July 16, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: RIN 0991-ZA49

Submitted Electronically to regulations.gov

Dear Secretary Azar:

AmerisourceBergen appreciates the opportunity to comment on the Department of Health and Human Services' Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (RIN 0991-ZA49) and to respond to the request for information contained therein. We appreciate the important work the administration has undertaken to improve access to affordable drugs.

We look forward to working with you to improve healthcare for all Americans by improving access to care while lowering costs for patients and taxpayers.

About AmerisourceBergen

Headquartered in Valley Forge, PA, and employing approximately 21,000 associates, AmerisourceBergen is one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care. With services ranging from drug distribution and niche premium logistics to reimbursement and pharmaceutical consulting services, AmerisourceBergen delivers innovative programs and solutions across the pharmaceutical supply channel.

AmerisourceBergen, among other members of the primary pharmaceutical distribution industry, provides logistical, inventory and other service support which manufacturers and pharmacies would otherwise have to perform themselves. Because of the services provided by the primary pharmaceutical distribution industry, the pharmaceutical supply chain is more efficient, reliable and secure, and patients

are able to get the medicines they need in a timely fashion, saving our healthcare system approximately $42 billion each year.[1] The primary pharmaceutical distribution industry is a very high-volume, yet very low profit margin industry; overall profitability for our industry has registered little notable change over the past several years. In a recently published study examining the pharmaceutical supply chain, the Berkeley Research Group concluded that the pharmaceutical wholesale distributor profit on overall branded drug costs was just under one percent.[2]

AmerisourceBergen distributes innovative, life-saving therapies to all sites of care. As a cost-efficient leader with visibility across the healthcare supply chain, AmerisourceBergen has the unique ability to assess the effect policies can have on all healthcare stakeholders. For example, AmerisourceBergen distributes the majority of specialty medications in the U.S. and operates the largest network of independent physician practices who heavily rely on stable, predictable Medicare Part B reimbursement, International Oncology Network Solutions, Inc. ("ION Solutions") and International Physician Networks, LLC ("IPN"). Our reach extends to customers in health systems, community practices, independent pharmacies and alternate care settings to ensure that their patients can access the right products at the right time. This expertise allows us to be an impartial arbiter of information as policies are debated that could potentially disrupt the marketplace, and of greater concern, patient care.

AmerisourceBergen shares HHS' commitment to advance policies intended to make healthcare more affordable. We encourage you to build upon policies that preserve access to high quality, cost-effective sites of care, including:

- Expanding market incentives and competition to lower drug costs;
- Eliminating flaws in government reimbursement and pricing programs that inhibit competition, such as prompt pay discounts;
- Ensure the viability of generics and biosimilars in order to enhance competition;
- Explore the potential of real-world outcomes data in value-based models.

[1]The Center for Healthcare Supply Chain Research, The Role of Distributors in the U.S. Healthcare Industry, 2011.
[2] The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders; 2017; Table 2 http://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf.

We agree that by recognizing and rewarding value, patients should ultimately and directly benefit from any innovative drug pricing policies. Our thoughts on several of the administration's policy proposals and questions included in the request for information are outlined in the comments below.

Biosimilars

AmerisourceBergen supports policies that facilitate greater competition and access to generic and biosimilar products. We support FDA implementation of the Biologics Price Competition Act (BPCIA) in a timely manner to encourage development of a robust biosimilars market. We support the education and outreach efforts by FDA to facilitate awareness, understanding and adoption of biosimilars. We also support necessary regulatory efforts to facilitate the approval and marketing of biosimilars, and a reimbursement framework that ensures a competitive environment encouraging of multiple biosimilars. To encourage uptake of biosimilars, CMS should eliminate co-pays for biosimilars for Medicare's Low-Income Subsidy (LIS) population.

Value-Based Purchasing Arrangements

AmerisourceBergen supports the movement towards value-based care and believes HHS should use its demonstration authority to test payment models that reward patient outcomes and efficiency. We believe that certain permanent changes need to be made outside of CMMI's demonstration authority to address the known barriers to pay for value arrangements. These include Medicaid's "best price" law and the anti-kickback statute (AKS). The Office of the Inspector General (OIG) should promulgate new safe harbors to protect value-based arrangements and adherence programs under the AKS. Likewise, numerous CBO and GAO reports have documented the chilling effect the Best Price law has had on lowering drug costs. Additionally, other drug reporting programs also hinge reimbursement on sales prices, which compounds the chilling effect on value-based systems by setting artificial pricing floors. The result is that many innovative, lower cost arrangements simply are not pursued.

For these arrangements to be most effective and for the Medicare system to transition more effectively toward one that pays for value over volume, it is necessary to meaningfully include providers—doctors and pharmacists—as participants in value arrangements. We believe their services should be considered in shared savings arrangements, but that the details of those arrangements should be left to private negotiations. CMS should provide freedom from regulatory constraints and the flexibility to providers who want to transition toward such models, such as exempting physicians from MIPS requirements if they participate in value-based purchasing arrangements. It is important that CMS include specialist-focused models (such as an advanced iteration of the Oncology Care Model). Historically, payment demonstrations have focused on primary care providers; it is critical that CMS consider models suggested by the specialty community. Moreover, specialists should be included on the Physician-Focused Payment Model Technical Advisory Committee (PTAC), or other such bodies HHS may convene to promote bottom-up model development.

To effectuate these changes, there is a need to enact clear exceptions to Medicaid best price, Average Sales Price, and Average Manufacturer Price reporting for value-based arrangements, coupled with clear guidance to reduce current ambiguity about how to capture value-based pricing for reporting purposes.

We support HHS' use of CMMI authority to test payment models to evolve Medicare's payment systems to focus on value. It is critical that CMMI demonstration projects prioritize patient-centric care, allow flexibility, but also allow site-neutral access to patients and payment predictability for providers as such models are tested. Because penalties associated with the fraud and drug price reporting laws carry significant penalties, we suggest working with Congress to provide statutory certainty about the types of arrangements that are allowed under these statutes. Doing so will provide clarity to the market and allow innovative, value-based payment arrangements to flourish.

Moving Drugs from Part B to Part D

As the administration seeks to lower drug costs, we urge you to evaluate the core tenets of the Medicare Part B program, which is essential in ensuring patients have access to quality, affordable healthcare, covering medical care provided in a doctor's office and medications administered in an outpatient setting to some of the most vulnerable Medicare beneficiaries diagnosed with serious conditions. Part B's ASP model is based on a market-determined price structure calculated based on millions of sales every year, and serves as a laudable model for encouraging and rewarding value by conferring risk to physician practices, controlling year over year price increases compared to Part D, incentivizing the introduction and adoption of less expensive therapeutic alternatives, and reflecting competitive market dynamics.

For these reasons and others more fully described below, AmerisourceBergen does not support shifting drug coverage from Part B to Part D. Such a shift could impede patient access to treatments by inserting a third-party between physicians and their patients, interfering with the clinical decision-making process for patient- and value-centric care. In addition, many of these medicines, which are typically more complicated products for more complex diseases and are more difficult to deliver, are not usually self-administered and are provided directly by a trained clinical provider. Inserting an intermediary between the patient and doctor is unwise, could delay expediency to treatment, erect operational challenges that could impede access. Moreover, such an approach is unlike how private payers administer and pay for such products.

We are concerned that, unlike Part B, which covers all medicines that are medically necessary, Part D plans are only required to cover two medicines per protected drug class and plans generally determine which medicines are made available to patients. Part D plans may also impose restrictions on those medicines (eg, prior authorization, step therapy) that could delay access to the most clinically appropriate treatment.

Data[3] clearly indicates that when a lower-priced alternative is available or enters the Part B market, prescribing overwhelmingly shifts to these alternatives as physicians are incentivized in various ways to not only prescribe the most efficacious and cost-effective therapies, but also to help ensure patient adherence to treatment regimens. No compelling evidence exists documenting Part B incentivizes inappropriate utilization of expensive drugs.

[3]IntrinsiQ Specialty Solutions. IntelliVIEW®. April 2018. Available via subscription at www.intrinsiq.com

Finally, the administration's proposed changes to Part B, such as shifting certain drugs currently reimbursed under Medicare Part B to Part D could exacerbate shifts in care to more expensive sites, impede access to community care, and raise the total cost of care.

CAP Program

AmerisourceBergen does not support re-institution of a CAP model. CAP 1.0 was not successful for myriad reasons, as it introduced additional taxpayer costs and confusion to the Medicare program and was not modeled to facilitate patient-centered care. There were many lessons learned from CAP implementation that point to flaws in both the statute and the implementing regulations. Despite an evolution of the market, which includes more players and more

sophisticated management and distribution strategies, we do not believe CAP can be successful and adds an additional layer of inefficiency that could impede patient access to needed medications.

Core among these flaws is the model does not correspond to any existing or viable specialty distribution or specialty pharmacy economic model. That is, the model seeks to have CAP vendors provide services like those provided by a specialty pharmacy but to do so at margins similar to those in the specialty distribution industry. There is simply no compensation for the additional risks and costs inherent in the current CAP program model, nor does it allow for truly efficient patient-centric care that ensures access to the right product for the right patient at the right time.

More specifically, CAP vendors have additional economic burdens without additional compensation.

- **Consigned Inventory.** Product owned by the CAP vendor is placed on consignment in the offices of physicians where the CAP has no direct control over the consigned inventory.
- **Inefficiency.** CAP vendors must own more inventory to meet the same level of patients' needs because, when inventory is dispersed, a CAP vendor cannot readily shift it to physicians and patients who need it when inventory has been consigned to another physician's office.
- **Co-Payments.** CAP vendors have no ability to collect co-payments and deductibles before services are provided and drugs are dispensed. This increases their bad debt risk and increases their expenses to collect payment from patients with whom they have no relationship.
- **Greater Cost.** The per-dose cost is typically lower when purchased in multi-packs or multi-dose vials. Under the CAP program, there was a greater reliance on single-dose vials because the program requires product to be labeled for a specific patient, which will tend to increase overall costs.
- **Greater Waste.** When multi-packs and multi-dose vials are used by CAP vendors, it increases the amount of drugs that are wasted because physicians can not use the vials for other patients.
- **Minimal Negotiating Leverage.** CAP vendors have little real ability to negotiate favorable terms with manufacturers and little real ability to require physician and patient compliance.

Correcting many of these flaws will require CMS to spend more money that will push costs greater than ASP+6%, and certainly more than after the sequester is applied.

In addition, the CAP law does not properly recognize the inherent incompatibility with the program and state pharmacy laws. That is, distributors and pharmacies operate under different restrictions. Drugs

sold by a distributor to a physician may be readily dispensed to any appropriate patient. However, drugs dispensed by a pharmacy for one patient cannot be re-directed to a different patient. A physician cannot simply use extra drugs – whether remaining in a single-use vial, a multi-use vial or a multi-pack – on a patient other than the patient for whom the pharmacy dispensed the drug. This fundamental and inherent conflict within the model added significant costs to vendors and ultimately the Medicare program.

MedPAC and others have suggested paying much less than acquisition cost for drugs (i.e., moving reimbursement down to ASP+3%) as a way to drive volume into the CAP program making CAP a viable business model. This is flawed reasoning and goes against one of MedPAC's core functions – to ensure that payments in Medicare are adequate. The logic is also flawed in that MedPAC assumes, and the CAP program was designed with, that specialty distributors and specialty pharmacies have a high degree of negotiating leverage with drug manufacturers and with physicians. This is simply not borne out by the facts; vendors do not have negotiating leverage with drug manufacturers or physicians.

Partly because of these flaws, the cost of drugs administered through the CAP exceeded 106 percent of ASP by approximately 3.2 percent in the aggregate for 2006 and 2007. CAP produced cost savings to Medicare during just two quarters of the program. We see no way to correct these issues absent a fundamental rewrite of the program to make it either specialty pharmacy or specialty distribution, which, we believe, should be considered by Congress, not HHS. We therefore ask that HHS not pursue CAP 2.0 but instead focus on preserving and protecting access to therapies under a structure in which physicians are incentivized to utilize cost-effective drugs, driving efficiency and minimizing waste. As described in the previous section, the current Part B model provides this structure by rewarding value by conferring risk to physician practices, controlling year over year price increases compared to Part D, incentivizing the introduction and adoption of less expensive therapeutic alternatives, and reflecting competitive market dynamics. Based on experience with CAP 1.0, additional layers of administrative gatekeeping by designated CAP vendors for the Medicare Part B program could have unintended or potentially opposite impacts of the desired goal by limiting access and potentially driving up costs for patients.

Gag Clauses

AmerisourceBergen fully supports the proposal, and more recently, CMS' letter to Part D plan sponsors calling out as unacceptable any form of gag clauses which prohibit pharmacists from informing patients when a less expensive option for their prescription is available. This will enhance patient access to medications, build patient trust in the pharmacist as a patient advocate and reduce healthcare costs for patients. In conjunction with eliminating gag clauses, we also believe that PBM contracts should prohibit the practice of requiring patients to pay more than the pharmacy's usual and customary cash price at the point of sale. We encourage HHS to consider this proposal as it refines the blueprint to lower prescription drug costs.

Promoting Generic Drugs to Increase Competition

Competition from generic drugs is critical to lowering drug prices. AmerisourceBergen applauds the recent efforts of the FDA to reduce the backlog of approvals for generic drug applications, and supports streamlining FDA responsibilities and processes to accelerate the product approval process to speed market entry for generic products. Ensuring access to reference product samples is a key component of this goal. While unintended, some limited distribution models and customer restrictive REMS programs can prevent access to reference or sample products for generic or biosimilar developers and clinical research organizations. This may slow down the competitive progress because samples can be difficult to obtain through reputable channels. Policies or legislation requesting innovator companies provide access to reference products through normal distribution channels (i.e. exceptions to limited distribution network) could encourage faster development of generics and biosimilars, and reduce the potential for downstream diversion of pharmaceuticals motivated by profit for difficult to access pharmaceuticals.

AmerisourceBergen also suggests the FDA prioritize review of generic drug applications when there is little market competition; we encourage the agency to continue a speedy yet thorough approval process that also discloses the types of generics approved.

Relatively more expensive branded entrants into the market have been offset by substantial generic entrants. While price increases are naturally inhibited by market dynamics consequent to the lag in ASP updating, price decreases and therefore decreases in ASP are naturally incentivized by the same mechanism when there is competition in a category. Generic entrants predominantly reimbursed under Part B have typically cannibalized their category, thus lowering prices. However, in many cases the ASP mechanism effectively drives generic pricing to levels so low that manufacturers exit the category. In some cases, this has resulted in shortages and substantial price increases when there remains a single or limited source for an extended period of time.

To ensure competition through the availability of multi-source products, HHS should consider establishing a floor reimbursement level upon market entry. For example, upon generics entry to a drug class, CMS could set an innovator baseline ASP that would establish a reimbursement floor for the generic. The generic product would be reimbursed at the HCPCS' ASP or the floor, whichever is greater, to ensure the reimbursement rate is high enough to motivate multiple manufactures to support availability of the generic drugs. Such an approach to multi-source product reimbursement would support the administration's goal of increased competition.

Manufacturer-Sponsored Co-payment Assistance Programs

AmerisourceBergen supports programs that improve patient adherence and reduce patient out-of-pocket expenditures. While we have no evidence to suggest that manufacturer-sponsored co-payment assistance programs drive up list prices, we are aware that many commercially insured patients utilize manufacturer-sponsored co-payment assistance programs to help lower their out-of-pocket costs for prescription drugs. It is our understanding that the vast majority of manufacturer-sponsored co-

payment assistance programs are for branded medications where there is no generic, therapeutically equivalent option on the market.

We are concerned that manufacturers may discontinue these valuable patient assistance programs if they must factor the value of the cards into their Average Manufacturer Price (AMP) and Best Price calculations under the Medicaid program. We think repealing the current exclusion would be antithetical to the Blueprint's overarching objective of reducing costs for consumers.

In a similar vein, we believe that updating the Anti-Kickback Statute prohibition on the use of manufacturer-sponsored co-payment assistance programs such that Medicare and other federal health care program beneficiaries can lower their out of pocket drug costs through the use of such manufacturer-sponsored co-payment assistance programs would help to reduce costs for consumers and increase medication adherence among federal health care program beneficiaries. The Department of Health and Human Services could do so by creating a safe harbor via regulation and perhaps limiting the use of manufacturer-sponsored co-payment assistance programs by federal health care program beneficiaries only for branded products with no generic, therapeutic equivalent.

Conclusion

We look forward to working with HHS and the administration to lower costs by improving competitive markets. We appreciate your consideration of our comments and stand ready to serve as a resource as you further develop policies to make health care more affordable and accessible for all Americans.

Sincerely,

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AmerisourceBergen Corporation