FSS PROGRAM INTRICACIES, CALCULATIONS AND PRICING ISSUES

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AGENDA

• VHCA Requirements for Covered Drugs
• FSS Program
• New Development under VHCA
• Negotiated vs. Statutory Price
• Pre-Award Disclosures and Defective CSPs
• Adding New Covered Drugs
• Price Reduction Clause; Negotiating the Tracking Customer
• Industrial Funding Fee
• Trade Agreements Act
VHCA REQUIREMENTS FOR COVERED DRUGS

- Section 603 of the VHCA, 38 USC 8126 requires, as a condition of Medicaid coverage, that manufacturers of “covered drugs”
  - Calculate and report the Non-Federal Average Manufacturer Price (NFAMP) for each covered drug, and charge the “Big 4” agencies no more than 76% of NFAMP less an additional discount if NFAMP exceeded the rate of inflation over the prior 12-month period
  - Offer all of their covered drugs for sale on the FSS at no more than this statutory amount (Federal Ceiling Price or FCP)

- VHCA defines “covered drug” as a prescription drug marketed under an NDA (incorporating the Medicaid statute’s definitions of single source and innovator multiple source drugs), and all biologics (regardless of approval pathway), including vaccines.

- Because FCP is a statutory ceiling, manufacturers must go through the normal FSS contract negotiation process in which the contracting officer determines a fair and reasonable price
FSS PROGRAM

• GSA administers Federal Supply Schedule program and delegates authority to VA to administer schedules for medical supplies and services, including the schedule for pharmaceuticals (Schedule 65 I B)

• Products on Schedule 65 I B are grouped into covered drugs (42-2A) and non-covered drugs (42-2B)

• Advantages of having a drug on the FSS even if not required by the VHCA
  – Authorized user may order without soliciting and competing requirements (except for task orders)
  – VA Policy requires purchasing items on FSS before open market
  – Having FSS contract is required for FSS BPAs (but not national contracts)
NEW DEVELOPMENT UNDER VHCA

• MDRP Final Rule - Interpretation of Innovator Drug could impact VHCA treatment of 505(b)(2) Drugs

  – VA allowed manufacturers to treat a drug submitted under a “paper NDA” as a non-innovator drug (not subject to the VHCA) because they were not originally marketed under an original NDA.

  – Before establishment of the ANDA process, manufacturers applied for approval to market their own version of a drug without the need for new drug testing, using the innovator’s data – an application based on the paper record.

  – Final Rule treats a drug approved by the FDA under a paper NDA as an innovator drug unless the manufacturer applies for and obtains approval from CMS to treat it as a non-innovator drug.

  – Unclear whether the VA will adapt CMS’ interpretation of the Medicaid statute as stated in the Final Rule and follow its designation as an I or N drug.
NEW DEVELOPMENTS CONTINUED

• CMS Final Rule allows any price charged a 340B covered entity to be excluded from AMP, ASP and Best Price, including prices available outside the program (e.g., inpatient, Medicaid carve out, non-patients, orphan drugs sold to ACA-added hospitals)

• VA exempts prices charged under the pharmaceutical pricing agreement (PPA) with HRSA, including sub-ceiling prices negotiated by HRSA’s prime vendor contractor, Apexus

• VA requires companies to obtain a hold harmless letter to exclude prices for inpatient drugs provided outside the 340B program – Apexus does not negotiate inpatient prices

• Unclear whether voluntary prices to new categories of hospitals for orphan drugs, which are not covered drugs under the PPA, will be treated the same as sub-ceiling prices, or inpatient prices – Apexus negotiates prices for orphan drugs on behalf of ACA-added hospitals
Congress authorized DoD to apply FCP to prescriptions of covered drugs dispensed to Tricare beneficiaries and manufacturers pay quarterly rebates based on difference between annual NFAMP and FCP.

House Armed Services Committee is considering a Pilot Program in which the lowest procurement price available to DoD would be extended to its retail pharmacy program, including discounts offered under Blanket Purchase Agreements, Temporary Price Reductions, and Distribution and Pricing Agreements.

Program would be for twelve months effective October 1, 2017.

Unclear if DoD will exempt BPAs and rebate agreements awarded through formulary class competitions, cancel them and re-compete the classes, or require the awardees to apply their voluntary BPA prices to retail transactions as they did with mandatory FCP rebates.
FSS PRICE VS. STATUTORY PRICE

- FSS price is the negotiated price independent of the VHCA and applies to covered drugs and non-covered drugs.

- Statutory price is the price that must be charged Big 4 agencies for covered drugs and calculated pursuant to the VHCA; it acts as a cap on the negotiated price and becomes the contract price if lower than the negotiated price.

- FSS price is the contract price available to a government agency and user of the FSS other than the Big 4 (Other Government Agency or OGA) unless the contractor elects to offer OGAs the statutory price.
The VHCA imposes a second price cap on multi-year contracts awarded by the VA, including FSS contracts.

After the first year of the contract, the price for a covered drug may not be increased more than the FSS price plus CPIU (Max Cap), even if 76% of NFAMP yields a higher price.

If the FSS price is less than FCP, it will set the Big 4 contract price for the coming year, and the OGA price cannot exceed the Max Cap, even if commercial prices have increased, and a price increase would otherwise be available under the contract’s Economic Price Adjustment (EPA) clause.

For purposes of applying the VHCA, the VA disconnected the first contract year from the actual contract award date:

- It standardized the VHCA contract year for all covered drugs (SIN 42-2A) under 65 IB contracts as commencing on January 1st (creating public law season).

- The VHCA “first year” occurs every five years regardless of the FSS contract term – 2014 was the last “first” year.
Manufacturers of covered drugs may establish a second pricelist for OGAs (dual pricer) at the negotiated FSS price, or offer OGAs the same price they offer the Big 4 capped at FCP (single pricer).

The VA considers the negotiated price to be the FSS contract price for purposes of the Max Cap. Because the negotiated price charged OGAs is higher than the statutory price, in years when the calculated statutory price is higher than in the prior year, using the OGA price as the FSS price gives the contractor a bump up.

Contractors that initially elected to offer the same price to all FSS customers may become dual pricers, but must ensure the FSS prices are negotiated by Sept. 30 to avoid the statutory price setting the Max Cap.

The VA also permits contractors to increase the negotiated price twice:
- When a new contract is actually negotiated and awarded, even if the Max Cap applied on January 1st of that year
- Under the EPA clause in the designated first year
PRE-AWARD DISCLOSURES IN FSS CONTRACT NEGOTIATIONS

- Awards of FSS contracts are not competed so Government’s negotiation of a fair and reasonable price is based on a comparison with the contractor’s Most Favored Customer (MFC) price; goal is to obtain the MFC price.

- Although FSS contracts are exempt from the requirement for cost or pricing data, GSA regulations require prospective FSS contractors to disclose Commercial Sales Practices (CSP) data using the solicitation format.

- All prices at or below the offered FSS price must be disclosed regardless of terms, and VA will seek justification if MFC price is not offered.

- Contractors are not required to give the Government their best price - the MFC price may be conditioned on terms unlike the FSS terms (e.g., exclusive supplier, based on performance metrics, bundled with purchase of one or more other products).
• Most Favored Customer (MFC):

“That customer or class of customer which receive(s) the best discount and/or price arrangement on a given item from a supplier. The term includes any entity which does business with the supplier. In MAS contracting, the Government’s negotiation objectives are developed based on a comparison of the MFC arrangement.”

• Customer or category of customer that receives the lowest net price regardless of terms/conditions
  – Not necessarily the customer with greatest volume
  – Not necessarily the customer who purchases products across market lines
  – But not a federal government customer (for now)
DISCLOSURE REQUIREMENTS – COMMERCIAL SALES PRACTICES

- If offering equal to or better than MFC price, all customers that receive MFC price must be disclosed.

- If not offering equal to or better than MFC price, all prices to all customers equal to or better than offered price (not just MFC) must be disclosed.

- “Commercial Sales Practices” format requires all price concessions as well as discounts:
  - Includes rebates
  - Includes prices in agreements even if no sales
  - Includes more favorable terms such as free shipping

- Offeror may explain exclusion of patient assistance programs and pharmacy assistance programs as price concessions to consumers and payors, rather than to purchasers/providers of direct care like VA.
• Offeror must certify that CSP information is current, accurate, and complete
  – Current means within 14 days of close of negotiations
  – Complete means all agreements in effect on the date of the offer not expiring before award

• GSA Clause (552.215-72) gives VA a contract right to reduce the price if CSP data is not current, accurate, and complete within 14 days of close of negotiation, even if omission was inadvertent, and the contractor will be liable for difference in price if the CO relied upon that information in negotiating the contract price

• Failure to provide current, accurate and complete prices in CSPs can be basis for False Claims Act liability
• New covered drugs must be added to the FSS contract at a temporary FCP (based on first 30 days of sales)
• Contractors have the option of adding a new covered drug sooner at a provisional price
• Even if a contractor is a dual pricer, the OGA price will be FCP until the FSS price is negotiated
• First-time manufacturers of covered drugs must enter into an interim letter agreement with the VA to make their covered drugs available for purchase during the FSS contract negotiation process
PRICE REDUCTION CLAUSE

• GSA Clause 552.238-75 is unique to FSS contracts

• Objective: Establish a method of ensuring the negotiated contract price continues to reflect the commercial marketplace, and remains fair and reasonable during life of contract, as CSPs provide only a snapshot in time and FSS contracts are long-term

• Clause applies to the documents upon which the contract award is based and the ratio between the FSS price and the price offered the customer or category of customers (CoC) upon which award is based (usually referred to as the Tracking Customer)

• At the time of award the CO establishes the Tracking Customer and price ratio – may be different Tracking Customers assigned to different contract items or groups of items
• Three Triggering Actions by Contractor

– Revises the commercial catalog, pricelist, or similar document upon which award was predicated to reduce prices – disclosure of catalog prices does not mean awarded FSS prices are predicated on them.

– Grants more favorable discounts or terms and conditions than those contained in the commercial catalog, pricelist, or other document upon which award was predicated

– Grants price reduction to the Tracking Customer (TC) that disturbs the price relationship between the Government and this customer – Most 65 I B contract prices are predicated on commercial contract prices to individual customers and CoCs, not pricelists, and VA focuses on the TC relationship.
PRC EXEMPTIONS

- PRC doesn’t apply to
  - Sales to Federal agencies or sales at prices set by federal statute
  - Prices to commercial customers under Firm Fixed Price definite quantity contracts with specified delivery in excess of contract’s maximum order threshold
  - Prices caused by errors in quotations or billing if adequately supported
  - Prices to state and local entities (if state and local is the TC) when the order is placed under the FSS contract
  - VA doesn’t recognize a general exception where terms and conditions differ from FSS contract (e.g., market share commitment)
  - Exclusions for performance based discounts to TCs should be agreed to in advance
  - Contractor should notify contracting officer when it believes PRC clause doesn’t apply to particular transactions with TCs
NEGOTIATING AND MAINTAINING TRACKING CUSTOMER PRICE RELATIONSHIP

• Tracking Customer is agreed to and ratio established before award
• MFC is VA’s objective but the CO may accept a different customer as the TC for purposes of the PRC
• TC should be one that is comparable to FSS purchasers and has transactions that can be readily monitored for price reductions
• May have different TCs for different products
• Contractor must have system capable of timely identifying reductions in invoiced prices and price adjustments to TCs
• TC must be established for a covered drug even if the contract price is not negotiated and there is no ratio
• If TC price drops below FCP, price is reduced to TC price and further reductions are reported using 1 to 1 ratio
• If the OGA price is equal to the TC price, VA will not allow Max Cap increase (CPIU)
INDUSTRIAL FUNDING FEE

- IFF is an administrative fee that GSA and the VA charge for administering the FSS program.

- Current IFF is .50% on FSS sales under Schedule 65 I B.

- IFF is collected from purchasing agencies and paid to the VA quarterly within 60 days from the end of the quarter. GSAR 552.238-74

- Sales must be tracked and reported by SIN and by the VA, Other Government Agencies, and State/Local Governments.

- IFF is not included in prices for purposes of VHCA.
• FSS price calculation with IFF (hypothetical $10,000 negotiated price)
  – Negotiated price divided by (1 minus the IFF%)
  – $10,000/(1-.005)= $10,050.25

• IFF remittance calculation on $1M sales
  – FSS sales price times the IFF rate
  – $1,000,000 x .005=$5,000 due the VA
TRADE AGREEMENTS ACT

- TAA allows federal agencies to buy US and designated country end products in acquisitions valued at $204,000 or more without regard to the Buy American Act, but also prohibits procurement of non-designated country end products, unless the agency makes a non-availability determination.

- Non-designated countries include China and India, which manufacture a large percent of API.

- Government procuring agencies apply Customs’ test for determining country of origin (COO) under the TAA: substantial transformation.

- Customs generally considers the COO of a drug’s API to be the COO of the finished product; however, applying the substantial transformation test to pharmaceutical and biological products is fact specific.

- Offers certify a product is a US or designated country product unless otherwise stated and the cert must be updated if there is a change in manufacturing location – manufacturers should have policies and procedures in place to monitor sourcing and TAA compliance.

- Non-compliance with TAA is a potential basis for bid protests and False Claims Act liability.
SPECIAL TAA POLICY FOR 42-2A DRUGS

- TAA applies to Schedule 65 I B contracts; however, VA has a special policy for covered drugs (SIN 42-2A)
- The VHCA requires these drugs be offered on the FSS regardless of whether they are not TAA compliant, but the VA could not put them on the contract
- New policy requires manufacturers of covered drugs to submit a mod to add a non-TAA compliant drug to the FSS at FCP with a form requesting a non-availability determination by the contracting officer
- Companies without FSS contracts will enter into interim agreements
- VA intends to determine covered drugs are unique and unavailable from other sources, but it’s unclear whether generic versions will have any impact on the non-availability determination for multiple source innovator drugs
- Policy applies only to FSS orders by the VA, not DoD or other agencies
- Timing issue – If OGA prices are not negotiated by Sept. 30, Max Cap for 2017 will be based on FCP
THANK YOU