Drug Distribution and Reimbursement in Federal Markets

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Introduction

The Department of Veterans Affairs (VA) and the Department of Defense (DoD) operate health systems that offer pharmaceutical companies access to robust patient populations in certain disease spaces. With more than 18 million combined beneficiaries, many in the industry seek to improve their positioning within these markets, but are often discouraged given the required deviation from commercial practices.

The VA and DoD are subject to a procurement process that is complex and highly regulated. They also utilize unique arrangements in an effort to standardize and streamline pharmaceutical procurement. For instance, the VA and DoD receive a negative distribution fee of approximately -10 percent from their contracted distributors on pharmaceutical purchases. Companies that fail to include these wholesalers in their distribution network often find that it results in low prescription fulfillment rates.

Initially, many companies decide that the VA and DoD portion of sales will be too low to warrant allowing the segment to influence distribution channel design. The result is often that uptake is even lower than expected, prompting an eventual shift to accommodate federal purchasing preferences.

However, as commercial payers and PBMs have consolidated, manufacturers have been faced with a new set of market access challenges that have ultimately prepared them to better navigate the Federal segment. Some of the resulting tactical adjustments have included an increased need to contract, implementation of steeper price increases to absorb the additional rebating, and incorporate payer and PBM distributors in channel design.

For example, after the Express Scripts and Optum merger, pharmaceutical companies began to see a decline in prescription fulfillment rates to Optum beneficiaries if they did not have ESI's own distributor, Acredo, contracted in their distribution network.

As pharmaceutical companies become accustomed to accommodating payer preference with regard to a variety of business arrangements, they may also become more willing to make deviations required to do business effectively in the Federal segment. Although consolidation has led to a power shift in the overall market that has made Federal segment complexities more palatable, key areas of risk remain that are highly differentiated from commercial practices.

VA and DoD Pharmaceutical Distribution

The government seeks to standardize procurement as much as possible in an effort to reduce the overall costs of procurement. The VA and DoD programs that streamline pharmaceutical and medical/surgical supply distribution are known as Prime Vendor Programs. A Prime Vendor is a single distributor of a pharmaceutical or brand-specific medical supply.

The VA and DoD operate separate Prime Vendor programs with similar terms. The VA currently has one Prime Vendor, McKesson, for the distribution of pharmaceuticals. The DoD has multiple Prime Vendors - AmerisourceBergen for distribution to Military Treatment Facilities and Express Scripts for retail and mail order channels. There are also back-up or small regional Prime Vendors for the DoD, but those arrangements cannot exceed 5 percent of all goods distributed to Federal facilities.

***Ms. Nagowski** offers over 15 years' experience overseeing Federal market procurements and is a recognized industry expert in market access for the pharmaceutical and biotechnology industries. Ms. Nagowski currently leads strategy development and statutory contracting activities for Federal Government payer markets. She specializes in helping clients understand how to effectively navigate the complexities of the Federal marketplace, while keeping patient access and revenue at the forefront of consideration.*

Under Ms. Nagowski's leadership, the D2 team of specialists, including former VA and DoD chief pharmacists, contracting and pricing personnel, and government affairs specialists, collaborate to provide best-in-class federal market solutions and strategies.

As noted above, the Prime Vendors for both services pay "negative distribution fees" on ordered drugs that are distributed to VA and DoD facilities. The full rationale around why these distributors are willing to offer this arrangement is lengthy, but primarily revolves around the government's ability to provide "fast pay" reimbursement. Wholesalers profit from floating funds, or earning interest, between the time the wholesaler receives payment from its customers and reimburses the drug manufacturer. These Prime Vendors also charge manufacturer's fees to participate in the program. These charges will generally offset the negative distribution fees.

Table 1. Pharmaceutical Prime Vendor (PPV) Program

	Distribution of:	Wholesaler	Key Terms
VA	Pharmaceuticals	• McKesson	Fast Pay: -10.05% Net 30: -9.65%
DoD	Pharmaceuticals	• Amerisource Burgeon: Military Treatment Facilities • Express Scripts – Mail Order & Retail	

Distribution Requirements of VA and DoD Contracts

Statutory pricing for drugs for the VA and DoD is identical. The VA and DoD leverage their combined purchasing power in the acquisition of pharmaceuticals with pricing established under a Federal Supply Schedule (FSS). For certain drugs, this contract typically involves a blend of statutory and negotiated pricing. From there, each health system has its own unique tools and procurement processes for pricing optimization.

The two primary supplemental discount vehicles used by the VA include a Temporary Price Reduction (TPR) and the National Contract. A TPR is a voluntary discount, meaning the government is not committing to any terms in return, and provides a 30-day termination clause. Manufacturer's can elect to include the DoD in this discount offering, but are not required to do so.

A "National Contract" is a supplemental discount offering by which the VA agrees to list a manufacturer's product as the preferred source in a class. Manufacturers often enjoy 90+ percent market share, and should expect to discount heavily to win this status. The DoD is always included as a customer under a VA National Contract.

Under FSS and Temporary Price Reduction terms, a manufacturer's decision to participate in the VA's PPV program is optional. However, under National Contract terms, participation in the PPV program is mandatory. Because manufacturers compete so aggressively for use of their product within the VA, they often find they are under water from a gross-to-net perspective once they fully realize their contractual obligations.

What's more, the National Contract is a five-year agreement. Should a manufacturer elect to decline an option year renewal, they may be subject to a negative past performance rating, which may impact future government contract opportunities.

The DoD primarily uses two supplemental agreements: a Distribution and Pricing Agreement (DAPA) and a Uniform Formulary Blanket Purchase Agreement (UFBPA) (NOTE: this is combined with a retail refund unsolicited "Additional Discount Program" (ADP) when manufacturer's bid). A DAPA can be used as a direct voluntary supplemental discount offering (discount above the FSS price) for the hope of increase utilization in the DoD -- but there is not a commitment for utilization.

A DAPA can also be a tool to smooth the purchasing pathway within the DoD for companies that elect NOT to participate in the PPV program. A DAPA will allow for the product to be loaded in the DoD Prime Vendor's ordering database so that military facilities can order the drug electronically. It is important to note that a DAPA is only applicable to the DoD, and will not improve electronic ordering capabilities within the VA.

The UFBPA is a solicited contracting opportunity for DoD formulary tier placement. Although manufacturer's have occasionally been successful in prompting the DoD to initiate a class review, this process is generally a reactive opportunity. This agreement does not require manufacturers to participate in the Prime Vendor program for award.

Prime Vendor Program Deviations

The VA's procurement process for ordering outside of the PPV is also a substantial operational lift on the organization. When a VA pharmacy needs to order a product, Prime Vendor ordering is delegated to Order Officers, VA personnel authorized to place orders through the PPV contract. A list of current Order Officer's is sent to McKesson on a weekly basis, and McKesson will grant PPV ordering access and Controlled Substance Ordering System access.

Orders that cannot be obtained through the VA's prime vendor, referred to as "open market" purchases, must be procured by a warranted contracting officer since this function is not within the authority of the PPV Order Officers. In many instances, the contracting officer will attempt to competitively bid the acquisition before issuing a purchase order, or at minimum post on 'fed biz ops.' From here, there are several additional steps involved in the procurement process, imparting a substantial operational lift on the health system.

Key Takeaways

As is the case in the commercial segment, each additional step required of a physician, office administrative staff, or patient further reduces the likelihood of the patients receiving the product. In practice, many have stated that unless the product is sole-source and truly lifesaving in nature, uptake will be affected by deviating from the government's preferred distribution providers.

Pharmaceutical distribution channel design has traditionally been a business decision by the manufacturer. It is often difficult for a small pharmaceutical company to get the attention they need from large wholesalers like McKesson and ABC, when their product isn't a big line item. However, this choice is shifting from the supplier to the purchaser, depending on which party is the power holder.

Understanding the challenges and requirements for working with the VA and DoD are an essential first step to conducting business. Proceeding carefully with the aid of those who regularly navigate this market can help companies see around the corners, and implement the right strategies early and effectively.