Biotechnology Innovation Organization

Position Statement

BIO Position on State Value-based, Innovative Payment Strategies

BIO and its member companies are committed to ensuring patients have timely access to the innovative treatments they need. BIO strongly supports states working together with the Centers for Medicare and Medicaid Services (CMS) and biopharmaceutical manufacturers on voluntary, alternative payment strategies that balance patient care and positive health outcomes against the needs and limitations of the states' finite resources. However, certain challenges still remain for CMS and states as we enter into this new era of negotiation.

- **States and companies are coming together in creative ways to address the challenges of the 21st century innovative health ecosystem.** It is important that government and the private sector maintain an innovative biopharmaceutical ecosystem that can eliminate barriers that hinder the evolution of innovative payment arrangements. BIO believes that the success of the voluntary approaches recently approved in Oklahoma and Michigan have the potential to demonstrate beneficial outcomes, stability in financing, and continued future innovation.

- **BIO, as well as CAHC and NEHI, a broad coalition of health plans, PBMs, and patient advocacy groups,[1] strongly supports innovative negotiation between states and biopharmaceutical companies, which will, in turn, help ensure patient access to necessary therapies.** We believe that value-, outcomes- or indication-based arrangements, and alternative payment models, all have merits to both states and biopharmaceutical companies. It is imperative that policymakers understand the variety of arrangements that exist and provide flexibility to ensure new models can be developed as health care evolves and new medications are developed. Each type of arrangement may bring with it a unique set of benefits or challenges to the patient, the payer, and the biopharmaceutical innovator. Given the complexity of these arrangements it is essential that these agreements remain voluntary.

    - For example, some of these models such as the subscription model may work best in the context of curative therapies, in which the course of therapy is completed with immediate value to the health system, while others may not have the same value-added immediate benefit.

- **CMS approvals of new state plan amendments in states such as Oklahoma and Michigan are paving the way for a new era of negotiation**. All states are required to balance their budgets either by their Constitution or by state law. Frequently, this pressure to balance their state budgets, can result in benefit cuts and restrictive policies in Medicaid denying many patients access to their needed prescription medicines. These new innovative payment policies enable states to provide patients access to groundbreaking, life-saving, and life-changing therapies

[1] Council for Affordable Health Coverage and the Network for Excellence in Health Innovation

while potentially meeting their budget needs (although the complexity of state budget cycles may pose difficulty in some states).

- **BIO supports continued discussion between states, CMS/HHS, and biopharmaceutical companies to ease the legal and policy-related challenges entities face in entering these alternative arrangements.** We are encouraged that the Department of Health and Human Services (HHS) and CMS are working to alleviate some of these biopharmaceutical industry concerns. BIO supports on-going discussions that will lead to the alleviation of these potential challenges, including Medicaid best price and the anti-kickback statute.

    - For example, the pay-over-time payment, or long-term financing, model poses problems for companies that are concerned about the Medicaid best price requirements.[2] These requirements mandate that the company provide "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer provider, health maintenance organization, nonprofit entity, or governmental entity within the United States."[3] Rebates are reported in a quarterly fashion under the Medicaid statute. If a "payment" is accepted on a quarterly basis that is only a fraction of what the drug therapy costs, the lower price paid that quarter could establish that as the "best price" nationwide for all Medicaid programs. This discourages companies from entering such agreements given the significant financial loss, as this new "best price" would apply to all sales to state Medicaid and other federal programs.

    - Outcomes- or value-based arrangements pose their own best price vulnerabilities. For example, the type of arrangement in which the company is only paid when positive health outcomes are achieved poses even greater difficulty for the company under "best-price". If the company is not paid (or provides a full refund after the fact) for a course of therapy that is ineffective for a given patient, then that price for that dose is $0.00, meaning, the new best price could now effectively be zero dollars.

    - Furthermore, it is essential that these arrangements not undermine beneficiary coverage requirements of the Medicaid Drug Rebate Program, 42 USC 1396(r-8) (Section 1927 of the *Social Security Act*).

    - In addition, there are other pitfalls that exist related to the Anti-Kickback Statute (AKS).[4] "The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully provide something of value with the intent to induce the purchase of items or services payable by a federal health care program."[5] For example, value-based arrangements tied to the performance of a drug can only be effective if adherence can be managed and ensured, as well. Poor medication adherence, or non-adherence, affects patient health by reducing the ability to manage and control diseases effectively. Non-adherent patients are more likely to experience preventable disease progression and other problems arising from poor health, as well as increased hospitalizations, doctor, and emergency room visits. Nevertheless, adherence programs

[2] 42 USC §1396(r-8)
[3] Ibid.
[4] 42 USC §1320a–7b
[5] AMCP Partnership Forum, November 2017

supported by companies to ensure outcome is achieved could be interpreted as a "kickback" under the broadly worded statute. Companies are exposed to potential legal risk under the AKS unless certain safe-harbors are created by the Office of Inspector General (OIG) or by Congress. BIO has urged the OIG to create AKS safe-harbors to allow for flexibility to enter into these types of arrangements both with states and private payers. Nevertheless, until these changes are implemented, companies that enter into these arrangements are doing so at risk. We are we are encouraged by the pending the regulation at the Office of Management and Budget (OMB) that would create a new safe harbor for discounts and value-based arrangements.

Definitions:

Value-based or outcomes-based arrangement— is an agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures.[6]

Pay-over-time arrangement— is an agreement that would allow payers to pay for a course of treatment for a set number of payments over an established period of time, for example, quarterly payments for a year or multi-year.

Indication-based arrangement— is an agreement that allows for payments based upon the drug's value for each indication, because a drug may be approved by the FDA for multiple indications and may have different benefits conferred for each indication.[7]

Subscription-based arrangement— is "an arrangement in which a product is paid for in anticipation of future repeated delivery (such as a newspaper subscription), with the seller providing a use agreement under prearranged terms. . . The subscribed population is identified and provided access for future use of the drug."[8]

[6] Definition developed by the AMCP Partnership Forum, as published in *Journal of Managed Care Pharmacy* (JMCP), November 2017.

[7] Kwon, Sarah, "Indication-Specific Drug Pricing: Simple in Theory, Complex in Reality," *Managed Care Magazine*, May 6, 2018. https://www.managedcaremag.com/archives/2018/5/indication-specific-drug-pricing-simple-theory-complex-reality

[8] Fuller, Robert L, MS and Norbert Goldfield, MD, "Paying for On-Patent Pharmaceuticals: Limit Prices and the Emerging Role of a Pay for Outcomes Approach," *Journal of Ambulatory Care Management,* April 2016.