

**PRICING COMPLIANCE ISSUES FOR  
PHARMACEUTICAL COMPANIES  
UNDER FEDERAL CONTRACTS**

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# I. Federal Contract Types

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- Federal Supply Schedule (FSS) Contracts
  - Department of Veterans Affairs (VA)
  - General Services Administration (GSA)
- Distribution and Pricing Agreements (DAPAs)
  - Department of Defense (DOD)

# I. Federal Contract Types (Cont'd)

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- Other Federal Contracts
  - Blanket Purchase Agreements
  - National Contracts
  - Prime Vendor Contracts

## II. Special FSS Pricing Compliance Issues

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

## II. Special FSS Pricing Compliance Issues (Cont'd)

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

## II. Special FSS Pricing Compliance Issues (Cont'd)

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- Federal Ceiling Prices (FCPs) for “Covered Drugs”
  - Administered by VA
  - 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 or DAPA Prices

# III. Common FSS Pricing Pitfalls

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

### III. Common FSS Pricing Pitfalls (Cont'd)

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



## III. Common FSS Pricing Pitfalls (Cont'd)

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

## III. Common FSS Pricing Pitfalls (Cont'd)

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- **Audit Obligations**
  - Failure to Maintain Records Required for Accurate Audit Trail
  - Failure to Anticipate and Address Problems Early in the Audit Process
- **Government Remedies**
  - Failure to Recognize Range and Severity of Sanctions Available to Government for Pricing Non-Compliance

## IV. Conclusion

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- Federal Government Offers Huge and Profitable Marketplace for Health Care Companies, But Pricing Pitfalls Are Serious
- Companies Must Be Prepared to Dedicate the Human and Capital Resources Required to Establish and Maintain Compliant Pricing Systems and Protocols