

GOVERNMENT CONTRACTS: FALSE CLAIMS AND COMPLIANCE

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Government Contracts: False Claims and Compliance

- I. Introduction: Pricing Obligations Under Government Contracts
- II. Federal Supply Schedule Contracts
- III. Pharmaceutical Price Agreements
- IV. Common Pricing Compliance Pitfalls
- V. Federal Compliance Enforcement

I. Introduction: Pricing Obligations and Risks Under Government Contracts

- Government Contracts Impose Unique Pricing Obligations, Particularly for Pharmaceutical Companies
- Non-Compliance Can Have Severe Ramifications, Including Treble Damages and Civil Penalties Under the False Claims Act
- Companies Must Be Prepared to Dedicate the Human and Capital Resource Required to Establish and Maintain Compliant Contracting Procedures and Pricing Systems

II. Obligations Under Federal Supply Schedule Contracts

- Federal Supply Schedule (FSS) Contracts
 - Veterans Administration (VA)
 - General Services Administration (GSA)
- Other Federal Contracts
 - Blanket Purchase Agreements
 - National Contracts
 - Prime Vendor Contracts

FSS Contract Compliance Requirements

- Price Discount and Disclosure Requirements
 - Contractor Must Disclose Best Commercial Prices, Including All Discounts
 - Government Relies on Contractor's Disclosure to Negotiate Fair Price

FSS Contract Compliance Requirements (Cont'd)

- Price Reduction Requirements
 - Contract Establishes “Tracking” Customer or Class of Customers
 - Contractor Required to Keep Government in Same or Better Price/Discount Relationship

III. Obligations Under Pharmaceutical Price Agreements

- VA-Administered Federal Ceiling Prices (FCPs)
 - Limited to “Covered Drugs”
 - Covers Purchases by VA, DOD, Public Health Service (PHS), and Coast Guard
 - Set at 76% of Non-Federal Average Manufacturer Price (non-FAMP), Less Additional Discount
 - FCPs May Be Higher or Lower Than Negotiated FSS Prices

III. Obligations Under Pharmaceutical Price Agreements (Cont'd)

- Medicaid Drug Rebates, Administered By Centers for Medicare and Medicaid Services (CMS)
 - Limited to “Covered Outpatient Drugs”
 - Covers State Reimbursement for Drugs Dispensed to Medicaid Patients

III. Obligations Under Pharmaceutical Price Agreements (Cont'd)

- Set For Innovator Drugs At the Larger of 15.1% of Average Manufacturer Price (AMP) or the Difference Between AMP and “Best Price” Per Unit, and Further Adjusted by the CPI-U
- Set For Non-Innovator Drugs at 11% of AMP Per Unit

III. Obligations Under Pharmaceutical Price Agreements (Cont'd)

- “Covered Entity” (Section 340B)
Ceiling Prices, Administered By HHS
Office Of Pharmacy Affairs
 - Limited to “Covered Outpatient Drugs”
 - Covers Purchases by Certain High-Volume Disproportionate Share Hospitals (DSHs) and a Wide Variety of Non-Profit Programs and Clinics Receiving Federal Assistance (e.g., AIDS Drug Assistance Programs)

III. Obligations Under Pharmaceutical Price Agreements (Cont'd)

- Set For Innovator Drugs At AMP for the Drug, Less the Average Total Rebate Required Under the Medicaid Rebate Program
- Set for Non-Innovator Drugs at AMP Less 11%

IV. Common Pricing Compliance Pitfalls

- Initial FSS Pricing Disclosures
 - Failure to “Sweep” Company to Identify All Discounts Offered to Best Customers
 - Failure to Appreciate Breadth of Government’s Definition of “Discount”
- FSS Price Reduction Obligations
 - Failure to Memorialize Agreed Price/Discount Relationship with Tracking Customers or Class

IV. Common Pricing Compliance Pitfalls (Cont'd)

- Failure to Institute Effective System to Monitor Price Discounts Given to Tracking Customers or Class
- Failure to Pass Through Price Reductions to Government
- FSS Modification Obligations
 - Failure to Recognize Significance of Pricing Certifications Given with Each Modification to Add Products

IV. Common Pricing Compliance Pitfalls (Cont'd)

- Pharmaceutical Pricing Obligations
 - Failure to Establish Systems that Efficiently Make Accurate Non-FAMP and AMP Calculations
 - Failure to Recognize Differences Between Non-FAMP Calculations for FCP Purposes and AMP Calculations for Medicaid Rebate and PHS “Qualifying Entity” Purposes

IV. Common Pricing Compliance Pitfalls (Cont'd)

- Difficulties Defining Innovator/Non-Innovator/Outpatient Drugs and Retailer/Wholesaler for Non-FAMP and AMP Purposes
- Audit Obligations
 - Failure to Maintain Records Required for Accurate Audit Trail
 - Failure to Anticipate and Address Problems Early in the Audit Process

IV. Common Pricing Compliance Pitfalls (Cont'd)

- Government Remedies
 - Failure to Recognize Range and Severity of Sanctions Available to Government for Pricing Non-Compliance

V. Federal Compliance Enforcement

- Pre- and Post-Award Audits and Subpoenas
- Non-FAMP, AMP, and Best Price Reporting Requirements and Penalties
- False Claims Act Sanctions
 - “Deliberate Ignorance” or “Reckless Disregard” Can Be Implied From Failure to Have Compliance Systems In Place
 - Exposure to Treble Damages and \$5,500-\$11,000 Penalty for Each “False” Invoice
- Other Civil and Criminal Sanctions
- Debarment, Suspension, and Exclusion