HDA
Healthcare Distribution Alliance

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April 8, 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:

On behalf of the Healthcare Distribution Alliance (HDA), we appreciate the opportunity to provide comments to the Notice of Proposed Rule Making (NPRM) regarding the Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals. We support the Department's objectives to help lower out-of-pocket costs for Medicare Part D and Medicaid Managed Care beneficiaries. Our members believe they can play a vital role in operationalizing the transition from back-end rebates to point-of-sale price reductions.

HDA is the national trade organization representing primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Our primary function in the pharmaceutical supply chain is to ensure the safe and efficient distribution of prescription medicines to healthcare providers and the patients they serve.

It is clear that the Administration is committed to transitioning from back-end rebates to point-of-sale price reductions. Our members believe that their existing chargeback systems can be leveraged to process point-of-sale price reductions as credits on invoices to pharmacies for amounts due to wholesale distributors for product purchases. HDA distributor members are uniquely positioned to process point-of-sale reductions via chargeback as cashless transactions ensuring pharmacies are not negatively impacted by payment delays.

We also want to ensure the transition is seamless such that Medicare and Medicaid beneficiaries continue to have access to all medically necessary drugs and therapies and that our pharmacy and provider customers are minimally impacted. In addition, we want to ensure the final rule implementing the change to point-of-sale price reductions contains sufficient definitions and safeguards needed to operationalize the transition and ensure that misaligned incentives do not remain in the post-rebate environment.

Role in the Supply Chain

Wholesale pharmaceutical distributors play a vital role in the U.S. healthcare supply chain. On a daily basis, pharmacies, hospitals and other healthcare providers place orders with HDA distributor members for the medicines, supplies and equipment they need to serve their patients. In turn, distributors maintain distribution centers that are stocked with every potential medicine, supply and piece of equipment their provider customers may need. This includes carrying a "full line" of products from almost all pharmaceutical manufacturers as well as many over-the-counter drugs and consumer goods. Essentially, distributors provide a one-stop-shopping opportunity for healthcare providers that is efficient, secure and highly cost effective.

Without primary distributors, each manufacturer would have to ensure that more than 200,000 pharmacy and provider settings in the United States receive the medications they need when and where patients need them. Manufacturers would need to deploy substantial financial, logistical and staff resources to provide medicines and supplies to hundreds of thousands of dispensing sites on a next-day basis. Likewise, healthcare providers would have to make hundreds of calls each day to various manufacturers to order products they need to treat the patients in their care. In both scenarios, manufacturers and providers would have to maintain and administer thousands of accounts receivable and payable rather than relying on a wholesale distributor to provide the full range of logistics and billing functions in a single transaction.

Because distributors provide these logistical, inventory and other services which manufacturers and pharmacies would otherwise have to perform themselves, the pharmaceutical supply chain is more efficient, reliable and secure. Patients are able to get the medicines they need in a timely fashion, saving our healthcare system billions of dollars each year.

Beyond Distribution

Pharmaceutical distribution has evolved from simply managing warehouses and shipping goods to meeting the evolving needs of our pharmacy and provider customers who operate in a rapidly changing healthcare environment. While HDA members are experts in supply chain logistics and operations, the industry is no longer focused solely on moving products from point A to point B. Today, pharmaceutical distributors provide a wide array of supporting services that enable the pharmaceutical supply chain to function efficiently and securely, delivering significant value to manufacturers and healthcare providers — and ultimately to patients.

HDA distributor members purchase drugs directly from manufacturers of FDA-approved medicines. Unlike third party logistics providers, wholesale distributors purchase drug products from pharmaceutical manufacturers at a manufacturer's list price or at a price negotiated with pharmaceutical manufacturers and take title and ownership of the products that are stored in their warehouses. Wholesale distributors sell drug products to downstream customers at list price or at discounted prices based on list price that the provider customer has negotiated with the wholesaler or with the pharmaceutical manufacturer directly. Wholesale distributors do not establish the list price of drugs.

This inventory of products, with its multi-billion dollar value, is maintained in secure and controlled facilities. Cold chain products are kept in refrigeration units. Controlled drugs are kept in secure vaults and cages. All products are tracked in sophisticated inventory management systems that measure inventory levels and are used to pick, pack and ship products when they are ordered by provider customers. All of this occurs on a 24 hour-a-day cycle and is why HDA members are able to provide next-day service to all of their downstream customers.

HDA distributor members provide valuable services to their customers, including the health systems, pharmacies and physicians treating Medicare and Medicaid patients. By working with full-line distributors, healthcare providers benefit from just-in-time inventories, saving the expense and staff necessary to carry expensive inventories and to operate secure storage facilities, both of which would add significantly to their cost of operations. In addition, distributors often provide financial services, such as credit terms, to their provider customers, including independent pharmacies and physician-run offices in rural areas.

Distributors also manage and maintain complex contract administration and chargeback systems for their manufacturer suppliers and numerous health system customers including those institutions participating in the 340B Drug Pricing Program. In serving these important healthcare providers, HDA distributor members not only fulfill their next-day delivery functions, but they also have sophisticated verification and reverse claims processing capabilities that allow manufacturers and providers to ensure products are being purchased at the correct price.

Managing Point of Sale Price Reductions Through Existing Distributor Chargeback Systems

Our members believe that their existing chargeback systems can be leveraged to process point-of-sale price reductions as credits on invoices to pharmacies for amounts due to wholesale distributors for product purchases. As such, wholesale distributors are uniquely positioned to process point-of-sale reductions via chargeback as cashless transactions ensuring pharmacies are not negatively impacted by payment delays. As noted above, wholesale distributors and manufacturers currently manage and maintain complex chargeback systems through which millions of chargeback transactions are exchanged each month. This enables hospital and other health system provider customers to purchase drug products through wholesalers at the discounted price such customers have negotiated with manufacturers or at prices mandated under various government programs.

On an annual basis, hundreds of millions of chargeback transactions are exchanged and processed, with the vast majority adjudicated within a matter of days. We believe these highly efficient systems might be leveraged to similarly route chargebacks, as defined in the proposed rule and on behalf of a manufacturer, to a dispensing pharmacy. That said, modifications to accommodate per-claim chargebacks would require investment given that they are not tied to a specific stock bottle or invoice from the wholesaler—as is the case with traditional chargebacks today.

Transparent and Timely Communication of Plan-Validated, Point-of-Sale Reductions Critical to Supporting Wholesaler Chargeback Option

The crux of enabling pharmaceutical wholesalers to serve as chargeback administrators is for the approved pharmacy claim to include an itemized chargeback amount due to the provider. Pharmacy claims are adjudicated electronically via standard transactions developed by industry at the National Council for Prescription Drug Programs (NCPDP) pursuant to and compliant with the Health Information Portability and Accountability Act (HIPAA). Through those standard transactions, pharmacies receive a paid claim message from a patient's health plan or its agent PBM (collectively referred to herein as health plan) that indicates that a claim is approved as well as the total and final payment due, including itemized accounting of the amount the plan will pay and the beneficiary out-of-pocket amount to collect.

Under the new chargeback system, it is still important for pharmacies to have full transparency at the point of sale for the total and final reimbursement due, including any chargeback amounts. As happens today, this information should continue to be validated and provided to the pharmacy through existing claim level remittances by the beneficiary's health plan. The plan continues to be best positioned to ensure accuracy of payment amounts based on the patient's benefit design and contract arrangements with manufacturers and pharmacies.

If the proposed rule was finalized, the NCPDP standard claim response message would need to separately itemize the applicable price reduction so that pharmacies could track the chargeback amount separate and apart from the amount the plan will pay.

While the enhancements needed to the standard are modest and straightforward, if OIG moves forward with January 2020 implementation, industry stakeholders would need to implement draft standards since the standards promulgation process is lengthy and the specific NCPDP claim standard is named in HIPAA. Guidance that ensures pharmacies remain compliant with HIPAA by implementing draft standards would be needed.

Transparent, timely and plan-validated communication of claims-level chargeback amounts due to the pharmacy will enable wholesalers to effectively adjudicate the chargeback payment to pharmacies. The source of this claims-level data could be the manufacturer, the health plan, pharmacy switches (i.e. healthcare clearinghouses) or a new source such as a CMS contracted third party administrator (TPA). We are willing to receive this claims-level data from any of these entities, but reiterate that it is critical that the data provided to us have

already been validated by the plan and are presented in a consistent format when exchanged among any and all entities in the pharmaceutical supply chain.

When the price reduction is routed through the wholesaler as a chargeback, it becomes a second receivable to the pharmacy (the plan amount being the first receivable). Having two payers for a claim occurs in the industry today, for example, with certain Medicaid beneficiaries and co-payment assistance programs among others. The reconciliation systems used by pharmacies can accommodate multiple payments for a claim. To ensure efficiency in the claims reconciliation process, the wholesale distributor would furnish a remittance advice using the HIPAA-named standard X12 835 for use by the pharmacy.

To enable the wholesaler to submit the discount or chargeback amount to the manufacturer on the pharmacy's behalf, the wholesaler could receive the itemized chargeback and pertinent claims data, submit the discount transaction to the manufacturer, receive the credit from the manufacturer, and have the amount flow to the dispensing pharmacy as a credit on invoices for product purchases. This would be a "cashless" transaction that quickly reduces gross amounts to net amounts and does not create misaligned incentives.

An important enabler would be to identify the chargeback administrator for each pharmacy, so that the chargeback detail is directed to the correct wholesale distributor. We recommend that the industry registry managed by NCPDP would be the ideal authoritative source and could easily be expanded to include each pharmacy's designated chargeback processor similar to the manner used to record payment address for payer payments.

Alignment of Part D Regulations

When finalized, the new proposed safe harbor will ensure Medicare and Medicaid beneficiaries will benefit from the price reductions negotiated by pharmaceutical manufacturers and Medicare Part D plans/Medicaid managed care plans and/or their agent PBMs. However, we are concerned that the rule may not provide operational regulations or technical guidance from CMS, which administers the Part D program, as well as other federal and state programs or agencies that might be affected by the proposed rule.

A number of regulatory changes would be required to address the transition to point-of-sale price reductions. For instance, the definition of "negotiated price" at 42 CFR 423.100 would need to be revised to incorporate reductions in price processed via chargebacks itemized at the point of sale through a formal rulemaking or at a minimum through guidance stating that such reductions in price can reasonably be determined at the point of sale. Likewise, to ensure timely payment of such point-of-sale price reductions to retail pharmacies, we recommend that payment of such reductions be subject to the existing Part D regulations that address prompt payment of claims. *See* 42 C.F.R. § 423.520.

In addition, the proposed rule does not address the status of price reductions for Medicare Part D plans that utilize flat-dollar co-payments that are actuarially equivalent to the Medicare Part D prescribed cost-sharing, where the price of the drug is not relevant for determining the amount of cost sharing by the Part D enrollee. This is another area where

CMS may need to refine existing regulations and certainly would need to provide additional guidance as to how to address such point-of-sale price reductions during the bid process and annual reconciliation for actuarially equivalent Medicare Part D plans.

As the supply chain shifts from rebates to reductions in price at the point of sale, there may be other topics and areas where CMS and/or state Medicaid agencies will need to issue additional rules or guidance to effectively operationalize the shift. We urge the OIG to coordinate with CMS throughout the rulemaking process so the agency will be better positioned to identify all areas where additional operational rules and guidance are needed related to its oversight and administration of the Medicare Part D program.

Dispute Resolution

In the event there are chargeback or pricing disputes, wholesale distributors work with their health system customers and manufacturers to quickly identify and resolve disputes. That will not be true in this instance, as any disputes would be between manufacturers and health plans, not the distributors. While the point-of-sale reductions can be validated during claims adjudication, there is still a need for subsequent review and audit to ensure health plan compliance with their discount agreements with pharmaceutical manufacturers.

In the case that a price reduction was improperly applied at the point of sale, the plan-pay amount on the claim could be understated by the price reduction. In this case, the manufacturer should dispute the claim and the plan would then refund the difference. No action should be required on the part of the pharmacy to reverse and rebill the original paid claim which could result in the beneficiary's out-of-pocket amount being increased. The dispute could come to light months after the dispensing date and should be handled solely between the health plans and the manufacturers, the two parties to the contract for point-of-sale price reductions.

Proposed Definition of Chargeback/Clarification of New Safe Harbor

The Administration has expressed a desire to remove misaligned incentives from the supply chain, especially those that contribute to the gross-to-net bubble. The Administration may wish to consider that some misaligned incentives may remain in place if the entities that control formulary access also operate as the chargeback administrator. The terms of chargeback processing, such as payment terms and fees, could be tied to list price, formulary positioning, placement, or other forms of misaligned incentives. We recommend that OIG amend the proposed definition of "chargeback" to state that such payments may be processed only by entities that do not control the Medicare Part D/Medicaid Managed Care Organization formularies. This would still provide many potential options for the administration of chargebacks such as through wholesale distributors, switches and even PBMs when they do not manage a formulary on behalf of a health plan.

Retail Pharmacy Concerns

We have been in dialogue with our downstream community pharmacy customers and understand they have two chief concerns about the proposed point-of-sale price reductions model.

The first is the potential lag time between dispensing a drug product to a beneficiary and full reimbursement to the pharmacy. Today, Medicare claims are paid within 14 days whether primary or secondary. We agree that any pharmacy should continue to be paid in full, including any potential chargebacks for point-of-sale price reductions, within the 14-day timeframe. Pharmacies, particularly independent pharmacies, already face difficult operating margins and pressures, and anything that delays or prolongs repayment will be problematic. Our members are confident that the efficiencies of distributor processing of chargebacks will easily meet, and likely beat, the prompt pay requirements. In order to ensure that pharmacies are made whole for such point-of-sale price reductions quickly and efficiently, CMS could amend its Part D regulations addressing prompt payment of claims to apply to the point-of-sale price reductions. *See* 42 C.F.R. § 423.520.

Secondly, two payers for these claims require additional tracking of receivables to ensure full payment. To reduce the burden on pharmacies, wholesalers also would submit appropriate claim-level detail on all chargebacks to pharmacies in the specified HIPAA named X12 835 standard for electronic remittance advices. In order to ensure that pharmacies are made whole for such point-of-sale price reductions quickly and efficiently, CMS could amend its Part D regulations addressing remittance advices to apply to the point-of-sale price reductions. *See* 42 C.F.R. § 423.520.

Timeline for Implementation

We will do everything within our capabilities to transition existing distribution and financial systems used by distributors and manufacturers to efficiently process and manage chargebacks resulting from applying price reductions at the point of sale. While OIG's aim of transitioning from rebates to point-of-sale price reductions on January 1, 2020 is aggressive, it is feasible as long as there are motivated trading partners which OIG could assure with clear guidance on the role of distributors serving as chargeback administrators. In addition, industry stakeholders would need approval to implement the new qualifier codes in the existing NCPDP standards and other guardrails from OIG, CMS and other state and federal agencies. In addition, CMS and perhaps state Medicaid agencies would need to issue timely operational guidance and regulations to seamlessly implement the transition to point-of-sale price reductions. However, we want to convey that the transition will be significant and has the potential to disrupt Medicare and Medicaid beneficiaries if supply chain stakeholders wait until the rule is final before investing in the planning, systems and infrastructure changes necessary.

As an industry, we are committed to making this transition as seamless as possible and minimize the potential disruption to the supply chain. The more time the supply chain has to

adapt and the clearer the guidance from OIG, the less disruptive it is likely to be for all stakeholders, including Medicare and Medicaid beneficiaries.

Clarification as to Application of Proposed Rule

In the NPRM, the agency notes that the changes in the proposed rule are to apply to formulary rebates negotiated by and paid to health plans (or their contracted PBMs) by pharmaceutical manufacturers only, and not to or from other entities in the pharmaceutical supply chain or other health care providers.

Wholesale distributors provide significant value to their downstream customers, particularly rural hospitals and small, independent pharmacies. Due to their volume purchasing capabilities, wholesalers are often able to offer these entities discounts and rebates on products that would otherwise not be available to them. By doing so, wholesalers help these healthcare providers increase their efficiency while significantly reducing their acquisition costs for the medicines they need to treat the patients in their care. If these discounts were no longer permitted, these smaller providers and pharmacies would face mounting financial pressure in an already difficult fiscal environment.

For the avoidance of doubt, we ask that OIG state in the final regulation that all rebates are still safe harbored under the Discount Safe Harbor, except formulary rebates paid by pharmaceutical manufacturers to health plans and/or PBMs.

Conclusion

We appreciate the importance of containing costs and helping Medicare and Medicaid beneficiaries reduce out-of-pocket spending. We believe that existing distributor chargeback systems can be leveraged to administer point-of-sale price reductions as credits on invoices to pharmacies for amounts due to wholesale distributors for product purchases. This would minimize disruption and ensure prompt reimbursement to the pharmacies serving Medicare and Medicaid beneficiaries. However, we will need significant guidance from not only OIG but also CMS.

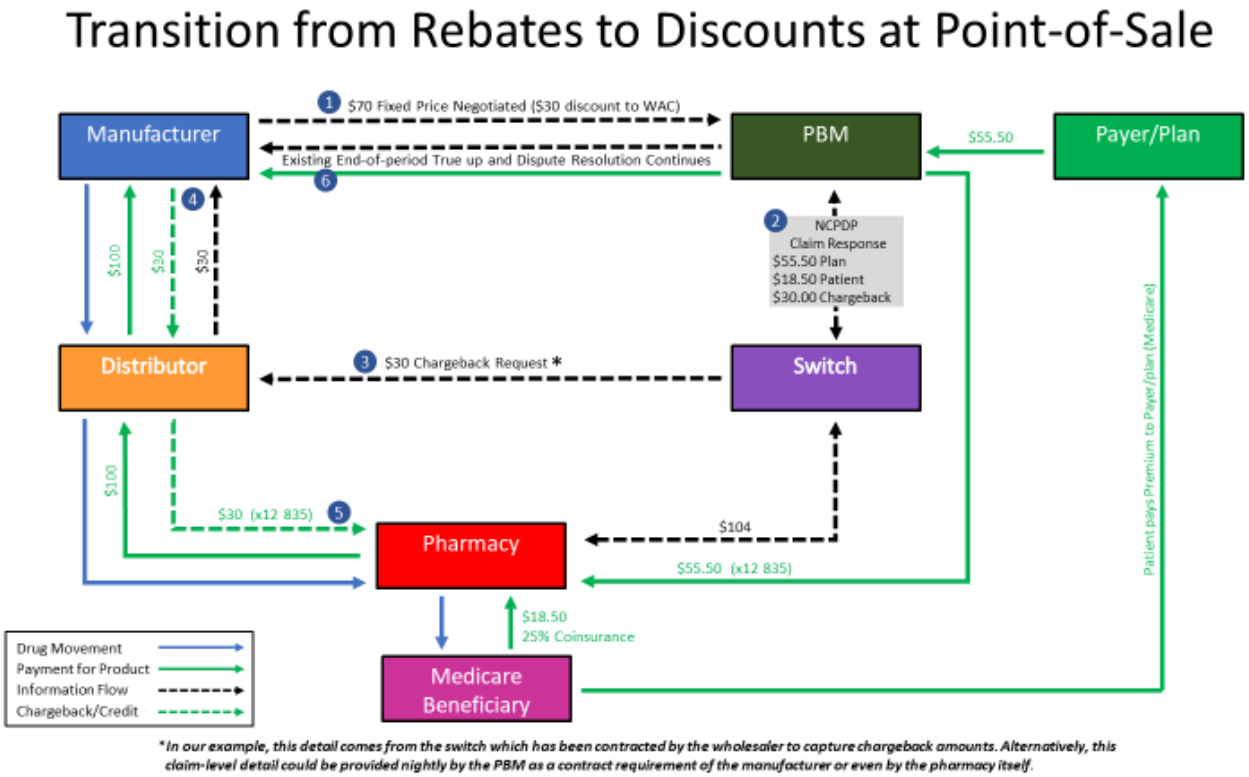
We are happy to work closely with the Department to provide additional feedback on the issues discussed in this letter and/or to address other questions about wholesale distributor capabilities. Specific questions or follow up to this comment letter should be directed to Patrick Kelly, HDA's Executive Vice President of Government Affairs, by email pkelly@hda.org or by phone at (703) 885-0233.

Sincerely,

John M. Gray
President and CEO

Appendix:

The following diagram documents the dispensing of prescription drugs 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 examples from the proposed rule and are based on a product with a $100 List Price (Wholesale Acquisition Cost - WAC). The diagram below portrays one of several potential arrangements in which a wholesale distributor serves as a chargeback administrator. In this example, the distributor would receive claims-level data from a pharmacy switch. As stated in our comment letter, alternatively, the claims-level data could be provided by a manufacturer, health plan or even a CMS contracted TPA.



(A full-page version of the above chart can be found on the last page of these comments.)

- **Point-of-Sale Price Reduction Contracts**
  The manufacturer and PBM (on behalf of its plan sponsors) negotiate a fixed price (not variable in relation to list price) for the product for favorable formulary positions. In this example, the manufacturer and PBM have agreed to a fixed price of $70 for the product, which represents a discount of $30 to the list price. ❶

- **Beneficiary at the Pharmacy**
  Continuing the example, a Medicare beneficiary presents a prescription for the drug product. The pharmacy submits the claim request to the PBM which calculates the

reimbursement as $104 based on list price (WAC X 1.2, less 15%, + $2 dispense fee) ❷ and calculates the patient's out-of-pocket amount using a basis of $74 to fully reflect the discount ($104 less the $30 discount) resulting in $18.50 based on the plan design of 25% coinsurance. The chargeback amount of $30 is separately itemized in the claim response.

It is critical to note that only the PBM is in the position to accurately calculate the patient's cost share as it is dependent on plan design, the plan phase for the beneficiary at the time of dispense, as well as the discount amount. To enable any entity other than the PBM to serve as chargeback administrator requires that the chargeback amount be itemized by the PBM at the point of sale. Today, the PBM would split the $104 between the plan share and the patient cost share. In a world without rebates, the amount must be split into three: the plan amount, the patient amount, and the chargeback amount.

The distributor has previously ordered and received the product from the manufacturer at the $100 WAC price which has been subsequently shipped to the pharmacy and paid to the wholesaler based on the $100 WAC price.

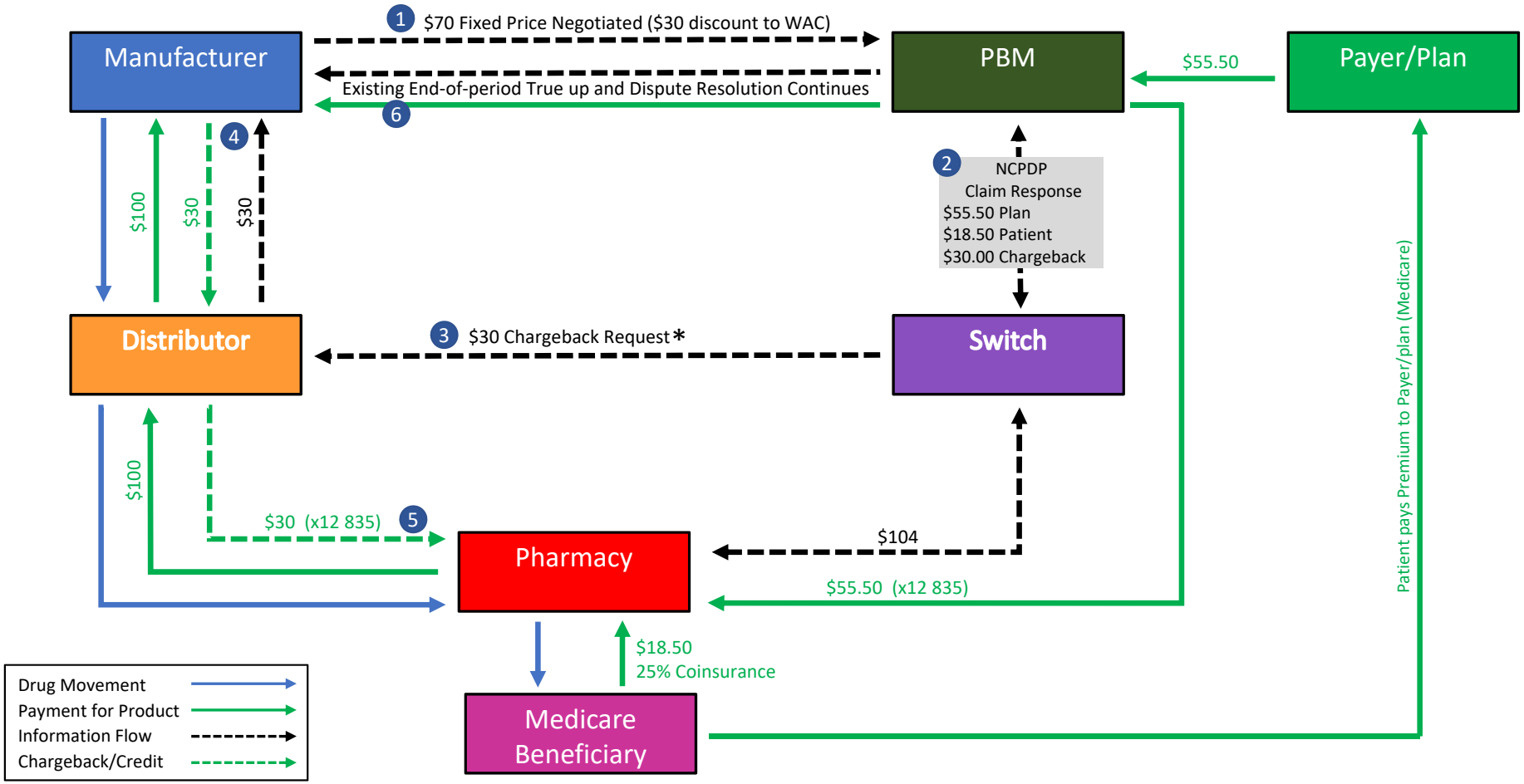
- **Back-end transactions – after the point-of-sale transaction**
  From the dispensing pharmacy's standpoint, the $30 chargeback amount has become a receivable. To enable the wholesaler to submit the claim to the manufacturer (indirectly on behalf of the pharmacy) it must receive claim-level detail. In our example, this detail comes from the switch ❸ which has been contracted by the wholesaler to capture chargeback amounts. Alternatively, this claim-level detail could be provided nightly by the PBM as a contract requirement of the manufacturer or even by the pharmacy itself.

- **Distributors as Chargeback Administrators**
  Following the diagram, the distributor would capture the claim-level detail from the switch and following a standard set of business rules agreed between distributors and manufacturers, submit a chargeback request to the manufacturer using the existing standards (x12 844) interface ❹ on behalf of their pharmacy customer. The manufacturer would approve the request and respond by crediting the distributors open receivable (x12 849) in a cash-less transaction. The distributor, in turn, would forward the $30 to the pharmacy in the form of a credit to its open receivable (EDI 810) ❺, which is a cashless transaction and follow it up with an electronic remittance advice (x12 835). This process would meet or exceed the 14-day prompt-pay requirement.

  As pharmacies already have distribution and financial agreements in place with distributors, distributors can fulfill the role of chargeback administrator for the point-of-sale discounts with minimal impact or disruption to existing business practices.

- **True-up and Dispute Resolution**[6]
  Today, manufacturers receive monthly or quarterly utilization data from PBMs and health plans as supporting documentation to rebate invoices. We see this existing step continuing in the world without rebates. Manufacturers review the claims detail to determine if each claim was eligible under the contract and to dispute claims where the discount was improperly applied. In the event that a price reduction was improperly applied at the point of sale, the result is that the plan-pay amount on the claim would have been understated by the price reduction. In other words, the plan benefitted from the mistake. In this case, the manufacturer should dispute the claim and the PBM would pass the amount due on to the health plan. No action should be required on the part of the pharmacy to reverse and rebill the original paid claim, which could result in the beneficiary's out-of-pocket amount being increased. The dispute could come to light months after the dispense and should be handled solely between the health plans and the manufacturers, the two parties to the contract for point-of-sale price reductions.

Transition from Rebates to Discounts at Point-of-Sale



**In our example, this detail comes from the switch which has been contracted by the wholesaler to capture chargeback amounts. Alternatively, this claim-level detail could be provided nightly by the PBM as a contract requirement of the manufacturer or even by the pharmacy itself.*