

Acquisition Plan (AP) Template

Revised July 2020

Purpose: This document provides the template for completing an Acquisition Plan (AP).

References: Federal Acquisition Regulation (FAR) 7.1

Requirements and Responsibilities: Acquisition Planning is required for all acquisitions. "Acquisition planning", means the process by which the efforts of all personnel responsible for phases of the acquisition lifecycle are coordinated and integrated through a comprehensive plan for fulfilling the agency need in a timely manner and at a reasonable cost. It should include information from the approved Acquisition Strategy (AS) detailing plans for managing the execution of the contract. The final approved AP must address the following as required by statute (41 USC 253(a)) as implemented through FAR 7.102 to promote and provide for:

- (1) Acquisition of commercial or non-developmental items, to the maximum extent practicable (41 U.S.C. 3307), see guidance in FAR 12 and the definition of commercial item in FAR 2101;
- (2) Full and open competition (see <u>FAR 6</u>) or to obtain competition to the maximum extent practicable, with due regard to the nature of the supplies or services to be acquired (41 U.S.C. 3306(a) (1));
- (3) Selection of appropriate contract type in accordance with FAR 16; and
- (4) Appropriate consideration of the use of pre-existing contracts, including interagency and intraagency contracts, to fulfill the requirement (See FAR 8.002 through FAR 8.004, FAR 17.5).

In accordance with FAR 7.101, the acquisition planner is responsible for developing and executing an AP. Within HHS, the primary acquisition planner is the Program/Project Manager (P/PM). The AP should incorporate applicable portions of the approved AS. It is incumbent upon the P/PM to coordinate the plan with all those who have a responsibility for the development, management or administration of any phase of the acquisition lifecycle and may include members of the Integrated Program Team (IPT). The IPT may include individuals with technical expertise based on the nature of the requirement and may include, but is not limited to, technical specialists in budget/finance, acquisitions, information technology, security, logistics and legal.

The Contracting Officer supports the P/PM by providing input and advising the P/PM on contracting strategy, appropriate contract type selection, and other contractual business matters. The Small Business Specialist (SBS) advises on small business considerations that may potentially impact the contracting strategy.

The AP must address all the technical, business, management, and other significant considerations that will control the acquisition. Ensure that the basic details supporting Program/Project impacts, for the areas identified in the approved AS, are included in the AP being submitted. The specific content of plans will vary, depending on the nature, circumstances, and stage of the acquisition.

For sections of this AP template that do not apply to the requirement, please indicate "Not Applicable (N/A)" and explain why, where necessary. The length and detail of an AP depends on the complexity of each individual acquisition. The AP shall be completed for all sections that apply to the acquisition.

Please do not include this page of instructions or the Additional Guidance beginning on page 17 of this document, in the final document or contract file.

Acquisition Plan (AP) Template

Acquisition Title	Product Replacement - ABX shortages Doxy tabs, Amoxi caps
Program/Project Title	Fy22 - Fy27 Doxy tab and Amoxi Cap Acquisitions
OPDIV/Division	SNS/OLB
Acquisition Year	Fy2021
Associated Acquisition Strategy (AS) Number (Approved Acquisition Strategy attached.)	
Program/Project Manager (P/PM) Name	Scott Andrews
P/PM Phone Number	404-661-1838
P/PM Email Address	evl4@cdc.gov

Key: Blue text will take you to further guidance within the document. Orange text will take you to Acquisition.gov.

(a) Acquisition Background and Objectives - FAR 7.105(a)

(1) Statement of Need - FAR 7.105(a)(1)

Introduce the plan by a brief statement of need. Summarize the technical and contractual history of the acquisition. Discuss feasible acquisition alternatives, the impact of prior acquisitions on those alternatives, and any related in-house effort.

The government has a need for varied configurations of Amoxicillin and Doxycycline hyclate (oral tablets and capsules) to care for persons impacted during an (anthrax) and other public health related events. The goal is to procure these products under the FSS/VA Schedule in bulk quantities in an effort to obtain significant discounts from small and large pharmaceutical producers and manufacturers under the schedule. The Government intends to award a firm fixed price contract to a vendor who is willing to add the smaller count pharmaceutical drug formulations and willing to repackage and relabel these products specifically for the Strategic National Stockpile. This requirement will be awarded with a base quantity, with the option to purchase additional quantities over the next five years depending on SNS's need and available funding.

An assessment was performed to determine capable vendors. The Government reserves the right to make multiple awards if necessary to meet the quantities needed for the Strategic National Stockpile.

The goal is to award a single contract in order to minimize the number of lot #'s per product in the SRP system, while simultaneously maximizing the quantity of the tab/cap per each Lot. Minimizing lot numbers should dramatically decease the strain on the FDA's Shelf-Life Extension Program (SLEP) testing program, which is explained in further detail below.

Technical and Contractual History

i. Provide a brief factual summary of the history of the requirement, including any legislative history. Discuss the scientific/technical/contractual history of the requirement and provide relevant prior acquisition information.

The Strategic National Stockpile (SNS) has acquired pharmaceuticals as required to meet its mission requirements since the year 2000.

Doxycycline tablets (Doxy tabs) and Amoxicillin capsules (Amoxi caps) were acquired between the years of 2004 and 2012. (b)(3):42

(b)(3):42 U.S.C. § 247d-6b(d)

This program

has enabled the original expiration shelf-life dates to be extended multiple times. However, the FDA has stated that all the SNS Doxy tabs and Amoxi caps inventory is reaching its maximum shelf-life extension (end of life) and thus will not be eligible for FDA SLEP program any longer.

The SNS has been a participant in the FDA SLEP testing program since 2005. The FDA SLEP program has limited lab testing resources and is only able to SLEP test the highest prioritized items in the SNS SLEP inventory. (b)(3)-42 U.S.C. 8 247d-6b(d)

<u>cquisition Alternatives</u> Discuss acquisition alternatives considered and the impact of prior acquisitions as they relate to the alternatives considered.
The Government was originally planning to compete this requirement full and open on sam.gov. However, market research, as further letailed in the attached market research document, indicated it would be possible for the Government to fulfill this requirement using the VA chedule. As use of Government schedules is preferred and significantly reduces the administrative burden on the Government, the Government is planning to make this award against the schedule.
cquisition Alternatives — Department Considerations Are there any Department of Health and Human Services (HHS) agency-wide IDIQ contracts or other acquisition alternatives nat can meet the needs of this requirement? If the requirement is for a service contract, describe the strategies for implementing erformance-based acquisition methods or provide the rationale for not using these methods [see FAR 37.102 (Public Law 106-98, section 821); FAR 7.105; and FAR 37.6]. Yes
√ No
There are no Department of Health and Human Services (HHS) agency-wide IDIQ contracts or other acquisition alternatives that can meet the seeds of this requirement.
Compatibility Discuss any compatibility requirements with future or existing systems/programs/projects. There are no compatibility requirements with future or existing systems/programs/projects.
Constraints E. Discuss any known cost, schedule, capability, or performance constraints. If such conditions exist, discuss the steps that will be taken to promote competition and socio-economic goals.
here are not any known cost, schedule, capability or performance constraints.
3) Cost - FAR 7.105(a)(3): Set forth the established cost goals for the acquisition and the rationale supporting them, ar iscuss related cost concepts to be employed, including, the following items:
Make sure the Independent Government Cost Estimate is attached and explain what the total estimated cost of this procurement inclusive of all options is.
The established cost estimate set forth in the IGCE is based on pricing obtained from the VA/FSS Schedule.
The Period of Performance is FY22-FY27 (Anticipated dates 09/30/2022 to 09/29/2027). The total estimated cost is \$342,521,531.00. Pricing on the VA/FSS Schedule is considered fair and reasonable.

Life-cycle cost

i. Discuss how life-cycle cost will be considered. If it is not used, explain why. If appropriate, discuss the cost model used to develop life-cycle-cost estimates.

Life cycle cost is normally associated with the purchase of a major system acquisition. It does not apply to this commercial acquisition for pharmaceutical supplies.

Design-to-cost

ii Describe the design-to-cost objective(s) and underlying assumptions, including the rationale for quantity, learning-curve, and economic adjustment factors. Describe how objectives are to be applied, tracked, and enforced. Indicate specific related solicitation and contractual requirements to be imposed.

Design-to-cost does not apply to this commercial product acquisition.

Application of should-cost

iii. Describe the application of should-cost analysis to the acquisition (see FAR 15.407-4).

A should-cost analysis applies to major systems acquisitions. This is an acquisition for commercial pharmaceuticals and therefore should-cost analysis does not apply.

(4) Capability or Performance - FAR 7.105(a)(4)

Specify the required capabilities or performance characteristics of the supplies or performance standards of the services being acquired and state how they are related to the need.

All product is required to meet FDA and DEA standards. SNS Science team will confirm alignment with these standards. Manufacturer must have the capability to ramp up production in response to an emergency if requested. Product must meet specific packaging and bottling requirements as detailed in the SOW.

(5) Delivery or Performance-Period Requirements - FAR7.105(a)(5)

Describe the basis for establishing delivery or performance-period requirements (see <u>FAR 11.4</u>). Explain and provide reasons for any urgency if it results in concurrency of development and production or constitutes justification for not providing for full and open competition. Provide the period of performance for this procurement, including all option periods.

The contract will be awarded with a Base QTY & 4 optional ordering periods. The period of performance-September-30-2022-September-29-2027.

(6) Trade-Offs - FAR 7.105(a)(6)

Discuss the expected consequences of trade-offs among the various cost, capability or performance, and schedule goals that reflects the changing needs and priorities of the program. Note: This section should not discuss trade-offs in relation to source selection.

The SNS does not expect consequences of trade-offs among the various cost, capability or performance, and schedule goals reflecting the priorities of the program.

(7) Risks - FAR 7.105(a)(7)

Discuss technical, cost, and schedule risks and describe what efforts are planned or underway to reduce risk and the consequences of failure to achieve goals. If concurrency of development and production is planned, discuss its effects on cost and schedule risks.

There are risks that for certain pharmaceuticals that are in short supply due to the COVID-19 pandemic, one vendor may not be able to provide the entire quantity. To mitigate this risk, we are reserving the right of the Government to issue multiple awards per product in order to meet the required quantity within 12 months.

Organizational Conflict of Interest

Review and discuss <u>FAR 9.5</u>-Organizational and Consultant Conflicts of Interest for roles and responsibilities concerning potential Conflicts of Interest as it pertains to the procurement. Explain mitigation strategies to avoid potential conflicts of interest.

There are no organizational or consultant conflicts of interest associated with this requirement.

(8) Acquisition Streamlining - FAR 7.105(a)(8)

Discuss plans and procedures to encourage industry participation by using draft solicitations, pre-solicitation conferences, and other means of stimulating industry involvement during design and development in recommending the most appropriate application and tailoring of contract requirements. Select and tailor only the necessary and cost-effective requirements, and state the timeframe for identifying which of those specifications and standards, originally provided for guidance only, shall become mandatory.

This requirement will be post on the VA Schedule as a small business set-a-side.

(b) Plan of Action - FAR 7.105(b)

(1) Sources - FAR7.105(b)(1)

i. Indicate the prospective sources of supplies or services that can meet the need.

In March 2021, an RFI was listed on beta sam gov that contained a full Doxy tab and Amoxi cap SNS SOW. SNS wanted to obtain current manufacturer and distributor capabilities and determine to what level the SOW requirements could be meet. In addition obtain current market costs that were based on inventory requirements for a 1-year base plus 4 option periods. The list of Doxy responders was (b)(3):42

(b)(3):42 U.S.C. § 247d-6b(d)

h)(3)·42 | I S C 8 The list of Amoxi responders was h)(3)·42 | I S C 8 247d-6h(d) Subsequent market research with

ii. Consider required sources of supplies or services (see <u>FAR 8</u>) and sources identifiable through databases including the Government-wide database of contracts and other procurement instruments intended for use by multiple agencies available at www.contractdirectory.gov/contractdirectory.

The VA schedule was reviewed for current contract schedules, market availability, manufacturers, shelf-life, and costs. The Government also met with representatives from the VA National Acquisition Center (NAC) as well as the VA's FSS schedules to determine the viability of making an award against these schedules in May of 2022. The Government was assured by these representatives that it would be possible for the Government to make a timely award against its FSS schedule if the vendor was willing to add the needed product to the schedule.

(b)(3):42 U.S.C. § 247d-6b(d)

(b)(3):42 U.S.C. § 247d-6b(d)

The Government reached out to both companies about the viability of purchasing these products in its needed quantities, as well as the viability of adding the smaller count bottles to the schedule on May 3rd, 2022. (b)(3):42 immediately expressed interest in providing this product and met with the Government to discuss further on May 6th, 2022. (b)(3): informed the

iii. Include consideration of small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns as required by <u>FAR 19</u>.

The HHS current subcontracting goal is 33.25% for Small Business (hereafter referred to as SB), 5.00% for Small Disadvantaged Business, including 8(a) Program Participants, Alaska Native Corporations (ANC) and Indian Tribes (hereafter referred to as SDB), 5.00% for Women-Owned Small Business and Economically Disadvantaged Small Businesses will be considered as this requirement will be a small business set-aside under the VA Schedule.

iv. Consider the impact of any consolidating and/or bundling that might affect small businesses participation in the acquisition (see <u>FAR 7.107</u>) (15 U.S.C. 644(e) and 15 U.S.C. 657q) (<u>PGI 307.104-70 (b)</u>). In accordance with <u>FAR 7.105(b) (1)</u>, when the proposed acquisition strategy involves bundling, identify the incumbent contractors and contracts affected by the bundling (see <u>FAR 7.107</u>Additional requirements for acquisitions involving consolidation, bundling, or substantial bundling.)

There is no consolidating or bundling associated with this requirement. This requirement is likely to be able to be performed by a small business concern. (See FAR 2.101).

v. Address the extent and results of the market research and indicate their impact on the various elements of the plan (see <u>FAR</u> 10).

This requirement will be a small business set-a-side under the VA Schedule. The Government believes it has adequate competition amongst three small businesses (b)(3):42 U.S.C. § 247d-6b(d) all of which have historically been able to successfully fulfill similar type of requirements in the past.

(2) Competition - FAR 7.105(b)(2)

i. Describe how competition will be sought, promoted, and sustained throughout the course of the acquisition. If full and open competition is not contemplated, cite the authority in <u>FAR 6.302</u>, discuss the basis for the application of that authority, identify the source(s), and discuss the rationale and basis why full and open competition cannot be obtained.

This requirement will be a small business set-a-side under the VA Schedule. These products will be competed on the VA Federal Supply Schedule in accordance with FAR Part 8. A Technical Evaluation panel will review and evaluate the responses.

ii. Identify the major components or subsystems. Discuss component breakout plans relative to these major components or subsystems. Describe how competition will be sought, promoted, and sustained for these components or subsystems.

There are no major components or subsystems. This requirement is for the acquisition of pharmaceutical products in support of the SNS mission.

iii. Describe how competition will be sought, promoted, and sustained for spares and repair parts. Identify the key logistic milestones, such as technical data delivery schedules and acquisition method coding conferences that affect competition.
There are no Spares or Repair Parts required for this requirement.
iv. When effective subcontract competition is both feasible and desirable, describe how such subcontract competition will be sought promoted, and sustained throughout the course of the acquisition. Identify any known barriers to increasing subcontract competition and address potential strategies to overcome them.
Due to the nature of the requirement, subcontracting is not likely. However, any large businesses will have to provide a small business subcontracting plan or a valid waiver.
(3) Contract Type Selection - FAR 7.105(b)(3)
Discuss the rationale for the selection of contract type. For other than firm-fixed-price contracts, see <u>FAR 16.103(d)</u> for additional documentation guidance. Acquisition personnel shall document the acquisition plan with findings that detail the particular facts and circumstances, (e.g., complexity of the requirements, uncertain duration of the work, contractor's technical capability and financial responsibility, or adequacy of the contractor's accounting system), and associated reasoning essential to support the contract type selection. The contracting officer shall ensure that requirements and technical personnel provide the necessary documentation to support the contract type selection.
Firm fixed-price for product(s).
(4) Source Selection Procedures - FAR 7.105(b)(4)
Discuss the source selection procedures for the acquisition, including the timing for submission and evaluation of proposals, and the relationship of evaluation factors to the attainment of the acquisition objectives (see FAR 15.3). When an EVMS is required (see FAR 34.202(a)) and a pre-award Integrated Baseline Review (IBR) is contemplated, the acquisition plan must discuss:
A Technical Evaluation Panel (TEP) will be formed to determine which vendor provides the Best Value to the government.
i. How the pre-award IBR will be considered in the source selection decision.
N/A
ii. How it will be conducted in the source selection process (see <u>FAR 15.306</u>).
N/A
$i\ddot{u}$. Whether offerors will be directly compensated for the costs of participating in a pre-award IBR.
N/A

(5) Acquisition Considerations - FAR 7.105(b)(5)
i. For each contract contemplated, discuss use of multiyear contracting, options, or other special contracting methods (see FAR 17); any special clauses, special solicitation provisions, or FAR deviations required (see FAR 1.4); whether sealed bidding or negotiation will be used and why; whether equipment will be acquired by lease or purchase (see FAR 7.4) and why; and any other contracting considerations. Provide rationale if a performance-based acquisition will not be used or if a performance-based acquisition for services is contemplated on other than a firm-fixed-price basis (see FAR 37.102(a), 16.103(d), and FAR 16.505(a)(3)).
This section does not apply because this requirement is a commercial supply contract and is not a performance-based acquisition. There are no known special contracting methods, special clauses, special solicitation provisions, or FAR deviations.
ii. For each order contemplated, discuss-
(A) For information technology acquisitions, how the capital planning and investment control requirements of 40 U.S.C. 11312 and OMB Circular A-130 will be met (see <u>FAR 7.103(v)</u> and <u>FAR 39</u>); and(B) Why this action benefits the Government, such as
when- (1) The agency can accomplish its mission more efficiently and effectively (e.g., take advantage of the servicing agency's specialized expertise; or gain access to contractors with needed expertise); or (2) Ordering through an indefinite delivery contract facilitates access to small business concerns, including small disadvantaged business concerns, 8(a) contractors, women-owned small business concerns, HUBZone small business concerns, veteran-owned small business concerns.
iii. For information technology acquisitions using Internet Protocol, discuss whether the requirements documents include the Internet Protocol compliance requirements specified in FAR 11.002(g) or a waiver of these requirements has been granted by the
agency's Chief Information Officer.
This is not a information technology acquisition
iii.a. Does Section 508 apply to this procurement? Will this procurement involve the acquisition of Electronic and Information Technology (EIT) products or services subject to Section 508? Will this procurement involve the production of audiovisual materials, publications, or public affairs services?
Yes ✓ No
14 110

iv. For each contract (and order) contemplated, discuss the strategy to transition to firm-fixed-price contracts to the maximum
extent practicable. During the requirements development stage, consider structuring the contract requirements, i.e., line items, in a
manner that will permit some, if not all, of the requirements to be awarded on a firm-fixed-price basis, either in the current
contract, future option years, or follow-on contracts. This will facilitate an easier transition to a firm-fixed-price contract, because
a cost history will be developed for a recurring definitive requirement.

This will be a Firm-Fixed price contract

(6) Budgeting and Funding - FAR 7.105(b)(6)

Include budget estimates, explain how they were derived, and discuss the schedule for obtaining adequate funds at the time they are required (see FAR 32.7). A completed IGCE must accompany this AP.

i. Independent Government Cost Estimate (IGCE) Date of Completion

4/14/2022

ii. Provide a brief explanation how the attached IGCE was developed.

The IGCE is based on current pricing found for these products on the VA NAC Pharmaceutical FSS.

iii. Discuss the schedule for obtaining both adequate funds and the right type of funds at the time they are required. If all necessary funds are not currently available, discuss the schedule for obtaining the additional funds. Provide detailed information on the funding amounts by providing data such as appropriation account, fiscal year, line item, and project name. If funding is from multiple projects, provide a complete listing of each source.

Acquisition Planning is used to capture all contracting requirements, which is used during the budget planning process. This process provides the visibility of all requirements needing funding. Total estimated value for this procurement is \$342,521,531.00

(7) Product or Service Descriptions - FAR 7.105(b)(7)

Explain the choice of product or service description types (including performance-based acquisition descriptions) to be used in the acquisition.

(b)(3):42 U.S.C. § 247d-6b(d)

(8) Priorities, Allocations, and Allotments - FAR 7.105(b)(8)

When urgency of the requirement dictates a particularly short delivery or performance schedule, certain priorities may apply. If so, specify the method for obtaining and using priorities, allocations, and allotments, and the reasons for them (see FAR 11.6).

No priorities for allocations, and allotments are planned

(9) Contractor versus Government Performance Consideration - FAR 7.105(b)(9)

Address the consideration given to OMB Circular No. A-76 (see FAR 7.3).

This section does not apply. OMB A-76 does not apply as this is not a services acquisition

Address the consideration given to <u>FAR 7.5</u> .	
Not Applicable - This is not an inherently governmental function.	
(11) Management Information Requirements - FAR 7.105(b)(11)	

earned value data to assess and monitor contract performance. In addition, discuss how the offeror's/contractor's EVMS will be verified for compliance with the Electronic Industries Alliance Standard 748 (EIA-748), Earned Value Management Systems, and the timing and conduct of integrated baseline reviews (whether prior to or post award). (See <u>FAR 34.202.</u>)

Contractor's deliveries will be monitored by the COR and all product received will be closely inspected prior to acceptance. The SNS warehouses will ensure all product deliveries were made in accordance to CGMP and SNS SOP's. The delivery Bill of Lading (BOL) and

Value Management System (EVMS) is to be used, discuss the methodology the Government will employ to analyze and use the

Contractor's deliveries will be monitored by the COR and all product received will be closely inspected prior to acceptance. The SNS warehouses will ensure all product deliveries were made in accordance to cGMP and SNS SOP's. The delivery Bill of Lading (BOL) and packaging lists will be compared to actual delivery of product to ensure product is labeled correctly and no external damages have occurred during transit. The SNS COR will also oversee LOT quantity and validate all vendor invoices to ensure contract requirements are met.

(12) Make or Buy - FAR 7.105(b)(12)

Discuss any consideration given to make-or-buy programs (see FAR 15.407-2).

(10) Inherently Governmental Functions - FAR 7, 105(b)(10)

This section does not apply. There is no known consideration to make or buy programs.

(13) Test and Evaluation - FAR 7.105(b)(13)

To the extent applicable, describe the test program of the contractor and the Government. Describe the test program for each major phase of a major system acquisition. If concurrency is planned, discuss the extent of testing to be accomplished and any testing milestones that will be met before production release.

This section does not apply. This is not a major systems acquisition; no test program applies.

(14) Logistics Considerations - FAR 7.105(b)(14) - Describe:

i. The assumptions determining contractor or agency support, both initially and over the life of the acquisition, including consideration of contractor or agency maintenance and servicing (see <u>FAR 7.3</u>); support for contracts to be performed in a designated operational area or supporting a diplomatic or consular mission (see <u>FAR 25.301-3</u>); and distribution of commercial items:

All awards and delivery of product will be FOB Destination to a USG designated location within the United States.

ii. The reliability, maintainability, and quality assurance requirements, including any planned use of warranties (see <u>FAR 46</u>);
This is for Commercial-Off-the-Shelf Pharmaceuticals governed by cGMP for quality assurance and enforced by DSNS Quality Assurance Team.
iii. The requirements for contractor data (including repurchase data) and data rights, their estimated cost, and the use to be made of the data (see <u>FAR 27</u>); and
This requirement does not involve patent, data, or copyrights services.
iv. Standardization concepts, including the necessity to designate, in accordance with agency procedures, technical equipment as "standard" so that future purchases of the equipment can be made from the same manufacturing source.
(15) Coxommont Furnished Property FAP 7 105(b)(15)
(15) Government-Furnished Property - FAR 7.105(b)(15) Indicate any Government property to be furnished to contractors, and discuss any associated considerations, such as its availability or the schedule for its acquisition (see FAR 45.102).
No Government-Furnished Property will be provided.
(16) Government-Furnished Information - FAR 7.105(b) (16)
Discuss any Government information, such as manuals, drawings, and test data, to be provided to prospective offerors at contractors. Indicate which information that requires additional controls to monitor access and distribution (e.g., technic specifications, maps, building designs, schedules, etc.), as determined by the agency, is to be posted via the enhanced controls the Government wide Point of Entry (GPE) (see <u>FAR 5.102(a)</u>).
Not Government-Furnished Information will be provided.

(17) Environmental and Energy Conservation Objectives - FAR 7.105(b)(17)

Discuss all applicable environmental and energy conservation objectives associated with the acquisition (see <u>FAR 23</u>), the applicability of an environmental assessment or environmental impact statement (see 40 CFR 1502), the proposed resolution of environmental issues, and any environmentally-related requirements to be included in solicitations and contracts (see <u>FAR 11.002</u> and <u>FAR 11.303</u>).

This section does not apply. There is no known no environmental or energy conservation objectives apply to this acquisition of commercial items.

(18) Security Considerations - FAR 7.105(b)(18)

i. For acquisitions dealing with classified matters, discuss how adequate security will be established, maintained, and monitored (see FAR 4.4).

No classified matters are involved.

ii. For information technology acquisitions, discuss how agency information security requirements will be met.

This acquisition does not pertain to any Information Technology requirements.

iii. For acquisitions requiring routine contractor physical access to a Federally-controlled facility and/or routine access to a Federally-controlled information system, discuss how agency requirements for personal identity verification of contractors will be met (see <u>FAR 4.13</u>).

There is no need for the contractor to have access to a Federally-controlled information systems and it will not be necessary to incorporate identity verification security considerations for this requirement.

iv. For acquisitions that may require Federal contract information to reside in or transit through contractor information systems, discuss compliance with FAR 4.19.

The contractor's information system will not contain this kind of Federal contract information.

(19) Contract Administration - FAR 7.105(b)(19)

Describe how the contract will be administered. In contracts for services, include how inspection and acceptance corresponding to the work statement's performance criteria will be enforced. In contracts for supplies or service contracts that include supplies, address whether higher-level quality standards are necessary (FAR 46.202) and whether the supplies to be acquired are critical items (FAR 46.101).

A FAC-COR-Level III will perform all technical functions as described in the COR appointment memorandum. Audits of product will be conducted by the DSNS as required. The products produced and stored under this contract must be FDA approved and shall be manufactured in accordance with the conditions approved by the Food and Drug Administration under appropriate patents for the medication. The current Good Manufacturing Practice regulations (cGMP') (21CFR Parts 210-211) will be the standard applied for manufacturing, processing and packing of drugs.

andardization concepts do not apply. The industrial readiness program; the industrial readiness program does not apply. The Defense Production Act; the Defense Production Act does not apply. The Occupational Safety and Health Act; Interactor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations plicable to its performance under this contract. Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (SAFETY Act) (see FAR 50.2); there is no technology to be procured appropriate for SAFETY Act protections. Foreign sales implications; there are no known Foreign sales implications.	20) Other Considerations - FAR 7.105(b)(20) - Discuss, as applicable:	
The industrial readiness program does not apply. The Defense Production Act; The Defense Production Act; The Occupational Safety and Health Act; Interpretational Comply with all applicable Federal, State and local laws, executive orders, rules and regulations plicable to its performance under this contract. Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (SAFETY Act) (see FAR 50.2); There is no technology to be procured appropriate for SAFETY Act protections. Foreign sales implications; There are no known Foreign sales implications.	:Standardization concepts;	
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The Occupational Safety and Health Act; Ontractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations plicable to its performance under this contract. Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (SAFETY Act) (see FAR 50.2); Interest is no technology to be procured appropriate for SAFETY Act protections. Foreign sales implications; Interest are no known Foreign sales implications. Special requirements for contracts to be performed in a designated operational area or supporting a diplomatic or consulassion;	The industrial readiness program does not apply.	
The Occupational Safety and Health Act; ontractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations plicable to its performance under this contract. Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (SAFETY Act) (see FAR 50.2); here is no technology to be procured appropriate for SAFETY Act protections. Foreign sales implications; here are no known Foreign sales implications. Special requirements for contracts to be performed in a designated operational area or supporting a diplomatic or consularisation;	i. The Defense Production Act:	
ontractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations plicable to its performance under this contract. Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (SAFETY Act) (see FAR 50.2); here is no technology to be procured appropriate for SAFETY Act protections. Foreign sales implications; here are no known Foreign sales implications. Special requirements for contracts to be performed in a designated operational area or supporting a diplomatic or consulation;	The Defense Production Act does not apply.	
Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (SAFETY Act) (see FAR 50.2); mere is no technology to be procured appropriate for SAFETY Act protections. Foreign sales implications; mere are no known Foreign sales implications. Special requirements for contracts to be performed in a designated operational area or supporting a diplomatic or consularsion;	. The Occupational Safety and Health Act;	
Foreign sales implications; here are no known Foreign sales implications. Special requirements for contracts to be performed in a designated operational area or supporting a diplomatic or consulatesion;	Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.	
Foreign sales implications; here are no known Foreign sales implications. Special requirements for contracts to be performed in a designated operational area or supporting a diplomatic or consulatesion;	. Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (SAFETY Act) (see FAR 50.2);	
here are no known Foreign sales implications. Special requirements for contracts to be performed in a designated operational area or supporting a diplomatic or consulatesion;	There is no technology to be procured appropriate for SAFETY Act protections.	
Special requirements for contracts to be performed in a designated operational area or supporting a diplomatic or consulassion;	i. Foreign sales implications;	
ssion;	There are no known Foreign sales implications.	
/A	ii. Special requirements for contracts to be performed in a designated operational area or supporting a diplomatic or consission;	onsula
/A	N/A	
i. Any other matters germane to the plan not covered elsewhere.	iii. Any other matters germane to the plan not covered elsewhere.	
o other considerations or germane matters to the plan are known.	No other considerations or germane matters to the plan are known.	

(21) Milestones for the Procurement Cycle - FAR 7.105(b)(21)

Procurement Milestone	N/A	Target Date	Revised Date	Completion Date
Acquisition Plan Approval		07/22/2022		
Statement of Work				07/11/2022
Specifications				
Data Requirements: Information Security Certification Checklist Completed (Appendix A of <u>HHS Security and Privacy Language for Information and Information Technology Procurements, Version 2.0 dated June 26, 2017.)</u>	X			
Completion of acquisition-package preparation				07/11/2022
Purchase request	X			
Justification and approval for other than full and open competition where applicable and/or any required D&F approval	X			
Issuance of synopsis	X			
Issuance of solicitation		08/03/2022		
Evaluation of proposal, audits, and field reports		09/05/2022		
Beginning and completion of negotiations		09/12/2022		
Contract preparation, review, and clearance		09/19/2022		
Contract Award		09/26/2022		
Please indicate any additional milestones below:				

(22) Identification of Participants in Acquisition Plan Preparation - FAR 7.105(b)(22)

Name	Role	Phone Number	Email Address
Scott Andrews	COR	404-661-1838	ev14@cdc.gov
imberly Golden	CO	770-488-2672	ixm9@cdc.gov

Reviews and Approvals of the Acquisition Plan (Required)

Budget Officer/Funds Certifying Official's Certification

Please se	elect one statement below.			
	I hereby certify that (a) this requirement rappropriation was made and complies with performance period of this acquisition.			
✓	I hereby certify that (a) this requirement rappropriation was made and complies with or first increment of performance of this a	th the Anti-Deficiency Act		· ·
	This acquisition will use the multi-year co- certify that: (a) this requirement represent was made and complies with the Anti-De- plus the estimated amount of the full cand	ts a bona fide need in the fi ficiency Act; and (b) funds	scal year or years	for which the appropriation
	Funds are not currently committed for thi	s acquisition.		
Name &	Supervisory Financial Advisor Title	Linda D. Signature Jackson -S	Digitally signed by Linda D. Jackson - S Date: 2022 08 05 11 28 13 -04'00'	Date

OPDIV Approvals:						
Official	Name & Title	Signature		Date		
Program/Project Manager (P/PM)	Shirley Mabry, Supervisory Logistics Specialis	Shirley M. Mabry - S	Digitally signed by Shirley M Mebry -S Date: 2021 02 08 13 47:35-05'00'			
Business Owner (Requiring Activity/COR)	Scott Andrews, COR	Scott D. Andrews -S	Digitally signed by Scott D. Andrews -S Date: 2021.02.05 07:05:16 -05'00'			
For OPDIV (if necessary)	David Allen, Supervisory Log Mgmt Specialist	David M. Allen -	Digitally signed by David M. Allen -S Date: 2021 02:08 14:16:31-05'00'			
For OPDIV (if necessary)						
Head of the Sponsoring Program Office(if applicable)	Steve Adams, Director, SNS					
Contracting Officer	Caleb Owen	Caleb W. Owen -S	Digitally signed by Caleb W. Owen—S Date: 2022/07/11/11/35/38-04/00*	07/11/2022		
Contracting Officer Supervisor	Acting Annette Wright, Lead Contract Specialist					
For OPDIV (if necessary)						
OPDIV Policy Review (if applicable)						

Officials	Name & Title	Signature	Date
OPDIV Office of Small and Disadvantaged Business Utilization (OSDBU)			
OPDIV Chief Information Officer (CIO) (if applicable)			
OPDIV Competition Advocate (if applicable)			
Head of the Contracting Activity (HCA)	Braxton, Makoto, Acting HCA		
	Department Approva	ls:	
Official	Name & Title	Signature	Date
Office of the General Counsel (Legal) (if applicable)			
HHS Competition Advocate (if applicable)			
HHS Office of Small and Disadvantaged Business Utilization (OSDBU)			
HHS Chief Information Officer (CIO) (if IT related)			
HHS Senior Procurement Executive (SPE)			

AP Submission Instructions: Per FAR 7.102(a) and HHS policy, a written AP is required for all acquisitions above the simplified acquisition threshold. This AP Template shall be used for all acquisitions with an estimated value (inclusive of options) greater than the threshold requiring Senior Procurement Executive (SPE) approval, or if the Program/Project (P/P) is designated as a Special Interest and/or High Risk P/P subject to HHS Acquisition Strategy Review Board (ASRB) oversight. For all acquisitions that require SPE review and approval, the AP must be submitted via the Acquisition Document Review (ADR) Portal. It is important to note that you must have an ADR Portal User Account in order to submit your AP via the ADR Portal. Please email OAP@hhs.gov for additional assistance and/or support.

ADR Portal: https://asfr.hhs.gov/OGAPA/DA/WorkforceDevelopment/oawsi/default.aspx

For all acquisitions not requiring SPE review and approval, and are equal to or greater than the simplified acquisition threshold, including task orders under Indefinite Delivery, Indefinite Quantity (IDIQ) contracts (FAR 7.105), OPDIVs may use this AP Template or their own template which must meet, at a minimum, the AP content requirements outlined in the FAR 7.105 and HHSAR 307, 105.

Additional Guidance

(a) Acquisition Background and Objectives - FAR 7.105(a)

(1) Statement of Need - FAR 7.105(a)(1)

Briefly describe the purpose of and need for the proposed requirement as defined in the approved AS. Start this section with a short, clear and concise statement of goals, objectives, and outcomes for this procurement; making sure to support all the details mentioned.

The Statement of Need should include the following:

- a. Applicable Conditions: State all significant conditions affecting the acquisition, including requirements for compatibility with existing or future systems/programs; and any known cost, schedule, and capability/performance constraints.
- b. Cost: State the established cost goals for the acquisition and the rationale supporting them. Discuss related cost concepts to be employed including as appropriate, life-cycle cost, design-to-cost, and application of should-cost.
- c. Capability or Performance: Highlight the required capabilities/performance characteristics of the supplies or the performance standards of the services being acquired and state how they relate to the need.
- d. Delivery or Performance-Period Requirements: Describe the basis for establishing delivery or performance-period requirements. Explain and provide reasons for any urgency if it results in concurrency of development and production or constitutes justification for not providing for full and open competition.
- e. Trade-offs: Discuss the expected consequences of the trade-offs among the various cost, capability or performance, and schedule goals.
- f. Risks: Discuss technical, cost, and schedule risks and describe what efforts are planned or underway to reduce risk and the consequences of failure to achieve goals. If concurrency of development and production is planned, discuss its effects on cost and schedule risks.
- g. Acquisition Streamlining: If specifically designated by the requiring agency as a program subject to acquisition streamlining, discuss plans and procedures to: encourage industry participation by using draft solicitations, presolicitation conferences, and other means of stimulating industry involvement during design and development in recommending the most appropriate application and tailoring of contract requirements; select and tailor only the necessary and cost-effective requirements; and state the timeframe for identifying which of those specifications and standards, originally provided for guidance only, shall become mandatory.

i. Technical and Contractual History

Discuss the scientific/technical context of the requirement and provide relevant acquisition information, including names previous/incumbent contractor(s), periods of performance, contract numbers, and performance problems.

- a. Technical History Past history of the requirement such as existing stage of the hardware/software/technology.
- b. Contractual History Chronological listing of past procurements. For each procurement, provide a brief summary as well as fill in the specific information listed.
 - Include names of previous/incumbent contractor(s), periods of performance, contract numbers, and performance problems.
 - Describe the considerations for use of either Statement of Work (SOW) (<u>HHS PGI 307.7108</u>),
 Statement of Objectives (SOO) (<u>FAR 37.602</u>), Performance Work Statement (PWS) (<u>FAR 37.602</u>).
 - When necessary for adequate description, a picture, drawing, diagram, or other graphic representation.

ii. Acquisition Alternatives

Describe the impact if prior acquisitions affect the feasible alternative. This should include any existing internal or Government-wide contracts that satisfy the same or similar needs, results of the market research conducted (FAR 10) that substantiate the need for the alternative chosen, and the potential for using Category Management and HHS Smarter Buying Program (HHSAR 312.1 and HHS PGI 307.104-7) to leverage Federal or HHS' Strategic Sourcing Vehicles, such as: the National Institutes of Health, Technology Assessment and Acquisition Center (NITAAC), the Government Wide Acquisition Contracts (GWACs); Indefinite-Delivery/Indefinite-Quantity (IDIQ) contracts: Blanket Purchase Agreements (BPA).

(2) Applicable Conditions - FAR 7.105(a)(2)

ii. Constraints

Discuss any factors that might limit or impact the cost, schedule, capability or performance of the requirement (e.g., congressional mandates, time constraints, and technology changes). If such conditions exist, discuss steps that will be taken to promote competition and socio-economic goals, strategies to mitigate the constraint(s), and details on any related contingency plans.

(3) Cost - FAR 7.105(a)(3)

Use of the Acquisition Gateway Independent Government Cost Estimate (IGCE) tool is recommended: https://hallways.cap.gsa.gov/app/#/igce.

Provide rationale for how the IGCE was developed, explain costs anticipated to increase/decrease over the program/project lifecycle, and describe how cost concerns will be mitigated. Discuss the specific cost techniques or concepts that may be employed.

Note: If the procurement, inclusive of all options, has a value equal to or greater than \$20,000,000, please refer to HHSAR 334 Earned Value Management System.

- i. Life Cycle-Cost –This technique considers not just the cost of the item being acquired, but the cost of the item over its life. For example, if purchasing a piece of office equipment such as a copier, Lifecycle costing could consider the cost of operation, including parts, supplies, maintenance, etc., in addition to the initial outlay for the piece of equipment. Discuss the costs that will increase/decrease over the program/project lifecycle.
- ii. Design-to- Cost -This technique is employed to try to achieve a balance between lifecycle cost, acceptable performance, and schedule. An example of when design-to-cost might be used is in development of a prototype before full production. Because the highest percentage of product costs are committed based on decisions made during concept development and design, it is imperative that costs be monitored during key decision points.
- iii. Application of Should-Cost This complex process is often appropriate for a major system acquisition (FAR 34). A Should-Cost Evaluation is a special form of cost-analysis that reviews the economy and efficiency of the contractor's existing work force, methods, or materials. Should-cost reviews are conducted by a multi-functional team that looks at contracting, contract administration, pricing, audit, and engineering issues to identify short and long-term improvements to reduce the cost of performance and to put the Government in a better position to develop a realistic objective for negotiation. Should-cost techniques can be applied to both a P/P as a whole or to overhead costs. This complex process is often appropriate for a major system acquisition.

(4) Capability or Performance - FAR 7.105(a)(4)

Explain why these capabilities may require use of commercial products or services, if applicable (see FAR 12).

(5) Delivery or Performance-Period Requirements - FAR7.105(a)(5)

Specify the period of performance required for total procurement and, if applicable, the estimated duration of each phase for this procurement. Describe the rationale for establishing the delivery or performance schedule (see <u>FAR 11.4</u>). For supplies and services, describe all factors considered including; urgency of need, industry practices, market conditions, transportation time, production time, capabilities of small business concerns, etc., that are expected to impact delivery/performance requirements.(see <u>FAR 11.402 (a)</u>)

For construction programs/projects, describe all factors considered including; nature and complexity of the project, construction seasons, required completion date, availability of materials and equipment, capacity of the contractor to perform, etc. that are expected to impact delivery/performance requirements (see <u>FAR 11.402 (b)</u>). Indicate whether the requirement is for construction management services or involves the acquisition of construction manager-at-risk services. Construction manager- at-risk is a delivery method that entails a commitment by the construction manager to deliver a project within a Guaranteed Maximum Price (GMP).

Discuss the Government's requirement in terms of delivery or performance-period (<u>FAR 11.4</u>). The delivery or performance schedule must be realistic and meet the needs of the Government; however, it should not be unnecessarily short or difficult to attain, as such actions restrict competition, result in higher prices, and are inconsistent with small business policies. In establishing delivery schedules, the following factors should be taken into consideration: urgent needs, industry practices,

market conditions, production time, small business capabilities, and the time needed for the Government to fulfill its obligations such as furnishing Government property/information or inspections. Also, explain how performance will be monitored.

(6) $\frac{\text{Trade-Offs} - \text{FAR 7.105(a)(6)}}{\text{FAR 7.105(a)(6)}}$

For IT investments, include or reference the applicable portion of the alternatives analysis section of the required <u>HHS</u> Enterprise Performance Life Cycle (EPLC) business case. For major construction/facilities capital investments, include or reference the applicable portion of the current HHS business case, reviewed and approved by an appropriate governance structure, and the supporting acquisition strategy along with the supporting AS.

The Business Case is a documented, structured proposal for business improvement that is prepared to facilitate a selection decision for a proposed investment or project by organizational decision makers. The Business Case describes the reasons and justification for the investment or project in terms of business process performance, needs and/or problems, and expected benefits. It identifies the high-level requirements that are to be satisfied, an analysis of proposed alternative solutions (with reasons for rejecting or carrying forward each option), assumptions, constraints, a risk-adjusted cost-benefit analysis, and preliminary acquisition strategy. It should identify why a business capability is necessary and what business benefits can be expected by implementing this project. Avoid identifying a specific product or vendor as the solution. The background information provided should be at a level of detail sufficient to familiarize senior managers with the history, issues and customer service opportunities that can be realized through improvements to business processes with the potential support of IT. This background information must not offer or predetermine any specific automated solution, tool, or product.

Ensure that agency planners on information technology acquisitions comply with the capital planning and investment control requirements in 40 U.S.C. 11312 and OMB Circular A-130. (FAR 7.103(v))

Ensuring that agency planners on information technology acquisitions comply with the information technology security requirements in the Federal Information Security Management Act (44 U.S.C. 3544), OMB's implementing policies including Appendix III of OMB Circular A-130, and guidance and standards from the Department of Commerce's National Institute of Standards and Technology. (FAR 7.103(w))

Additional information technology policy and guidance:

- Enterprise Performance Life Cycle Framework OVERVIEW DOCUMENT
- HHS Federal Information Technology Acquisition Reform Act (FITARA) Implementation-Revised HHS IT Governance Framework
- HHS Federal Information Technology Acquisition Reform Act (FITARA) HHS Implementation Plan, September 2015
- Memorandum: HHS Cloud Computing and Federal Risk and Authorization Management Program Guidance
- HHS Policy for Software Asset Management (SAM)
- HHS Policy for Capital Planning and Investment Control (CPIC), September 2016
- HHS Policy for IT Enterprise Performance Lifecycle (EPLC), October 6, 2008
- HHS Rules of Behavior for the Use of HHS Information and IT Resources Policy
- IT Policies & Standards
- Leadership For IT Security & Privacy Across HHS
- HHS Section 508 OCIO and ASPA Roles, Responsibilities and FAQs Federal Information Security Management
 Act (44 U.S.C. 3544), OMB's implementing policies including Appendix III of OMB Circular A-130, and guidance
 and standards from the Department of Commerce's National Institute of Standards and Technology.
- OCIO Federal IT Acquisition Reform Act Approval Guidance
- Vendor Management Office Information Technology Acquisition Review Processes

(7) Risks - FAR 7.105(a)(7)

i. Discuss methods for assessing, monitoring and controlling issues to mitigate, manage and/or minimize any technical, cost, and schedule risks identified that may affect the ability of program to accomplish and meet the program/project objectives for a successful outcome. Discuss major areas of technical risk and address any other risks including strategic market, legal, human capital, and change management risk. For each risk identified, explain the proposed mitigation effort(s). For IT investments, provide the HHS Enterprise Performance Life Cycle (EPLC) Risk Management Plan. Ensure that the Risk Management Plan accurately establishes that the security and privacy requirements have been identified and planned for. For

major construction/facilities capital investments, include or reference the applicable portion of the current HHS Business Case.

Examples of technical risks may include, but are not limited to, the exposure to natural or human-induced hazards, animal colony outbreaks of disease, etc. Examples of schedule risks may include, but are not limited to, the schedule being optimistic instead of realistic, the product or effort required being larger than estimated, etc. Cost risks may include, but are not limited to, supplies, facilities, tools, or acquisitions costing more than estimated; the scale or scope of a P/P increasing, causing increased costs, etc.

Risk response strategies include:

- 1. Avoidance To avoid a risk, requirements may be changed.
- 2. Transference A risk that can be transferred by other actions is an acceptable option only when the overall risk to the Government is lowered by doing so.
- 3. Mitigation A risk can be mitigated by handling the unwanted outcome in an acceptable way.
- 4. Acceptance Some risks may be appropriately accepted through recognition and control.

Ensuring that contracting officers consult the Disaster Response Registry Search via <u>sam.gov.</u> as a part of acquisition planning for debris removal, distribution of supplies, reconstruction, and other disaster or emergency relief activities inside the United States and outlying areas. (See <u>FAR 26.205</u>).

- A program or project can be designated as "High Risk" by the OPDIV Leadership or the HHS Acquisition Strategy
 Review Board (ASRB) if it meets one or more of the following criteria: 1) has one or more risks with a high probability
 of occurring and significant associated consequences; and, 2) the program or initiative has been designated as "High
 Risk" by the U.S. Government Accountability Office (GAO).
- A program or project can be designated as "Special Interest" by their OPDIV Leadership or the ASRB if it meets one or more of the following criteria: 1) high technical complexity; 2) Congressional interest; 3) requires a large commitment of resources; 4) the P/P is critical to achievement of a capability or set of capabilities; 5) the P/P is part of a system of systems; 6) the P/P affects more than one Division across HHS; and, 7) the P/P is led by a P/PM who is not FAC-P/PM certified within one year of appointment as the P/PM, 8) as designated by the Office of the Secretary.

ii. Organizational Conflict of Interest

Review FAR 9.5 – Organizational and Consultant Conflicts of Interest for roles and responsibilities concerning potential Conflicts of Interest. The P/PM and the CO must collaborate to assess and, if necessary, mitigate the potential organizational conflict of interests. The CO should obtain the advice of counsel and the assistance of appropriate technical specialists in evaluating potential conflicts and in developing any necessary solicitation provisions and contract clauses.

(8) Acquisition Streamlining - FAR 7.105(a)(8)

Discuss planned actions that will be taken to streamline the acquisition including, but not limited to, conducting outreach efforts to stimulate industry involvement, using draft solicitations, Statements of Work (SOWs), Performance Work Statements (PWSs), or Statements of Objectives (SOOs) for industry comment, and limiting the size of proposals. Discuss the possible use of reverse auctions or exchanges with industry described at FAR 15.201 and FAR 15.202.

(b) Plan of Action - FAR 7.105(b)

(1) Sources - FAR 7.105(b)(1)

i. List the prospective source(s) of supplies or services to meet the need.

iii Describe the consideration of small business as required by FAR 19. Ensure consultation with the HHS Small Business

Specialist (SBS). At a minimum, address compliance with HHS Federal Procurement Forecasting requirements (HHS Procurement Forecast Data Repository (PFDR)), planned set-aside(s), and document consideration of small business, veteran-owned business, service-disabled veteran- owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns (FAR 19).

iv. In accordance with FAR 7.105(b)(1), when the proposed AS involves consolidation or bundling, identify the incumbent contractors and contracts affected by the bundling.v. List the prospective source(s) of supplies or services to meet the need identifying opportunities utilizing Category Management and the HHS Smarter Buying Program methods (HHSAR 312.1 and HHS PGI 307.104-72). Discuss the potential applicability of required Government sources, existing HHS and Government wide contracting vehicles, and sources identified via market research, including small husiness considerations. Address compliance with Federal and HHS acquisition regulations. Include the results and impact of market research on the acquisition.

(2) Competition - FAR 7.105(b)(2) and FAR 7.102

For a proposed non-competitive acquisition, attach a Justification and Approval (J&A) following FAR, HHSAR and PGI guidance in Parts 6, 8, and 16 whichever apply.

(3) Contract Type Selection—FAR 7.105(b)(3)

In accordance with <u>FAR 7.102</u>, the AP should promote and provide details, which support the selection of an appropriate contract type in accordance with <u>FAR 16</u>. Explain why an existing contract vehicle cannot be used.

Firm-fixed-price contracts are preferred, if considering any other contract type, include details to justify the type of contract chosen providing details of the selected contract type and an explanation as to why a Firm Fixed Price (FFP) contract cannot be used. For example, if you choose a Cost Plus - Award Fee contract an Award Fee plan is required. The Award Fee plan must identify how the award-fee evaluation criteria are linked to acquisition objectives which shall be defined in terms of cost, schedule, and technical performance. Award fee contracts also require preparation and approval of a Determination & Finding (D&F) Memorandum. Many other types of contract also require a D&F (see FAR 16 and HHSAR 316 for details).

As a collaborative effort among the team members, the P/PM and the acquisition personnel must document in the AP the facts and circumstances, (e.g., complexity of the requirements, uncertain duration of the work, contractor's technical capability, and financial responsibility or adequacy of the contractor's accounting system), and associated reasoning essential to support the contract type selection. The CO must ensure that requirements and technical personnel provide the necessary documentation to support the contract type selection. Provide details on the following, if applicable:

- Review and consider existing intra-agency and interagency contracts vehicles to determine if existing vehicles can meet the Government's needs prior to issuing a new contract;
- Document the rationale to issue a new or use an existing vehicle (FAR 17.5);
- FFP is the preferred contract type if a new contract vehicle is required; and,
- Other than FFP.

(4) Sources Selection Procedures - FAR 7.105(b)(4)

Reference the Source Selection Plan which will provide specific details on the Source Selection Procedures for the anticipated procurement. Discussions and documentation under this section does not satisfy the requirement to construct and document a detailed source selection plan which is a separate inclusion in the contract file. A solicitation in which green products or services may be supplied or used (i.e., within the scope of <u>FAR 23.1</u>, Sustainable Acquisition Policy) shall include a separate evaluation factor for sustainability. The factor may be in the form of a technical evaluation criterion or a mandatory qualification criterion, as appropriate. The method of evaluation and relative importance of the sustainability criterion shall be agreed to by the Contracting Officer, Program/Project Manager, and the OPDIV Green Procurement Manager. Please review <u>APM 2011-05</u>. For a design-build source selection, provide the proposed Phase I and Phase II evaluation criteria. For a design-build source selection, provide the proposed initial selection evaluation criteria and final selection (interview) evaluation criteria. Also, if applicable, identify whether there will be a design competition and the factors that will be used.

In accordance with <u>FAR 7.103 (r)</u> Making a determination, prior to issuance of a solicitation for advisory and assistance services involving the analysis and evaluation of proposals submitted in response to a solicitation, that a sufficient number of covered personnel with the training and capability to perform an evaluation and analysis of proposals submitted in response to a solicitation are not readily available within the agency or from another Federal agency in accordance with the guidelines at <u>FAR 37.204</u>.

(5) Acquisition Considerations—FAR 7.105(b)(5)

i. This section should describe the basic contracting decisions made with respect to the acquisition. These include:

- Special contracting methods to be employed multi-year contracting, options, etc.
- Any special clauses or provisions which may be required.
- Any FAR deviations that may be needed.
- Whether Sealed Bidding or Negotiated procurement was chosen and why.
- If acquiring equipment, the decision to acquire by lease or purchase and why.
- A discussion of performance-based contracting and rationale if not used.
- If the requirement is for public accommodations, commercial facilities, conferences or meetings. (see HHSAR 311)
- Rationale behind using another agency either through consolidation of requirements for a new acquisition or use of
 their existing procurement vehicles. Discussion should include the impact on the various socio-economic P/Ps and
 sources.
- For information technology requirements, how compliance with capital planning and investment control requirements of OMB A-130 and 40 U.S.C. 11312 were assured.
- For requirements for the design, development, or operation of a system of records on individuals assure compliance with the policies and procedures that apply pursuant to the Privacy Act of 1974 (<u>5 U.S.C.552a</u>), <u>OMB Circular No.A-130</u> including Personally Identifiable Information (PII), and the Freedom of Information Act (<u>5 U.S.C.552</u>, as amended). (see <u>FAR 24</u>, <u>HHSAR 324</u> and <u>PGI 324</u>)
- For acquisitions of foreign supplies, services, construction materials, and contracts performed outside the United States, consideration has been given to the applicability of the Buy American Act (41 U.S.C. chapter 83) and the Trade Agreements Act. (see FAR 25, and PGI 325)
- Encouraging agency planners to consider the use of a project labor agreement (see <u>FAR 22.5</u>).
- Ensuring that contracting officers consult the Disaster Response Registry via https://www.sam.gov, Search Records, Advanced Search, Disaster Response Registry Search as a part of acquisition planning for debris removal, distribution of supplies, reconstruction, and other disaster or emergency relief activities inside the United States and outlying areas. (See FAR 26.205).

Discussion/documentation under this section does not satisfy requirements for individual J&A. Discuss Determinations and Findings (D&F), or other approvals, waivers, or exemptions required under the FAR.

iii. Does Section 508 apply to this procurement (please consult the HHS Section 508 website for further guidance and send HHS Section 508 questions to: 508helpdesk@hhs.gov)? If "Yes," the Statement of Work (SOW)/Performance Work Statement (PWS)/Statement of Objectives (SOO) must include a list of applicable Section 508 accessibility standards from the United States Access Board (36 CRF Part 1194). Include appropriate documentation and justification for Section 508 exceptions, if applicable. Will this procurement involve the acquisition of Electronic and Information Technology (EIT) products or services subject to Section 508? If "Yes," please specify the technical evaluation factors that will be used to evaluate the products or services offered. Discuss how Section 508 requirements and standards will be used in evaluation criteria and the development of materials if applicable. Will this procurement involve the production of audiovisual materials, publications, or public affairs services? If "Yes", please briefly describe the approach that will be used to make all files Section 508 compliant. Files may include, but are not limited to: captioning, audio descriptions, videos, tables, graphics/pictures, registration forms, presentations (both audio and video) or other types of proprietary format files (e.g., Adobe Portable Document Format (.pdf), Microsoft Office PowerPoint (.ppt), and Microsoft Excel (.xls)). Verify that Applicable Section 508 standards are identified and planned for and that the vulnerability and impact of being non-compliant with Section 508 has been included in the overall risk management planning.

Ensuring that acquisition planners specify needs and develop plans, drawings, work statements, specifications, or other product descriptions that address Electronic and Information Technology Accessibility Standards (see 36 CFR part 1194) in proposed acquisitions (see <u>FAR 11.002(e)</u>) and that these standards are included in requirements planning, as appropriate (see subpart <u>FAR 39.2</u>, <u>HHSAR 339</u> and <u>PGI 339</u>).

(6) Budgeting and Funding-FAR 7.105(b)(6)

ii Briefly provide an explanation as to how the IGCE was developed and the methodology used for estimating cost. Include the source of the data used and the rationale used to formulate the IGCE. If the SOW, SOO or PWS identifies subtasks, the IGCE should include corresponding costs for each subtask. All travel rates utilized in the IGCE should be consistent with those specified in the Federal Travel Regulations.

iii. Provide current funding data for each appropriation.

(7) Product or Service Descriptions-FAR 7.105(b)(7)

FAR 7.102 requires promoting and providing for acquisition of commercial or non-development items, to the maximum extent practicable, see guidance in FAR 12 and the definition of commercial item in FAR 2.101. The AP shall provide details supporting the procurement of existing commercial or non-developmental items or services. If not, then develop a justification requesting approval from the SPE to procure a noncommercial item or service.

Ensuring that agency planners include use of the metric system of measurement in proposed acquisitions in accordance with 15 U.S.C.205b (see FAR 11.002(b) and agency metric plans and guidelines). FAR 11.002(b) The Metric Conversion Act of 1975, as amended by the Omnibus Trade and Competitiveness Act of 1988 (15 U.S.C.205a, et seq.), designates the metric system of measurement as the preferred system of weights and measures for United States trade and commerce, and it requires that each agency use the metric system of measurement in its acquisitions, except to the extent that such use is impracticable or is likely to cause significant inefficiencies or loss of markets to United States firms. Requiring activities are responsible for establishing guidance implementing this policy in formulating their requirements for acquisitions.

(8) Priorities, Allocations, and Allotments-FAR 7.105(b)(8)

Specify the method(s) for obtaining and using priorities, allocations, and allotments. Explain the rationale for using these priority methods and identify information for preferential or priority rating when applicable.

(9) Contractor versus Government Performance—FAR 7.105(b)(9)

Address the consideration given to OMB Circulator No. A-76 (see FAR 7.3) and HHS Service Acquisition Initiative (SAI) guidance. Agencies are required by Office of Management and Budget (OMB) Circular A-76, dated May 29, 2003, to classify all activities performed by Government personnel as either commercial or inherently governmental functions. OMB Circular A-76 requires that commercial activities should be subject to the forces of competition through either a streamlined or standard competition between the Government and industry. If the work for this acquisition was previously performed by government employees, this section should address consideration given to OMB Circular A-76. (See FAR 7.3)

(10) Inherently Governmental Functions—FAR 7.105(b)(10)

Discuss consideration of inherently governmental functions, as detailed in FAR 7.5. An inherently governmental activity is an activity that is so intimately related to the public interest as to require performance by Government personnel. These activities involve the exercise of substantial discretion in applying Government authority and/or in making decisions for the Government. Inherently governmental activities normally fall into two categories: the exercise of sovereign Government authority or the establishment of procedures and processes related to the oversight of monetary transactions or entitlements. Review the Office of Federal Procurement Policy Letter 11-01 for further information regarding inherently governmental functions.

(11) Management Information Requirements—FAR 7.105(b)(11)

Explain the checks, balances, and separation of duties that will be used to monitor the contractor's performance. Examples might include use of performance monitoring techniques such as use of computer programs like Microsoft Project, PERT or Gantt charts, regularly scheduled meetings, key milestone reviews, etc. If an earned value management system (EVMS) is to be used, discuss the methodology the Government will employ to analyze and use the earned value data to assess and monitor contract performance.

(12) Make or Buy-FAR 7.105(b)(12)

"Make or Buy programs" means that part of the contractor's written plan for a contract identifies those major items to be produced or work efforts to be performed in the prime contractor's facilities, and those to be subcontracted. (see <u>FAR</u> 15.407-2)

(13) Test and Evaluation—FAR 7.105(b)(13)

Any special test procedures of the contract should be addressed such as prototype development, dual development, millstone testing, and special inspections, etc.

(14) No additional guidance.

(15) Government – Furnished Property – FAR 7.105(b)(15)

In this section, identify any Government property to be furnished to contractors, also known as Government-Furnished Property (GFP), and discuss any associated considerations such as availability or the schedule for its acquisition (see <u>FAR</u>

45.102). The section should also address how furnishing the property is in the Government's best interest and the overall benefit to the Government significantly outweighs the increased cost of administration including ultimate property disposal, discuss how furnishing the property does not substantially increase the risk to the Government, and why the Government requirements cannot otherwise be met. Other issues that may be addressed include:

- Any schedule for providing the property;
- The condition of the property;
- Whether use of the GFP is optional or required;
- Any plans for ensuring appropriate control and accountability for GFP; and,
- Issues related to ultimate disposal of the property (e.g., hazardous content, appropriate disposition, protection of sensitive data, etc.).

Ensure that any GFP including materials, facilities, equipment, and information that are to be provided under the contract are clearly identified in the AP. Consult the OPDIV Property Management Officer, as appropriate, to ensure that the proposed acquisition meets HHS personal property requirements for cannibalization, accountability, sensitivity, reporting, reutilization, and disposal.

(16) Government-Furnished Information—FAR 7.105(b)(16)

Describe how this data will be provided during the competitive process, such as through individual copies to offerors, providing data on the agency web site, or by establishing a reading library. Discuss the schedule and means for providing the information to the successful contractor after award and the impact that any delays by the Government in providing the data might have upon contract performance.

(17) Environmental and Energy Conservation Objectives - FAR 7.105(b)(17)

Ensure provisions identified in <u>FAR 7.103 (p) (1), (2), (3) and (4)</u> have been considered. <u>Review APM 2011-05</u>, Sustainable "Green" Acquisition, to verify if the acquisition is subject to the requirements. If applicable, discuss how the acquisition will meet the requirements of APM 2011-05.

Discuss acquisition of products containing recovered materials, including the special requirements for printing and writing paper. If applicable, provide a justification for not buying Environmental Protection Agency (EPA)-designated recycled content and environmentally preferable and energy-efficient products and services as an attachment to the AP. Review the requirements of FAR 23, Environmental, Energy, and Water Sufficiency, Renewable Energy Technologies, Occupational Safety, and Drug-Free Workplace. Describe how the contract will consider the purchase and use of green products and services to the maximum extent practicable, to include bio-based products, recycled content products, water-efficient, energy-efficient, Energy Star®, products with the lowest watt stand-by power, environmentally preferable products, alternative fuels, hybrid and alternative fuel vehicles, non-ozone depleting substances, renewable energy; and Environmental Protection Agency (EPA, the Department of Energy (DOE), and the United States Department of Agriculture (USDA) designated items.

Discuss the impact of any environmental or energy conservation efforts associated with the acquisition, including use of recovered materials and preference for environmentally preferable products and services. If hazardous or toxic materials might be involved or a bio-product of the contract performance, indicate actions which may be taken to mitigate potential environmental damage. If the contract performance requires an environmental assessment or environmental impact statement, provide the details of this requirement.

(18) No additional guidance.

(19) Contract Administration - FAR 7.105(b)(19)

Discuss if a post-award conference is planned or desired. Also, discuss special requirements of the contract such as quality control procedures, inspection, and acceptance criteria. In accordance with FAR 1.602-2, for all contracts and orders for services other than those that are firm-fixed price, a COR must be designated and authorized by the Contracting Officer after nomination by the requirements official to administer the contract. A COR may be designated for firm-fixed price contracts and orders as appropriate. In accordance with PGI 301.602-4, the Contracting Officer shall ensure that a COR candidate is currently certified under HIHS' FAC-COR program before designating authority to that individual to act as a COR. Even if an individual is FAC-COR-certified, a candidate becomes a COR only when a Contracting Officer provides in writing the authorities the individual may exercise for a specified contract or order including inspection and performance of the contract. Authority for such designations rests solely with the Contracting Officer. The Contracting Officer shall retain in the contract or order file the individual's active FAC-COR certificate. In the event the designated COR is unable to act due to any reason,

pursuant to FAR 1.602-2(d)(7)(iv), the Contracting Officer must designate an alternate COR. The authority designated to a COR is non-delegable. If all or part of the administrative functions will be delegated, they should be set forth in this section. Please note, the Contracting Officer is not precluded from retaining and executing the COR duties as appropriate.

(20) No additional guidance.

(21) Milestones for the Procurement Cycle - FAR 7.105(b)(21)

The Acquisition Milestone Plan should be realistic and consistent with the requirements of the proposed acquisition. The acquisition milestones specified in the table below are examples which may be tailored to each unique acquisition. The P/PM, CS, and CO must sign the schedule where provided. The CO/CS must update and revise the schedule, as necessary, to track progress of the acquisition and maintain the schedule as part of the contract file. The review and approval of the signatories of the AP must mutually agree to any revisions to the milestone dates that will impact meeting the scheduled award.

As a collaborative effort among the team members, the P/PM and CO will identify each significant event from acquisition initiation through the end of the contract action (pre- and post-award). The same milestones may not be present in every acquisition P/P. Tailor the milestones to the specifics of each procurement.

A certifying official is the official within an agency or organization that is responsible for verifying that payments made by the federal government are legal, proper, and correct.

BUSINESS ATTACHMENT 1

Company Name	Item No.		NOC #	Quantity in Eaches	Unit of Measure (UoM)	Eaches Per UOM	Quantity in DoM	UoM Price per product	Total Cost
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Total for All Products