



Life Sciences Contracting 101

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Topics

1. Relevant Statutory and Regulatory Frameworks
2. Commercial Contracting and General Compliance Obligations
 - Schedule Contracting and Prime Vendor Programs
 - Pricing Requirements under the Veterans Health Care Act of 1992
 - Office of Federal Contract Compliance Programs
 - Gift Rules and Lobbying
 - Sourcing and Supply Chain
3. Additional Considerations for Research and Development

Schedule Contracting: Structural Differences

- “Evergreen” – 5 year base, 5 year option
- No direct competition to get on schedule
- Subject to streamlined procedures in FAR Part 8
 - Blanket purchase agreements (“BPAs”) can further streamline purchases
 - Orders and BPAs are not subject to standard bid protest limitations
 - Similar, but separate from, government-wide acquisition or “GWAC” contracts and other multiple-agency contracts or “MACs”
 - Set-asides can occur at BPA and order level; different rules on small business status
- All federal agencies can purchase, including in the legislative and judicial branches (+ contractors, tribes, and states in some circumstances)
- Split into U.S. Department of Veterans Affairs and General Services Administration contracts

Federal Supply Schedules

Agency	Schedule	Coverage
VA	65 I B	Drugs and Biologics <i>(branded, generic, prescription, and over-the-counter)</i>
VA	65 II A	Medical Equipment <i>(medical devices; surgical and hospital dressing, instruments, and supplies)</i>
VA	65 VII	Invitro Diagnostics, Reagents, Test Kits, & Test Sets <i>(lab test reagents, controls, and materials, test strips, and glucose monitors)</i>
VA	65 V	X-Ray Equipment & Supplies <i>(components, accessories, and consumables)</i>
VA	66 III	Cost-Per-Test Clinical Analyzers <i>(test equipment)</i>
VA	621 II	Medical Laboratory Testing and Analysis Services <i>(test performance)</i>
GSA	MAS	Limited Laboratory and Medical Equipment <i>(e.g., blood analyzers for clinical hematology)</i>

- Need to make minimum sales to remain on schedule
- Distinct from VA and DoD formularies for drugs and biologics

Prime Vendor Programs

- Now fee-for-service and earned interest through payment terms
- Manufacturers typically pay administrative fee and may accept payment of lower price offered by prime vendor
- VA Pharmaceutical Prime Vendor
 - Currently single vendor for all regions
 - Subject to pricing requirements of the Veterans Health Care Act of 1992
- VA Medical/Surgical Prime Vendors
 - Currently multiple vendors covering different regions
 - Must be used by VA medical centers
- DoD Prime Vendors
 - Currently multiple vendors covering different regions
 - TRICARE Mail Order Pharmacy has separate program, with 1 vendor for pharmaceuticals and 1 vendor for pharmacy benefit management services

Pricing Requirements under VHCA of 1992

- Medicaid reimbursement for outpatient drugs contingent on entering into Master Agreement with the U.S. Department of Veterans Affairs
- Must offer each Covered Drug on the Federal Supply Schedule
- Must enter Pharmaceutical Pricing Agreement capping Schedule or “depot” prices of Covered Drugs for 1 year at 76-percent of Non-Federal Average Manufacturer Price, less required discounts for purchases by state veterans homes and Big 4
- Failure to follow prevents payment for any drug or biologic from (i) Medicaid, (ii) any entity receiving funds under the Public Health Service Act, and (iii) Big 4
- Big 4 – The U.S. Department of Defense, the U.S. Department of Veterans Affairs, the Coast Guard, and the Public Health Service
- Covered Drugs –
 - Innovator multiple-source drug (*approved new drug application, including authorized generic*)
 - Single source drug (*approved new drug application, including authorized generic*)
 - “Any” biologic

Non-Federal Average Manufacturer Price

- Non-FAMP: Weighted average price for form and dose paid by wholesalers in the United States taking into account cash discounts or similar price reductions, but excluding:
 - Prices paid by the U.S. Government
 - Prices deemed by VA to be nominal
- Period: Measured over 1-year period ending one month before date of pharmaceutical pricing agreement or, when data is not available, as set by Secretary
- Report: 30 days into last quarter before agreement goes into effect for 1-year period leading into quarter; while agreement is in effect, report 30 days afterward

Federal Ceiling Price

- FCP: Non-FAMP x 0.76
 - Additional discount required if Non-FAMP increases higher than CPI-U in prior year
 - Cannot be set or increased above CPI-U increase in prior year
- Average wholesale price, Medicaid average manufacturer price and best price, and 340B price are not directly relevant to FCP

Additional Pricing Considerations

- Tracking Customer
 - Establishes Schedule price baseline through set ratio
 - Can be a group of customers
 - Can establish different tracking customers for different products
- Price Reduction
 - Can negotiate whether certain discounts or rebates count
 - Does not apply to sales:
 - at prices set by law or regulation (e.g., at FCP on Schedule)
 - to U.S. Government agencies
 - based on different terms
 - for more than maximum Schedule ordering threshold
- Price Increases

Dual Pricing

- Contractors can offer different prices to Big 4 and other government agencies
- Must be elected at award for all Covered Drugs on Schedule, but can be renegotiated
- Not possible until FSS is negotiated (interim agreements control until then)
- Single Price Users
 - Can still offer temporary price reductions, but must do so for all FSS purchasers
 - Only need to disclose prices equal to or lower than FCP
 - Price reduction clause does not apply to single prices set at FCP until tracking customer price falls below FCP

System for Award Management

- Online Government database (www.sam.gov) where registration is required before submitting proposals for, and to receive payments under, prime contracts
- Limited subcontractor registration will likely be required in the future
- Can opt-out of public display
- Relevant Representations:
 - Small business and socioeconomic status for prime and subcontractors
 - Tracking whether principals, including directors, subject to certain criminal or civil judgments, beyond what is disclosed for the Securities and Exchange Commission
 - Limited/restricted data rights assertions
 - Trade Agreements Act/Buy American Act origin
 - Place of manufacturing/performance

Office of Federal Contract Compliance Programs

- No employment discrimination; required employee and applicant notices
- “Affirmative action” to promote, but plan at ≥ 50 employees & $\geq \$50k$ award ($\$100k$ vets)

Race, Color, National Origin
Sex, Sexual Orientation, Gender Identity
Religion
Compensation Discussions

- Contract or sub $> \$10k$ over 12 months
- EEO-1 at plan thresholds through first-tier

Protected Veteran Status

- Contract or sub $\geq \$150k$
- Job listing requirements for state agencies
- VETS-4212 Report (*no employee trigger*)

Disability

- Contract or sub $> \$10k$

Office of Federal Contract Compliance Programs

- OFCCP Requirements apply by operation of law
- Apply to government and commercial operations across “single entity”
- Inapplicable to work performed outside the United States (which includes Puerto Rico) with employees who were not recruited in or transferred from the United States
- Quotas not permitted for affirmative action
- Whistleblowers protected
- Bolded, full-text flow-down clause required:

Contractor and subcontract shall abide by the requirements of 41 C.F.R. §§ 60-1.4, [60-1.7, 60-1.35(c), 60-300.5(a), 60-741.5(a)], and 29 C.F.R. part 471, Appendix A to Subpart A, as updated from time to time. [Among other requirements,] these regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities, and prohibit discrimination against all individuals based on their race, color, religion, sex, sexual orientation, gender identity, or national origin. Moreover, these regulations require that covered prime contractors and subcontractors take affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or veteran status.

Gift Rules

- Gifts include any item of value, including discounts
- Exclusions:
 - Modest non-meal food and drink (e.g., coffee and donuts)
 - Plaques/trophies
 - Discounts and prizes available to all or class of Government or military employees
 - Attendance and meals at event to present on behalf of an agency
 - Market value paid by employees
 - Government contracts and agency acceptance (*but consider appropriation laws*)
- Exceptions:
 - \$20/50 in a year organization wide
 - \$100 informational materials in year organization-wide
 - Outside business/employment relationships
 - Widely attended gatherings

Promotion at VA and DoD Facilities

- Agency-wide rules govern promotional activities at VA facilities
 - Must have appointment, and promotion to students/residents limited
 - Without permission from Chief of Pharmacy Services, may only promote drugs and related supplies on VA National Formulary or with criteria-for-use developed by VA
 - May not provide food under any circumstances
 - Educational programs must be approved in advance, and patient materials cannot include company logo without approval
 - Drug samples may only be provided to designated contacts
- DoD rules on promotion are generally set by each facility
- Health care providers can be considered VA or DoD employees even if they also have a private practice
 - Risk of confusion with privileges and VA or DoD facility
 - Gift rules do not apply to outreach that is clearly directed at private practice or membership in another group

Hiring Government Personnel

- Items customarily provided in employment discussions are permissible for current Government employees, but disqualification is generally required
- No employee or consultant compensation to procurement, payment, or settlement officials for award >\$10 million for 1 year after serving in role for award
- For DoD, personal and substantial participation in acquisition >\$10 million and certain high-level officials need to obtain written ethics opinion for 2 years after end of service
- 2-year restriction on representing back on matters under official responsibility
- 1-year restriction on senior employees representing back to former agency or advising ex-U.S. entity on engagement (*if very senior, extends to 2 years, covers any contact with executive level position, and for 1 year covers assistance with engagement*)
- Lifetime restriction on matters with personal and substantial participation
- Ethics pledges can extend or add to restrictions

Lobbying

- Cannot use appropriated funds to attempt to influence any federal official or employee
 - Safe harbor presumes no violation if sufficient profit or fee
 - Cost contracts still subject to restriction on reimbursement
 - Government employees subject to same restriction, including indirectly through contractors
- Must disclose lobbying contacts for specific awards and forward disclosures from subcontractors
 - Relationship to Lobbying Disclosure Act
 - Programmatic lobbying not covered

PIA, OCIs, Kickbacks, and Contingent Fees

- Procurement Integrity Act:
 - Restriction on obtaining bid or proposal or source selection information
 - Some argument that the restriction only applies to Government employees
- OCIs:
 - Unequal access to information, biased ground rules, or impaired objectivity
 - Access to information impaired objectivity need to be considered in health care
- Kickbacks:
 - Nothing of value for favorable treatment in award of prime contract or subcontract
 - Need to report reasonable grounds to believe violation has taken place
- Contingent Fees:
 - No fee contingent on success in obtaining government contract
 - Not applicable to contracts for commercial items or “bona fide agency”

Defining Subcontracts

- Many clauses require entering into for performance of higher-tier contract
- Some clauses exclude long-term vendor agreements that benefit multiple contracts (e.g., reporting of first-tier subcontracts and service reporting)
- But, OFCCP takes extremely broad view of “necessary for performance” or undertaking portion of higher-tier obligation
 - OFCCP view of necessity
 - Traceability
- Cost accounting shorthand
- Potential “Vendor” Exception:

“The term [subcontract] does not include agreements entered into by a contractor for the supply of commodities that are intended for use in the performance of multiple contracts with the [Department of Defense/Federal Government] and other parties and are not identifiable to any particular contract”

Interpreting the FAR and Supplements

52.203-7 Anti-Kickback Procedures.

As prescribed in 3.502-3, insert the following clause:

ANTI-KICKBACK PROCEDURES (MAY 2014)

(a) Definitions.

“Kickback,” as used in this clause, means any money, fee, commission, credit, gift, gratuity, thing of value, or

Implementing Instructions

Clause Version
(only updated with new solicitations
or modifications)

3.502-3 Contract clause.

The contracting officer shall insert the clause at 52.203-7, Anti-Kickback Procedures, in solicitations and contracts exceeding the simplified acquisition threshold, other than those for commercial items (see part 12).

Part

For 52, Implementing Part

Example Subcontract Flow-Down Requirements

FAR Clause	Title	Notes
52.203-12*	Limitation on Payments to Influence Certain Federal Transactions	- Subcontractor representation on lobbying for award
52.203-13	Contractor Code of Business Ethics and Conduct	- High monetary threshold for applicability - Code of business ethics & conduct, diligence to detect conduct, and reporting of credible evidence of criminal conduct or false claims
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	- Prohibits restrictions on reporting to federal officials - Safe harbor language for employees and subcontractors can be helpful
52.204-21	Basic Safeguarding of Covered Contractor Information Systems	- Requires cybersecurity safeguards
52.209-6*	Protecting the Government's Interest when Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment	- Requires contract clause disclose excluded status - Helpful to also screen subcontractors against exclusion databases
52.245-1*	Government Property	- Inventory, handling, and disposal requirements

* Not listed in FAR 52.244-6 or FAR 52.212-4(e)(1).

Telecommunications and Security Equipment

- At Prime Contract Level: No use of Covered Telecommunications Equipment or Services as necessary part of or critical technology for performance of government or commercial work
- At Subcontract Level: No use of Covered Telecommunications Equipment or Services as necessary part of or critical technology for performance of government work
- Reporting of noncompliance required
- Covered Telecommunications Equipment or Services –
 - Huawei Technologies Company, ZTE Corp., and affiliates
 - Public safety, government facility, critical infrastructure, or national security, Hytera Communications Corp., Hangzhou Hikvision Digital Technology Co., Dahua Tech. Co., and affiliates
 - Entity identified as controlled or otherwise connected to the government of China
 - Except: Backhaul, roaming, and interconnection arrangements

Human Trafficking

- Organization-wide policy required
 - Covers obvious human trafficking in addition to recruiter rules, retention of citizenship documents, housing, return transportation, and commercial sex acts carried out by employees at any time during performance even if not related to performance
 - Credible information of human trafficking must be reported
- Some responsibility for overseeing subcontractors
- Ex-U.S. performance > \$500k can require plan for compliance under particular contract
- Must report credible evidence of violation

Small Business Subcontracting

- Efforts to use small business subcontractors are required
- Subcontractor small business status needs to be tracked, with HUBZone representations being confirmed in Government database
- Small business subcontracting plans required >\$750k
 - Commercial-item contracts typically use organization-wide
 - If commercial plan, tracking required for all sales and indirect costs
 - Plans not required for small businesses or commercial-item subcontracts
 - Progress toward goals periodically reported
 - VA sets rigid goals
- On set-aside prime contract side, greater risk with “front” resellers, limitations on subcontracting, and ostensible subcontractor rule

Trade Agreements Act

- Applies to prime contract awards >\$183k
- Origin based on “substantial transformation”
 - Typically active pharmaceutical ingredient, cell line, or equivalent
 - Packaging, assembly, and labelling generally not considered
- Substantial transformation cannot occur in non-designated countries like China, India, Brazil, Vietnam, Malaysia, the Philippines, Thailand, Iran, Iraq, or Russia

Acetris

- FAR reference to U.S.-made end products permitted TAA products to be mined, produced, or manufactured in the United states in lieu of being substantially transformed in the United States
- Procuring agencies must make independent evaluation and not rely on U.S. Customs and Border Protection decisions for definition of U.S.-made end product

Relationship between TAA and VHCA

- Schedule products generally must comply with the Trade Agreements Act
- In 2016, VA began requiring Covered Drugs to be listed even if not compliant with TAA (*only SIN 42-2A, not 42-2B*)
- Individual non-availability determination is required for each item
- *Acetris* made U.S.-made end products compliant without non-availability determination

Questions?

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