

October 27, 2017

**BY ELECTRONIC DELIVERY**

Eric D. Hargan  
Acting Secretary  
US Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: HHS DRAFT Strategic Plan FY 2018-2022**

Dear Acting Secretary Hargan,

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the Health and Human Services (HHS/the Agency) Draft Strategic Plan for Fiscal Years 2018-2022 (Strategic Plan).<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. Our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, including productivity and quality of life, but also have reduced healthcare expenditures to due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO strongly supports HHS' mission to enhance the health and well-being of Americans, by providing for effective health and human services and by fostering sound, sustained advances in the science of underlying medicine, public health, and social services; and the associated strategic planning process. We consider it especially important to focus on activities that advance patient access to the most timely and appropriate care and treatment, to help improve health outcomes and reduce healthcare costs over the short- and long-term. Our comments, detailed in the balance of this letter, focus on patient access and coverage considerations for the following Strategic Goals of the Plan:

- Strategic Goal 1: Reform, Strengthen, and Modernize the Nation's Healthcare System
- Strategic Goal 2: Protect the Health of Americans Where They Live, Learn, Work, and Play
- Strategic Goal 4: Foster Sound, Sustained Advances in the Sciences

As HHS states, "the goals and objectives of the Strategic Plan are presented in separate sections, they are interrelated", likewise, the overarching themes we detail in this letter should be considered when assessing goals and objectives across the Strategic Plan.

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<sup>1</sup> HHS Strategic Plan, FY 2018-2022, Draft, September 2017. Available at:  
<https://www.hhs.gov/sites/default/files/hhs-draft-strategic-plan-fy2018-2022.pdf>

## **I. Strategic Goal 1: Reform, Strengthen, and Modernize the Nation's Healthcare System**

HHS states the intention to meet this goal through promoting greater affordability and balancing spending, strengthening healthcare quality and patient safety, improving access and expanding choices, and investing in the healthcare workforce to improve outcomes for those served by the Agency. BIO supports these efforts to deliver high-value, high-quality, patient-centric care.

The objective of promoting affordable healthcare includes balancing spending on premiums, deductibles, and out-of-pocket costs by promoting preventive care to reduce future medical care costs; strengthening informed consumer decision-making and transparency about cost of care; strengthening coverage options to reduce consumer cost, promotion of higher value and lower cost healthcare options; incentivizing quality and value based care; all with the application of analyzed data to meet these aims. To these strategies, BIO offers the following comments and considerations:

- BIO strongly supports HHS efforts to increase access to preventive care and services, which help to reduce disease burden and healthcare system costs. Access to high-value, evidence based prevention services, including screening for cancer and other diseases and vaccinations, is a central component of critical preventive care services with lasting impacts for patients and to the overall healthcare system.
- BIO believes tools to enhance patient and beneficiary understanding and awareness of healthcare coverage and decision-making are an important component in ensuring patient access to timely and appropriate care. It is BIO's belief that transparency measures should apply across the healthcare spectrum and be grounded in the goal of improving timely access and information that supports informed patient/provider clinical decision making and health insurance enrollment decisions, and that helps ensure smarter healthcare spending without distorting market dynamics or harming the innovation ecosystem.
- BIO supports HHS activities that address patient cost burden, such efforts help ensure access to timely and appropriate treatment. In addition to the focus on premiums, BIO believes that attention should be paid to beneficiary out-of-pocket costs that may place an undue burden on accessing specific healthcare services, ultimately impacting a patient's overall health outcomes and costs to the healthcare system over the short- and long-term.
- BIO supports the HHS goal to apply appropriate clinical guidelines and quality measures that prioritize preventive services for early stage disease detection. We encourage HHS to work closely with measure stewards and stakeholders across the healthcare spectrum, including patients and providers, in development of quality measures and guidelines that are relevant in the context in which they are applied.

- BIO believes that the aims of incentivizing quality and value based care can also be met through innovative delivery of treatment options in the form of value-based arrangements. We encourage the Agency to work with manufacturers to seek out opportunities to provide patient access to innovative products through this pathway.

The objective of improving access to health care and expanding choices of service and care options prioritizes expanding coverage options; improving consumer understanding of healthcare options and consumer-directed healthcare decisions; designing healthcare options that are responsive to consumer demands; and reducing disparities in access to healthcare. To this objective, BIO offers the following comments and considerations:

- BIO strongly supports ensuring timely and comprehensive updates to Medicare fee-for-service coverage, as detailed in the Strategic Plan, in a manner that continues to provide timely access to necessary healthcare interventions. The Medicare Part B program provides coverage to some of the most vulnerable beneficiaries, ensuring they have access to treatments that require physician expertise in delivery in their preferred site of care. Changes to this critical program could have detrimental impacts for beneficiaries.
- BIO is encouraged to see the reference to expanding choice in the Medicare Part D program, as this will help ensure beneficiaries receive the coverage most suited to their healthcare needs. The Medicare Part D program continues to be successful in delivering needed prescription drugs with continued increases in the value of the benefit, stability in premiums, and a high level of beneficiary satisfaction.
- BIO believes that new payment pathways aimed at transforming the way care is delivered, under the Quality Payment Program, represent a continued opportunity for the Agency to advance quality and deliver patient-centric care.

## **II. Strategic Goal 2: Protect the Health of Americans Where They Live, Learn, Work, and Play**

This goal encompasses a broad range of activities in partnership with governmental and non-governmental organizations across the spectrum to advance health promotion and wellness, promoting healthcare access, preventing and controlling communicable and chronic disease, reducing the impact of mental health and substance use disorders, and preparing for and responding to public health emergencies and disasters.

The second objective of this goal is specifically aimed at preventing, controlling and treating communicable and chronic disease through strategies including preventing and controlling infectious disease; reducing the emergence and spread of antibiotic-resistant infections; supporting early detection and treatment of communicable and chronic diseases; supporting chronic disease management interventions; and funding research into opportunities to prevent, treat, and control chronic conditions and communicable diseases. To this objective, BIO offers the following comments and considerations:

- BIO supports efforts to combat the spread and emergence of antibiotic-resistant infections through increased surveillance and detection, expansion of diagnostic and identification tools and improvements in appropriate use of antibiotics. We also urge HHS to ensure that reimbursement policies appropriately value the societal benefits of innovative antibiotic and antimicrobial resistance products that can address these broad public health needs.
- BIO is encouraged to see the continued commitment of HHS to detect and treat both communicable and chronic diseases. Improvements in early detection of a broad range of diseases, such as cancer, Alzheimer's disease and other dementias, heart disease, chronic pain, and hepatitis, can help ensure timely initiation of care and treatment options. Early detection of communicable and chronic diseases should also prioritize access to innovative treatment options that represent the best possible health outcome for each patient.
- As stated above, access to vaccinations is a central tenet of preventive service delivery with a well-studied positive impact on population health and to the overall healthcare system. BIO applauds the commitment through this objective to increase access to core preventive immunizations and to advance vaccine development. Additionally, we urge HHS to ensure that access to Advisory Committee on Immunization Practices (ACIP) vaccines is not precluded by reimbursement or coverage barriers.

This goal also includes an objective directed at reducing the impact of mental health and substance use disorders through expanding prevention, screening, and early identification of these illnesses; improving access to high-quality care and treatment; improving access to recovery support; building capacity to promote collaboration among government and communities; investing in evaluation to promote evidence-based interventions; and leveraging technology and innovative solutions. To this objective, BIO offers the following comments and considerations:

- BIO strongly supports HHS efforts to apply a broad public health approach to prevent opioid misuse and preventing opioid use disorder. BIO and its member companies are committed to developing solutions that will allow for an America free of prescription and opioid addiction through advancing development of and access to innovative medicines and approaches to treatment for both pain and addiction.

### **III. Strategic Goal 4: Foster Sound, Sustained Advances in the Sciences**

This goal encompasses activities aimed at improving surveillance, epidemiology, laboratory services; strengthening the scientific workforce and infrastructure; advancing scientific knowledge in the areas of prevention and treatment and leveraging such knowledge to improve health outcomes.

- BIO is extremely supportive of the ongoing HHS efforts to advance scientific understanding to improve diagnostic capabilities and allow for more timely initiation of treatment, advance treatment and therapeutic options to improve patient health outcomes and reduce health system costs, and to prevent

diseases. This is a good first step in recognizing the value of laboratory diagnostics and establishing reimbursement rates that recognize the value of these advanced tests in delivery of personalized, targeted treatments and reduction of overall healthcare costs.

#### **IV. Conclusion**

BIO appreciates the opportunity to comment on the HHS DRAFT Strategic Plan for 2018-2022. We support the Agency's efforts to enhance the health and well-being of American's through the focus of quality detailed in the Strategic Plan. We look forward to working in partnership with HHS to address the items raised in this letter. Should you have any questions, please do not hesitate to contact me at 202-962-9200.

Respectfully Submitted,

/s/

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Vice President,  
Healthcare Policy and Research

/s/

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Director,  
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