VA FSS PHARMACEUTICAL SOLICITATION FROM BEGINNING TO END

Elizabeth F. Lindquist
CBI’s 19th Annual Medicaid and Government Pricing Conference
May 10, 2017
Overview/Roadmap

Background → Initial Steps → Solicitation Response

Additional Resources ← Proposal Review and Negotiation Process ← Proposal Submission
• Veterans Health Care Act of 1992 ("VHCA") (Public Law No. 102-585)
  
  — Imposed pricing requirements on pharmaceutical manufacturers, including the requirement to enter into a Master Agreement, Pharmaceutical Pricing Agreement, and Federal Supply Schedule ("FSS") contract with the VA
  
  — A manufacturer of “covered drugs,” as defined in section 603 of the VHCA, may not participate in Medicaid, Medicare, and certain other Federal programs unless it makes its covered drugs available to FSS-eligible purchasers for procurement at reduced prices through the FSS
  
  — By submitting a proposal for and receiving an FSS contract award, a manufacturer meets the statutory mandate in the VHCA to make its covered drugs available for procurement on the FSS
Background

- Veterans Health Care Act of 1992 ("VHCA") (Public Law No. 102-585)
  - Section 603 of the VHCA specifically requires that manufacturers:
    - Sell "covered drugs" to the "Big Four" Federal agencies through the FSS at prices that do not exceed the Federal Ceiling Price ("FCP")
    - The Big Four: the VA, Department of Defense, Coast Guard, and the Public Health Service (including the Indian Health Service)
    - Calculate and report to the VA Non-Federal Average Manufacturer Price ("Non-FAMP") data quarterly and annually, and FCP data annually
Background

• **Covered Drugs**
  
  — In general, an FDA-approved prescription drug marketed under:
    
    — A new drug application ("NDA") (including authorized generic drugs – *i.e.*, generic drugs marketed under an NDA);
    
    — Supplemental new drug application ("SNDA");
    
    — Antibiotic drug approval ("ADA"); or
    
    — Biologic license application ("BLA")

  — Includes single source drugs, innovator multiple source drugs, and biologics
Background

- VA Federal Supply Schedule ("FSS") Program
  - Directed and managed by the U.S. General Services Administration ("GSA")
  - Allows Federal agencies (and certain authorized non-Federal entities) to procure a wide variety of products and services at established prices
  - The GSA has delegated authority to the VA to procure medical equipment, supplies, services, and pharmaceuticals under the VA FSS Program
Background

• VA Federal Supply Schedule ("FSS") Program
  — In furtherance of this grant of authority, the VA National Acquisition Center ("VA NAC") solicits, awards, and administers long-term, government-wide contracts with manufacturers and other vendors for items on nine FSS "schedules"
  — A schedule is a listing of companies that supply comparable commercial products and services through contracts awarded by the Federal government (e.g., VA FSS contracts)
Background

• Schedule 65IB Special Item Numbers ("SINs")

Schedule 65IB
Drugs, Pharmaceuticals, and Hematology Related Products

SIN 42-2A Items
Must be listed
Single source and innovator multiple source drugs, biologicals, and insulin

SIN 42-2B Items
May be listed
Generic and multiple source drugs, human blood products, and/or over-the-counter drugs
Background

- VA Federal Supply Schedule ("FSS") Program
  - Solicitation Number M5-Q50A-03-R7
    - An “open and continuous” request for Schedule 65IB product offers
    - Outlines information that must be provided with a submitted offer
    - Includes provisions, clauses, representations, certifications, and other requirements and obligations that become part of an executed FSS contract
    - Most current version is available at FedBizOpps.gov
    - Terms periodically updated through “Mass Modifications”
Initial Steps

ONE DOES NOT SIMPLY

EXECUTE A VA FSS CONTRACT
Initial Steps

• Analysis of Products to Determine Which Meet the Definition of a “Covered Drug”
  — The covered drug determination is a manufacturer’s responsibility
  — Evaluate products and determine what products may be SIN 42-2A versus SIN 42-2B
  — Evaluate any newly acquired or launched products
  — Evaluate and determine the source of all API for all offered products for TAA disclosures
  — Review VA guidance, including “Dear Manufacturer” Letters, for questions regarding specific types of products (e.g., radiopharmaceuticals, vaccines)
Initial Steps

• Determine whether your company qualifies as a “Small Business Concern” under Schedule 65IB
  
  — If your company meets the definition of a “small business” in the context of the VA FSS Program, the company will self-certify to this fact during the process of registering in the System for Award Management and submitting its solicitation response
  
  — The applicable size standard is 750 employees
    
    — U.S. subsidiary of a global parent company
    
    — Changes in business size during contract term
Initial Steps

• System for Award Management Registration
  — Determine if the company is registered in SAM.gov
  — A nine-digit Data Universal Numbering System ("DUNS") number is a prerequisite to SAM.gov registration
  — Examples Certifications and Representations
    — Investigate status of “responsibility matters”.
    — Assess equal opportunity/affirmative action policies and procedures
Initial Steps

- System for Award Management Registration
  - Offeror must certify to the validity of the information entered in SAM, and information provided by the offeror will be validated and shared with other authorized Federal government offices and electronic systems.
  - The VA also checks submitted data (which is certified) against publicly available sources of information (e.g., Dunn & Bradstreet).
Initial Steps

• VA Master Agreement
  — A manufacturer of covered drugs must enter into a Master Agreement with the VA under which the manufacturer makes each of its covered drugs available for sale on the FSS
  — The Master Agreement outlines a manufacturer’s responsibilities and obligations associated with the VHCA
  — The terms and conditions of the Master Agreement are non-negotiable and the same for all Schedule 65IB contractors
  — The Master Agreement is an evergreen document and, as such, does not expire
Initial Steps

• VA Pharmaceutical Pricing Agreement
  — A manufacturer of covered drugs must also enter into a Pharmaceutical Pricing Agreement and agree to sell to the Big Four purchasers through the FSS or a depot contract at prices no higher than the FCP
  — Addendum A to the Pharmaceutical Pricing Agreement is updated annually to reflect the FCPs of covered drugs for the calendar year
Initial Steps

• VA Interim Agreement
  — The VA requires that manufacturers execute an Interim Agreement while negotiating a VA FSS contract
  — As part of this process, manufacturers are required to provide to the VA:
    — All relevant information regarding its offered products
    — Relevant information about the offeror, including contact information
    — Proof of registration in the Federal government’s System for Award Management (SAM.gov) database
Initial Steps

- For a new contract offer, to begin the FSS contract negotiation process, and obtain the Master Agreement, Pharmaceutical Pricing Agreement, and Interim Agreement documents, send an initial request to interim_agree.ammhinfss@va.gov
“Sorry I’m late. It took me forever to find this place.”
Solicitation Response

- Identify or reassess responsible stakeholders
- Review and analyze the solicitation
- Develop a solicitation response strategy
- Hold initial meeting(s) with stakeholders
- Gather and collect required data
- Discuss and review data, representations, certifications, and other solicitation responses with stakeholders and legal
Solicitation Response

• Assemble your Dream Team

- Managed Markets
- HR
- IT
- Compliance
- Finance
- Procurement / Supply Chain
- Business Unit Heads
- Pricing
- Legal
- Trade
- Manufacturing / Quality
- Sales
- Marketing

King & Spalding
Solicitation Response

• Review and analyze the solicitation
Solicitation Response

• Review and analyze the solicitation
  — For each part of the solicitation applicable to your company, consider drafting a spreadsheet that includes a tab for each solicitation document and the following fields:
    — FAR clause/provision number, name, and version
    — A summary of the key requirements imposed by the FAR clause/provision and whether applicable to your company
    — Who or what function has responsibility for compliance
    — Compliance status/certification of compliance status
## Solicitation Response

**Review and analyze the solicitation**

<table>
<thead>
<tr>
<th>Number</th>
<th>Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Read Me First</td>
</tr>
<tr>
<td>02</td>
<td>Solicitation Document</td>
</tr>
<tr>
<td>03</td>
<td>Regulations Incorporated by Reference</td>
</tr>
<tr>
<td>04</td>
<td>Vendor Response Document</td>
</tr>
<tr>
<td>05</td>
<td>Commercial Sales Practice Format</td>
</tr>
<tr>
<td>06</td>
<td>Price Proposal</td>
</tr>
<tr>
<td>07</td>
<td>Past Performance Evaluation</td>
</tr>
<tr>
<td>08</td>
<td>Small Business Subcontracting Plan</td>
</tr>
<tr>
<td>09</td>
<td>Overseas Delivery</td>
</tr>
<tr>
<td>10</td>
<td>Overseas Price Proposal</td>
</tr>
</tbody>
</table>

*King & Spalding*
Solicitation Response

• 01 – Read Me First

— Provides a comprehensive overview of the VA FSS contract negotiation process, key requirements, and includes a helpful checklist of required items

— States that an offeror must complete the GSA “Pathway to Success” webinar and submit a copy of the certificate of completion with the company’s proposal

— Suggests that offerors consider submitting a Dun and Bradstreet Open Ratings Report with the initial offer submission

— Complete the “Vendor Response Document Checklist” on pages 9-10 prior to submitting your offer
Solicitation Response

• 02 – Solicitation Document
  — Contains special clauses and provisions that have been identified by the VA as essential for acquisition of Schedule 651B products
    — Instructions for Pre-Award Review Process
    — Recalls
    — Contract Terms and Conditions
    — Economic Price Adjustment Clause
    — Industrial Funding Fee and Sales Reporting
    — Price Reductions Clause
    — Modifications
Solicitation Response

02 – Solicitation Document

- Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items
- Pre-award On-Site Equal Opportunity Compliance Review
- Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights
- Display of Department of Veterans Affairs Hotline Poster
Solicitation Response

• 03 – Regulations Incorporated by Reference
  – Contractor Code of Business Ethics and Conduct
  – Trade Agreements
  – EEOC clauses
  – Assignment of Claims
Solicitation Response

• 04 – Vendor Response Document
  – Manufacturing Facilities/Place of Performance
  – Dealers and Suppliers
  – Utilization of Dealers/Distributors/Specialty Distributors
Solicitation Response

• 05 – Commercial Sales Practices Format
  – CSP disclosures:
    – Commercial sales data
    – Most Favored Customer for each product
    – Proposed Tracking Customer
    – Justification for pricing where the VA is not receiving the best price
    – Deviations and frequency of deviations in pricing policy
    – Country of origin
Solicitation Response

• 05 – Commercial Sales Practices Format
  – Inventory written commercial contracts for pricing policies and terms
  – Analyze preferential terms that translate to value (e.g., bundling, non-standard warranties)
  – Interview sales and finance personnel involved in commercial sales process to determine adherence to pricing practices and identify deviations from those practices
  – Determine frequency and justifications for deviations from standard pricing
Solicitation Response

• 05 – Commercial Sales Practices Format
  — Key Considerations
    — Information and data disclosed in the CSP must be current, accurate, and complete
    — Contractor must update disclosure for any changes to proposed price lists, discounts, or discounting policies which occur after the submission of the offer, but prior to the close of negotiations
Solicitation Response

• 06 – Proposal Price List Preparation
  — Document contains a list of proposed pricing terms to be submitted to the VA by the company

• 07 – Past Performance Evaluation
  — Return with new FSS offers
  — Requires three references from Federal, State, or Local governments and/or private companies with whom the company has recently conducted business for the products offered under the Schedule 65IB solicitation
    — These references will be contacted by the VA and asked to complete a survey in order to validate the company’s ability to perform
Solicitation Response

• 08 – Small Business Subcontracting Plan
  — Required for all contracts:
    — (1) With an estimated value over $700,000 (for the full contract term, including options)
    — (2) With further subcontracting opportunities
    — (3) When the contract holder is classified as an “other than small business”

• 09 – Overseas Delivery
  — Return with offers proposing overseas delivery

• 10 – Small Business Subcontracting Plan
  — Return with offers proposing different pricing for overseas delivery
“Can I offer you anything?”
Proposal Submission

- Read the solicitation package in its entirety
- Ensure all information provided to the VA is current, accurate, and complete
- Provide proof of registration requirements
- Make sure the offer meets the minimum requirements of the solicitation
- Use the solicitation checklist in the “Read Me First” document to ensure the completeness of the offer
Proposal Submission
Proposal Review and Negotiation Process

BRACE YOURSELVES

CONTRACT NEGOTIATIONS ARE COMING
Proposal Review and Negotiation Process

VA receives proposal and assigns it to a VA contracting officer.

Initial review by VA contracting officer.

Full proposal evaluation and analysis by VA contracting officer.

VA contracting officer submits the proposal for review.

VA contracting officer requests the offeror’s Final Proposal Revision.

Contract negotiations.
Proposal Review and Negotiation Process

• Understand the review process and anticipated timelines and manage expectations internally
  — Procurement Action Lead Time: 180 calendar days for new offers (*excluding OIG review time of at least 90 calendar days)
• Provide timely and complete responses to all requests for information and clarification requests
• Ask questions
• Be ready to negotiate the company’s best offer
Additional Resources

- VA FSS Help Desk
  - fss.help@va.gov

- VA Office of Acquisition and Logistics webinars, FAQs, and other training resources
  - https://www.va.gov/oal/business/fss/training.asp
  - https://www.fss.va.gov/faqs

- Procurement Technical Assistance Centers
  - http://www.aptac-us.org

- Outside counsel
Questions?

Elizabeth Lindquist
elindquist@kslaw.com
(202) 626-5585