



Healthcare Distribution Alliance

PATIENTS MOVE US.

July 16, 2018

The Honorable Alex Azar  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, Room 600E  
Washington, DC 20201

**Re: Request for Information on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Docket ID: CMS-2018-0075)**

Dear Secretary Azar:

On behalf of the Healthcare Distribution Alliance (HDA) we appreciate the opportunity to provide comments to the Request for Information on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. We are committed to working with you to do what we can to bring further efficiencies into the pharmaceutical supply chain to accomplish many of the objectives set forth in the Blueprint.

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.

We applaud your efforts to address the high cost of healthcare in the United States. Since 1876, HDA has represented an industry whose overarching mission is to get the right medicines to the right patients at the right time, safely and efficiently. Safety and efficiency continue to be the defining values that wholesale distributors bring to the nation's pharmaceutical supply chain. And for the record, our industry would never oppose efforts by manufacturers to voluntarily reduce the list price of drugs that would ultimately reduce costs for patients.

As is the case with any trade association, our antitrust policy precludes HDA from being privy to, or providing a venue for any discussion about prices and/or the components of prices among members. As members may not discuss pricing, pricing formulas, policies or the terms of their purchase and sales contracts in any HDA sponsored venue, the organization is unable to provide any comments or answer questions about specific drug products, their prices or negotiations that take place between member companies and their suppliers and/or customers. Each member company of HDA must exercise its independent business judgement in pricing its services or products, dealing with its customers and suppliers and choosing the markets in which it will compete.

That being said, we have compiled the following information about the role of wholesale distributors in the pharmaceutical supply chain that will hopefully be helpful in your efforts. We have also offered comments on potential revival of the Competitive Acquisition Program under Medicare Part B and potential efforts to alter the current legal and regulatory environment surrounding manufacturer-sponsored co-payment assistance programs.

### **Role in the Supply Chain**

The U.S. healthcare supply chain is complex, and the nation's primary pharmaceutical distributors play a vital role within it. Each day hundreds of thousands of healthcare provider locations must receive needed medicines and other healthcare products from thousands of manufacturers. These manufacturers and providers are served predominantly by HDA's primary distributor members, who operate out of about 176 warehouses and purchase directly from authorized manufacturers — a relatively small, but highly efficient and effective network.

Every day HDA members work around the clock to safely and efficiently ship 15 million healthcare products (medicines, medical supplies, durable medical equipment, etc.) to pharmacies, hospitals and other healthcare providers to keep their shelves stocked with the medications and products they need to treat and serve their patients.

Distributors are unlike any other supply chain participants — their core business is not manufacturing, and they do not prescribe medicines or dispense to patients. Their key role is to serve as a conduit for medicines to travel from manufacturer to patient while making sure the supply chain is fully secure and as efficient as possible.

HDA distributor members focus significant resources on the safety and security of the supply chain, and their secure supply chain efforts may in fact be the most important service they provide to the overall pharmaceutical delivery system. In 2013, HDA strongly advocated for the enactment of the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality Security Act, which sets a framework for unit level traceability of medicines by 2023.

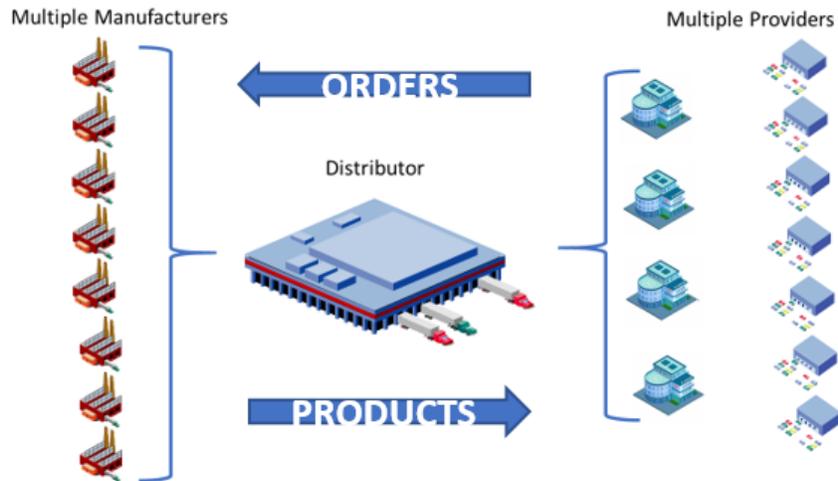
Today, HDA members are working closely with the Food and Drug Administration, as well as state regulatory authorities and our trading partners, to build the systems and processes necessary to implement the DSCSA and achieve unit-level traceability of prescription drugs.

### **Relationship with Supply Chain Trading Partners**

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 every pharmaceutical manufacturer as well as many over-the-counter and consumer and durable goods.

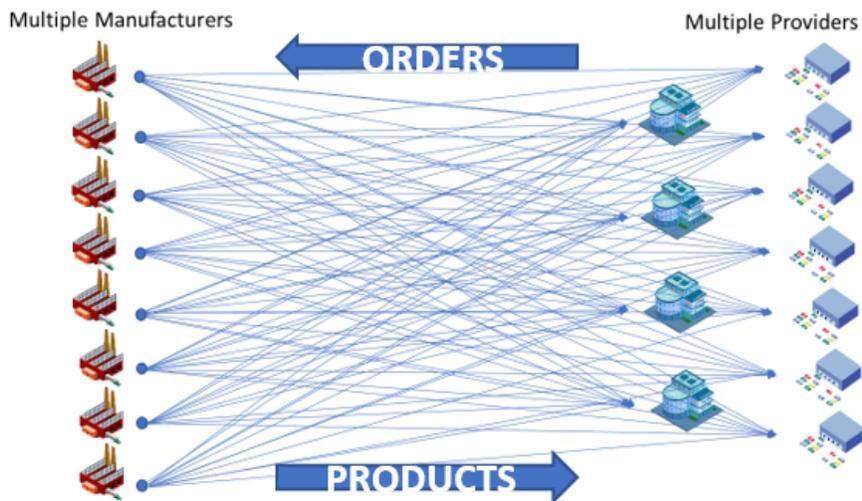
In order to provide this comprehensive inventory of products, distributors must maintain business relationships with every brand, generic and specialty drug manufacturer as well as with manufacturers of OTC and consumer products and supplies.

## Efficiency of Pharmaceutical Distributors



Without pharmaceutical distributors, manufacturers would have to provide financial credit services and set up accounts receivable for the more than 200,000 healthcare providers across the United States. Without pharmaceutical distributors, pharmacies and providers would have to carry weeks of inventory and undertake the time-consuming process of placing individual orders with each and every manufacturer for products that they need for patient care on a daily basis.

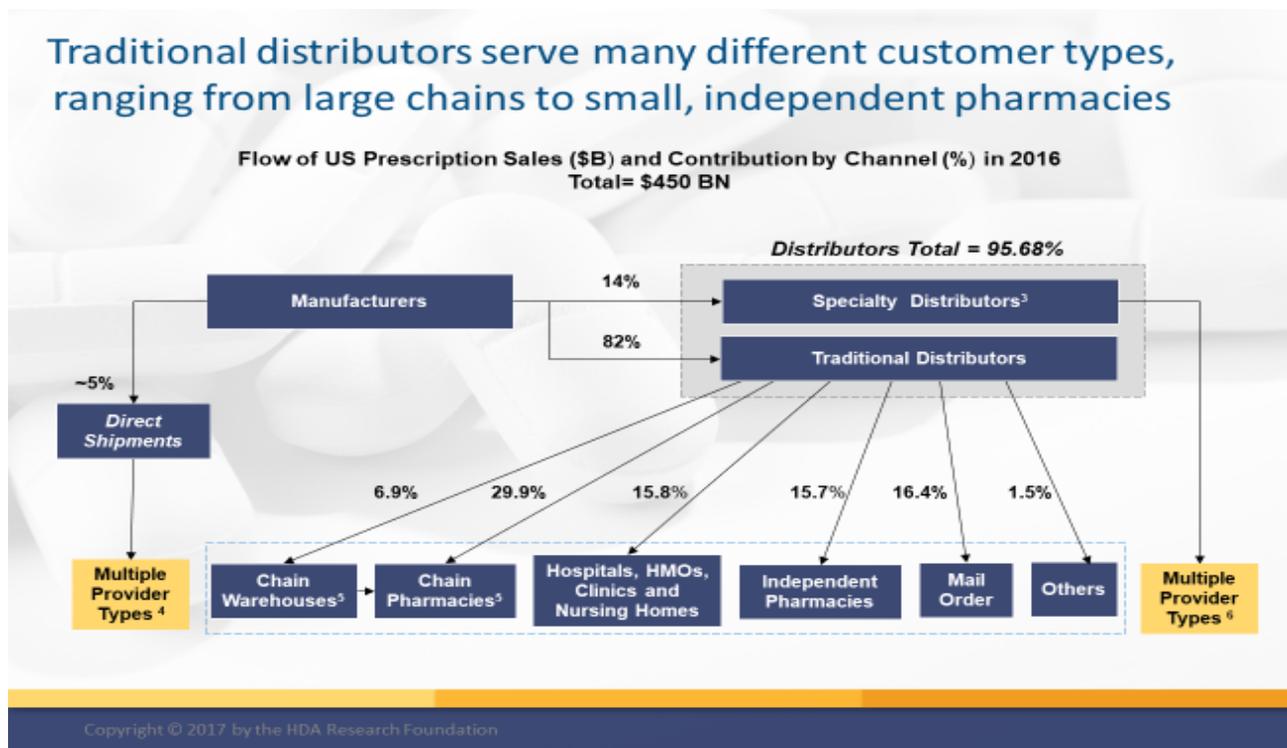
## Without Pharmaceutical Distributors



By working with full-line distributors, providers can maintain just-in-time inventories, saving pharmacies and hospitals the expense and staff necessary to carry extensive inventories or have large storage facilities, both of which would add significantly to their cost of operations.

At their core, distributors provide on-time and complete shipment of ordered drugs in a safe and efficient manner. In addition, they often provide financial credit, pharmacy management systems and in-store retail support to pharmacy providers, among many other services.

Traditional distributors serve a broad array of provider types — mostly retail and hospital settings, including chain pharmacy warehouses, mass merchandisers and food chains, and chain pharmacies. Specialty distributors (and specialty subsidiaries) serve other provider settings such as physician offices, home care and specialty pharmacies.



### Relationship with Manufacturer Suppliers

The work of primary distributors also enables manufacturers to concentrate on developing and producing needed medicines without the added expense and logistical challenges of determining how to get those medicines to providers and patients across the United States. However, pharmaceutical distribution has evolved over the last decade from simply managing warehouses and shipping goods. While HDA members are primarily supply chain logistics and operations experts, this is no longer an industry focused solely on moving products from point A to point B. Rather, pharmaceutical distributors provide a wide array of supporting services that enable the pharmaceutical supply chain to function efficiently and safely, delivering significant value to manufacturers and healthcare providers — and ultimately to patients.

Some examples of these core services include: receiving orders and shipping pharmaceutical products in a safe, efficient manner; inventory handling and inventory management, providing manufacturers with data about where (and in which settings) their products are utilized; verifying downstream customer eligibility to purchase products at pricing established under various programs or contracts between such customers and given manufacturers; and processing relevant chargebacks to manufacturers.

In the early 2000's, the pharmaceutical distribution industry transitioned from a historical arbitrage business model to a fee-for-service model. The arbitrage, or "buy and hold" model relied heavily on the spread between what distributors paid to purchase drugs from manufacturers and corresponding price appreciation of the products prior to sale to downstream customers.

The current fee-for-service business model is predicated on "bona fide service fees" charged to manufacturers for the various distribution and logistics services that primary distributors provide. These fees, which are not passed on to the downstream customer, represent a fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement. This model reduces demand volatility — aligning order patterns more closely to actual patient demand, and eliminates artificial demand spikes, allowing for a supply chain that operates more smoothly and predictably.

While the current fee-for-service model has reduced volatility in the supply chain, the system may need to adapt to changing market dynamics. Any compensation systems, including Inventory Management Agreements (IMAs) that fluctuate with manufacture pricing are unlikely to be well-aligned with a long-term goal of reducing drug prices. A new compensation model might be more compatible with ensuring that the current high standard of safety and efficiency of the U.S. pharmaceutical supply chain is maintained regardless of trends in drug pricing. Of course, any discussion about new compensation models must occur only between individual trading partners.

As stated earlier, without primary distributors, each manufacturer would have to ensure that more than 200,000 pharmacy and provider settings receive the medications they need when they need them, employing substantial financial, logistical and staff resources to provide medicines and supplies to hundreds of thousands of dispensing sites. Because distributors provide these logistical, inventory and other service support which manufacturers and pharmacies would otherwise have to perform themselves, 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 billions of dollars each year.

### **Primary Wholesale Distributors' Role in Drug Pricing**

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.<sup>1</sup>

Traditional pharmaceutical wholesale distributors purchase pharmaceuticals from manufacturers based on the Wholesale Acquisition Cost (“WAC”), a publicly available figure reported for each pharmaceutical product by the manufacturer to various compendia such as Medi-Span and RedBook, which publish such prices. WAC represents the manufacturer’s list price, and does not include rebates, prompt payment, or other adjustments in price resulting from proprietary negotiations between manufacturers and wholesalers, PBMs and downstream payer groups or other customers. Pharmaceutical manufacturers set the WAC price for their products. Wholesale distributors are not privy to how such WAC pricing decisions are made. Wholesale distributors typically purchase pharmaceuticals from manufacturers based on WAC and they also charge manufacturers distribution fees related to their services, as previously discussed.

Wholesale distributors do not control the price of pharmaceuticals. Rather, the price of pharmaceuticals is dictated by manufacturers of such products, as well as other market forces, which include the available supply and the introduction of competing generic products. Wholesale distributors typically sell branded drugs to downstream customers based on WACs established solely by pharmaceutical manufacturers. Wholesale distributors might also sell generic drugs to downstream customers based on WACs established solely by pharmaceutical manufacturers and published in the various pricing compendia. Alternatively, they may price generic drugs sold to downstream customers in response to market forces, which includes supply of competing generic drugs.

Primary distributors purchase drugs from virtually every generic manufacturer in order to have the specific products that hospitals, pharmacies, and other healthcare providers prefer. In some cases, the provider’s acquisition cost of a generic product may have been negotiated by the provider with the manufacturer directly or indirectly by a group purchasing entity negotiating on the provider’s behalf. The distributor’s broad inventory base results in service and cost efficiencies for these providers because they can get all of their products from the same distributor in one delivery with the distributor processing the difference in the direct or indirect negotiated price for the product as a chargeback to the generic drug manufacturer.

For independent retail and small chain pharmacies, it is often the distributor that fills the vital role of aggregating demand and negotiating discounts that would otherwise not be available to these providers. These programs—commonly referred to as generic sourcing programs—provide smaller pharmacies with the efficiency of dealing with one distributor as well as significantly reduced acquisition costs for generics. These aggregated buying programs can also be offered to other customers of the distributor, providing a safety net in cases where the customer’s preferred generic may be in short supply or on back order.

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<sup>1</sup> 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](http://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf).

Overall, the pricing in the distributor's generic sourcing programs follows the market price. The market pricing of generic drugs is in essence the pricing of any traditional commodity. With more alternatives and a surplus of supply, pricing goes down. In instances of fewer alternatives and less supply, prices may increase. The generic market changes daily and is very competitive. Generic purchasers generally have a wide array of alternatives to choose from and check pricing routinely.

### **Competitive Acquisition Program (CAP) for Medicare Part B Drugs**

We understand the interest in reviving the CAP program for Medicare Part B drugs with the aim of eliminating or reducing the perceived incentive for physicians and other providers to prefer drug products with the largest "spread" between acquisition cost and the Average Sales Price (ASP)- based reimbursement. However, despite significant changes in the healthcare market place and more

sophisticated management and distribution strategies, our past experience with the CAP program leads us to believe it will only add an additional layer of inefficiency and may actually impede patient access to needed medications.

Chief among our concerns is the fact that the CAP 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.

While we believe the CAP program is fundamentally flawed, if the Department does proceed with implementing a CAP 2.0 program, we urge it to proceed with the following guiding principles:

- Ensure that Medicare Part B beneficiaries and the physicians that treat them continue to have full access to all products and treatments currently covered under the Medicare Part B program.
- Ensure that whatever administrative processes need to accompany a robust, functional CAP program do not become a potential barrier to access.

Ultimately, we have concerns that additional layers of administrative gatekeeping by designated CAP vendors for the Medicare Part B program may have unintended or potentially opposite impacts by limiting access and potentially driving up costs for patients.

### **Manufacturer-Sponsored Co-payment Assistance Programs**

HDA supports any program that improves patient adherence and reduces patient out-of-pocket expenditures. 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. In addition, we have seen no evidence

suggesting that manufacturer-sponsored co-payment assistance programs drive up list prices for these products, and we are aware many commercially insured patients utilize such programs to help control their out-of-pocket costs for prescription drugs.

If manufacturers must factor the value of the cards into their Average Manufacturer Price (AMP) and best price calculations under the Medicaid program, they may discontinue these valuable patient assistance programs. 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 loosening the Anti-Kickback Statute prohibition on 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 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, therapeutically equivalent product.

### **Conclusion**

The goal of pharmaceutical wholesale distributors is a simple one: to ensure efficient, secure and timely delivery of products to providers so those providers can concentrate on patient care and ensure their patients have regular access to the medications they need. These services result in benefits to patients in terms of availability of secure medications and have made the United States pharmaceutical supply chain one of the safest and most efficient in the world.

As we stated earlier, we are not, and would never oppose manufacturers voluntarily reducing prices that would lead to lower costs for patients. We are also not opposed to considering alternatives to the current fee-for-service compensation model as long as we can continue to maintain the current high standard of safety and efficiency of the U.S. pharmaceutical supply chain.

We appreciate this opportunity to comment on the Blueprint and share information about our industry and would welcome the opportunity to meet with you and answer any questions you may have about the role of distributors in the pharmaceutical supply chain.

We applaud your efforts to address the high cost of healthcare and are committed to working with you and your team.

Sincerely,

A handwritten signature in black ink, appearing to read "J.M. Gray". The signature is stylized and written in a cursive-like font.

John M. Gray  
President and CEO