



August 29, 2014

BY ELECTRONIC DELIVERY

Sylvia M. Burwell
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Proposed Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Charter

Dear Secretary Burwell:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the proposed changes to the Medicare Evidence Development and Coverage Advisory Committee's (MEDCAC's) charter, which were released on August 1, 2014.¹ BIO represents more than 1,000 biotechnology companies, state biotechnology centers, academic institutions, and related organizations both in the United States and abroad. BIO members are critical contributors to the research and development of innovative health care, agricultural, industrial, and environmental biotechnology products.

The novel therapeutics, vaccines, and diagnostics our members bring to market can improve health outcomes and reduce healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions—but only if patients have access to them. Consequently, BIO has a vested interest in MEDCAC's role as an advisor to the Centers for Medicare and Medicaid Services (CMS) on issues of coverage, which can impact whether beneficiaries have timely access to the medical technologies that are most appropriate for them. BIO believes that the diverse composition of MEDCAC has the potential to lend tailored expertise to the issues that come before the Committee, but in the past not all members were able to participate to the same extent.

BIO supports the proposed changes to the MEDCAC charter because we believe they address this issue effectively. Specifically, many of the changes serve to remove the "nonvoting" status previously assigned to all six required representatives of the industry. If finalized, these changes will allow members representing industry to participate to the same extent as all other MEDCAC at-large members. This is important to be able to more effectively leverage the clinical, scientific, and policy expertise these members possess to better inform the Committee's recommendations to CMS. These industry representatives also can provide needed perspective on the practicalities of medical technology research and development and use. Thus, we urge that these proposals be finalized and the updated charter approved.

¹ Centers for Medicare and Medicaid Services. 2014 (August 1). Proposed MEDCAC Charter. Baltimore, MD: CMS, Available at: <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=25>.

BIO would also like to take this opportunity to remind CMS that one of MEDCAC's primary strengths is the ability to populate MEDCAC panels for a specific meeting with committee members who have the most relevant expertise on the issues to be discussed. In part, the number of members is kept relatively high—up to 100 Special Government Employees and Representatives—in order to maintain access to a diversity of experts willing to participate on the Committee. However, it is our observation that this expertise has not always been deployed as judiciously as needed, such that the expertise of participants on individual MEDCAC panels has not always been the most appropriate for the issues being discussed. BIO is concerned that, in these instances, the Committee's recommendations may not be on the soundest scientific, clinical, or policy footing. Therefore, simultaneous to approving the proposed changes to the charter, we urge MEDCAC to review its internal policies for assigning members to particular meeting panels to better ensure that those making coverage recommendations have the specific expertise and experience to do so well.

BIO reiterates our appreciation for the opportunity to comment on the proposed changes to the MEDCAC charter and looks forward to continuing to engage with the Committee on important issues impacting Medicare beneficiaries' access to needed care. Please do not hesitate to contact me with any questions.

Respectfully submitted,

/s/

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