

December 3, 2010

***BY ELECTRONIC DELIVERY***

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

**Re: Medicare Program; Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program [CMS-1345-NC]**

Dear Administrator Berwick:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) Request for Information (RFI) regarding Accountable Care Organizations and the Medicare Shared Savings Program.<sup>1</sup> BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

As the representative of an industry devoted to improving health care through the discovery of new therapies, we support policies that help ensure access to innovative and life-saving therapies and vaccines for all individuals. We support the development and use of appropriate, evidence-based quality measures throughout the health care system. We also believe that access to cutting-edge therapies will not only improve the quality of care, but may reduce costs through improved preventive care and reduced hospitalizations.<sup>2</sup> These comments focus specifically on the question posed in the RFI regarding the development of the quality performance standard that the Patient Protection and Affordable Care Act ("Affordable Care Act") requires the Secretary to develop in order to measure provider performance in the Shared Savings Program.

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<sup>1</sup> 75 Fed. Reg.70165 (November 17, 2010).

<sup>2</sup> See Nichol, K.L. The additive benefits of influenza and pneumococcal vaccinations during influenza seasons among elderly persons with chronic lung disease, *Vaccine* July 30 1999: 17 Suppl 1:S91-93; Jha, Ashish, Performance measures, vaccinations, and pneumonia rates among high risk patients in Veterans Administration Care, *American Journal of Public Health*, Dec 2007, Vol 97, No 12, pp 2167-2172; Lichtenberg, Frank R. "The Impact of New Drugs on US Longevity and Medical Expenditure, 1990-2003: Evidence from Longitudinal, Disease-Level Data." *AEA Papers and Proceedings*, May 2007.



BIO supports policies to improve the quality and efficiency of health care, and we appreciate CMS's efforts to promote quality care for beneficiaries. New payment models developed by the Affordable Care Act, such as Accountable Care Organizations (ACOs), hold promise in changing and improving the way that health care is delivered to patients.

The use of standardized quality measures by ACOs has the potential to reduce disparities in care, and BIO supports efforts to assist ACOs in reaching the quality performance standard as determined by the Secretary. Quality measures used in the determination of shared savings for ACOs must be patient-centered and evidence-based. We encourage CMS to establish measures and measure reporting in ways that facilitate their incorporation into provider's current practices, with a minimum of additional administrative burden. CMS has allowed flexible means for reporting quality measures in other programs, and we encourage the agency to establish flexible methods for ACO quality measure reporting through a notice and comment rulemaking process.

In terms of identifying specific measures for use by ACOs, CMS may give consideration to the work of the National Quality Forum's (NQF) Measures Prioritization Advisory Committee (MPAC). The National Priorities Partnership has pointed to MPAC's work and identified it as something that could inform the development of the National Quality Strategy.<sup>3</sup> The MPAC's May 2010 report identifies a prioritized list of 20 high-impact Medicare conditions, representing 95% of costs to the program.<sup>4</sup> MPAC has conducted a scan of existing measures related to these conditions, as well as a gap analysis to inform the development of additional measures.

The MPAC has also indicated that it will be considering other measurement streams that are important for addressing the needs of special populations. We recommend that CMS consider the use of measures currently available, or developed for special populations as a result of that work, in the Shared Savings Program.

CMS should engage with patients, providers, and other stakeholders through formal rulemaking to ensure a robust and valuable set of quality measures. A transparent and inclusive process with stakeholder collaboration will ensure measures that are scientifically and clinically relevant. In addition, the quality measure set must be updated regularly to reflect current guidelines in order to promote the provision of up-to-date care to beneficiaries. Such measures must capture the most recent clinical information to ensure consistency and relevance with the evolution of scientific and clinical advancements.

BIO believes that any potential changes to payment policies that may impact patient care must be based on a comprehensive analysis of appropriate, scientifically rigorous evidence to ensure that patient access to quality care is maintained. As policymakers evaluate such proposals, the potential ramifications for patients, whether direct or indirect, must be considered. In addition, such policies must maintain flexibility for patients and their physicians to choose the therapy most appropriate to achieve optimal quality outcomes. For example, beneficiaries in

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<sup>3</sup> National Priorities Report: Recommendations to the Secretary of Health and Human Services on Priorities for the 2011 National Quality Strategy, October 14, 2010, Appendix D, p. 3.

<sup>4</sup> National Quality Forum, Measure Prioritization Advisory Committee Report, "Prioritization of High-Impact Medicare Conditions and Measure Gaps," May 2010.

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ACOs should be informed they will be entitled to all the services and benefits that would be covered outside the ACO, including services from specialty providers outside the ACO.

BIO appreciates the opportunity to comment on this RFI. We look forward to continuing to work with CMS to address these critical issues in the future. We also applaud CMS's efforts to promote quality care for Medicare beneficiaries and believe that access to innovative therapies is an imperative part of this process. 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 attention to this very important matter.

Respectfully submitted,

/s/

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and Health Policy