BIO Public Statement: Essential Health Benefits Listening Session

October 25, 2011

Thank you for the opportunity to present comments on behalf of the innovative biotechnology industry which is working to prevent, treat, and cure diseases through the most advanced science. My comments today focus on the affordability and access of prescription drugs as part of the Essential Health Benefits (EHB) package.

BIO appreciates IOM's emphasis on improving health outcomes while controlling costs. 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 case. In that way, our member's novel therapeutics, vaccines, and diagnostics create value in the healthcare system. The progress made in medical innovation over the past 30 years has resulted not only in improved health outcomes, but has also produced savings in the form of reduced hospitalizations and improved productivity and quality of life for patients afflicted with devastating diseases.

As established in the Affordable Care Act (ACA), plans under the Exchanges are prohibited from designing benefits in ways that discriminate against individuals with diverse healthcare needs, such as those with rare diseases. Access to the ten categories of care outlined in the ACA should be determined based upon individual patient medical condition and clinical circumstance-- judgments best made between patients and their caregivers. "One-size-fits-all" policies that ignore the variability among individual patients in treatment efficacy, safety, and tolerability must be avoided. Additionally, the Secretary should establish a clearly-defined appeals and exceptions process to ensure adequate beneficiary protections.

In order to ensure that plans available through the Exchange remain affordable, HHS should allow for flexible cost sharing across benefit categories, while ensuring that the EHB is not designed with very high cost sharing for medications for patients with severe disease. Studies have shown that, even for severe life-threatening diseases such as cancer, significantly more

patients abandon treatment at higher co-pays. The use of specialty tiers, for example, creates barriers to improved patient outcomes and results in patients foregoing necessary medications. When patients do not adhere to their treatment regimens as established by their health care providers, their conditions may worsen, creating higher health system costs down the road. We urge HHS not to permit benefit designs that impose such excessive cost-sharing for critical medications covered under both pharmacy and medical benefits.

Under current law, as stated in the ACA, all new health plans, including Qualified Health Plans, will be required to cover a specific set of preventive services, including the recommendations of the United States Preventive Services Task Force (USPSTF) with an A or B rating and vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) at no cost-sharing. BIO encourages HHS to re-state current law in the context of this new regulation to both avoid any confusion and facilitate the correct actuarial calculations that must be made for the Exchanges.

As stated in the ACA, the EHB should be "equal to the scope of benefits provided under a typical employer plan." A recent study conducted by actuarial firm Milliman confirmed that "almost all employers (99%) with healthcare coverage offer prescription drug benefits, which almost always cover brand and generic drugs with little exclusion."[1] We believe this broad access to a variety of therapies should be carried into the Exchanges to ensure that beneficiaries have consistent access to prescription drugs.

As HHS considers various models for structuring the EHB, the agency should consider looking to various aspects of Medicare Part D that have contributed to the program's success. Part D plans currently have the flexibility to design and manage effective benefit plans, yet must provide access to a wide range of medications. We urge HHS to consider similar types of formularies in implementing the EHB. As it does in Part D, HHS should consider the importance of ensuring access for those beneficiaries with life-threatening diseases. For example, the six protected classes established under the MMA recognize the unique nature of certain conditions and that access to the complete range of therapeutic options is critical to delivering quality care. These classes should be extended into the EHB. Also, patients should have the opportunity to access new therapies following FDA approval. For example, under the Part D program plans must make a reasonable effort to review a new FDA-approved product within 90 days and make a decision within 180 days. More broadly, to the extent that Qualified

[1] Milliman Inc. "Essential Health Benefits: What is Typical?" May 16, 2011. Available at: http://insight.milliman.com/article.php?cntid=7637

Health Plans create drug formularies that prefer some treatments over others, those formularies must be clinically appropriate and not solely focused on costs. Additionally, utilization management procedures must not in and of themselves impede or otherwise interfere with clinical decision making.

Competition has successfully kept costs down in the Part D program, allowing individuals the opportunity to choose the plan that best meets their needs. Multiple drug plans compete in every region, leading to costs that are substantially less than predicted. This has been accomplished while maintaining rules that require meaningful patient access to a wide range of medically necessary medications.

In conclusion, we urge HHS to, at every step in the process, preserve and protect the patient-provider relationship. To achieve the best possible outcomes, providers must have the flexibility to tailor the appropriate course of treatment for each patient based on individual patient medical condition and clinical circumstances. We thank you again for the opportunity to present comments today.