INDIAN HEALTH SERVICE
National Pharmacy and Therapeutics Committee
Formulary Brief: ***Federal Drug Pricing & the PPV***
-February 2025-

Background:
The Indian Health Service (IHS) participates in the U.S. Department of Veterans Affairs (VA) Pharmaceutical Prime Vendor (PPV). The IHS National Supply Service Center (NSSC) manages the PPV contract for all Federal, Tribal, and Urban Indian Organization stakeholder participants.

Discussion:
For the purposes of this document, a covered drug as defined by the statute is any legend drug that is approved by the Food and Drug Administration (FDA) under a New Drug Application or Biological Licensing Agreement.

PPV participants have access to five different pricing types:

- Federal Supply Schedule (FSS)
- Joint National Contracts (NAT)
- Big Four Pricing (BG4)
- Temporary Price Reductions (FSR)
- WAC (wholesale Acquisition Cost) Based Generic Pricing (WPG)

The FSS price is mandated for covered drugs, and the rules pertaining to this pricing are found in Public Law 102-585 Section 603. It is a calculated price based on pricing that is offered by the manufacturer using both the non-Federal Average Manufacturer's Price and the Federal Ceiling Price. The FSS price is MANDATED for covered drugs. The FSS price is NOT mandated for non-covered drugs. These drugs would typically be generics with an Abbreviated New Drug Application (ANDA) on file with the FDA. However, a manufacturer may *choose* to add their drug to the FSS even if it is a generic ANDA drug.

The BG4 price is an additional discount that manufacturers can offer to the Big Four agencies (VA, Department of Defense [DoD], Public Health Service, and Coast Guard). If the manufacturer does not offer a separate BG4 price, then it is assumed that the BG4 price and the FSS price are the same for all government entities.

Joint National Contracts (JNC) occur when the VA and Other Government Agencies (OGA) determine the need for either a standardization benefit or an economic benefit (or both) exists for a particular drug or class of drugs. The VA, DoD, IHS, and OGAs meet once quarterly to discuss drug spend, shortages, and the potential for better pricing or standardization. All agencies combine their data to look for outliers that would best fit into this role for a competed JNC. There are many factors that determine potential drug candidates for a JNC; these include, but are not limited to, drug class competition, drug manufacturer competition, manufacturer availability to meet the demand, package sizing, and economic impact. If there is only one manufacturer that could compete for a JNC, then no solicitation will be made for a contract. If there are two or more manufacturers that can compete for a contract, and those manufacturers have informed the VA that they will be capable of meeting inventory demands, then the VA may choose to solicit for a contract. Once the determination to move forward with a contract occurs, the VA will ask all other OGAs if they want to participate in the contract. If the OGA determines that it is in its best interest to participate, then that agency will provide data regarding their utilization of that product or products from the last 12 months to the VA. These numbers are included in the solicitation to ensure that agency receives at least that quantity each year. Each manufacturer will offer their best price during the solicitation product, and the VA will accept the lowest cost item that is technically acceptable. This could be a branded, generic, or repackaged product. After the award has been made, this is now a contract that binds all participants to purchase the awarded product (it is a requirements contract). These contracts typically offer the absolute best pricing and allow for product availability and stability during shortages.

Temporary Price Reductions (FSR) are prices offered by a manufacturer to one or more agencies as a discount below the FSS price. These prices are temporary and not binding in any way (the price can be pulled by the manufacturer at any time). FSR prices cannot be accepted by the VA as a direct competitor to a JNC product. In other words, if drug X and drug Y were both candidates to compete for a JNC, and drug X wins the contract with the lowest bid, drug Y will NOT be allowed to then offer a FSR to directly compete against the winning product. Drug Y had an opportunity to offer a lower price during the solicitation of the JNC and chose to offer a higher price than drug X. FSR pricing may be offered when a drug manufacturer wants to gain market share in the government or wants to keep its current market share against new competitors. As an example, insulin X may currently have 50% of all market share in the government and insulin Y may want to increase its market share from 15% to 40%. To accomplish this, the manufacturer of insulin Y may offer a FSR below the price of insulin X. In turn, insulin X may offer its own FSR to maintain its market share.

WAC Based Generic pricing allows for contract compliance on the PPV when no generic manufacturers choose to offer a drug at FSS pricing. These products are generic products that have no FSS, BG4, JNC or FSR options available on the contract for purchase. The PPV then allows for these products to be offered at WAC pricing on the contract to prevent these items from being procured on the open market. These products must still follow pertinent laws such as the Trade Agreements Act (TAA).

If you want to review more information on Federal Drug Pricing for the PPV, most information can be found in Public Law 102-585 Section 603 and the FAR Subpart 25.4 for the TAA information.

If you have questions regarding drug pricing, please contact the National Supply Service Center Customer Support at ihsnssccustomerservice@ihs.gov.

If you have any questions regarding this document, please contact the NPTC at IHSNPTC1@ihs.gov. For more information about the NPTC, please visit the NPTC website.