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By Electronic Delivery

Alex M. Azar II, Secretary
U.S Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Cc: Dan Best, Senior Advisor to the Secretary for Drug Pricing Reform
John O'Brien, Deputy Assistant Secretary, Health Policy

RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Department of Health and Human Services' (HHS' or the Department's) Request for Information on the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (the RFI/Blueprint).¹ BIO strongly supports efforts to help improve patient access to, and the affordability of, the amazing medical breakthroughs that our member companies are developing, and we pledge to work constructively with HHS to achieve this goal.

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. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

BIO members represent the entire biotechnology innovation ecosystem – from universities and research institutes, to start-up biotechnology companies, to the private investors that risk massive amounts of capital to fund these companies, to the larger, established companies that play a critical role in bringing these life-changing innovations through the development and approval process and into the marketplace. Of our approximately 1,000 members, the vast majority of them are small companies engaged in some of the most challenging, cutting-edge research in the world. They typically have no marketed products

¹ 83 Fed. Reg. at 22692 (May 16, 2018).

and no profits, and thus are heavily reliant on private capital to fund their work. They take enormous risks every day to develop the next generation of biomedical breakthroughs for the millions of patients suffering from diseases for which there currently are no effective cures or treatments.

To that end, BIO adamantly advocates for patient access to the most appropriate therapy available, and agrees with the Administration that more can and should be done to lower patients' out-of-pocket (OOP) costs so that patients can access their prescription medicines. We are interested in continuing to actively engaging with the Department to ensure that any changes to the current system meet the Administration's goals of improving competition, supporting better negotiation, and reducing OOP spending for patients without disrupting patient access or hampering future innovation. As the Administration considers these issues, it is important to acknowledge which parts of our system are currently working well, and to look for opportunities to build upon those successes to the benefit of patients, while also spurring innovation.

First and foremost, this is an extraordinary time for biotechnology. The therapies in development and coming to the market are unlike any we have seen in the history of medicine. We have entered into a new era of medicine, and BIO members are making discoveries that were unimaginable a decade ago. The days of traditional chemical drugs that treat broad classes of patients in blunt ways are giving way to the development of entirely new ways to treat and ultimately cure disease for targeted patient populations using living organisms, including a patient's own cells. We have already seen the first wave of these advances reach the marketplace, with many more already in the Food & Drug Administration (FDA) regulatory process.

As noted in the HHS Blueprint,

"The United States is first in the world in biopharmaceutical investment and innovation. Combining our free market system and generous public investment made America home to the first chemotherapy treatments for cancer, the first effective treatments for HIV, the first cure for Hepatitis C, and now, the first therapies that turn our own immune systems against cancer...The American pharmaceutical marketplace is built on innovation and competition."

However, BIO and our members recognize that too many patients – even those with insurance – cannot afford the life-saving cures and treatments that biopharmaceutical companies are developing. We stand with the Trump Administration in our shared commitment to addressing this serious problem. To accomplish this, we must harness – not abandon – the free market that has delivered amazing innovations for patients and made America first in the world in biomedical innovation. That's why BIO has joined with stakeholders across the healthcare spectrum – including insurers, Pharmacy Benefit Managers (PBMs), employers, and patient groups – in a coalition that developed and supports

consensus, market-based reforms to lower drug costs without harming innovation. Through the Council for Affordable Health Coverage (CAHC), BIO and our allies are working to:

- Increase marketplace competition by speeding regulatory approval of more innovative drugs, and promoting greater and faster generic and biosimilar entry once patents and exclusivities for innovator drugs have expired;
- Move towards a drug payment system that is based on value and patient outcomes rather than volume, by removing regulatory and legal barriers that hamper value-based arrangements and communications between innovators and payers;
- Empower patients and providers with more information on formulary coverage, OOP costs, and value to help them make more informed choices; and
- Oppose ideas that would impede innovation like price controls, drug importation, or direct government “negotiation” of drug prices in Medicare.

BIO also actively engages with the Network for Excellence in Health Innovation (NEHI) – a national nonprofit, nonpartisan organization composed of stakeholders from all key sectors of the healthcare system dedicated to advancing innovations that improve health, enhance the quality of healthcare, and achieve greater value for the money spent. NEHI’s research has focused on financing innovation, payment and delivery system reform, and health information technology in an effort to improve value-based care. Delivery and regulatory reforms promoted by NEHI and CAHC are also consistent with the landmark 21st Century Cures Act shepherded through Congress last year on a strongly bipartisan basis, as well as the more recently enacted Food & Drug Administration Reauthorization Act (FDARA). BIO was a strong supporter of both of these pieces of legislation, which we believe will help expedite the delivery of new innovations to patients in need, while also speeding competition among branded medicines and from more generics and biosimilars. We all want to see FDA approve generic drugs as efficiently as possible and for the backlog of generic drug applications to be reduced quickly. More choice and competition are good for patients and the healthcare system overall.

We also believe it is critical to focus on cost and spending across all health care sectors, rather than focusing on any one sector in isolation. With regards to drug spending, the Centers for Medicare & Medicaid Services (CMS) reported that growth in retail prescription drug spending in 2016 was just 1.3 percent, slower than the growth in spending on hospital services (4.7%), physician services (5.4%) and overall health spending (4.3%).² In 2017, drug costs decreased 0.8% for Medicare Part D plans and by 5.4% for Medicaid plans.³ Additionally, commercial members of Prime Therapeutics, the PBM for 20 million Blue Cross Blue Shield patients, actually experienced a 3.4% *reduction* in the unit cost of drugs.⁴

It is also important to recognize where market forces are in place today. Despite some assertions that the average sales price (ASP) is not a competitive model, we would reiterate that ASP includes the discounts and rebates that are negotiated in the commercial

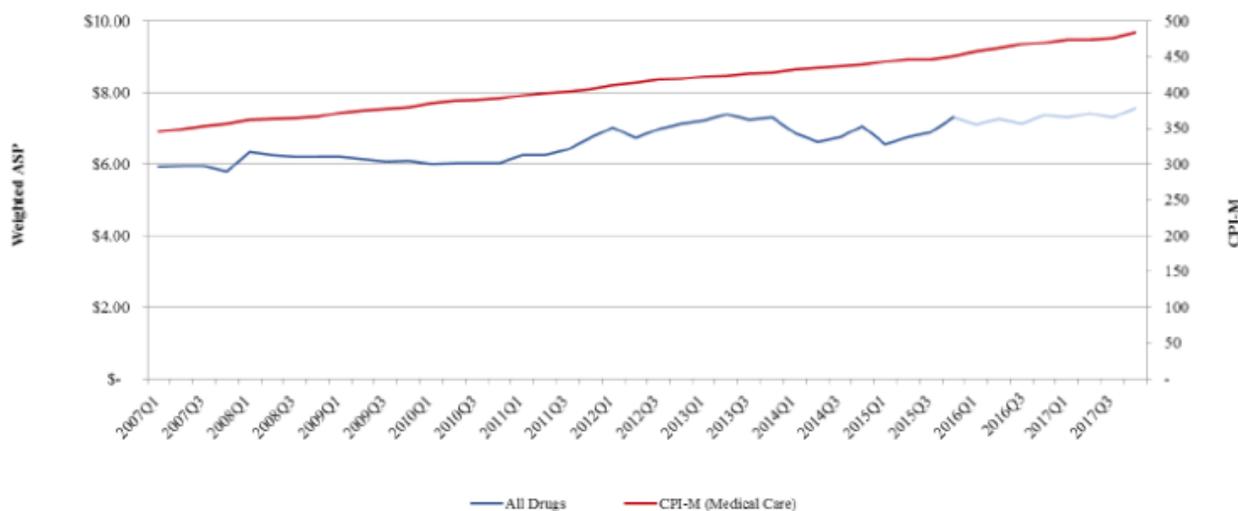
² [CMS National Health Expenditure Data \(Historical\)](#). January 2018.

³ Prime Therapeutics [Spring 2018 Part D Trend Report](#) and [Spring 2018 Medicaid Trend Report](#).

⁴ Prime Therapeutics [Spring 2018 Commercial Trend Report](#).

marketplace, with weighted average ASPs across all of these medicines growing slower than the consumer price index for medical services over the last 10 years (see chart below).⁵ Further, given that Part B medicines are critical to treating patients diagnosed with diseases that require intensive management, such as cancer and autoimmune disorders, any changes to the system under consideration must first determine the impact on beneficiary access to these prescription medications.

Figure 4: Weighted ASP for All Drugs vs. CPI-M



* 2016 and 2017 Weighted ASP numbers are projections.

BIO shares the Administration’s goal of creating solutions that do not disrupt care in the community setting and reduce the associated provider burdens of drug acquisition. To that end, we look forward to working with the Department to develop patient-centric and market-based policies in Medicare Part B that aim to increase competition while preserving patient access to needed medicines. Additionally, we thank the Administration for proposing solutions to reduce beneficiary OOP costs for prescription medicines covered under the Part D program. While costs for the Medicare Part D program have continued to remain below initial estimates,⁶ with robust negotiations,⁷ stability in premiums,⁸ and high overall beneficiary satisfaction for coverage of pharmacy drugs,⁹ we believe continued efforts to improve patient access by lowering OOP costs is important to ensure these program trends continue. BIO strongly supports policies to establish an OOP maximum in the catastrophic

⁵ [Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2007-2017](#). The Moran Company, December 2017.

⁶ [Competition and the Cost of Medicare’s Prescription Drug Program](#). Congressional Budget Office, July 2014.

⁷ [Report to the Congress: Medicare and the Healthcare Delivery System](#), Section “Manufacturers’ Rebates” p. 157-158. MedPAC, June 2015.

⁸ See: Annual Release of Part D National Average Bid Amount and other Part C & D Bid Information. Centers for Medicare and Medicaid Services, 2009-2015. Available at: [2009](#), [2010](#), [2011](#), [2012](#), [2013](#), [2015](#), [2016](#).

⁹ [Survey: Medicare Prescription Drug Benefit Earns High Marks 10 years After Enactment](#). MarketWatch, September 2013.

phase of the Part D benefit, as well as efforts to reduce beneficiary cost-sharing through implementing policies that ensure beneficiaries see the benefit of manufacturer rebates at the point-of-sale.

We applaud the Department for taking a broad overview of the pharmaceutical market in considering changes that can help lower the cost of prescription medicines to patients. The extensive background information provided in the Blueprint and RFI is a helpful tool to elucidate the full range of structural and financial incentives in the biopharmaceutical market. This market is admittedly complex – with many entities operating in diverse market segments, each with their own patient populations, regulations, and unique characteristics. Careful consideration of how any proposed policy changes will shift the incentives in this system will be paramount as the Department explores the proposals contemplated in the RFI. Even with regard to the proposals on which we offer detailed comments below, we strongly recommend that the Department engage in continued dialogue with all stakeholders - seeking additional expert analysis and feedback on the impact and implications of such changes, and consideration of small scale, voluntary pilots – before issuing specific regulatory proposals or engaging in further policy development.

Our members are committed to policies that support a robust and competitive biopharmaceutical market and that enable patients to access all of that market’s innovative and transformational therapies. We believe it is critical for the Department to be transparent about what specific issue each proposal or potential proposal seeks to address (i.e. patient OOP cost, patient access to the most timely and appropriate course of treatment, physician cost or incentives, government savings), and fully considers the impact across all of these areas. To that end, we have developed guiding principles to assess the many questions and potential policy changes posed by the RFI. We also believe the Department should keep these principles top of mind as it considers these and other transformations to our healthcare system. These changes should:

- **Ensure patient access through lower OOP costs and choice of clinically appropriate therapy;**
- **Promote holistic, market-driven solutions; and**
- **Sustain biopharmaceutical innovation.**

Additionally, it is crucial that HHS consider the impacts of these proposals collectively and alongside other transformations currently taking place in the system. First, when taken together, many of these proposals have the potential to confound other proposals’ intended outcomes, and the Department must consider how to achieve the stated goals above without creating unintended consequences by implementing conflicting policies. Second, current shifts are underway with an increased emphasis on quality and patient outcomes through the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs), as well as other innovations being driven by the Center for Medicare & Medicaid

Innovation (CMMI). The potential interruptions to these delivery innovations by any new policies must be considered as well.

Below please find our detailed feedback on items of key priority to BIO and our members contained in the RFI. We look forward to additional dialogue with the Department as it works to meet the goals outlined in the Administration's Blueprint.

I. Preserving Timely and Appropriate Patient Access to Physician Administered Drugs

As the Department is aware, the Medicare Part B program covers drugs that require special handling and delivery, and typically require administration under a physician's care and supervision (e.g., intravenous infusions, intraocular injections). These therapies, which are often biologic products, are delivered directly to physicians who then administer them to patients and bill Medicare for the care of some of the program's most vulnerable beneficiaries. Patient OOP cost-sharing is capped at 20%, with many beneficiaries paying much less as a result of their enrollment in Medigap plans or additional retiree benefits.¹⁰ Additionally, in 2019, Medicare Advantage enrollment will total approximately 22 million,¹¹ or 39.5 percent of all Medicare beneficiaries enrolled in Parts A and B. These beneficiaries are protected by an annual limit on their maximum OOP spending on medical services.

In the Part B program, prescription drug spending represents less than 10% of the total spending in the benefit and less than 4% of Medicare spending overall.¹² The ASP-based reimbursement structure used in Part B has the benefit of leveraging private market negotiations, keeping program spending below medical inflation over the last 10 years.¹³ The ASP formula factors in rebates and discounts negotiated for these drugs in the commercial marketplace.

Given the vulnerability of the patients served by these therapies, the types of community providers administering these medicines, and the delivery and handling requirements associated with them, it is critical that the introduction of new models or pathways for delivery and reimbursement of these therapies does not hinder patient access or unduly burden providers. Changes that shift patient site of care can have significant impacts for patient health outcomes and increase overall healthcare expenditures.

As the Administration assesses potential policy proposals to alter the current coverage and reimbursement structure under Part B, an analysis of the range of implications – both positive and negative— is necessary to determine the impact on patients and providers. Any

¹⁰ [Medigap Enrollment and Consumer Protections Vary Across States](#). Kaiser Family Foundation, July 2018.

¹¹ [FY 2019 Budget in Brief](#). U.S. Department of Health and Human Services, February 2018.

¹² See: [MedPAC June 2016 Data Book; Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2006-2015](#), \$25.7 billion on prescription drugs covered under Part B; [2016 Annual Medicare Trustees Report](#), \$279 billion total Part B spending.

¹³ [Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2007-2017](#). The Moran Company, December 2017.

new policy must be patient-centric, market-based, and deliver a tangible benefit to patients, including by lowering OOP costs without negatively impacting the providers' ability to deliver care in the most appropriate setting as determined by the patient and provider.

a. The movement of drugs between Parts B and D of the benefit structure, or introduction of the tools used in Part D into Part B, can increase patient out-of-pocket costs and presents complex operational challenges.

BIO strongly urges the Department to cease movement on proposals to shift drugs currently covered under the Part B program to the Part D program. Such a change would create serious instability for patients – both through increased OOP costs and hurdles in having the drug delivered in the appropriate site of care - with little overall savings.¹⁴ There are significant complexities associated with transitioning any drugs from Part B to Part D, particularly when considered alongside the other proposals the Administration has made for modifications to the Part D program, explored further in the next section of this letter.

First and foremost, from the patient perspective, assessing the associated OOP cost of drugs delivered under Part B versus under Part D varies significantly due to a number of factors.¹⁵ These include the mix of drugs used by a beneficiary, the beneficiary's income level, whether the beneficiary has any Part D coverage or additional supplemental coverage for Part B, coupled with the drug price and how the beneficiary's respective Part B drugs might be placed in the cost structure of a Part D plan formulary. In addition to concerns regarding the impact on OOP costs, we are concerned that the effect on premiums remains unclear. It is likely premiums will increase for Part D plans due to the shift of large subsets of new drugs, without substantially reducing beneficiary premiums for supplemental (i.e. Medigap) coverage in Part B.

First, it is critical to note that not all Medicare beneficiaries are enrolled in coverage through the Part D program. Roughly, 71% of beneficiaries are enrolled in Part D plans.¹⁶ Further, analysis conducted by the Moran Company demonstrates that of the 12.41 million beneficiaries currently using Part B drugs, approximately 70% could be worse off if drugs moved from Part B to Part D.¹⁷ More than 5.8 million beneficiaries currently using Part B drugs will definitely face higher OOP costs if their Part B drugs are moved into Part D.^{18,19} An additional 2.96 million beneficiaries could face higher OOP costs based on the likely placement of their Part B drugs on the specialty tier in Part D, facing up to 33% coinsurance, unless their drug spending is high enough to benefit from catastrophic

¹⁴ [Estimating the Effects of Consolidating Drugs Under Part D or Part B](#). Acumen, LLC, September 2011.

¹⁵ [Press Release: Avalere Analysis Highlights the Complexities of Transitioning Medicare Part B Drugs to Part D](#). May, 2018.

¹⁶ [Medicare Part D in 2016 and Trends over Time](#). Kaiser Family Foundation, September 2016.

¹⁷ [Moving Part B Drugs to Part D: Policy and Analytic Considerations](#). The Moran Company, July 2018.

¹⁸ *Id.*

¹⁹ This represents nearly 10% of Medicare beneficiaries based on Kaiser Family Foundation numbers noting that there are 59 million people on Medicare. See: [The Medicare Prescription Drug Benefit](#). Kaiser Family Foundation, October 2017.

coverage.²⁰ Overall, only an estimated 650,000 beneficiaries currently using Part B drugs would clearly benefit from a policy that moves Part B drugs to Part D, due to the fact that they are low income subsidy beneficiaries who do not qualify as dual eligibles.²¹

In addition to concerns around OOP cost increases, there are a number of potential barriers that may negatively impact timely access to the most appropriate course of treatment for a patient's health condition. As detailed above, medicines delivered under Part B are generally specialty biologic products, for which there may not be approved alternatives. Even in instances where more than one product exists in a category or class, it is important that patients and their providers have the flexibility to choose which product is the best course of treatment given a patient's condition, including comorbidities or other disease state considerations. For this reason, BIO has serious concerns about how the Department is proposing to further manage these medicines.

Patients may face scenarios where the most appropriate drug for their course of treatment is either placed in a high-cost formulary tier or is unavailable on the formulary at all, for those not in a protected class. This situation could have the effect of increasing patient cost-sharing, or contributing to negative health outcomes that lead to additional costs due to the need for other healthcare interventions. BIO believes that the use of formularies in the context of Part B drugs can have serious negative consequences for a patient's ability to access the most clinically preferred treatment for his/her given condition.

Second, many of these specialty biologics require specific storage and handling (e.g., cold chain) in addition to healthcare provider supervision during delivery, and therefore are generally delivered in the physician office setting. If these drugs were shifted into the Part D benefit, it is unclear how they would continue to be distributed and billed – Would retail pharmacies be tasked with distributing these products to patients? Would providers have to bill the Part D program? Would specialty pharmacies have to rapidly expand their services to fill the role? Would patients have to obtain their own medicines at the pharmacy and bring them to the physician's office at their appointment? All of these scenarios present serious challenges and concerns for getting critical medicines to patients in a timely and safe manner.

Allowing patients to pick-up Part B products from the pharmacy and bring them to their physician's office or site of care for administration ("brown bagging") introduces the significant possibility of improper storage, negatively impacting the safety and efficacy of the medicine, also adding a layer of inconvenience for some of Medicare's sickest and most vulnerable patients. While specialty pharmacies (SPs) are already equipped to manage these products, there are potential patient safety risks for drug acquisition via "white bagging", where medicines are ordered on a per patient basis rather than stocked by the physician office as they are today. Further, SPs would need to expand their capabilities to

²⁰ Unless drug price decreases are significantly large enough to offset the higher specialty tier costs, or beneficiary drug spending is high enough to move them into catastrophic coverage in Part D.

²¹ These are beneficiaries who use Part B drugs who do not currently purchase a Medigap or ESI plan but do receive LIS subsidies, but are not dually eligible.

take on this role, and Part D plans and providers who do not have existing relationships with SPs would need to build them for drug acquisition and reimbursement.

For providers to continue to receive and deliver products through Part D that were previously under Part B, some would require new mechanisms and processes to be incorporated into the healthcare delivery chain. Today, physicians acquire Part B products and bill Medicare directly and are reimbursed for associated handling and delivery of these products through the ASP add-on. Changing the reimbursement structure for movement of Part B products to Part D eliminates this associated payment. Without sufficient payment to providers for delivery and storage of these products, patient access to critical prescription medicines could be at risk. Further, physician practices and hospital systems work today with group purchasing organizations or wholesalers to acquire drugs delivered under Part B. New capabilities would likely need to be introduced to allow Part D plan sponsors to interact with these entities and the ability of physicians to appropriately bill the Part D program for beneficiary care would need to be incorporated into the administrative workflow. The introduction of any of these required new processes for the acquisition and delivery of Part B drugs shifted into Part D, coupled with the potential associated OOP cost increases, could cause serious confusion and potential delays in or abandonment of care for Medicare beneficiaries.

A real time example of the challenges of moving Part B drugs to Part D is the existing coverage structure for preventative vaccines in the Medicare program, which was recently analyzed by Avalere.²² Currently, some vaccines are covered under Part B with others covered in Part D, and uptake of Part D vaccines falls behind that of Part B vaccines. While there are many factors contributing to low adult immunization rates, financial barriers stand out as one of the most impactful and avoidable barriers to prevention. Vaccine coverage under Medicare is a patchwork, and Medicare beneficiaries often face some of the highest vaccine OOP costs. Like coverage under commercial insurance plans, Medicare Part B provides first-dollar coverage for influenza and pneumococcal vaccines, as well as for Hepatitis B vaccine for high-risk patients. All other vaccines, including Tdap and shingles vaccines, are covered under the optional Part D program. Since there are no vaccine cost-sharing limits for Part D plans, patient OOP costs are often high.

Research shows that, similar to other medications, higher patient OOP costs for vaccines lead to a lower chance of vaccination. An Avalere study evaluated the relationship between vaccine co-pays in Part D patients and Tdap and Zoster vaccination claims in their doctor's office. The results showed that, compared with no co-pay, patients who had to pay a co-pay amount of \$26–50, \$51–75, or \$76–100, respectively, are 1.39, 1.66, or 2.07 times as likely to cancel their zoster vaccination.²³ Another recent study found that patient OOP cost is one of the most significant predictors of vaccine abandonment, after adjusting for other factors.²⁴

²² [Shifting Drugs from Medicare Part B to Part D: Learnings from Medicare Coverage of Vaccines](#). Avalere, June 2018.

²³ [Adult Vaccine Coverage in Medicare Part D Plans](#). Avalere, February 2016.

²⁴ [Factors Associated with Zostavax Abandonment](#). August 2016.

In addition, Part D vaccines are not routinely stored – as Part B vaccines are – in physician’s offices and even some pharmacies, due to the associated administrative burden and inability of providers to bill Part D. CMS has issued guidance on potential workaround options, but these have been insufficient in impacting meaningful uptake of Part D vaccines.²⁵ Further, physician inability to verify beneficiary coverage and cost-sharing liability under the Part D benefit has proven a barrier, with more than half of providers who prescribe Part D vaccines to beneficiaries referring them to the pharmacy for purchase.²⁶

Due to the wide range of concerns—including patient access to the most clinically appropriate therapy, increased OOP costs, and challenges and uncertainties regarding drug acquisition and delivery—BIO strongly urges the Department against moving forward with a policy that would shift drugs from Part B to Part D, or otherwise increase drug management similarities between the two distinct benefit structures.

b. If not carefully designed, proposals to create new methods of delivering Part B drugs can impede patient access to the highest standard of treatment for their given condition and create additional financial or administrative barriers for physicians providing care to these vulnerable beneficiaries.

The RFI discusses leveraging the Competitive Acquisition Program (CAP) or similar authority to support better negotiation and provide new opportunities for physicians who do not wish to bear the financial burdens or risk associated with drug acquisition. While BIO supports the goal of creating solutions that allow community physicians to continue to practice and reduces the associated burdens of drug acquisition, we have serious concerns about disruptions to the buy-and-bill marketplace in the form of reinvigorating CAP or introducing negotiating tools mentioned into the Part B system.

First, we note the previous inability of the CAP structure to effectively work for providers, vendors, and patients, or to produce the desired savings and outcomes.²⁷ In its original iteration, the program failed to attract and maintain sufficient participation from both vendors and providers, and payment amounts for drugs were higher than under the standard ASP-based reimbursement structure.²⁸ For these reasons, BIO does not believe that reinvigorating the original CAP program will advance the Administration’s goals and are concerned that such an action would significantly hinder patient access while simultaneously increasing the administrative burden for providers. However, we would like to work with the Department on the development of alternative approaches – potentially utilizing existing statutory authority under CAP – that would increase competition in Part B while preserving patient access.

²⁵ [Shifting Drugs from Medicare Part B to Part D: Learnings from Medicare Coverage of Vaccines](#). Avalere, June 2018.

²⁶ *Id.*

²⁷ [Evaluation of the Competitive Acquisition Program for Part B Drugs, Final Report](#). Centers for Medicare and Medicaid Services, Office of Research, Development, and Information, December 2009.

²⁸ *Id.*

Fundamentally, we believe that the use of formularies and other utilization management tools to drive better negotiation is highly problematic and inappropriate for drugs administered through the Part B program. As detailed above, these are generally complex treatments for the most serious of health conditions. These products interact dynamically with patients' immune systems, which means that an individual patient can fare better or worse on a treatment (in terms of efficacy and side effect profile): one size does not fit all. It is imperative that patients have the ability to work with their providers to refine their treatment regimen, maximizing individual patient health benefits. BIO is concerned that these proposed tools may have the effect of forcing inappropriate treatment choices, therefore affecting health outcomes. Even with substantive patient protections – i.e., appeals and exceptions processes, minimum formulary standards, formulary transparency, emergency fill requirements, or “grandfathering” of established treatment regimens – patients can and will experience serious care delays which could have significant negative health outcomes for patients.

Further, these tools result in additional burdens for physicians who are working to deliver timely and appropriate treatment to the patients they serve. Such tools will require additional care management and administrative work for physicians. If a new means of drug acquisition in the Part B program is introduced, physicians will face additional requirements, such as: management of medical documentation and reporting processes; establishment of new health information technology systems and protocols; management of dual or segregated drug inventories for Medicare and non-Medicare populations; and the implementation of prior authorizations and exceptions requests (dependent upon program parameters). These are of particular concern as the healthcare delivery system is already working on transformations in care focusing on quality, patient-centric care through MIPS and APMs. All of these things take away from the provider's primary role – to deliver the best care possible for their patients.

We believe that HHS must ensure that any new proposals for healthcare delivery carefully balance appropriate patient access with workability for providers. BIO strongly urges the Department against the use of a structure that introduces significant uncertainty for patients and their providers by potentially delaying access to the most appropriate form of treatment and to weigh additional proposals accordingly against these considerations. As the Department considers alternatives to the current system, we encourage HHS to continue dialogue with relevant stakeholders across the healthcare spectrum on workable solutions, and we reiterate the need for proposed changes to be voluntary and ensure appropriate and sufficient payment for those involved in the delivery of these important drugs and biologicals to patients.

- c. The proposal to implement an inflation cap on ASP would destabilize patient access to community care where volume-weighted ASP has remained below medical inflation.***

BIO has significant concerns about the implementation of an inflation limit for Part B drugs as detailed in the Administration's FY 2019 Budget and reiterated in this RFI. This policy is an unnecessary price control in the healthcare marketplace, where the current payment calculation reflects the true costs to providers in the market by accounting for the average price of a drug's sale to all commercial US purchasers, including: volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, and chargebacks and rebates (exclusive of Medicaid).

Changes in reimbursement levels for the therapies delivered through the Part B program are not analogous to updates to pricing in other sectors of the healthcare market, and market competition contributes to the overall stability of volume-weighted ASP.²⁹ Policies aimed at putting the patient first should, prioritize patient access to care in the most appropriate and preferred site of treatment. An inflation cap can create a situation where providers are purchasing drugs above ASP and then not being reimbursed to sufficiently cover acquisition cost and the associated delivery and handling of the product. Such pressures on reimbursement can force community physicians to shift care to the hospital outpatient department, which can be more costly based on additional care and services delivered; and can create convenience and access issues if patients are forced to travel outside of their community to receive care.³⁰ For these reasons, BIO urges the Department not to move forward with such a proposal.

II. Continuing Successful Delivery of Pharmacy Drugs through the Medicare Part D Prescription Drug Benefit

The successes of the Medicare Part D program continue to be well-documented: costs have remained well below initial estimates, average beneficiary premiums have remained relatively stable, the benefit structure has fostered robust negotiations, and beneficiary satisfaction with their prescription drug coverage has remained high. BIO believes that any change to the Medicare Part D program should prioritize reductions in patient OOP costs and enhancements in patient access to and choice in treatments delivered through the Part D program.

The Administration's Budget and the RFI make reference to the "Five Part Plan for Part D" which detail several proposals. Some of the included policies could have positive impacts for beneficiaries by reducing their OOP costs, but others could have serious negative implications by jeopardizing patient treatment choice while increasing overall spending on the benefit. BIO supports efforts that will have the effect of reducing beneficiary OOP costs, but has strong concerns where some proposals may impede access or lead to increased

²⁹ [Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2007-2017](#). The Moran Company, December 2017.

³⁰ A study in the Journal of Clinical Oncology found that "many practices pay prices above ASP+6% reimbursement for key products" and concluded that economic strain and inadequate reimbursement can limit patient access when practices are forced to go out of business. Favret, U. B., W. M. Jordan, M. S. Krichof, M. E. Neltner, and D. A. Chudzik. 2008. An examination of oncology drug purchasing compared to average sales price [Abstract]. *Journal of Clinical Oncology* ASCO Annual Meeting Proceedings (Post-Meeting Edition) 26(15S; May 20 Supplement): 20500.

beneficiary spending over time. While we acknowledge that the Administration notes the “Five Part Plan for Part D” is intended to be implemented together, we support implementation of some of its elements, but share significant concerns with others. We discuss each of these in turn below.

a. Establishing an out-of-pocket maximum in the Medicare Part D catastrophic phase will help reduce annual spending for vulnerable beneficiaries.

BIO strongly supports establishing an OOP maximum in the catastrophic phase as it helps reduce patient annual cost-sharing burden and create greater predictability for Medicare beneficiaries. From 2013 to 2016, OOP costs for beneficiaries in the Part D program have grown 13%.³¹ In 2015, 3.6 million (9%) Medicare Part D beneficiaries had total drug spending above the catastrophic coverage threshold.³² One million of these enrollees did not receive additional subsidies to assist with their OOP costs and spent six times more OOP than the average enrollee with low-income subsidies.³³

A cap on OOP spending would directly benefit these Medicare beneficiaries, helping to alleviate significant burden and cost exposure for beneficiaries that are likely to continue to have high healthcare needs. A recent analysis found that “a cap for all Part D enrollees in 2015 would have raised monthly premiums by only \$0.40 - \$1.31 per member.”³⁴ Further, the use of such a cap mirrors the commercial market where a maximum exists for co-payments and co-insurance that includes prescription drug spending.³⁵ However, the establishment of an OOP cap should be delinked from the idea in the President’s Budget to invert plan liability in the catastrophic phase as a shifting in plan liability could lead to increased restrictions on access and coverage by plans.

The establishment of an OOP maximum can serve as a basis for implementation of additional policies that help reduce what patients pay OOP for their healthcare. An OOP cap is critical to addressing affordability for patients, but further steps should be taken to address that the majority of costs are clustered early in the benefit year for patients using certain medications. Such additional steps include considering how to smooth cost-sharing throughout the year to further increase consistency and predictability for patients.

b. Beneficiaries should pay lower prices at the pharmacy counter based on the robust negotiations occurring in Part D.

A second element of the proposal that seeks to address high beneficiary cost-sharing is requiring plans to share all or a minimum portion of Part D rebates at the point-of-sale

³¹ [Press Release: More Medicare Part D Enrollees Are Reaching Catastrophic Coverage](#). Avalere, May 2018.

³² [No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending](#). Kaiser Family Foundation, November 2017.

³³ *Id.*

³⁴ [Growing Number of Unsubsidized Part D Beneficiaries with Catastrophic Spending Suggests Need for an Out-of-Pocket Cap](#). Health Affairs. Vol 37, No 7: Chronic Care, Prescription Drugs & More. July 2018.

³⁵ [Definition: Out-of-pocket maximum/limit](#). Healthcare.gov.

(POS). As previously expressed in our comments in response to the FY 2019 Part D Proposed Rule, BIO is supportive of efforts to reduce Medicare beneficiary cost burden at the pharmacy counter through implementation of policies that ensure beneficiaries see the benefit of manufacturer rebates at the POS.

We are again encouraged by the mention of this policy in the most recent RFI. It is BIO's longstanding position that patients should see direct benefit from the rebates negotiated by health plans and PBMs in the form of reduced cost-sharing. Numerous studies have shown that patient cost-sharing is an important factor in medication adherence, with patients less adherent when their cost-sharing requirements increase. One study that specifically looked at patient adherence to diabetes medications found that a \$10 increase in the patient cost-sharing index resulted in a reduction in adherence between 5.4 and 6.2 percent.³⁶ Nonadherence is associated with poorer health outcomes and higher overall healthcare expenditures, with a recent estimate of \$100 billion in annual avoidable nonadherence costs in the United States.³⁷ Reducing patient cost-sharing not only benefits the beneficiary by increasing access, but also decreases overall costs to the healthcare system by improving health outcomes through increased medication adherence.

As we stated before in previous comments, we urge the Department to carefully consider all potential impacts of any methodology intended to share rebate savings with patients. Such a policy could have different effects on different beneficiaries—including an increase in premiums—based on a number of unique and specific circumstances. Further, it may be beneficial for a policy of this nature to be implemented through a phased, stepwise approach to inform future policymaking and the impact on plan design, contracting, formulary coverage, and premiums. This could help ensure that beneficiary access and satisfaction are not negatively impacted. In addition, any methodology should maintain manufacturer pricing confidentiality, as it is a critical element in maintaining the competitive nature of the Part D program—whereby robust negotiations between entities help bring costs down for beneficiaries. Protecting the proprietary nature of rebate information is vital to ensuring pharmaceutical manufacturers and pharmacies/PBMs are able to engage in rigorous negotiation to bring down costs and drive competition in the Part D marketplace while helping to ensure that patients benefit from a policy that passes on rebates at the POS. BIO encourages the Department to consider and work with stakeholders on possible routes for implementation of such a policy, while maintaining the competitive nature and confidentiality of rebates in the Part D program.

Additionally, the Department poses many questions in the RFI related to reducing the impact of rebates provided by manufacturers. In testimony before Congress and in public remarks on the Administration's Blueprint, the Administration has also opined on a system in which rebates are eliminated entirely. Whether implemented only partially or in one market, or implemented market-wide through legislation, such a change would alter the

³⁶ Gibson TB, Song X, Alemayehu B, Wang SS, Waddell JL, Bouchard JR, Forma F. Cost sharing, adherence, and health outcomes in patients with diabetes. *Am J Manag Care*. 2010;16(8):589-600.

³⁷ Sacks N, Burgess J, Cabral H, McDonnell M, Pizer S. The effects of cost sharing on adherence to medications prescribed for concurrent use: do definitions matter? *J Manag Care Spec Pharm*. 2015;21(8):678-87.

fundamentals of the pharmaceutical supply chain. It would also take a substantial amount of time – potentially years – to implement entirely. When discussed at such a high level, it is impossible to fully appreciate the ripple effects of how eliminating rebates would impact both the biopharmaceutical marketplace – including innovation in that marketplace – and patients’ ability to afford their medicines. BIO urges the Department to carefully analyze the entirety of system changes that may occur from such a potentially transformational change in order to avoid harmful unintended consequences.

c. The introduction of potential formulary flexibility and changes to the protected classes creates significant uncertainty for Medicare beneficiaries.

The RFI refers to allowing for increased flexibility to manage drug costs including within the six protected classes. BIO has serious concerns with any proposal to allow Part D plans to make adjustments within the protected classes and to reduce the number of drugs required in each category and class, as these can have serious implications for patient choice, access and outcomes.

The protected classes were established at the outset of the Part D program, because “it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be discouraged from enrolling in certain PDPs, as well as to mitigate risks and complications associated with an interruption of therapy for vulnerable populations.”³⁸ These protected classes were codified by Congress in 2008 and reaffirmed in the Affordable Care Act,³⁹ and are linked to the non-discrimination requirements under the Part D program. BIO firmly believes that the protected classes continue to provide necessary and significant benefit in avoiding disruptions or delays in access to treatment for some of Medicare’s most vulnerable patients.

For the disease states covered in the protected classes, such as cancer, HIV/AIDS, depression, schizophrenia, and organ transplant recipients, it is critical that patients and their physicians have the ability to make treatment modifications based on associated co-morbidities or changes in clinical treatment needs. We believe that further managing these classes, solely for the ability of PDPs to secure lower negotiated prices, has the potential to create serious hurdles and barriers to access and is inconsistent. Further, Part D plans already have the ability to manage the protected classes. Studies have demonstrated that these classes of drugs benefit from significant generic use,⁴⁰ and have more utilization management tools applied to them by Part D prescription drug plans than they do in the commercial health insurance market.⁴¹

³⁸ CMS, Pub. 100-18 – Medicare Prescription Drug Benefit Manual, Ch. 6 § 30.2.5.

³⁹ Pub. L. No 110–275, 122 Stat. 2581 (July 15, 2008); Pub. L. No. 111-148, 124 Stat. 471 (March 23, 2010).

⁴⁰ [Policy Proposal: Revising Medicare’s Protected Classes Policy](#). The Pew Charitable Trusts, March 2018.

⁴¹ [An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans](#). Avalere, June 2013.

d. The proposal to limit the number of required covered drugs in each category and class from two to one is harmful to patient access.

Additionally, the proposal to limit the number of required covered drugs in each category and class from two to one has the effect of forcing a patient onto a less clinically preferable treatment even when better alternatives exist. As noted above, the Medicare Part D program already benefits from robust negotiations for drug placement on plan formularies. However, patients are not benefiting from lower OOP costs at the pharmacy counter from the savings received by plans through these negotiations. Further narrowing the class requirements can leave patients without alternative options should the single treatment covered not be preferable for their care. Beneficiaries would then be required to go through additional hurdles of appeals and exceptions to seek alternative options. These administrative hurdles simply delay patient access to the best treatment option for their disease or condition which can potentially lead to adverse reactions and complications.

BIO urges the Department not to move forward with these proposals that limit beneficiary choice both for the incredibly vulnerable patients who receive medications included in the protected classes, and more broadly across the benefit by reducing the number of drugs required to be covered in each category and class.

e. Helping reduce patient out-of-pocket costs at the pharmacy counter by addressing “gag clauses”

BIO supports the Department’s efforts to help lower patient OOP costs through the elimination of “gag clauses” included in PBM contracts, prohibiting pharmacies from telling patients when they can pay lower cost-sharing for drugs if not purchased under their insurance plan. We believe that such efforts can help patients be better informed about their healthcare and overall costs, and appreciate the letter sent from the Centers for Medicare & Medicaid Administrator to all Part D plan sponsors regarding these contracting practices.⁴²

f. Discounts provided by manufacturers in the coverage gap should continue to count toward beneficiary true out-of-pocket costs (TrOOP), and changes to the reinsurance structure of the catastrophic benefit should not be introduced.

The component of the five part plan to exclude manufacturer discounts from a beneficiary’s TrOOP is inappropriate as it would increase costs for patients, at a time when they are already experiencing higher costs. When proposed by the Medicare Payment Advisory Commission (MedPAC) in 2016, Avalere estimated that exclusion of manufacturer discounts from the TrOOP calculation would increase beneficiary OOP costs by \$5.1 billion between 2017 and 2021.⁴³ This would impact 1.1 million Part D enrollees who would experience an

⁴² [Letter from Administrator Seema Verma to All Part D Plan Sponsors RE: Unacceptable Pharmacy Gag Clauses](#), May 2018.

⁴³ [Assessing the Impact of MedPAC’s Proposed Part D Reforms to Modify Beneficiary Cost Sharing](#). Avalere, September 2016.

average increase of \$1,000 per year in OOP spending.⁴⁴ We believe that policies to impact financing and spending in the Part D program should not be made on the backs of beneficiaries, subjecting them to higher costs. BIO strongly discourages the implementation of such a policy.

g. Eliminating generic cost-sharing for low income subsidy (LIS) beneficiaries

BIO commends the Department's efforts to reduce beneficiary out-of-pocket costs, however, as detailed in our comments on the "Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program Proposed Rule",⁴⁵ we have concerns where policy changes for LIS beneficiaries may lead to inappropriate product switching, or categorization of certain biological products as "generics" for purposes of cost-sharing.⁴⁶ We refer HHS to our previous comments in order to ensure that changes within the benefit structure consider both OOP costs and patient access to the most appropriate form of treatment.⁴⁷

h. Additional restructuring of the catastrophic phase of the Part D benefit

In addition to the other changes mentioned above, BIO has concerns around discussion to changes in plan liability in the catastrophic phase of the Part D benefit. Restructuring the liability in the catastrophic phase to shift the majority of responsibility to plans is likely to lead to significant restrictions on beneficiary access to needed drugs, potentially leading to discrimination against sicker beneficiaries. Plans already use stringent utilization management techniques to restrict access, as seen by use of multiple tiered formularies with progressively higher cost-sharing imposed on beneficiaries. This idea to shift plan liability could exacerbate the problem, leading to higher nonadherence rates which ultimately increases federal health care costs.

III. Transforming to Value-Driven, Patient-Centric Care and Treatment

BIO thanks the Administration for exploring the use of Value-based Arrangements (VBAs) and the regulatory changes necessary to increase their uptake and execution. BIO's member companies are innovative organizations committed to developing novel treatments

⁴⁴ *Id.*

⁴⁵ See: BIO Comments RE: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program. January 16, 2018.

⁴⁶ In the Proposed Rule, CMS proposed treating follow-on biological products as generics for non-LIS catastrophic and LIS cost-sharing. BIO noted that by definition these products are not generic and such changes in the benefit structure could be replicated in treatment of patients, with potential serious negative consequences.

⁴⁷ See: BIO Comments RE: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program. January 16, 2018.

and cures for patients in all disease states. As we work to increase patient access to these therapies, we appreciate HHS' efforts to modernize the healthcare system and regulatory environment to meet this goal. The federal government has stated its intent to shift towards a more value-driven healthcare system and we support that aim. BIO believes that the expansion of VBAs between manufacturers and payers can play a role in achieving that goal.

The economics of both private and government payer reimbursement are increasingly aligned with VBAs (e.g., readmission penalties, shared savings). However, the misalignment between the government's stated policy goals (e.g., to pay for performance) and the underlying regulatory environment creates regulatory uncertainty for manufacturers exploring VBAs. In order to address these barriers, regulations, guidance, and safe harbors need to be updated to account for these market dynamics, and to obtain greater alignment with the government's policy aims.

BIO remains focused on creating a safe and predictable regulatory environment to enable manufacturers and health plans to experiment with VBAs, in particular with respect to government price reporting (GP) and Anti-Kickback Statute (AKS) considerations. A variety of stakeholders, including payers, biopharmaceutical companies, and pharmacy benefit managers, have acknowledged GP requirements and the AKS as some of the major regulatory impediments to successfully implementing a VBA.^{48,49} Average Manufacturer Price (AMP), Best Price (BP), and ASP are designed to capture pricing at a quarterly per-unit level – the “traditional” pricing approach prevalent when these benchmarks were created (which remains the standard approach today). Determination of the Medicaid drug rebate amount, including determination of AMP and BP, requires: a price per unit, such as per pill, per milligram, or per vial (i.e., a “unit” rebate amount); measured by quarter and by customer; finalized within 12 quarters of when originally due (30 days after quarter ends). However, many VBAs reject per-unit prices, and instead are population-, indication-, or course-of-therapy-based. As such, applying unit-based price reporting rules to novel arrangements like outcome-oriented contracts or indication-specific pricing likely will result in the reported data having unintended consequences that disincentive the use of VBAs.

This consideration is particularly relevant for BP, which can be set by a single transaction. Evaluating a VBA for BP purposes using a per-unit approach may generate a BP figure that does not accurately reflect the pricing of the overall arrangement. In order to facilitate uptake of these arrangements, pricing structures included in VBAs should be carved-out from the traditional government pricing reporting requirements, such as BP, or alternative methodologies should be explored.⁵⁰ Excluding price concessions offered under a VBA from

⁴⁸ [Regulatory Barriers Impair Alignment of Biopharmaceutical Price and Value](#). National Pharmaceutical Council, 2018.

⁴⁹ [Reward Results: Moving Forward on Value-based Contracting for Biopharmaceuticals](#). Network for Excellence in Health Innovation, March 2017.

⁵⁰ For instance, Section 1927(c)(1)(A) of the Social Security Act (The Best Price Provisions) could be updated to specifically exclude any prices chartered under a VBA. Were such a change to be made, then, we would propose to work with the Administration on a specific statutory definition of Value Based Arrangement that could be included as (iv) in Section 1927(c)(1)(C) of the SSA.

statutory price reporting would decrease the existing disincentives for manufacturers to engage in these arrangements, including with private payers operating Managed Medicaid and Medicare Advantage plans, which could lead to cost savings for CMS and public payer beneficiaries. Additionally, we urge the Administration to utilize a transparent and inclusive guidance and/or rulemaking process to explore alternative methodologies to current pricing requirements and regulations that do not inhibit the use of VBAs. BIO looks forward to working with HHS to achieve this goal.

In addition to government price reporting considerations, the AKS raises significant concerns and uncertainties for manufacturers interested in exploring VBAs. In order to account for the shift of the U.S. healthcare market over the last two decades toward the development and adoption of VBAs for the purchase of biopharmaceutical therapies, there is a need for the Office of Inspector General (OIG) to modernize its safe harbor provisions. As BIO has stated in letters to HHS previously, the OIG should develop new safe harbors specific to certain services often incorporated into VBAs (e.g., data analytics, adherence support). As manufacturers take on more risk, these types of solutions or services become more important elements in helping achieve specified clinical outcomes. However, with respect to federal healthcare programs, the current safe harbor regulations and OIG's guidance to date have created uncertainty over whether certain VBAs can be clearly protected under the existing safe harbors to the AKS. Modernizing the AKS safe harbors to address the shift to a value-based purchasing regime will help promote the adoption of VBAs for biopharmaceuticals that could improve health outcomes and reduce costs to Federal healthcare programs – both criteria for modifying and establishing safe harbor provisions.⁵¹ To that end, we implore HHS to create safe harbors and waivers for BP reporting requirements, as well as the AKS statute, to decrease uncertainty and increase the uptake of innovative payment models, including VBAs.⁵²

Another regulatory barrier that has negatively impacted manufacturers' ability to effectively engage with payers on VBAs has been FDA rules governing manufacturer product communications with healthcare providers and payers. Economic evidence and real-world outcomes that are not included in product labeling would be valuable endpoints for VBAs, and allowing manufacturers to discuss this evidence is critical to increase the effectiveness of such arrangements. FDA has recently made important advances in this area by finalizing its Drug and Device Manufacturers Communications with Payors, Formulary Committees, and Similar entities Guidance.⁵³ We appreciate the efforts made to date to increase communications between industry and payers through the implementation of this guidance. Additionally, we urge HHS to continue to work to allow open and free communication

⁵¹ 80 Fed. Reg. at 79,805.

⁵² We note that whole-scale reform to formally recognize VBAs would also likely require an exception to the Physician Self-Referral Statute at 1877(h)(1) in order to permit more value flexibility in arrangements set forth between physicians and health care practices, hospitals, and the like. Again, we would be interested in exploring the specific details of these updates with the Administration as this process unfolds.

⁵³ [Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Questions and Answers](#). U.S. Department of Health and Human Services, Food and Drug Administration, June 2018.

between parties interested in developing novel payment arrangements that increase patient access to needed therapies and treatments.

Modernizing the current regulatory environment to decrease uncertainty for payers and manufacturers to enter into VBAs can provide alternative reimbursement mechanisms for both existing and new medicines. Further, CAHC – of which BIO is a member – has estimated that the above proposals (exempting VBAs from BP and AMP; instituting safe harbors from AKS for VBAs; and allowing pre-approval communication between manufacturers and payers) would lead to annual health system savings of nearly \$50 billion after ten years. Federal budgetary savings would be about \$3.7 billion over the 10 year budget window. BIO believes that alternative payment models have a big role to play in the future of how healthcare is delivered and reimbursed. New and innovative therapies target the underlying cause of the disease and are often able to substantially mitigate, and in some cases, cure a devastating chronic or life-threatening illness after a single treatment (i.e. transformative therapies). For some of these therapies, VBAs could serve to mitigate insurers’ short-term risk, promote patient access, and reward innovation, in turn, sustaining the innovation ecosystem.

For instance, potentially curative therapies such as gene therapy can provide a number of health and quality of life benefits to patients and the healthcare system more broadly. However, as revolutionary as these therapies are from a clinical perspective, they are equally transformative in their ability to challenge the existing reimbursement paradigm due to the imbalance they create between the timeframe in which payment is made (i.e., following administration) and the timeframe over which clinical benefits accrue to patients and to the healthcare system overall (i.e., potentially years or even decades). In particular, for public and private payers alike, the ability to pay for a high-cost, single-administration therapy over the long term, via multiple payments, instead of one payment at the time of administration, is appealing. Such long-term payment models offer the opportunity and option for payers to decrease upfront spending for curative therapies, thereby helping to mitigate some of the “budget shock” that is causing concern in the payer community. However, the inflexibility in the current reimbursement paradigm, explored above, can preclude the use of such payment models and pose challenges for patient access to new medicines.⁵⁴

BIO looks forward to being an active partner in HHS-led processes to develop and obtain stakeholder feedback on the development and appropriate use of VBAs for both existing and new treatment options. While there are many different arrangements to be explored within the context of VBAs, indication-based pricing is one type of alternative payment model that has been discussed specifically in this RFI. As HHS continues to explore potential VBAs, indication-based pricing appears to be a model that, for certain innovative products, could ensure appropriate access while lowering Medicare costs and improving quality outcomes. However, it is important that HHS carefully evaluate the impact on patient access to the

⁵⁴ For example, amortizing the cost of a one-time administered drug over a five year period in arrangements with commercial payers would trigger Medicaid rebate provisions (“Best Price”) that would result in deep and unsustainable discounts for every prescription of that same drug covered by Medicaid.

most appropriate form of treatment particularly when taking into account the current coding and claims processing infrastructure. As each VBA is unique and must be evaluated independently based on the details around how such a proposal is implemented, it is critical that HHS continue to engage in robust stakeholder dialogue to inform the accuracy and appropriateness of alternative payment arrangements.

IV. Ensuring the 340B Program Serves its Original Intent

The 340B Drug Discount Program is a critical program implemented to help uninsured and vulnerable patients gain greater access to prescription medicines. However, exponential growth of the program – as noted by the Administration – underscores the importance of modernizing the program to ensure it serves patients in need while remaining compliant with program rules. As we have expressed in the past, BIO remains concerned that, without clarification of key program requirements and stronger enforcement, the 340B Program will continue to benefit the providers of 340B drugs much more than benefit the population it was enacted to help. For this reason, BIO appreciates HHS’ focus on the 340B Program within the context of the RFI and its efforts to determine what changes are necessary to help refocus the program towards its intended purpose.

The 340B Program has experienced dramatic growth in recent years. According to the RFI, “It is estimated that discounted drug purchases made by covered entities under the 340B program totaled more than \$16 billion in 2016—a more than 30 percent increase in 340B program purchases in just one year.”⁵⁵ In 2017, program purchases totaled a record \$19.3 billion and accounted for more than 6% of the total U.S. pharmaceutical marketplace.⁵⁶ Much of this unprecedented growth is due to the lack of a clear patient definition, the expansion of the type of facilities eligible for 340B, the unlimited expansion of contract pharmacies in 2010, and the increased consolidation of cancer clinics and child sites under covered entity facilities.

Despite this expansion of the program, studies have found that the growth is not necessarily benefitting patients in need. In fact, from 2012 to 2016, the amount of “uncompensated care as a percentage of hospitals’ total expenses has declined” from 6.1 percent to 4.3 percent.⁵⁷ Further, it has been shown that overall healthcare costs – both to patients and payers – have increased in part, because the consolidation of community practices into hospitals has shifted the site of care to the hospital outpatient setting where the reimbursement rate is significantly higher. According to the Berkeley Research Group, a contributing factor is that 340B hospitals have an incentive to expand outpatient facilities in order to increase purchasing volume for “procedures that typically include a sizeable drug reimbursement.”⁵⁸ The same study found that these 340B hospitals receive over a 50

⁵⁵ 8 Fed. Reg. 22,692 (May 16, 2018).

⁵⁶ Fein, Adam J. [The 340B Program Reached \\$19.3 Billion in 2017 – As Hospitals’ Charity Care Has Dropped](#). Drug Channels. 07 May 2018.

⁵⁷ *Id.*

⁵⁸ [340B Growth and the Impact on the Oncology Market Space: Update](#). *White Paper*, Berkeley Research Group, December 2015.

percent higher reimbursement rate for Part B oncology drugs compared with community oncology practices.⁵⁹ Recognizing the growth and need for increased program integrity, the Government Accountability Office (GAO) and OIG have consistently called for more specific guidance from HRSA and improved oversight of 340B covered entities.^{60,61} While congressional committees have recently taken steps to identify opportunities to improve oversight and compliance, such efforts to ensure program integrity must continue and expand.

To that end, BIO is supportive of recent legislative efforts to place a temporary moratorium on the addition of certain hospitals and associated sites of such hospitals into the program, and to establish new reporting requirements for hospitals to quantify their revenues from the 340B program. Such reporting requirements would increase the availability of data from certain hospitals and their associated sites in a manner similar to the information that grantees are already required to provide. These transparency provisions coupled with the enactment of a moratorium would afford the Administration and Congress the opportunity to enact meaningful reform to ensure funds received through 340B revenue benefit those patients and facilities that need it most.

BIO supports the social safety-net and a 340B drug discount program that is focused on serving the specific population for whom it was intended. However, without more specific guidance on program requirements, it is clear that existing perverse incentives will continue to drive up healthcare costs through expansion of the program without benefiting the vulnerable patients who need access to prescription medicines. BIO cautions the Administration to carefully consider how any proposals intended to alter drug pricing and reimbursement will impact the care being delivered in the community setting, driving up the overall cost of care. While there are a number of areas that require additional clarity and guidance, BIO offers specific feedback and recommendations below on several key factors that currently obfuscate operation under and compliance within the program.

a. Program Eligibility – Patient Definition

BIO has long advocated for a definition of the term “patient” that is both auditable and properly limits the scope of the 340B program to individuals who have a true patient-to-provider outpatient relationship with a 340B covered entity. While essential to ensuring compliance with the program, the term “patient” is not defined by the 1992 340B statute. Moreover, BIO does not believe the existing definition of “patient,” adopted by HRSA in 1996 (now 22 years ago), effectively prevents the diversion of 340B drugs to individuals who do not qualify as patients, such as individuals who do not receive medical care directly from the covered entity and individuals who are merely customers of a contract pharmacy

⁵⁹ *Id.*

⁶⁰ GAO, Report to Congressional Committees. [Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Need Improvement](#). U.S. Government Accountability Office, GAO11-836: September 2011.

⁶¹ [Testimony before the United States House of Representatives Committee on Energy and Commerce: Examining HRSA’s Oversight of the 340B Drug Pricing Program](#). Erin Bliss, Assistant Inspector General for Evaluation and Inspections, Office of the Inspector General, U.S. Department of Health and Human Services, July 2017.

but not of the covered entity. The GAO and OIG share BIO's concern and have repeatedly noted that the lack of clarity regarding key elements of the patient definition has increased the risk that some covered entities will continue to divert 340B covered outpatient drugs to individuals who do not qualify as 340B patients.^{62,63}

[T]he [Government Accountability Office] GAO found in a report issued in 2011 that HRSA's current guidance on the definition of an eligible patient lacks the necessary specificity to clearly define the various situations under which an individual is considered eligible for discounted drugs through the 340B Program.⁶⁴ Subsequently, a 2014 [Office of Inspector General] OIG report found significant variability in 340B prescription eligibility resulting from the myriad different methods by which contract pharmacies identify 340B-eligible patients, with some of those differences stemming from the varying and inconsistent interpretations of the definition of patient applied by different covered entities.⁶⁵ HRSA itself acknowledged this risk of diversion when it sought to revise the "patient" definition in 2007.⁶⁶

A limiting and precise definition of the term "patient" is critical to ensuring program integrity and to preventing diversion of covered outpatient drugs. BIO is supportive of clarifying the definition of "patient" to ensure that an individual's relationship with the covered entity is established on a prescription-by-prescription and order-by-order basis. To that end, we strongly urge the Administration to include the following factors – which are largely consistent with the 2015 HRSA Mega-Guidance – in any revised definition of "patient" in order to determine when an individual's prescription is eligible for a drug acquired under the 340B program:

- The individual must receive a health care service at a covered entity or an outpatient hospital facility that is registered for the drug discount program and listed on the public Internet website of the Department of Health and Human Services—HRSA relating to this section;
- The individual receives an outpatient in-person health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity, and the covered entity bills for the services on behalf of the provider;
- The individual receives a drug that is ordered or prescribed by the covered entity provider, including any renewals of existing prescriptions, as a result of the service;

⁶² "340B Drug Pricing Program Omnibus Guidance," *Federal Register*, page 52,300, August 28, 2015.

⁶³ See: [BIO Final Comments to 340B Omnibus Guidance](#), October 27, 2015.

⁶⁴ GAO, Report to Congressional Committees. [Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Need Improvement](#). U.S. Government Accountability Office, GAO11-836: September 2011.

⁶⁵ [Contract Pharmacy Arrangements in the 340B Program](#). U.S. Department of Health and Human Services, Office of the Inspector General, OEI-05-13-00431: Feb. 4, 2014.

⁶⁶ See 72 Fed. Reg. at 1544 ("[I]t is possible that some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program.").

- In the case of a covered entity that has a contract with a State or local government described in subclause (III) of subsection (a)(4)(L)(i) of the 340B statute, the individual receives a health care service or range of such services, to include the ordering or prescribing of a covered outpatient drug, from the covered entity pursuant to such contract;
- The individual is classified as an outpatient when the drug is ordered, prescribed, or administered as demonstrated by how the service was reimbursed by the applicable payer, or, where the covered entity does not seek such reimbursement, how the service would have been reimbursed under title XVIII of the Social Security Act; and
- The individual has a relationship with the covered entity such that the covered entity creates and maintains auditable health care records demonstrating that—
 - The covered entity has a provider-to-patient relationship with the individual;
 - Responsibility for the individual’s health care service that resulted in the prescription or order for the drug is with the covered entity.

Including these factors in any proposed definition of “patient” would provide increased clarity and auditability over the existing definition. However, we recognize that certain exclusions and exemptions should apply.⁶⁷ BIO would be happy to further discuss these exclusions and exemptions with HRSA or HHS to provide additional detail and clarity.

b. Contract Pharmacy

Since the inception of the 340B Program in 1992, the 340B statute has never authorized—nor even made reference to the concept of—contract pharmacies. Nevertheless, HRSA’s most recent guidance from 2010 permitted all covered entities, regardless of whether they maintained an on-site pharmacy, to enter into an unlimited number of contract pharmacy arrangements.⁶⁸ This expansion of contract pharmacies has substantially increased the scope of the 340B Program, as well as the risk for diversion and duplicate discounts, without demonstrably benefitting low-income or otherwise vulnerable patients. By mid-2017, the contract pharmacy program had grown to over 52,000 unique contract pharmacy arrangements—at approximately 20,000 contract pharmacy locations—compared to just 1,300 contract pharmacy arrangements in 2010.^{69,70}

⁶⁷ For example, exclusions could include: the individual is an inmate of a correctional facility; the health care service received by the individual from the covered entity consists only of the administration or infusion of a drug or drugs, or the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting, without a covered entity provider-to-patient encounter; the health care service received by the individual from the covered entity is provided by a health care organization that has only an affiliation arrangement with the covered entity, even if the covered entity has access to the affiliated organization’s records; or the primary relationship between the individual and the covered entity is one of employment.

⁶⁸ 75 Fed. Reg. at 10,275.

⁶⁹ [Status of Agency Efforts to Improve 340B Program Oversight](#). U.S. Government Accountability Office, GAO-18-556T: May 15, 2018.

⁷⁰ Fein, Adam J., [The Booming 340B Contract Pharmacy Profits of Walgreens, CVS, Rite Aid, and Walmart](#). Drug Channels, July 2017.

As we have stated in previous public comments, as well as in meetings with HRSA, BIO is concerned with the propriety of, and legal underpinning for, the guidance creating contract pharmacies. As promulgated in HRSA's 1996 guidance, contract pharmacies provided an avenue through which covered entities without an on-site pharmacy could contract with a *single* off-site contract pharmacy.⁷¹ At that time, pharmacies were expected to keep all inventory purchased at the discounted 340B rate separate from the rest of their drug inventory to order to prevent diversion and duplicate discounts. However, as the use of contract pharmacies has grown, pharmacy inventory monitoring and replenishment protocols have also changed, seemingly without regulatory oversight. To illuminate this point, we note that HHS OIG has found that: "retail contract pharmacies often have no way to distinguish a 340B patient from any other customer filling a prescription at their stores. To address this reality, most contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory."⁷² As we have noted in past communications with HRSA, "this has led to a system in which contract pharmacy arrangements take advantage of normal retail operations and 340B drugs are purchased by covered entities as replenishment inventory for retail pharmacy operations."⁷³ In these virtual inventory systems—which have now essentially replaced the on-site method of ensuring separate 340B inventory at the majority of, if not all, contract pharmacies—a computer is responsible for differentiating between the inventory sold between non-340B eligible patients and patients eligible for 340B drugs. Given the inability of many contract pharmacies to accurately distinguish those patients who are eligible for 340B drugs at the point-of-sale, it is obvious more oversight and clarity is required.

Additionally, there is no evidence that contract pharmacy arrangements are benefitting the low-income or otherwise vulnerable patients of covered entities through improved access. The OIG has found that at least some covered entities using contract pharmacy arrangements "do not offer the discounted 340B price to uninsured patients at their contract pharmacies," which results in "uninsured patients pay[ing] the full non-340B price for their prescription drugs at contract pharmacies," while for-profit pharmacies derive a profit from their prescriptions.⁷⁴ In a recently released study by GAO on the contract pharmacy program, 25 out of 55 covered entities surveyed did not offer any discount to the uninsured or underinsured at the contract pharmacy counter.⁷⁵ Such an outcome clearly undermines the stated goals of the 340B program to help uninsured individuals, instead providing revenue to for-profit entities.

As the contract pharmacy program was never mentioned or envisioned in the 340B statute, BIO continues to express our concerns with the legal basis for recognizing contract pharmacy arrangements at all. BIO is open to working with HRSA as it considers next steps

⁷¹ See 61 Fed. Reg. 43,549 (Aug. 23, 1996).

⁷² [Testimony before the United States House of Representatives Committee on Energy and Commerce: Examining HRSA's Oversight of the 340B Drug Pricing Program](#). Erin Bliss, Assistant Inspector General for Evaluation and Inspections, Office of the Inspector General, U.S. Department of Health and Human Services, July 2017.

⁷³ BIO Letter to HRSA RE: Use of Contract Pharmacies in the 340B Program, March 2018.

⁷⁴ [Contract Pharmacy Arrangements in the 340B Program](#). U.S. Department of Health and Human Services, Office of the Inspector General, OEI-05-13-00431: Feb. 4, 2014.

⁷⁵ [Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement](#). U.S. Government Accountability Office, GAO-18-480: June 2018.

in ensuring access for rural providers and others in the program who do not have access to an on-site pharmacy.

c. Child Sites

Off-site facilities associated with a 340B hospital that are reimbursable under the covered entity's Medicare cost report are eligible to register as "child sites" of the parent hospital. Each facility must register if it provides care that results in utilization of drugs acquired under the 340B program. Nothing in the 340B statute explicitly provides for an offsite hospital outpatient facility to participate in the 340B program. Rather, 340B eligibility for hospital "child sites" is a policy developed by HRSA alone. Implementation of such a policy runs contrary to HRSA's hesitancy to exercise its enforcement authority in other areas, specifically for duplicate discounts. That said, over the last several years, the number of child sites has grown exponentially, which may be due in large part to the availability of deeply discounted 340B pricing allows 340B hospitals to generate higher net revenues than independent physician offices for administering the same medicine. This opportunity—never intended or foreseen by Congress—creates financial incentives for 340B hospitals to purchase independent physician practices and bring them under the 340B umbrella. Recent studies suggest that these incentives are, in fact, driving 340B hospital acquisitions of formerly independent physician practices.⁷⁶

Of concern, it has been found that "financial gains for hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients" who the 340B program was intended to serve.⁷⁷ Several studies have documented a marked increase in acquisition of physician offices by 340B hospitals which has contributed to a shift in site of care from the physician office to the hospital outpatient setting. Specifically, a Berkeley Research Group analysis demonstrated a noticeable shift in site of care from the physician office to the 340B hospital outpatient setting that steadily increased from 2008 to 2015.⁷⁸

⁷⁶ Desai, Sunita, Ph.D. and McWilliams, J. Michael, "[Consequences of the 340B Drug Pricing Program](#)," New England Journal of Medicine, February 8, 2018. Accessed 6/18/2018.

⁷⁷ *Id.*

⁷⁸ [Site of Care Shift for Physician-Administered Drug Therapies](#). Berkley Research Group, October 2017.

Site of Care for Breast Cancer Drug Therapies Reimbursed in Medicare Part B (2008-2015)



Note: Analysis includes top ten drugs reimbursed under Part B and used for breast cancer treatments.

Site of Care for Rheumatoid Arthritis Drug Therapies Reimbursed in Medicare Part B (2008-2015)



Note: Analysis includes top ten drugs reimbursed under Part B and used for rheumatoid arthritis treatments.

The consequences of such a shift in site of care have been extensively documented. The 2016 Magellan Rx Management Medical Pharmacy Trend Report found that “medical benefit drug cost is often more than double in the hospital outpatient setting versus the physician office for top categories such as autoimmune diseases and oncology support medications.”⁷⁹ Another analysis conducted by Milliman found that if chemotherapy infusions had not shifted into the hospital outpatient department, spending from 2004 to 2014 would have been 7.5 percent lower for Medicare patients and 5.8 percent lower for commercial patients.⁸⁰ These numbers are not only significant given their impact on overall healthcare spending, but shift in site of care to the hospital outpatient setting significantly increases patient costs as well.

To ensure that the 340B program is operating as intended and serving those in need, child sites should be required to provide at least the same level of charity care as their parent entity. Moreover, the child site should have the same patient eligibility requirements as the

⁷⁹ [Medical Pharmacy Trend Report: 2016 Seventh Edition](#). Magellan Rx Management. 2017.

⁸⁰ Bruce Pyenson et al., [Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004–2014](#). Milliman Report, April 2016.

parent site, in order to ensure they are serving the same patient demographic. In addition, we strongly recommend that child sites be required to meet Medicare provider-based status requirements. As we noted in our 2015 comments in response to the Mega-Guidance, provider-based status is the standard used by Medicare for assessing that a facility is in fact an integral part of a parent hospital, such that the parent hospital may permissibly bill Medicare for services provided by that facility. To illustrate, this standard assesses, among other things, that the child site is operated under the ownership of the parent; that there is full integration of clinical services, medical records, and financial operations between the parent and the child site; and that the parent maintains the same monitoring and oversight over the child sites as it does over other provider departments.

d. 340B Duplicate Discounts

The 340B statute prohibits covered entities utilizing a covered drug from submitting that claim to Medicaid in a manner that triggers a Medicaid rebate.⁸¹ This statutory prohibition – known as a “duplicate discount” – was reinforced by Congress in the Affordable Care Act (ACA). Yet, despite this clear statutory prohibition, more than 25% of audited covered entities have reported duplicate discount violations.⁸² The manufacturer liability from duplicate discounts is significant – representing 10-15 million dollars for every 100 million dollars in discounted product sales.⁸³ With discounted 340B sales now exceeding 19.3 billion dollars, manufacturer liability on duplicate discounts can conservatively be estimated between 2 to 3 billion dollars annually. It is therefore critical for HRSA to exercise its enforcement authority to prevent duplicate discounts and ensure compliance with the statute.

Several factors have exacerbated the problem of duplicate discounts: (1) the expansion of Medicaid rebates to managed care organizations without an effective means for identifying duplicate discounts; (2) the significant growth in contract pharmacies and the use of third-party administrators (TPAs); and (3) inadequate oversight enforcement by HRSA.⁸⁴

i. Discrepancies in the Application of the Medicaid Exclusion File and Exacerbation by the Expansion of Medicaid Rebates to Managed Care Organizations and Lack of Means to Identify Duplicate Discounts

Generally, HRSA places responsibility for ensuring duplicate discounts are not occurring on the covered entity.⁸⁵ Since 1993, HRSA has been using one primary means of ensuring duplicate discounts do not occur for “covered outpatient drugs” provided to Medicaid fee-

⁸¹ Section 340B(a)(5)(A) of the Public Health Service Act

⁸² Hardaway, Jason, “[340B/Medicaid Duplicate Discount Risk to Manufacturers](#),” *CiiTA Whitepaper*, CiiTA Monograph Series, 2016.

⁸³ Hardaway, Jason, Identifying Duplicate Discounts: 340B and Medicaid. CiiTA Presentation, 12 May 2016.

⁸⁴ Hardaway, Jason, “[340B/Medicaid Duplicate Discount Risk to Manufacturers](#),” *CiiTA Whitepaper*, CiiTA Monograph Series, 2016.

⁸⁵ [Clarification of HRSA Audits of 340B Covered Entities](#). Health Resources and Services Administration, March 5, 2012.

for-services (FFS) patients, which is the “Medicaid Exclusion File” (MEF).^{86,87} The MEF is intended to notify states and manufacturers which drug claims are not eligible for Medicaid rebates by indicating which covered entities are dispensing 340B purchased drugs to Medicaid patients.⁸⁸ And, as the 2017 House Energy and Commerce Committee Report notes, “this measure counts on the integrity and continued participation of covered entities to disclose accurate and current information.”⁸⁹ However, due to the lack of consistency with the use of the MEF at the state level, it has been an ineffective mechanism to appropriately and accurately prevent duplicate discounts. Covered entities are required by HRSA to determine whether they will use drugs acquired under the 340B program for their Medicaid patients (i.e., “carve in”) or use only non-340B discounted products for their Medicaid patients, (i.e., “carve-out”). Those covered entities that “carve-in” are required to be listed on the MEF, while those that “carve-out” must guarantee that Medicaid patients do not receive any 340B discounted drug product.⁹⁰ The majority of covered entities choose to “carve-in” Medicaid claims, and some states even require the “carve-in” method to be used.⁹¹ Nevertheless, HRSA audits often find misclassifications under the MEF system, which can lead to the payment of duplicate discounts.

In 2010, the ACA included a provision that extended Medicaid rebates to outpatient drug utilization in managed care organizations (MCOs). The extension of these rebates has created a new liability for manufacturers, as duplicate discounts are now occurring for Medicaid patients in MCOs. Difficulty stems from the fact that HRSA does not have a MEF, or any other similar mechanism, to identify and segregate claims processed under Medicaid MCOs. As the House Energy and Commerce Committee reports, “this is a very significant and growing problem because an increasing number of Medicaid programs rely on MCOs to deliver Medicaid benefits. In 2014, 76 percent of Medicaid enrollees were in some type of managed care.”^{92,93} Further, the problem of duplicate discounts pervade within AIDS Drug Assistance Programs (ADAPs) because of how Medicaid rebates are applied.⁹⁴

⁸⁶ “Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases”, 58 *Federal Register*, 34058 (June 23, 1993).

⁸⁷ [340B Medicaid Exclusion File](#), Health Resources and Services Administration, October 2015.

⁸⁸ [Review of the 340B Drug Pricing Program](#), House Energy and Commerce Committee Report, 2017.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ Hardaway, *CiITA Whitepaper*, 2016.

⁹² House E+C Report, 2017. Citing: *Medicaid Managed Care Enrollment and Program Characteristics, 2014*, Centers for Medicare and Medicaid Services, available at <https://www.medicare.gov/medicaid-chip-program-information/by-topics/data-and-systems/medicaid-managed-care/downloads/2014-medicare-managed-care-enrollment-report.pdf>.

⁹³ “State Efforts to Exclude 340B Drugs from the Medicaid Managed Care Rebates,” OIG Report, 2016.

⁹⁴ Duplicate discounts, and a lack of sufficient tools to prevent them, are also a persistent problem within AIDS Drug Assistance Programs (ADAPs). ADAPs are a unique covered entity type, in that they can receive rebates from manufacturers instead of only being eligible for upfront 340B discounts on drug purchases. However, HRSA explicitly prohibits ADAPs collecting rebates on drugs purchased at 340B prices, as this would constitute a duplicate discount. Like MCOs, the MEF method of preventing duplicate discounts does not apply to ADAPs, therefore there is no reliable system for which to prevent double dipping. It is imperative that HRSA exercise its statutory authority to maintain program integrity and establish means through which the duplicate discount prohibition can be enforced across MCOs and ADAPs in addition to state FFS Medicaid programs.

ii. Impact of Contract Pharmacy Expansion and Use of Third-Party Administrators

Earlier in our comments, we noted the significant growth in contract pharmacy arrangements and the related program integrity concerns. Also, of significant concern is this growth in contract pharmacies has increased the occurrence of duplicate discounts. Medicaid claims are processed at the point-of-sale at the contract pharmacy counter, while the virtual inventory process and retroactive reconciliation qualifies or identifies claims post-adjudication, as noted above.⁹⁵ As BIO indicated in previous correspondence to HRSA, this post-adjudication process can sometimes occur over a period of weeks, months, or sometimes years after the drug was dispensed.⁹⁶ Covered entities that use contract pharmacies are responsible for overseeing those pharmacies to ensure compliance with 340B Program prohibitions on drug diversion and duplicate discounts.⁹⁷ The covered entities often contract with third-party administrator (TPAs) to conduct their reviews of 340B claims and reclassification. HRSA requires that covered entities and contract pharmacies have in place plans to ensure compliance with diversion and duplicate discount prohibitions.⁹⁸ However, separate adjudication processes for Medicaid and 340B results in two independent data sets with no process in place to reconcile these two separate data streams.⁹⁹ The sheer number and complexity of contract pharmacy arrangements and the expanded use of TPAs has allowed the difficulties and gaps in Medicaid claims adjudication, and identification of 340B-eligible patients to become even more problematic.

iii. Inadequate Oversight Enforcement

In order to maintain program integrity, HRSA conducts approximately 200 audits of covered entities and manufacturers per year and the number of audits is divided proportionately.¹⁰⁰ Audits increased after GAO recommended in a 2011 report that the level of oversight needed to improve based on the growth of the program and the implementation of the 2010 Contract Pharmacy Guidance.¹⁰¹ According to the GAO, "HRSA's audits include covered entities that are randomly selected based on risk-based criteria (approximately 90 percent of all audits conducted each year), and covered entities that are targeted based on information from stakeholders such as drug manufacturers (10 percent of the audits conducted)."¹⁰² To date, HRSA has identified no violations of the program in its manufacturer audits – i.e., all are providing discounts at the ceiling price or below.¹⁰³ On the contrary, **two-thirds of covered entities audits have found violations of the**

⁹⁵ Hardaway, CiiTA Whitepaper, 2016.

⁹⁶ BIO Letter to HRSA RE: Use of Contract Pharmacies in the 340B Program, March 2018.

⁹⁷ [Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement](#). U.S. Government Accountability Office, GAO-18-480: June 2018.

⁹⁸ *Id.* [AND] HRSA 2010 guidance.

⁹⁹ Hardaway, CiiTA Whitepaper, 2016.

¹⁰⁰ [Testimony of Capt. Krista Pedley, Office of Pharmacy Affairs, HRSA at the Senate Labor, Education, Health, and Pensions Committee](#). US Senate, June 19, 2018.

¹⁰¹ [Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Need Improvement](#). U.S. Government Accountability Office, GAO-11-836: September 2011.

¹⁰² [Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement](#). U.S. Government Accountability Office, GAO-18-480: June 2018.

¹⁰³ Capt. Pedley Testimony, June 19, 2018.

program. Significant violations occur in the duplicate discount area. These audit figures are believed to be conservative due to gaps in contract pharmacies and a lack of a system to ensure Medicaid MCOs are appropriately identifying claims.¹⁰⁴

Moreover, when audits of covered entities identify program violations, the subsequent oversight is lacking. HRSA's March 2010 Contract Pharmacy Guidance eliminated the requirement for covered entities to audit contract pharmacies annually. Instead, there is now an "expectation" that audits would take place annually.¹⁰⁵ HRSA has no means of ensuring that audits are occurring regularly, and although covered entities are expected to notify manufacturers when audits uncover adverse findings of duplicate discounts, the lack of guidance leaves this issue largely unregulated.¹⁰⁶ Nevertheless, there is an existing gap in enforcement because while HRSA requires covered entities to reimburse the manufacturers for the duplicate discounts it received, there are no additional penalties or consequences for the covered entity to deter future violations.

Recommendations

Given the inextricable link between Medicaid and the 340B program, coordination between HRSA and CMS is critical to address the concerns we have outlined. BIO has offered solutions on rectifying many of the issues with duplicate discounts and diversion in the past, most specifically in our response to the proposed Omnibus Guidance in 2015. Many of our recommendations align with those proposed by the National Association of Medicaid Directors (NAMD) in 2015.¹⁰⁷

- HRSA and CMS should work together to develop a system that can track all 340B discounted products and differentiate them from State Medicaid claims.
- HRSA and CMS should identify, and require the reporting of, standard summary-level, and claims-level data points, such as new claims for modifiers on all claims to identify 340B.
 - OIG has identified claims-level data points as an effective means of tracking 340B discounted drugs versus Medicaid adjudication. BIO continues to recommend that CMS and HRSA adopt data points shared with the Agency in June 2014 by the 340B Pharmaceutical Company Operational Work Group, which are based upon claim elements of the National Council for Prescription Drug Programs (NCPDP).¹⁰⁸
- Program integrity should continue with increased auditing by HRSA, with the application of additional resources.

¹⁰⁴ Hardaway, Jason, CiiTA Presentation, 5-12-2016.

¹⁰⁵ 75 Fed. Reg. 10272 (March 5, 2010).

¹⁰⁶ *Id.*

¹⁰⁷ [Medicaid and the 340B Program: Alignment and Modernization Opportunities, Working Paper Series](#). National Association of Medicaid Directors (NAMD), 2015. (Accessed: June 28, 2018).

¹⁰⁸ [BIO Comments RE: 340B Drug Pricing Program Omnibus Guidance](#), October 2015.

- We recommend that CMS also identify and require the use of a standard formatting of these data points.
- BIO also supports the following recommendations developed by NAMD:^{109,110}
 - HRSA should address complexities presented by the virtual replenishment model with contract pharmacies.
 - HRSA should implement HRSA-level editing of NPI number in order to ensure accuracy of the data on the MEF and minimize the impact on states, covered entities, and manufacturers.
 - HRSA and CMS should maintain congruency of NPI and 340B ID on the MEF and the Covered Entity File.
 - HRSA should publish a quarterly change file, because while the MEF is published quarterly, the Agency does not make a change file available, requiring states to perform file comparisons to determine additions and deletions.
 - HRSA should develop a solution for providers serving Medicaid patients across state Lines, because the MEF lists providers under the state in which the covered entity is operating. Providers that serve patients in other states, may bill a different Medicaid program. A policy should be developed to accurately identify these providers.
 - HRSA should establish mechanisms to improve communications between covered entities and state Medicaid agencies regarding compliance with the 340B Program.

e. Additional Rebates Manufacturers Provide over the Statutory 340B Discounts for Drugs that have been Dispensed to 340B Patients Covered by Commercial Insurance

As noted in the RFI, the pharmaceutical distribution system is complex, involving multiple layers of contracted parties to get products from manufacturers to patients. In addition to 340B discounts, manufacturers often provide contracted discounts to commercial payers, wholesalers, distributors, and PBMs – all which often apply to the same physical units of drugs. As a result, discounts are being stacked upon many other discounts that are provided to other parts of the supply chain, including public (Medicare Part D and other government programs) and private payers, PBMs, pharmacies, and wholesalers. Given the growth of the 340B program, this increases market distortions that augment the pressure on prices in the rest of the commercial marketplace.^{111,112}

f. Impact of Program Growth on List Prices and Cross-Subsidization

¹⁰⁹ *Id.*

¹¹⁰ NAMD, 2015.

¹¹¹ R. Conti and M. Rosenthal, "Pharmaceutical Policy Reform — Balancing Affordability with Incentives for Innovation," *N Engl J Med* 2016; 374:703-706.

¹¹² Fein, Adam J., [Market Distortions from the 340B Drug Pricing Program](#). Presentation, National Leadership Summit on 340B, May 2018.

While it is impossible to predict how any one company would react in specific circumstances to proposed regulatory changes such as the implementation of government mandated price discounts, BIO believes market forces dictate that downward pressure from price controls in one part of the market will lead to increased pressure on prices in other market segments. Therefore, these mandated price discounts overall have an adverse effect on prices elsewhere in which no government price controls are in effect. The unanticipated growth in this program has likely had an overall upward impact on list prices. As the 340B ceiling price is tied to Medicaid Best Price provisions, the expansion of Medicaid coupled with the growth of 340B driven by expansion of eligible covered entity types, unchecked growth in child sites, and the explosion of contract pharmacy arrangements has substantially increased the percentage of overall pharmaceutical sales subject to government-mandated pricing. As a result, cost-shifting to other market segments is likely to occur. In other words, while companies make their own individual pricing decisions, a manufacturer could set their overall prices in the commercial market based upon the fact that they are forced to pay lower prices in government programs, thereby increasing overall list prices. Companies that bring these treatments to market must factor in a variety of elements including the risk of unexpectedly high 340B sales volume which could have an impact on reinvestment into research, including research on treatments for rare disease.

V. Using Closed Formularies and Waiving Coverage Requirements through a Medicaid Pilot Demonstration Could Cause Serious Harm to Patient Access

For a long time, BIO has advocated that CMS evolve its payment policies to better reflect the realities of pharmaceutical contracting in the innovative biopharmaceutical marketplace. With the advent of value-based contracts in the commercial marketplace, the general payment methodologies used in most Medicaid programs have lagged behind commercial plans in innovation. This ultimately disadvantages patients, since they are not able to benefit from these alternative financing arrangements that better balance access with financial risks born by an insurer. In that regard, we were pleased to see CMS's approval of a state plan amendment that specifically contemplates value-based arrangements within the current Medicaid Rebate context. While we are still studying the details of this specific approval to understand how it may ultimately benefit patients, we nevertheless acknowledge this as a meaningful step forward in the way CMS and the states appear to be thinking about value in the context of prescription drug coverage.

At the same time, we applaud CMS for its recent decision to clarify that commercial-style formularies that blanketly deny access in the Medicaid context are impermissible.¹¹³ As we have said in many settings responsive to CMS requests: the Medicaid Rebate program represents a balance struck by Congress that ensures robust access to necessary prescription medications for vulnerable patients while also ensuring Medicaid programs received the best price available for those medicines. Significantly augmenting that balance within the traditional Medicaid construct would be problematic for Medicaid programs and devastating for patients in the long-run.

¹¹³ [CMS Letter to MassHealth](#), June 2018.

With the foregoing considerations in mind, BIO is concerned that the proposed 5-state pilot program outlined in the President's 2019 budget and reiterated in the RFI would disrupt the carefully constructed balance of access and value already provided for in the current Medicaid structure. Particularly in light of CMS's recent movement towards value-based purchasing in the Oklahoma state plan amendment (SPA) approval, we would urge CMS to see this evolution develop before allowing any state to simply exit traditional Medicaid.

a. A Closed Formulary Approach Jeopardizes Patient Care for Negligible, if Any, Benefit

The 5-state demonstration styles itself as a method to "test drug coverage and financing reforms," but if Massachusetts' initial proposal is any guide, this demonstration would likely be nothing more than denying access to vulnerable patients in an effort to extract price concessions. In reality, apart from putting patients in compromising positions, we find it difficult to see what else would be accomplished by this proposal. As BIO outlined in its letter to HHS in October regarding the Massachusetts request, a waiver of compliance with § 1927's coverage requirements would have a detrimental effect on patient outcomes by restricting access to medically necessary drugs. As one example, despite the availability of a variety of drug treatments for epilepsy, approximately 30% to 40% of all epilepsy patients still cannot adequately manage their seizures.¹¹⁴ Additionally, for those patients who can control their seizures, many often take three to five drugs at a time to ensure such control. Should CMS authorize states to limit coverage to a single drug in a therapeutic class, most epilepsy patients would be left without adequate therapy to manage their condition.¹¹⁵

Infectious diseases are also an instructive example. A restrictive, closed formulary could negatively impact Medicaid patients by limiting access to appropriate therapies for infectious diseases such as HIV. Effective management of HIV requires providers to utilize the best medication for each patient based on individual needs, as patients may react differently to antiretroviral therapies. Prohibiting or limiting timely access to the wide range of available HIV medications can lead to higher viral loads, making HIV patients sicker and more likely to transmit HIV to others, increasing costs to Medicaid and the health system. Open, immediate access to a full range of HIV therapies has led to fewer new infections and increased health.¹¹⁶

All too often proponents of implementing closed formularies in Medicaid assert that it would give Medicaid beneficiaries comparable coverage to Medicare Part D and private commercial sector plans. In reality, this claim could not be further from the truth. One of the fundamental principles in Medicare Part D is choice. Most Medicare Part D beneficiaries choose from a variety of different benefit plan options that best suits their medical needs. Choice is also a predominant factor in the private sector, particularly those in the state

¹¹⁴ [The Epilepsies and Seizures: Hope through Research](#). National Institutes of Health, National Institute of Neurological Disorders and Stroke.

¹¹⁵ BIO Letter RE: Massachusetts MassHealth § 1115 Demonstration Waiver Amendment Request, October 2017.

¹¹⁶ O'Connor, Jemma et al., "Effect of immediate initiation of antiretroviral therapy on risk of severe bacterial infections in HIV-positive people with CD4 cell counts of more than 500 cells per µL: secondary outcome results from a randomized controlled trial," *The Lancet: HIV*, March 2017.

insurance exchanges where, patients are able to choose a plan based on the best options available to them. They may look at plan formularies on-line and determine which plans have their drug therapies covered on the formulary. Medicaid patients have no such choice, yet Medicaid patients are among the sickest and most vulnerable in society. More often than not these patients have medical needs that are far greater than those in the commercial marketplace. This is the reason patients in Medicaid were afforded the protections outlined in § 1927. And yet nothing discussed regarding this 5-state demonstration indicates that patients would have any new ability to choose among plans.

What is more, Medicaid coverage is critical for people with rare diseases, especially children. Individuals with rare diseases very often have diagnostic and treatment costs so severe that they have to rely on Medicaid. In many cases it is their only option. And yet without the ability to shop for a suitable plan, evolving Medicaid into a commercial-style formulary could severely limit a rare disease patient's access to necessary medications; or, at a minimum, begin requiring these vulnerable patients to jump through innumerable hoops to get access - likely something that would push some patients to abandon therapy, which would inevitably increase Medicaid costs once they end up in the hospital.

Therefore, we strongly believe that any legislation to create such demonstration authority should include guardrails to protect patients from potential harm.¹¹⁷ Such protections should include:

- Some minimum drug coverage criteria, e.g., two drugs per therapeutic class, when available.
- Prescriber prevails policy, to ensure the doctor and patient are the final arbiters of health care, not an administrator.
- Exceptions process with standardized forms for providers/patients, [as the Administration has indicated would be included], but it also must include expeditious timeframes within which a decision must be made; current Medicaid rules require a prior authorization request be responded to within 24 hours and receive a 72-hour supply of a prescription drug in cases of an emergency. There is no reason this same standard should not be required even within the context of the proposed pilot program.
- No negative changes to the formulary during the calendar year unless there is a safety concern based upon new FDA warnings or recalls, i.e., drugs should only be added not withdrawn from the formulary (additions should be allowed because of new drug approvals).
- Continuity-of-care protections

¹¹⁷ We agree with the Administration that such a 5-state demonstration would require legislation to authorize the changes. See: [Lower the Price of Drugs by Reforming Payments](#), 2019 Budget Fact Sheet.

- If a patient is stabilized on a medication and the formulary changes such that the patient's drug is no longer on the formulary, the patient should not have to change medications; and
- If a patient is stabilized on medication prior to enrollment in the Medicaid program and his or her drug is not available on the formulary, the patient should not have to change medications.
- Guardrails on 'protected classes' – HHS should conduct research to determine which classes of drugs pose immediate health risks to Medicaid beneficiaries if any appropriate therapy cannot be accessed and require that all formularies cover all or substantially all products in these classes.

Any legislation should also include a sunset for the pilot, i.e., three years. In order to fully assess the results of the pilot demonstration, a comprehensive annual report should be required by CMS to include: data on savings or net cost to the plan, the number of approvals and denials as a result of the exceptions process, the number of patients forced to change their drug therapy as a result of formulary changes, and the average times for response to an exceptions request. Also, a demonstration should require the State and the Department to issue a Notice of Proposed Rulemaking for public comment, including a public hearing, on any demonstration. BIO would be pleased to work with CMS through the rule making process to help shape any resulting proposals.

VI. ACA Limitations on rebates over 100%

a. BIO Opposes the Proposal to Return to Rebates above 100% of AMP, because Manufacturers Should Not Be Required to Pay the State More than the Cost of the Drug and the Administration's Premise is Flawed

BIO supports policies that enhance and protect an innovative free-market ecosystem. Biopharmaceutical innovation can only thrive when these free-market principles are upheld. Government-mandated discounts and rebates are a form of price controls that hinder these free market principles. The "Average Manufacturer Price" (AMP) is defined in § 447.504 of the Code of Federal Regulations (CFR) as:

*The average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.*¹¹⁸

Essentially, the AMP is the average price the manufacturer would receive for retail, which is a minimum of 23% higher than what Medicaid pays. Yet, the Department is considering requiring in some cases a company to pay more than 100% of the AMP, which is based on private sector pricing. This would essentially mean a company is paying the Medicaid

¹¹⁸ 81 Fed. Reg. at 5349 (February 1, 2016).

program to use its drug rather than being reimbursed anything. This policy is fundamentally tied to the additional rebate within § 1927. This additional rebate holds the Medicaid harmless from price increases that outpace inflation. Price increases are based upon market dynamics and the AMP would shift quarterly based upon what is happening in the private sector. The government's receipt of the drug for free is the penalty for price increases and protects the Medicaid program from run-away price increases. To require a rebate that is greater than the price of the drug is overly punitive and would no longer effectively amount to a "rebate."

In the RFI and the Blueprint, the Administration makes the argument that this cap of no more than 100% rebates causes runaway price increases. Nevertheless, if this were true, then prescription drug prices after the cap was imposed in 2010 would be increasing exponentially. However, the data does not support this contention. In fact, seven out of the last ten years have seen prescription drug spending decrease.¹¹⁹ Moreover, according to CMS, spending on prescription drugs grew at a rate of only 1.3% in 2016, much slower than overall health care expenditures, which grew at a rate of 4.3%. Outpatient prescription drugs spending only accounted for 9.8% of total U.S. health care spending.¹²⁰ If the assertion the Administration makes were true, then price increases would have grown dramatically not slowed, after 2010 when this 100% rebate cap was implemented as part of the ACA.

Each company makes individual decisions on pricing when subjected to specific development costs, regulatory policies and market dynamics. Companies must also weigh considerations of clinical value, as well as the economic value to the patient and the health care system, as a whole. In essence, the damage to marketplace dynamics occurs by the imposition of original mandated rebates and discounts at AMP minus 23.1%, not by the fact that inflationary penalties may be limited at 100%. This suggested policy implies that the Department believes companies ought to be paying more than 100% of the price they charge across retail outlets nationwide. This is troubling because the Department is suggesting, by proposing such a policy, that any price increases may not be warranted and does not consider marketplace dynamics. Further, as is suggested in the Blueprint, Medicaid and 340B are increasing pressure on prices in other markets, removing this cap could lead to higher overall prices in Medicaid and cross-subsidization in the commercial markets.

The cost of developing a new drug has increased exponentially since the 1970s. A study conducted by the Tufts Center for the Study of Drug Development found that developing a drug that gains market approval can take over 10 years, and cost roughly \$2.6 billion.¹²¹ Furthermore, unlike other estimates, this cost estimate takes into account the high failure rate for most pharmaceutical advancements and the significant investments that are spent on products that never make it to market. Additionally, the pharmaceutical industry spends

¹¹⁹ Fein, Adam J., [CMS Confirms It: Drug Spending Slows, Hospital and Physician Spending Grows](#). Drug Channels, December 12, 2017.

¹²⁰ Hartman, Micah, et al., [National Health Care Spending In 2016: Spending and Enrollment Growth Slow After Initial Coverage Expansions](#), *Health Affairs*, December 6, 2017.

¹²¹ Lamberti M. and Getz, K. Profiles of New Approaches to Improving the Efficiency and Performance of Pharmaceutical Drug Development. Tufts Center for the Study of Drug Development. May 2015.

significantly more than every other industry on research and development (R&D). On average, pharmaceutical companies spend 18 percent of revenue on R&D; and when looking just at the U.S., one study found that, in 2013, 23.4 percent of domestic sales went to domestic R&D.¹²² Moreover, those that seek to demonize price increases often fail to understand that those price increases may be factoring in opportunities in R&D that exist today that might not have been available when a manufacturer's drug entered the marketplace.

VII. Exclusion of Certain Payments, Rebates, or Discounts from the Determination of AMP

BIO commends the Department for exploring how policy changes implemented as part of the ACA may have resulted in cost-shifting. However, we urge HHS to proceed with caution with any policy recommendation changing the calculation of AMP and potential legislation to accomplish these changes. Given the wide variety of policy changes that were implemented when the ACA passed, it is difficult to determine the impact of these policy changes without extensive study. The determination of AMP is a complicated and complex issue, and any "re-determination" ought to be approached cautiously in order to fully understand the impact of such a policy in light of many other potential reforms.

VIII. Manufacturer Patient Assistance Programs Serve a Critical Role in Helping Patients Afford Their Healthcare

Manufacturer assistance helps patients afford their medications and plays an important role in improving medication adherence in the commercial market. Research shows that higher OOP costs correlate to higher levels of patient abandonment of medication, as well as increased use of medical services. By helping to reduce patients' financial exposure to health plan cost-sharing, manufacturer assistance increases the chances that patients take their medicines as prescribed by their physician – improving patient outcomes and reducing unnecessary costs to the healthcare system.

Over the past several years, an increasing number of health plans have shifted towards benefit structures with higher patient cost-sharing. A report from the Centers for Disease Control and Prevention found that enrollment by adults with employer-based coverage in high-deductible health plans rose from 26.3% in 2011 to 43.2% in 2017.¹²³ Another study found that between 2004 and 2014, average beneficiary cost-sharing payments more than doubled, while average beneficiary payments toward deductibles more than tripled.¹²⁴

Research demonstrates the connection between such increased cost-sharing and negative outcomes for patients, who become unable to afford their medication. Patients with high deductible plans and multiple chronic conditions may have much higher amounts of debt

¹²² [Business Research and Development and Innovation Survey: 2011](#). National Science Foundation.

¹²³ Michael E. Martinez, et al., Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, January–September 2017, at fig. 11 (Feb. 2018).

¹²⁴ [Payments for cost sharing increasing rapidly over time](#). Kaiser Family Foundation, April 2016.

and may be far more likely to delay therapy.¹²⁵ This effect is pronounced with respect to medication adherence. In a literature review in *Health Affairs*, the authors found that “when monthly out-of-pocket costs for prescription drugs exceed \$150-\$200, rates of new therapy abandonment approximately double, the odds of being adherent are reduced by 39 percent, and the risk of discontinuation increases by 27-58 percent.”¹²⁶ A study of a large U.S. retail pharmacy chain and PBM detected a relationship between cost-sharing and abandonment at an even lower cost threshold: in that study, when cost-sharing for prescription drugs set by health plans exceeded \$50, patients were much more likely to abandon their medicine at the pharmacy counter.¹²⁷ Such poor medication adherence is to the detriment of patients and the healthcare system as a whole, as patient adherence correlates with better clinical outcomes and substantial savings due to a reduction in the use of healthcare services (for example, hospitalizations and emergency department visits).¹²⁸

Greater cost-sharing in the form of high-deductible health plans and coinsurance on covered services places a growing financial burden on patients accessing the treatments they need. As patients’ out-of-pocket exposure continues to rise, we believe that manufacturer assistance plays a key role in preserving beneficiary access to medication. However, we note with growing concern health plans’ development and implementation of so-called “copay accumulator programs,” which we believe prohibit manufacturer assistance from working as intended.

The Department also questions whether or not the exclusion for manufacturer assistance in calculation of AMP and Best Price should be eliminated. We do not support such a change, as CMS regulations – in their current form – are consistent with the rebate program statute, which does not include transactions with patients (through financial support or otherwise) as AMP or Best Price eligible.¹²⁹ Moreover, changing the law to include manufacturer assistance in the calculation of Best Price and AMP could discourage the use of these programs, threatening the wellbeing of patients who rely on financial support and raising the likelihood of medication abandonment and other adverse outcomes.

IX. Biosimilar Development, Approval, Education, and Access

BIO and its membership have long advocated for quick and complete implementation of the Biologics Price Competition and Innovation Act (BPCIA) as a method to ensure the marketplace for biologic medicines remains dynamic, innovative, and competitive. Our membership has a longstanding policy of advocating for policies to ensure a competitive biologics market and a robust marketplace for the development of biosimilars and interchangeable biologics.

¹²⁵ Anuradha Jetty et. al, “[High-Deductible Plans May Reduce Ambulatory Care Use](#),” Robert Graham Center (Nov. 1, 2016); Michael Laff, “[Study: High Deductibles Cause Patients to Delay Care](#),” American Academy of Family Physicians (Nov. 22, 2016).

¹²⁶ Catherine Starner et. al, Specialty Drug Coupons Lower Out-Of-Pocket Costs And May Improve Adherence At The Risk Of Increasing Premiums, 33 *Health Affairs* 1761-1769, 1762 (Dec. 2014) (examining biologic anti-inflammatory drugs and drugs for multiple sclerosis).

¹²⁷ [Payments for cost sharing increasing rapidly over time](#). Kaiser Family Foundation, April 2016.

¹²⁸ M. Christopher Roebuck, et al. “Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending,” 30 *Health Aff.* 1 (Jan. 2011).

¹²⁹ 42 U.S.C. § 1398r-8(c)(1)(C)(i), (k)(1)(A).

BIO has engaged with FDA and HHS throughout the implementation of the BPCIA, and we are encouraged to already see 11 biosimilar approvals in the US in such a short period of time since the passage of BPCIA.¹³⁰ To that end, BIO recently provided lengthy comments to FDA on draft guidances regarding Analytical Similarity¹³¹ and Biologic Interchangeability¹³² in an effort to help inform FDA's further regulatory roll-out of the biosimilar and interchangeable biologics marketplace.

Particularly with respect to the topic of interchangeable biologics – keeping in mind that FDA has not even finalized its proposed guidance outlining its regulatory approach – we were somewhat concerned when reading the Blueprint Request for Information question asking how “the interchangeability of biosimilars can be improved.” FDA has to-date engaged in a comprehensive public notice and comment process on the draft interchangeability guidance, to collect scientific, policy, patient, and provider feedback to help inform how the Agency shapes policy in approving biosimilars. BIO believes this is the correct approach. Any theoretical future policy change, as seems to be suggested in the Blueprint, could “improve” the process of deeming products interchangeable should be considered within the guidance development process already initiated by the agency.

If FDA believes that the general approach it outlined in the draft guidance on interchangeability needs to be meaningfully modified, BIO would be pleased to provide input and additional public comment to a re-issued draft guidance or proposed rulemaking. In the end, we share FDA's goal of ensuring the marketplace for biosimilars and interchangeable biologics is both robust and competitive. To best ensure this result FDA must continue to solicit and meaningfully consider public input into future policy and regulatory changes impacting this marketplace.

X. Addressing Foreign Pharmaceutical Pricing Disparities

BIO appreciates HHS's focus in the Blueprint on trade, market access, and intellectual property issues that result in foreign countries not paying their fair share of the research and development costs for innovative medicines. As provided by the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (Trade Promotion Authority), elimination of foreign price controls and establishing regulatory reimbursement regimes that are transparent, fair, non-discriminatory and provide for full market access for U.S. products is a *Principle Trade Negotiating Objective* for the United States Government. As such, BIO encourages the U.S. government to take the following actions:

- a. Establish the factual basis** to build global support for burden sharing of biomedical research, including creating private sector incentives for that

¹³⁰ See: [Biosimilar Product Information, FDA-Approved Biosimilar Products](#). Updated June 2018.

¹³¹ Docket No. FDA-2017-D-5525: Statistical Approaches to Evaluate Analytical Similarity.

¹³² Docket No. FDA-2017-D-0154: Draft Guidance for Industry on Considerations in Demonstrating Interchangeability With a Reference Product (January 18, 2017).

research. This should include updating the 2004 Commerce Department study on impact of price controls on global research and development.

b. Build consensus with developed countries based on evidence that the U.S. bears a disproportionate burden supporting global biomedical research and development, with the goal of securing an agreement in principle between nations that supports and rewards innovation.

c. Use trade agreements to create specific disciplines on pricing and reimbursement practices:

- *Pursue more rigorous enforcement of existing Free Trade Agreement (FTA) commitments* – for example, in Korea and Australia; use consultation and enforcement provisions of each agreement to set goals and monitor.
- *Inclusion of pricing and reimbursement provisions in new FTAs* – expanding on provisions in Australia and Korea. We strongly recommend that commitments must be *specific* to the national systems of the countries involved to be meaningful, and address concrete policies and practices that discriminate against innovative products and/or undermine incentives for innovation. This would include both pricing and reimbursement policies, as well as applications of health technology assessment that systematically undervalue the benefits of new and innovative products.
- *Possible additional commitment areas beyond transparency and accountability* (i.e., the level of existing FTAs) on pricing and reimbursement practices that undermine global innovation, as noted above.

d. Use of other U.S. trade policy tools:

- Making price controls a higher and more explicit priority in annual “Special 301” process – e.g., citing worst offenders as “Priority Foreign Countries,” which can result in trade sanctions if not resolved. The annual Special 301 process is meant to address practices of foreign countries that violate U.S. intellectual property rights or impede market access for U.S. IP products. National pricing and reimbursement practices for new medicines clearly fall under this rubric.
- Initiating Section 301 Reviews of worst offenders as “unfair trade practices” which would need to be resolved to avoid trade sanctions. By systematically undervaluing the benefits of new products or impeding access to them, foreign pricing and reimbursement practices for new medicines can

undermine or significantly impair the comparative advantage that innovative U.S. companies have in the global market place, and thus constitute and unfair trading practice.

BIO welcomes the opportunity to work with Administration trade officials to outline specific countries and practices that should be prioritized in addressing this issue.

* * *

BIO appreciates the opportunity to respond to this call for feedback on the Administration's RFI and Blueprint. As noted, we look forward to continuing to work with the Department to develop policy proposals that ensure patient access and choice, while reducing out-of-pocket costs; promote holistic, market driven reforms; and sustain biopharmaceutical innovation. Should you have additional questions, please do not hesitate to contact us at 202-962-9200.

Sincerely,

/S/

Crystal Kuntz
Vice President, Healthcare Policy and Research
Biotechnology Innovation Organization