significant impact on the Medicare population: more than two-thirds of Medicare beneficiaries suffer from least two or more chronic conditions.³ In addition to diseases commonly identified as "chronic,"—like those mentioned in 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

¹ Senate Committee on Finance. 2015 (May 15). *Letter Announcing Formation of the Bipartisan Working Group on Chronic Care*, available at: <http://www.finance.senate.gov/newsroom/chairman/release/?id=9f9f2d3e-401e-409b-a53a-22bbe3f56f2c>.

² Centers for Disease Control and Prevention (CDC). 2015. *Chronic Diseases: The Leading Causes of Death and Disability in the United States*, available at: <http://www.cdc.gov/chronicdisease/overview/>.

³ 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>.

population and on the broader healthcare ecosystem.⁴ 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.⁵ Thus, the role of innovative therapies in any mechanism to improve care for this population will be critical. In particular, BIO offers comments related to two issue areas where the Working Group has specifically requested feedback:

- **Transformative policies that improve patient outcomes through Alternative Payment Models (APMs):** BIO believes that APMs can provide increased efficiency and care coordination for patients with chronic diseases, but without careful attention to how an APM is structured, these models can establish perverse incentives to “cherry-pick” only the healthiest patients and encourage stinting on appropriate care.
- **The effective use, coordination, and cost of prescription drugs:** BIO asks the Working Group to examine several different facets of effective use and care coordination, including: the impact of existing out-of-pocket cost policies on patient adherence, which is closely tied to the effective use of therapies; the importance of coverage to ensure patient access to appropriate therapies; and the state of data infrastructure to support improved care coordination.

These issues are discussed in more detail below.

I. Transformative policies that improve patient outcomes through APMs.

In the RFI, the Working Group requests stakeholder feedback on both existing APMs—in particularly the Medicare Shared Savings Program (MSSP) and demonstration programs underway at the Centers for Medicare and Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI)—and new APM structures with the potential to transform chronic care for Medicare beneficiaries. BIO has arranged our comments in these two categories in this section, though we believe there are several core elements any APM must incorporate to ensure improved patient outcomes while decreasing overall healthcare expenditures. These core elements include: the use of quality measures that are disease-specific and meaningful to patients and providers; a robust risk-adjustment methodology; patient access to the most appropriate therapies for them, including new-to-market therapies; and robust monitoring of patient experiences. Mechanisms to operationalize these core elements in new and existing APMs are discussed in greater detail below.

A. Feedback on Necessary Elements of New APM Structures

BIO believes that APMs—a term that captures a broad category of payment reform models including medical homes, accountable care organizations (ACOs), and shared-savings

⁴ 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>).

⁵ 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>.

programs—can provide increased efficiency and care coordination for patients with chronic diseases. However, APMs must be carefully structured to avoid establishing perverse incentives that encourage underutilization of appropriate care or the “cherry-picking” of healthier patients over those that require more intensive, complex care. In assessing the appropriateness and ability of an APM to meet the needs of the population with the chronic disease in question, the Working Group should consider whether any model under consideration meets the following criteria.

First, the APM must rely on robust quality measures that 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 included in the model. This last criterion of a robust quality measure 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, the APM must employ a risk-adjustment methodology that accounts for the underlying differences in an individual provider’s, or provider practice’s, patient population. Such a robust risk-adjustment methodology is important to avoid unduly penalizing providers that treat sicker patients, who may incur higher total expenditures or exhibit poorer health outcomes because of their underlying health status.

Third, the APM must include mechanisms to ensure patient access to the most appropriate therapy for them, including to new-to-market therapies. The exact mechanism will depend on the structure of payment/reimbursement utilized by the APM. For example, in an APM that assesses a provider based on a comparison of his/her total expenditures for a patient population over a period of time compared to a benchmark, this mechanism can be a full carve-out for new technologies, in which these new-to-market therapies are reimbursed separately and that reimbursement is carved-out of the total expenditures attributed to the provider.

Fourth, the APM must establish a performance period that is meaningful in the context of the chronic disease(s) included in the model and the care available to included patient populations. BIO is concerned that, for a chronic disease in particular, defining an “episode of care” for the purposes of an APM performance period that is based on a specific period of time may be arbitrary and may not accurately capture important clinical or cost outcomes. This is especially true for specialty care of complex, chronic diseases. Instead, the Working Group should consider APMs that establish performance periods—and correspondingly, risk-adjust—around well-characterized clinical features of the targeted chronic diseases, and to target chronic diseases where the patient populations and subpopulations affected are well-characterized to allow for accurate comparisons between patients treated by different provider practices.

Fifth, the APM must establish robust monitoring of provider and patient experiences, which is critical to ensure that the APM does not limit patient access to appropriate care. This is particularly important for APMs that target patients with chronic diseases because treatment for these diseases spans years, and even decades. Thus, the negative impact of underutilization of appropriate care may not be detectable immediately, despite the potential to result in poorer health outcomes for patients and increased total healthcare expenditures for Medicare (e.g., in terms of increased avoidable hospitalizations, surgical procedures, and physician office visits).

BIO believes these five elements are foundational in the design of an APM that promotes improved patient outcomes. We encourage the use of these five core elements as a rubric for the initial evaluation of any APM that targets providers who treat patients with chronic diseases.

B. Feedback on Existing APMs

As an initial matter, BIO reiterates our appreciation for the opportunity to have commented on the recent CMS *Medicare Shared Savings Program; Accountable Care Organizations Proposed Rule*.⁶ On June 5, CMS released the MSSP Final Rule, and while we appreciate the Agency's efforts to improve the program, we bring to the attention of the Working Group several important issues that were not resolved in the Final Rule.⁷ We believe these recommendations have particular relevance with regard to improving the program's impact on quality of care for patients with chronic diseases, and ask the Working Group to consider them moving forward as they assess the current structure of the MSSP.

First, BIO reiterates our recommendation 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 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.

Second, we believe the quality measures used to assess patient care for those beneficiaries whose providers are participating in the MSSP should be reevaluated against the criteria BIO identified in Section I above with respect to appropriateness and specificity for chronic diseases. We reiterate our concern that without robust quality measures, it may be difficult to ascertain the impact of the MSSP model on patient access to appropriate care.

Third, we believe that additional scrutiny is needed of the utilization management techniques employed by ACOs participating in the MSSP to ensure they do not result in discriminatory "cherry-picking" of the healthiest patients to minimize the risk of shared losses. In response to the Proposed Rule, BIO noted the particular need to monitor the potential for "gaming the system" in the proposed Track 3 given the prospective assignment of beneficiaries in this track. This may be an initial area for additional scrutiny as the Working Group reviews the MSSP and its potential impact on the diagnosis and treatment of chronic conditions.

Fourth, we reiterate our concern that additional oversight is needed to prevent ACOs from engaging in cost shifting and taking other steps to game the system, in light of the fact that ACOs are not responsible for all costs incurred by beneficiaries in the Medicare system. Since ACOs are accountable for Part B but not Part D spending, there is the potential for providers to, for example, direct patients towards an oral drug covered under Part D rather than a physician-administered innovative product that would be covered under Part B, which may be more appropriate for some patients. Moreover, from the perspective of Medicare policy, it is problematic to reward "paper savings" achieved through cost shifting from one part of the program to another.

⁶ 79 Fed. Reg. 72,760 (December 8, 2014).

⁷ 80 Fed. Reg. 32,692 (June 9, 2015).

Fifth, we remain concerned with the robustness of the risk-adjustment methodology employed by the MSSP. The Final Rule did not address the need to continuously refine this methodology and assess its ability to prevent providers from being unduly penalized for treating sicker patients. Specifically, it is unclear whether the current methodology adequately captures the impact of underlying patient and disease characteristics on patient outcomes and overall healthcare expenditures. This is of particular concern for patients with chronic diseases given the significant heterogeneity of that population and its potential impact on total expenditures and health outcomes.

Finally, with respect to ongoing CMMI demonstrations, we note that many of the concerns with the MSSP expressed in this section are echoed when considering the role of CMMI's Pioneer ACO and Next Generation ACO models in furthering improvements in care for patients with chronic diseases.

II. The effective use, coordination, and cost of prescription drugs

A. Elements of the Effective Use of Prescription Drugs

In considering the effective use of prescription drugs, we urge the Working Group to recognize that a key component of effective use is patient adherence to the treatment regimen prescribed. Adherence, in turn, can be impacted by factors including how positively a treatment impacts the symptoms that are the most important to the patient and the extent to which the regimen mitigates negative side effects.

This is particularly true in the case of treatment regimens that include biologicals. The differences between how biologicals, even those in the same drug class, can impact an individual patient—in terms of response to a therapy and the mitigation of side-effects—is based on the fact that biologicals, as large protein molecules synthesized in living cells, have increased structural complexity that can affect a product's function and clinical safety, efficacy, and immunogenicity. Based on the highly specialized nature of these therapies, patients must have access to the full range of available therapies to work with their provider to determine which is the most appropriate for their individual clinical situation. Additionally, a robust literature base supports the link between adherence and out-of-pocket (OOP) costs for patients: as cost-sharing for patients increases, adherence to medications decreases, which can result in poorer health outcomes.⁸ Thus, to promote adherence as a facet of effective use, we strongly urge the Working Group to study the role of OOP costs in current chronic disease management and work with a diverse group of stakeholders to consider mechanisms to mitigate the impact of these costs to patients.

A corresponding, crucial component of effective use is access: to benefit from innovative therapies, patients must have timely access to them. While the factors that impact access are numerous, we would like to bring to the Working Group's attention an access issue impacting patients with obesity that is a direct product of federal policy. More than two-thirds (68.7 percent) of American adults are either overweight or obese, and "[a]s obesity rates rise, the risk of developing obesity-related health problems—type 2 diabetes, coronary heart disease and stroke, hypertension, arthritis and obesity-related cancer—increases exponentially."^{9,10} Moreover, studies have found that even modest decreases in obesity can

⁸ Eddy, 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):45-44.

⁹ Fryar C.D., et. al. 2012. Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults: United States, Trends 1960-1962 Through 2009-2010. *National Center for Health Statistics* (accessed May 2013).

¹⁰ Trust for America's Health (TFAH) and Robert Wood Johnson Foundation (RWJF). 2012. *Fast as in Fat: How Obesity Threatens America's Future*, p. 23, available here: <http://stateofobesity.org/files/fasinfat2013.pdf>.

result in national savings of \$158 billion over ten years.¹¹ Yet despite this overwhelming evidence, and the movement by many private insurers to cover obesity therapies, Medicare does not cover therapies to treat this recognized disease.¹² Thus, BIO urges the Working Group to address access to obesity therapies for the Medicare population among your initial efforts to improve chronic care.

B. Coordinating the Use of Prescription Drugs

In considering the coordination of prescription drugs for the chronic disease population, we urge the Working Group to recognize that a key component of coordinated care is improving the infrastructure for the efficient and timely communication of healthcare data. Patients with chronic diseases often see several healthcare providers for their routine care, and the ability for these providers to communicate efficiently and make treatment recommendations based on the same set of healthcare data is crucial to improving care coordination, and in turn, quality of care for this population.

A recommendation that BIO has had the opportunity to make to the Committee, and to CMS, in the past is the need for the Department of Health and Human Services to work with stakeholders to identify and implement mechanisms to improve the utility of electronic health records (EHRs) in aggregating and communicating important information about the real-world use of biopharmaceuticals. Strengthening this capability can help to ensure providers and patients have access to the most relevant, real-time information before making healthcare decisions and can promote an ecosystem that fosters longer-term innovation. Not only is the availability of these data important, but it will be equally important to ensure that these data are interpreted holistically with the goal of better tailoring care to an individual patient's circumstances and not used to limit access to appropriate care.

Additionally, in considering care coordination, BIO asks the Working Group to consider the important role of comprehensive medication management measures (CMM), beyond just medication reconciliation, to assess whether a patient is fully benefiting from a therapy and achieving optimal therapeutic outcomes. A robust CMM strategy ensures each patient's medications (whether prescription, nonprescription, alternative, traditional, vitamins, or nutritional supplements) are individually assessed in order to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the co-morbidities and other medications being taken, and able to be taken by the patient as intended. CMM includes an individualized care plan that achieves the intended goals of therapy and includes appropriate follow-up to determine actual patient outcomes. We note that, when applied across the appropriate patient populations, CMM has been shown to significantly improve health outcomes for patients and reduce overall healthcare costs, particularly for patients with chronic conditions that require complex medication regimens.^{13,14}

¹¹ *Id.* at 24.

¹² This Medicare policy has historically been based on the statutory exclusion of drugs for "anorexia, weight loss or weight gain" from coverage, see 42 U.S.C. 1396r-8 (d)(2), despite the fact that the American Medical Association has identified obesity as a disease, which, BIO believes, distinguishes it from "weight loss," see AMA. 2013 (June 18). *AMA Adopts New Policies on Second Day of Voting at Annual Meeting*, available at: <http://www.ama-assn.org/ama/pub/news/news/2013/2013-06-18-new-ama-policies-annual-meeting.page>.

¹³ For example, see Isetts B. J., A. R. Brummel, D. Ramalho de Oliveira, and D. W. Moen. 2012. Managing Drug-related Morbidity and Mortality in the Patient-centered Medical Home. *Medical Care* 50(11): 997-1001; also see Brummel, A., A. Lustig, K. Westrich, M. A. Evans, G. S. Plank, J. Penso, and R. W. Dubois. 2014. Best Practices: Improving Patient Outcomes and Costs in an ACO Through Comprehensive Medication Therapy Management. *Journal of Managed Care & Specialty Pharmacy* 20(12): 1152-1158.

III. 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,

A handwritten signature in black ink that reads "Jim Greenwood". The signature is written in a cursive, flowing style.

James C. Greenwood
President & CEO

¹⁴ Patient-Centered Primary Care Collaborative. 2012. *Integrating Comprehensive Medication Management to Optimize Patient Outcomes: A Resource Guide*, available at: <https://www.pcpcc.org/sites/default/files/media/medmanagement.pdf>.