



*Submitted Electronically to regulations.gov*

April 08, 2019

Mr. Aaron Zajic  
Office of Inspector General  
Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue SW  
Washington, DC 20201

**Re: Response to NPRM Regarding Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals (OIG-0936-P)**

Dear Mr. Zajic:

AmerisourceBergen Corporation (“AmerisourceBergen”) appreciates the opportunity to comment on the Department of Health and Human Services’ Notice of Proposed Rule Making regarding the Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals. AmerisourceBergen supports the administration’s goal of lowering out-of-pocket prescription drug costs for patients. We believe that reducing patients’ costs at the point of sale helps to improve medication adherence, which in turn can contribute to lower overall healthcare costs for both patients and payors. We also agree that federal healthcare programs stand to benefit from robust competition in both the cost and quality of the pharmaceuticals they cover. Thus, while AmerisourceBergen supports policies that lower the cost of pharmaceuticals for patients, it is equally important that such policies’ incentives are aligned to maintain access to the full range of products that are most therapeutically beneficial as determined by healthcare professionals.

We support the administration’s goal of reducing prices for patients at the point of sale through the creation of a new safe harbor for point-of-sale discounts (“POS Discounts”). Our comments below emphasize the benefits associated with the administration of POS Discounts by pharmaceutical wholesalers and distributors through chargeback mechanisms, and the fact that wholesale distributors and manufacturers can operationalize, in an incremental fashion, the chargeback structure outlined in the proposed rule to meet a January 2020 start date. The U.S. pharmaceutical distribution industry possesses the fundamental technology, tools and relationships to facilitate patient access to discounted or net price pharmaceuticals at the pharmacy counter given our unique positioning in the supply chain as a link between manufacturers, pharmacies, and ultimately, patients.

## About AmerisourceBergen

AmerisourceBergen is headquartered in Valley Forge, PA and employs approximately 21,000 associates. We are one of the largest global pharmaceutical sourcing and distribution services companies, helping healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care. AmerisourceBergen distributes innovative, life-saving therapies to all sites of care; our reach extends to customers in independent pharmacies, community practices, health systems and alternate care settings to ensure that patients can access the right products at the right time.

### Pharma Manufacturers

Product sourcing, distribution and commercialization services across all product types, including:

- Brand
- Generic
- Specialty
- Biosimilar
- Over the counter (OTC)
- Medical devices



### Healthcare Providers

Providing pharmaceuticals, healthcare products and business services that enable quality care across all sites, including:

- Community and independent pharmacies
- Specialty pharmacies
- Pharmacy benefit managers (PBMs)
- Health systems
- Alternate sites of care
- Physician practices
- Veterinary clinics
- Livestock producers and animal health dealers

While our primary function is to ensure the safe and efficient distribution of prescription medicines to healthcare providers and the patients they serve, the role of pharmaceutical distributors has evolved over the last decade. While AmerisourceBergen and other members of the primary pharmaceutical distribution industry are supply chain logistics and operations experts, we are no longer an industry focused solely on moving products from point A to point B. Pharmaceutical distributors provide a wide array of supportive services to manufacturers and healthcare providers that deliver significant value and enable the pharmaceutical supply chain to function efficiently and securely, ultimately to the benefit of patients. Beyond our next-day delivery, as an example, we facilitate the ability of health systems and alternate site pharmacies to purchase product at net prices, contracted with manufacturers, rather than list prices. This critical supply chain function relies on a proven chargeback process developed in concert with manufacturers that has been operating efficiently for decades.

As an example of our reach and valued role in the supply chain, AmerisourceBergen offers a full range of solutions to the 20,000 retail pharmacy locations we serve daily, so they can operate efficiently as a pillar of community-based care. For example, Elevate Provider Network, our Pharmacy Services Administration Organization (PSAO), represents more than 4,600 pharmacies, negotiating reimbursement contracts with Pharmacy Benefit Managers (PBMs) on behalf of its members and providing a robust infrastructure that helps pharmacies submit clean claims as well as track and reconcile claim payments. Our analytics tool contains hundreds of millions of claims used to help our pharmacies improve Star scores on medication use measures and to increase operational efficiency, so they can focus on patient care.

Through the solutions and relationships outlined above, and as the link between manufacturers, pharmacies, and patients, wholesale distributors possess the fundamental tools and trusted relationships to facilitate patient access to discounted pharmaceuticals at the pharmacy counter.

### **Transitioning from Rebates to Discounts**

We understand the overarching objectives of the proposed rule to be:

1. To continue to enable PBMs and health plans to negotiate discounts;
2. To ensure patients receive the full benefit of those discounts in their out-of-pocket spending; and
3. To enable an alternative method for processing discounts that discontinues the misaligned incentives of today's system, under which traditional rebates and the absence of point-of-sale mandates may create gross-to-net financial incentives to the detriment of patients and government health care programs, including Medicare Part D.

Our comments focus primarily on the ability of pharmaceutical wholesalers to serve as chargeback administrator for such point-of-sale price reductions, as contemplated by the proposed rule.<sup>1</sup> Not only are AmerisourceBergen and our industry peers ready to serve this role, we believe wholesalers occupy the most effective position in the channel to eliminate the gross-to-net distortions which HHS discusses in detail in the proposed rule, and to efficiently serve the pharmacies that care for Part D and Medicaid beneficiaries.

Enabling pharmaceutical wholesalers to serve as chargeback administrators would create a “cash-less” discount model since chargebacks issued by the manufacturer are applied to the wholesalers’ open receivables which would then flow to the retail pharmacies’ open receivable. This model is the closest to an “upfront” discount model and moves the full industry towards net prices, not list prices, for patients.

The following figure<sup>2</sup> illustrates the process flow whereby, using existing pathways and standardized processes, POS discounts can be offered to reduce patient out-of-pocket costs, and pharmacies can be made whole for these amounts through wholesaler administered chargebacks.

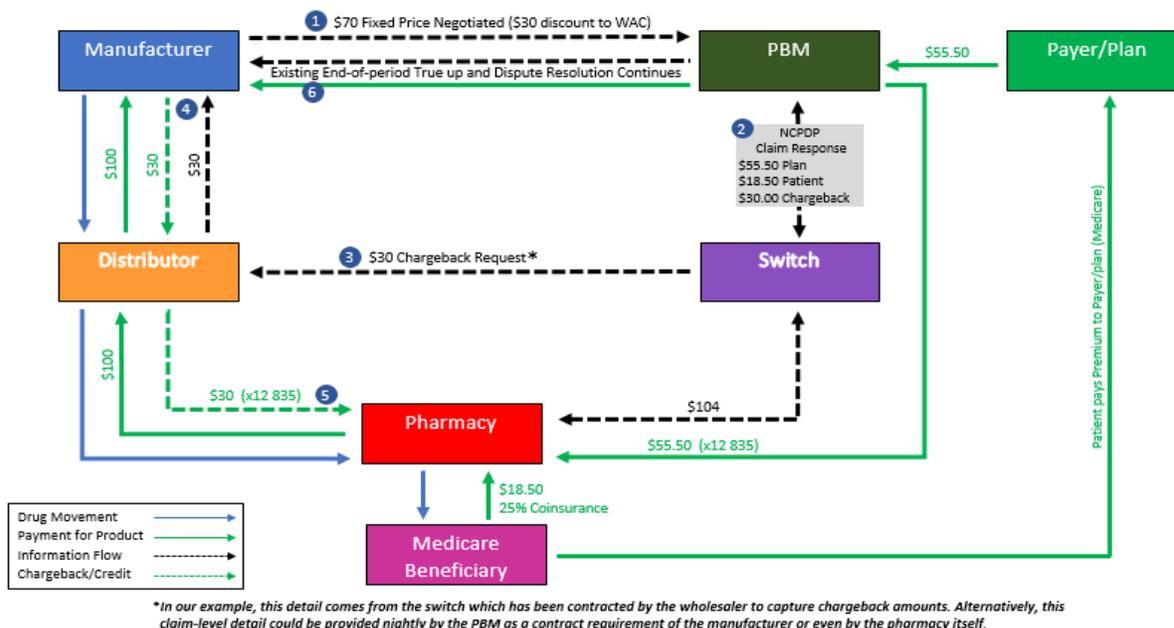
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<sup>1</sup> Proposed rule at 2361.

<sup>2</sup> The figure documents the dispensing of the product with the beneficiary’s cost-share based on the discounted price of the drug product at the point of sale as well as the subsequent data flows and processes used to make the dispensing pharmacy whole with the wholesaler serving as the chargeback administrator. The dollar amounts in the chart use the example included in the proposed rule and are based on a product with a \$100 List Price (Wholesale Acquisition Cost - WAC).

Figure 1. Wholesaler-Facilitated POS Discount Chargeback Model

## Transition from Rebates to Discounts at Point-of-Sale



AmerisourceBergen believes that administering POS discounts through the existing chargeback system used in the distribution of the physical product has several advantages,<sup>3</sup> including:

- Independent, third party administration of POS discounts is more consistent with the proposed rule’s overall focus on eliminating gross-to-net distortions and enhancing transparency with respect to manufacturer pricing relationships with PBMs.
- Leveraging existing relationships between pharmacies and wholesalers ensures accountability. Pharmacies can hold wholesalers accountable; if a pharmacy is displeased with the services one wholesaler provides, they can choose to do business with another wholesaler. Thus, wholesalers are highly incentivized to ensure pharmacies promptly receive POS discounts to which they are entitled.
- Chargebacks could be applied as credits to a pharmacy’s account; we believe chargebacks could often be applied against its account before the account is due from the wholesaler. This system therefore has the advantage of minimizing financing risks for pharmacies and reducing gross dollars flowing through the system.

<sup>3</sup> AmerisourceBergen and other wholesalers are also part of an ongoing pilot project to enhance the existing chargeback systems using block chain technology. We envision this project will lead to an even more efficient chargeback system to support chargebacks in the retail pharmacy channel.

- Having the chargeback applied against the account used to purchase the product clearly differentiates the arrangement as a form of manufacturer discount, in contrast to other payments that a pharmacy might receive from payors or other entities serving in this function, which could make the discount look like a revenue source, not a discount to cost of goods.
- Congress, in its goal to further secure the supply chain, enacted the DSCSA in 2013. When fully implemented, the law's product serialization requirement could further support tracking the discount to the physical product, and wholesalers' existing role in supply chain integrity positions them to play this role.

Not only do wholesalers occupy the right place in the distribution channel to facilitate POS discounts, wholesalers' existing capabilities enable the industry to deliver on a January 1, 2020 start date. In other words, the rails have already been laid to support a point-of-sale discount system, and trading partner agreement for operational processes can be relied on in the short term as more fully enhanced systems are developed between trading partners over time.

- AmerisourceBergen and our peers have a long history of facilitating manufacturer discounts with health systems and alternate site pharmacies, enabling these customers to purchase pharmaceuticals at prices negotiated with manufacturers. In 2018 alone, AmerisourceBergen exchanged over 300 million chargeback transactions with manufacturers with greater than 99% successfully completed in three business days or less.
- Not only do the wholesalers have these systems in place, manufacturers also have these reciprocal systems in place today.
- While these systems will require the development of procedures to facilitate chargebacks in the retail pharmacy channel, the overall systems will largely remain the same, and those systems already contain the requisite building blocks for the administration of POS discounts. For example:
  - As reflected in the schematic above, the NCPDP claim response format already provides the requisite fields for denoting the amounts of plan payments, patient cost-sharing obligations, and POS discounts to be provided by a manufacturer via the chargeback mechanism (identified by a new value in the price qualifier field).
  - We have identified at least three potential readily administrable mechanisms (from a PBM via a nightly feed, from pharmacies via a nightly feed, or in real-time from claims processing switch organizations) for a pharmacy's designated wholesaler to secure this information to administer the POS discount.

- To meet a January 2020 start date, wholesalers and manufacturers would agree to a set of contractual business rules to facilitate retail pharmacy discounts using existing capabilities, provide the manufacturer access to the claim-level chargebacks in a separate feed using NCPDP standards, and then continue to evolve our mutual systems to more fully meet the unique nature of retail chargebacks.

If HHS moves forward with this safe harbor policy change, accountability throughout the channel will be important, and the final safe harbor regulation should be consistent with these principles. We envision the following set of accountabilities:

- PBMs and manufacturers would continue to be accountable to negotiate POS discount contracts and exchange discount information using the existing NCPDP standards for manufacturer rebates. Manufacturers may require, as a condition to their POS discount contracts, that PBMs make available NCPDP claims responses to facilitate the identification of POS discount amounts.
- PBMs would be accountable to accurately itemize the POS discount amount on the NCPDP standard claim response sent to a pharmacy at the point of sale.
- PBMs may not take any other action to impede wholesalers' processing of the POS discount through the chargeback mechanisms.
- Wholesalers would be accountable to secure the pertinent POS discount data from claims responses, from switch organizations, PBMs, or directly from their pharmacy customers as is sometimes the case currently. To the extent that the wholesaler secured such information from claims processing switch organizations, such organizations would be accountable to accurately and promptly furnish the chargeback data to the wholesaler in a standard NCPDP format.
- Wholesalers would be accountable to accurately and promptly submit the chargebacks to the manufacturer using the existing EDI 844 standard with the contents based on a modified set of business rules for retail chargebacks that would continue to evolve, and the final rule should specify that the payment of POS discounts through chargeback arrangements must be made within the same 14-day timeframe applicable to the submission of the original pharmacy claim to the payor.
- Manufacturers would be accountable to promptly respond to the EDI 844 chargeback request with the appropriate credit to the wholesaler's open receivable account using the existing EDI 849 process.
- The wholesaler, upon receiving the manufacturer credit, would be accountable to accurately and promptly apply the credit to the pharmacy's account using the existing EDI 810.

- The wholesalers would be accountable to deliver an electronic remittance advice in the NCPDP 835 format to its pharmacy customers to reconcile claims.
- PBMs would continue to be accountable to provide end-of-period reports using existing NCPDP standards for manufacturer rebates for end-of-period true-ups.
- Manufacturers would be accountable to continue to validate discounts were appropriately applied. Accountability for disputes based on improperly applied discounts would fall to the manufacturer, PBM and health plan. Wholesalers, pharmacies and patients would not have a role in the dispute resolution process.

In short, AmerisourceBergen is confident that with specific direction in the final rule from HHS, manufacturers and wholesalers can quickly identify, develop, and implement a set of business practices using the existing infrastructure, technologies, and claims media for a January 2020 start date.

To enable the wholesaler-administered chargeback model, we recommend HHS address the following in the final rule:

1. Modify the safe harbor language so that the second prong reads “the full value of the reduction in price is provided to the dispensing pharmacy as a credit to its purchase account used to purchase product”;
2. A commitment to coordinate with CMS as may be necessary to develop Part D policy guidance compatible with the HHS OIG safe harbor language;
3. Since even minor changes to the named standards require a lengthy process, HHS must articulate that stakeholders are compliant with the HIPAA-named standards (e.g., NCPDP claim) by implementing draft changes needed to support the new policy; and
4. Include language specifying that a PBM must refrain from taking any action that would impede the manufacturer and wholesaler from the proper administration of POS discounts through chargeback mechanisms, similar to existing standards applicable to sellers under the discount safe harbor

#### **Additional General Comments on the Proposed Rule**

In addition to our primary comments above relating to the advantages and feasibility of timely implementation of the safe harbor through existing chargeback processes, Amerisource Bergen offers the following additional general comments.

First, in the proposed rule, HHS notes that the elimination of safe harbor protection for existing rebates negotiated by and paid to health plans and/or PBMs is not intended to affect safe harbor protection that may be available to other entities in the pharmaceutical supply chain or other health care providers. We support this interpretation, and for the avoidance of doubt, we ask that OIG reiterate in the final

regulation that discounts, including those taking the form of rebates, are still permitted under the Discount Safe Harbor when paid to any entity other than a health plan and/or PBM.

Second, in promulgating the final rule, we urge the Secretary to be cognizant of potential unintended adverse reimbursement consequences that the rule may have on pharmacies, which may adversely affect patients' access to more cost-effective therapies.

### **Conclusion**

Thank you for the opportunity to comment on the proposed rule. We appreciate the importance of containing costs and helping Medicare and Medicaid recipients reduce out-of-pocket spending and, ultimately, improving adherence in support of improved patient outcomes and overall lower healthcare costs. We agree that the proposed rule has the potential to achieve these goals and to eliminate incentives that are frustrating policymakers, consumers and taxpayers.

The pharmaceutical wholesaler industry's value proposition and demonstrated ability to collaborate with all healthcare stakeholders uniquely positions us to further enable access and create additional efficiencies within the supply chain. Relying on existing NCPDP rebate standards and slightly modified existing pathways between PBMs and manufacturers, as HHS contemplates in the proposed rule, wholesaler distributors' systems could be readily leveraged to facilitate point-of-sale price reductions in time for the proposed 2020 implementation.

We look forward to continuing to serve as a resource to the administration.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert P. Mauch". The signature is fluid and cursive, with a long horizontal stroke at the end.

Robert Mauch  
EVP & Group President  
AmerisourceBergen Corporation