

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00092

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NAME OF OFFEROR OR CONTRACTOR
PHLOW CORP 1558286

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
1	<p>Tax ID Number: 84-4910906 DUNS Number: 117445813 Reference BAA-18-100-SOL-00003 Cost Plus Fixed-Fee contract providing base period funding to furnish U.S.- based advanced manufacturing of COVID-19 essential medicines (b)(4)</p> <p>(b)(4)</p> <p>(b)(4) DOL General Decision No. VA20200155 as revised applies to construction work under this contract. Period of Performance: 05/18/2020 to 05/17/2030</p> <p>Overall Project Management</p> <p>1) Cost Plus Fixed Fee (CPFF)</p> <p>2) EVMS reporting NOT required</p> <p>3) SOW: The base award will comprise the task of managing the program per the contract and to assure the program is executed completely, to USG standards, and per proposed timelines. Scope of this base award includes the direct labor for the project management of the first 5 task orders to be completed in the first 4 years of the contract.</p> <p>(b)(4)</p> <p>Requisition No: OS259204</p> <p>Accounting Info: 2020.199COV2.25103 Appr. Yr.: 2020 CAN: 199COV2 Object Class: 25103</p> <p>(b)(4)</p>				(b)(4)
2	<p>Near - Term Fill Finish</p> <p>4) CPFF/ Period of performance: See below (1 year)</p> <p>5) EVMS reporting NOT required</p> <p>6) SOW: The first task is to provide BARDA MCMs/Essential Medicines for COVID-19 Response to meet critical market demand. (b)(4)</p> <p>(b)(4)</p>				(b)(4)

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3	<p>(b)(4)</p> <p>Requisition No: OS259204</p> <p>Accounting Info: 2020.199COV2.25103 Appr. Yr.: 2020 CAN: 199COV2 Object Class: 25103</p> <p>(b)(4)</p> <p>Near-Term API Manufacture</p> <p>1) CPFF/ Period of performance: See Below(2 years)</p> <p>2) EVMS reporting NOT required</p> <p>3) SOW: This task will be executed in the first 2 years of the contract to ensure U.S.-Based Production of Active Pharmaceutical Ingredients (API) for COVID-19 MCMs or Essential Medicines currently experiencing a shortage. (b)(4)</p> <p>(b)(4)</p> <p>(b)(4) They will establish immediate, U.S.- Based, development and surge capacity ramp-up for essential active pharmaceutical ingredients (APIs) and their chemical precursor ingredients to support COVID -19 response efforts and national supply chain security.</p> <p>a) (b)(4)</p> <p>(b)(4)</p> <p>b) (b)(4)</p> <p>(b)(4)</p> <p>c) Ability to rapidly manufacture, provided regulatory relief is granted, additional COVID-19 MCMs/essential medicine API needed for the COVID-19 response</p> <p>d) (b)(4)</p> <p>(b)(4)</p> <p>e) (b)(4)</p> <p>(b)(4)</p>				<p>(b)(4)</p>

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4	<p>(b)(4)</p> <p>f) (b)(4)</p> <p>(b)(4)</p> <p>g) (b)(4)</p> <p>(b)(4)</p> <p>h) (b)(4)</p> <p>(b)(4)</p> <p>i) (b)(4)</p> <p>(b)(4)</p> <p>Requisition No: OS259204</p> <p>Accounting Info: 2020.199COV2.25103 Appr. Yr.: 2020 CAN: 199COV2 Object Class: 25103</p> <p>(b)(4)</p> <p>SAPIR Build</p> <p>1) CPFF/ Period of performance: See Below (4 years)</p> <p>2) EVMS reporting required</p> <p>3) SOW: This task will occur over the first 4 years of the contract to establish a BARDA MCM/Essential Medicine Strategic Active Pharmaceutical Ingredient Reserve (SAPIR) Facility. (b)(4)</p> <p>(b)(4)</p> <p>a) Operationalizing the Nation's First Strategic Active Pharmaceutical Ingredient Reserve (SAPIR) Facility</p> <p>b) Design, build, and validate warehouse (b)(4)</p> <p>(b)(4)</p> <p>c) Implement a facility maintenance and stability program, perform maintenance, calibration and upkeep for facility and continue stability program on all API's</p> <p>(b)(4)</p> <p>Requisition No: OS259204</p> <p>Continued ...</p>				<p>(b)(4)</p>

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ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
5	<p>Accounting Info: 2020.199C002.25103 Appr. Yr.: 2020 CAN: 199C002 Object Class: 25103 (b)(4)</p> <p>Advanced Manufacturing Capability 1) CPFF/ Period of performance: See Below (4 years) 2) EVMS reporting required 3) SOW: This task will occur over the first 4 years of the contract to establish a U.S. - Based, End-to-End, Advanced Manufacturing Capability for BARDA MCMs/Essential Medicines, and their Ingredients. This involves (b)(4)</p> <p>(b)(4)</p> <p>development of a U.S. - based, advanced manufacturing infrastructure to support novel processes that reduce waste, improve yields and reduce cost for strategic MCMs/ Essential Medicines. Development of the U.S. - Based, Advanced Manufacturing Infrastructure (b)(4) including:</p> <p>a) (b)(4) (b)(4)</p> <p>b) Initializing continuous manufacturing process development of key MCMs/Essential Medicines in shortage (b)(4) (b)(4)</p> <p>c) (b)(4) (b)(4)</p> <p>d) (b)(4) (b)(4)</p> <p>e) (b)(4) Continued ...</p>				(b)(4)

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ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	(b)(4) Requisition No: OS259204 Accounting Info: 2020.199COV2.25103 Appr. Yr.: 2020 CAN: 199COV2 Object Class: 25103 (b)(4)				
6	(b)(4) 1) EVMS reporting NOT required 2) (b)(4) (b)(4)				0.00
7	(b)(4) Option Period 1 See POP below (1 year) (b)(4)				0.00
8	(b)(4) Option Period 1 See POP below (1 year) (b)(4)				0.00
9	(b)(4) Option Period 2 See POP below (1 year) (b)(4)				0.00
10	(b)(4) Option Period 2 See POP below (1 year) (b)(4) (b)(4)				0.00

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ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
11	(b)(4)				0.00
	Option Period 2 See POP below (1 year) (b)(4)				
12	(b)(4)				0.00
	Option Period 3 See POP below (1 year) (b)(4)				
13	(b)(4)				0.00
	Option Period 3 See POP below (1 year) (b)(4)				
14	(b)(4)				0.00
	Option Period 3 See POP below (1 year) (b)(4)				
15	(b)(4)				0.00
	Option Period 4 See POP below (1 year) (b)(4)				
16	(b)(4)				0.00
	Option Period 4 See POP below (1 year) (b)(4)				
17	(b)(4)				0.00
	Continued ...				

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ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	(b)(4) Option Period 4 See POP below (1 year)				
18	(b)(4) Option Period 5 See POP below (1 year)				0.00
19	(b)(4) Option Period 5 See POP below (1 year)				0.00
20	(b)(4) Option Period 5 See POP below (1 year)				0.00
21	(b)(4) Option Period 6 See POP below (1 year)				0.00
22	(b)(4) Option Period 6 See POP below (1 year)				0.00
23	(b)(4) Option Period 6 See POP below (1 year) Continued ...				0.00

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	<p>- PSC: AN17 NAICS: 325412, HHS/BARDA COR is Arlene Joyner, (202) 205-8691, arlene.joyner@hhs.g</p>				

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SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1 BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This contract is intended to establish a program where essential medicines already on the FDA drug shortage list, and/or have been exclusively manufactured using foreign sources, are manufactured and immediately supplied to health care systems in urgent need due to the current COVID-19 national pandemic. These are medicines, for example, (b)(4)

(b)(4) With the rise in hospitalizations due to COVID-19, the shortages of these medicines have been further magnified and the lack of supply has become a more substantial issue and these medicines are needed even more than during non-pandemic times. The contract is also to maintain a facility, producer, manufacturer, or other supplier available for furnishing supplies or services in case of a future national emergency and to achieve industrial mobilization so that at least nine years' worth of replenishments will be available in the United States. The Contract will establish and maintain a domestic supply chain necessary to secure Essential Medicines, including Generic Medicines, and Active Pharmaceutical Ingredients (API) necessary to treat COVID-19 patients in the short-term as well as alleviate the long term risk of domestic shortages to help address future pandemic threats. This will establish a manufacturing capability and capacity to potentially produce raw materials and active pharmaceutical ingredients and final drug products for critical COVID-19 and other essential medicines.

B.2 PRICE/COST

This contract contains the price/cost provisions agreed upon by the United States Government and Phlow Corporation (hereinafter, the "Contractor").

B.2.1 Contract Budget Ceiling

The contract has a cost/price ceiling that the Contractor exceeds at its own risk. The Contractor is responsible for managing its performance in accordance with the final scope of work and costs/prices incorporated into the contract. The Government is not obligated to reimburse the Contractor for costs incurred in excess of costs/prices agreed upon at time of award.

Table B.1

Contract Ceiling Amount (without Option Periods)
\$354,256,000

B.2.2 Price/Cost Schedule

The following Cost-Plus-Fixed-Fee (CPFF) Contract Line Item Numbers (CLINs) are included in this contract:

Table B.2

CLIN	Activity	CLIN Type	Fee	POP	Total Costs Not to Exceed
CLIN 0001 BASE	Program Management	CPFF	(b)(4)	Base: 5/18/2020 - 5/17/2024	(b)(4)
CLIN 0002 BASE	Provide BARDA MCMs/Essential Medicines for COVID-19 Response to Meet Critical Market Demand	CPFF	(b)(4)	Base: 5/18/2020 - 5/17/2021	
CLIN 0003 BASE	U.S.-Based Production of Active Pharmaceutical Ingredients (API) for COVID-19 MCMs/Essential Medicines in Shortage	CPFF	(b)(4)	Base: 5/18/2020 - 5/17/2022	
CLIN 0004 BASE	Establish MCM/Essential Medicine Strategic Active Pharmaceutical Ingredient Reserve (SAPIR) Facility for USG	CPFF	(b)(4)	Base: 5/18/2020 - 5/17/2024	
CLIN 0005 BASE	Establish a U.S.-Based, End-to End, Advanced Manufacturing Capability for BARDA MCMs/Essential Medicines, and their Ingredients	CPFF	(b)(4)	Base: 5/18/2020 - 5/17/2024	
				Total Base CLINs:	\$354,256,000.00
CLIN 0006 OPTION PERIOD 1	(b)(4)	CPFF	(b)(4)	Option year 1: 5/18/2024 - 5/17/2025	(b)(4)
CLIN 0007 OPTION PERIOD 1	(b)(4)	CPFF	(b)(4)	Option year 1: 5/18/2024 - 5/17/2025	
CLIN 0008 OPTION PERIOD 1	(b)(4)	CPFF	(b)(4)	Option year 1: 5/18/2024 - 5/17/2025	
CLIN 0009 OPTION PERIOD 2	(b)(4)	CPFF	(b)(4)	Option year 2: 5/18/2025 - 5/17/2026	
CLIN 0010 OPTION PERIOD 2	(b)(4)	CPFF	(b)(4)	Option year 2: 5/18/2025-5/17/2026	
CLIN 0011 OPTION PERIOD 2	(b)(4)	CPFF	(b)(4)	Option year 2: 5/18/2025-5/17/2026	

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Phlow Corporation, 75A50120C00092

CLIN 0012 OPTION PERIOD 3	(b)(4)	CPFF	(b)(4)	Option year 3: 5/18/2026 -5/17/2027	(b)(4)
CLIN 0013 OPTION PERIOD 3	(b)(4)	CPFF	(b)(4)	Option year 3: 5/18/2026 -5/17/2027	(b)(4)
CLIN 0014 OPTION PERIOD 3	(b)(4)	CPFF	(b)(4)	Option year 3: 5/18/2026 -5/17/2027	(b)(4)
CLIN 0015 OPTION PERIOD 4	(b)(4)	CPFF	(b)(4)	Option year 4: 5/18/2027 -5/17/2028	(b)(4)
CLIN 0016 OPTION PERIOD 4	(b)(4)	CPFF	(b)(4)	Option year 4: 5/18/2027 -5/17/2028	(b)(4)
CLIN 0017 OPTION PERIOD 4	(b)(4)	CPFF	(b)(4)	Option year 4: 5/18/2027 -5/17/2028	(b)(4)
CLIN 0018 OPTION PERIOD 5	(b)(4)	CPFF	(b)(4)	Option year 5: 5/18/2028 -5/17/2029	(b)(4)
CLIN 0019 OPTION PERIOD 5	(b)(4)	CPFF	(b)(4)	Option year 5: 5/18/2028 -5/17/2029	(b)(4)
CLIN 0020 OPTION PERIOD 5	(b)(4)	CPFF	(b)(4)	Option year 5: 5/18/2028 -5/17/2029	(b)(4)
CLIN 0021 OPTION PERIOD 6	(b)(4)	CPFF	(b)(4)	Option year 6: 5/18/2029 -5/17/2030	(b)(4)
CLIN 0022 OPTION PERIOD 6	(b)(4)	CPFF	(b)(4)	Option year 6: 5/18/2029 -5/17/2030	(b)(4)
CLIN 0023 OPTION PERIOD 6	(b)(4)	CPFF	(b)(4)	Option year 6: 5/18/2029 -5/17/2030	(b)(4)
				Total OPTION CLINs:	\$458,174,247
				TOTAL CONTRACT VALUE (incl. potential options):	\$812,430,247

B.3 CONTRACT TYPE

This contract consists of the following contract type:

- Cost-Plus-Fixed-Fee (CPFF)

B.4 ADVANCE UNDERSTANDINGS

The contract contains advance understandings between the Government and the Contractor. Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost, will be included in this Section if the Contracting Officer has granted his/her approval prior to contract award. Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Office.

a. Indirect Rates and Ceiling

- i. Pending the establishment of final indirect cost rates, which shall be determined based on audit of actual costs as provided in Subpart 42.7 of the Federal Acquisition Regulation, the Contractor shall be reimbursed for allowable indirect costs at the agreed upon provisional billing rates. The Contractor's audited final indirect costs are allowable, **to the extent that they do not lead the Contractor to exceed the total estimated costs for performance of the contract**, or the Ceiling Rates established under this contract. The Contractor is also directed to the requirement to provide the USG with notice, that actual costs are expected to exceed the costs estimates, as required by 52.232-20(b). The contractor is responsible for tracking all costs during performance, including indirect costs, and providing all required notices.
- ii. Any costs over and above the established cost ceiling shall not be reimbursed under this contract or any other Government contract, grant, or cooperative agreement without prior approval of the Contracting Officer per FAR Clause 52.232-20 Limitation of Cost.
- iii. The Government is not obligated to pay any additional amount, should the final indirect cost rates exceed the established ceiling rates of the contract. In the event that the final indirect cost rates are less than the negotiated ceiling rates, the Government's obligation shall be reduced to conform to the lower rate. The negotiated rates will be established and negotiated after the contract award.

(b)(4)



b. Priority Rating

HHS may assign a priority rating to this Contract. The Contracting Officer may unilaterally modify this contract to add FAR Clause 52.211-15, Defense Priority and Allocation Requirements (Sep 1990) and assign a Health and Human Services priority rating under Defense Priorities and Systems Regulation (15 CFR 700).

c. Option Year Terms

Consistent with FAR 17.207 (c)(3), before exercising an option in the “out” years 5 through 10 of the Phlow contract, a determination will be made regarding whether there is a USG industrial mobilization need for the continuing production and storage of drugs and drug components and whether the options and estimated costs in the Phlow contract represent the most advantageous offer to satisfy the agency’s continuing need for those services.

d. Pre-Contract Costs

Within the dollar limitation set forth under SECTION B, the Contractor shall be entitled to reimbursement for costs incurred in an amount not to exceed \$15,000,000.00, per the Advance Agreement between the USG and the Contractor, dated March 21, 2020, which if incurred after this contract had been entered into, would have been reimbursable under the provisions of this contract.

e. Non-Personal Services and Inherently Government Functions

1. Pursuant to FAR 37.104, no personal services shall be performed under this contract. All work requirements shall flow only from the Contracting Officer's Representative (COR) to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All individual employee assignments, and daily work direction, shall be given by the applicable employee supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.
2. Pursuant to FAR 7.5, the Contractor shall not perform any inherently governmental functions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change the contract and that if the other contractor believes this communication to be a direction to change their contract, they should notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

3. The Contractor shall insure that all its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of the contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

f. Confidential Treatment of Sensitive Information

The Contractor shall guarantee strict confidentiality of the information/data that it is provided by the Government and designated by BARDA as confidential information during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

g. Contract Number Designation

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number that appears on the face page of this contract, as follows:

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h. Manufacturing Standards

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of all product manufactured through this contract. If at any time during the life of this contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of these products and such failure results in a material adverse effect on the safety, purity or potency of these product (a material failure) as identified by CBER and CDER, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

i. Facility Use/Access

In consideration for funding the proposed construction activities, and capacity and capability expansion, the Contractor's U.S.-based facilities and entire capacity shall remain operational and accessible to the USG for six (6) years after completion of the contract's base period. Access shall be provided for purposes of potential additional development, manufacturing, and storage of essential medicines or APIs.

B.5 PROVISIONS APPLICABLE TO DIRECT COSTS

B.5.1 This section prohibits or restricts the use of contract funds for the following, unless otherwise approved in advance by the Contracting Officer. However, the government shall approve travel between the Contractor(s) site and BARDA, as required to execute this contract.

- a. Conferences and Meetings.
- b. Food for Meals, Light Refreshments, and Beverages.
- c. Acquisition, by purchase or lease, of any interest in land or real property.
- d. Purchase or lease of any item of general-purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.).
- e. Travel to attend general scientific meetings.
- f. Foreign travel.
- g. Consultant, CPA, attorney costs that are direct will be approved by the CO in advance.
- h. Patient care costs.
- i. Accountable Government Property (defined as non-expendable personal property with an acquisition cost of \$1,000 or more) and "sensitive items" (defined as items of personal property (supplies and equipment that are highly desirable and easily converted to personal use), regardless of acquisition value.
- j. Printing Costs (as defined in the Government Printing and Binding Regulations).
- k. Travel Costs.

B.5.2 Contracting Officers Authorization (COA)

The Contractor shall submit a Contracting Officer's Authorization (COA) approval request, to the Contracting Officer, for subcontractors, consultants and equipment purchases proposed during the course of this contract. COAs for subcontractors and consultant agreements shall be submitting when the potential subcontract is expected to exceed \$250,000. During an emergency declaration, the \$250,000.00 limit will increase to \$750,000.00. Sufficient time shall be provided for the Government to fully assess the transaction proposed. The supporting documents shall include, but not be limited to:

1. Competition activities, as well as technical and cost/price evaluation activities performed, in the selection of the subcontractor(s);
2. The subcontractor's qualifications/capabilities statement as they pertain to the activities included in the proposed subcontract;
3. The subcontractor's willingness to perform under the Contractor (i.e. commitment letters/preliminary agreements), with a list of specific duties included in the proposed subcontract;
4. The priority that the work will be given and how it will relate to other work;
5. The amount of time and facilities available for the subject requirement; and
6. A complete subcontractor cost proposal or quote, in similar format as the Contractor's cost proposal.

C. DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1 BACKGROUND AND PURPOSE

The Pandemic and All Hazards Preparedness Act (PAHPA) established BARDA as the focal point within HHS for the advanced development and acquisition of medical countermeasures to protect the American civilian population against Chemical, Biological Radiological and Nuclear (CBRN), Influenza and Emerging and Infectious Diseases emergent and naturally occurring threats to public health. PAHPA was reauthorized in 2013 by the signing of Pandemic and All Hazards Preparedness Reauthorization Act (PAHPRA). BARDA's mission is to develop and procure needed medical countermeasures, including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures, against a broad array of public health threats, whether natural or intentional in origin.

During this current era of the COVID-19 National Pandemic, there is expectation that the number of hospitalizations will surpass the number of beds available in the US. From the Washington Post news article on March 15, 2020, "The U.S. Department of Health and Human Services estimates a pandemic influenza, such as the one that hit the United States in 1957, would result in 38 million needing medical care, 1 million needing hospitalization and 200,000 needing to be in intensive care. In a severe scenario, such as in the 1918 influenza epidemic, the numbers would go up to 9.6 million hospitalizations and 2.9 million needing intensive care. The United States, in comparison, has only about 924,107 hospital beds and 97,776 intensive care beds, according to a 2018 American Hospital Association survey." The impact of full hospitals is that the gaps and concerns with national supply of essential medicines are further amplified and have become more critical. Prolonged shortages of important medicines are increasing in the U.S., with more than 200 drugs already in short supply. There is a substantial lack of API manufacturing capacity and infrastructure in the U.S. focused on essential medicines, especially critical generics. Although the exact reliance on foreign sources for our generic medicine supply is unknown, some estimates include greater than 95% of Generic Chemical Precursors, 80% of Generic Active Pharmaceutical Ingredients and 40% of Finished Generic Dosage Forms are sourced from foreign countries, including primarily from China. This presents substantial national health supply risks and security challenges. This has been exemplified during the present COVID-19 pandemic where India has already stopped the export of at least 26 APIs and medicines and China sources have threatened to stop exports of key medicines that would be used to treat COVID-19 patients. Countries are locking down borders, and the threat to our global supply chain is real.

As the U.S. faces the threat of the novel coronavirus (COVID-19), it is essential that an uninterrupted supply of fully domestic-made generic life-saving medicines are available to ensure the nation's health security.

The initial focus of the agreement will be establishing a never-done-before program where essential medicines that are already on the FDA drug shortage list are manufactured and immediately supplied to health care systems in urgent need of these medicines, particularly due to the current COVID-19 national pandemic. (b)(4)

(b)(4)

(b)(4)

(b)(4)

Although the proposed contract with Contractor will initially focus on the immediate use of existing inventory of generic essential medicines, it will also allow BARDA to review the stores of other generic medicines that may be needed to support COVID-19 hospitalized patients. Following review, those predetermined products selected in the current Contractor's proposal to be developed may be replaced by other products that are more urgently needed.

The next program objective will be to use the CM technology to develop continuous manufacture process for APIs small scale and eventually large scale in sufficient quantities to store material in a government owned strategic stockpile. This will be for both APIs and other starting raw materials that currently are only available through purchasing from suppliers outside of the US. In order to implement this concept to bring manufacturing domestic, a new hybrid manufacturing

(b)(4) continuous manufacturing technologies will be (b)(4) utilized to manufacture additional APIs. (b)(4)

(b)(4) Finally, the Contractor's program shall tech transfer their continuous manufacturing technology to the Medicines on Demand program within (ASPR Foundry).

C.2 OVERVIEW

Activities that may be supported under this contract include:

- a. Evaluation, purchasing and distribution of essential medicines generic and/or on drug shortage list;
- b. Facility design, modification (retrofit/renovation), commissioning and qualification, and facility validation;
- c. Product-dedicated manufacturing equipment;
- d. Generic drug and API process development and manufacturing scale-up development;
- e. Product lot release assay development and process validation;
- f. Generic medicines and API manufacturing including consistency lots;
- g. Fill/finish capacity evaluation, expansion, and validation.

C.3 STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Scope of Work submitted by the Contractor in response the Coronavirus Pandemic and submitted as the "U.S.-Based Advanced Manufacturing for COVID-19 Essential Medicines and Future Threats" on March 18, 2020. The program is designed to enhance domestic manufacturing of COVID-19 Essential medicines and APIs. The following are the overall objectives and are supported by the CLINs described subsequently:

- a. Addresses the near term threat of generic drug shortages that are critical for COVID-19 surge hospitalized patient treatment.
- b. Provides domestic self-sufficiency for manufacturing critical, generic API's and finished medicines to prevent future shortages.

CLIN structure:

- a. CLIN 0001: Program Management
- b. CLIN 0002: Provide BARDA MCMs/Essential Medicines for COVID-19 Response to Meet Critical Market Demand
- c. CLIN 0003: U.S.-Based Production of Active Pharmaceutical Ingredients (API) for COVID-19 MCMs/Essential Medicines in Shortage
- d. CLIN 0004: Establish BARDA MCM/Essential Medicine Strategic Active Pharmaceutical Ingredient Reserve (SAPIR) Facility
- e. CLIN 0005: Establish a U.S.-Based, End-to-End, Advanced Manufacturing Capability for BARDA MCMs/Essential Medicines, and their Ingredients
- f. CLINs 0006 through 0023: Optional CLINS (b)(4)

(b)(4)

The following table describes in more detail the scope of these CLINS.

Table C.1

CLIN	Activity	Key Deliverables
CLIN 0001	Program Management	<ul style="list-style-type: none"> • PM designated. • Reports submitted to PO/CO. Example: monthly technical progress reports, annual technical progress report, and biweekly meeting minutes. <p>(b)(4)</p>
CLIN 0002	Provide BARDA MCMs/Essential Medicines for COVID-19 Response to Meet Critical Market Demand	<ul style="list-style-type: none"> • Immediate availability of (b)(4) MCMs/Essential Medicines within 14 days of award to support the COVID-19 Response, ramping up enough surge capacity to treat up to 1 million patients within 6 months • Availability of (b)(4) MCMs/Essential Medicines within 4 weeks of award s, ramping up enough surge capacity to treat up to 1 million patients within 6 months
CLIN 0003	U.S.-Based Production of Active Pharmaceutical Ingredients (API) for COVID19 MCMs/Essential Medicines in Shortage	<ul style="list-style-type: none"> • Securing (b)(4) additional MCMs/Essential Medicines as requested by the USG • Availability of a supply of (b)(4) MCMs/Essential Medicines to support the COVID-19 Response within 6 months • Ability to rapidly manufacture, provided regulatory relief is granted, additional COVID-19 MCMs/essential medicine API needed for the COVID-19 response
CLIN 0004	Establish MCM/Essential Medicine Strategic Active	Operationalizing the Nation's First Strategic Active Pharmaceutical Ingredient Reserve (SAPIR) Facility

	Pharmaceutical Ingredient Reserve (SAPIR) Facility for USG	
CLIN 0005	Establish a U.S.-Based, End-to End, Advanced Manufacturing Capability for BARDA MCMs/Essential Medicines, and their Ingredients	Development of the U.S. - Based, Advanced Manufacturing Infrastructure (b)(4) including: (b)(4) • Initializing continuous manufacturing process development of key MCMs/Essential Medicines in shortage (b)(4) (b)(4) (b)(4)
OPTION PERIOD CLINs 0006, 0009, 0012, 0015, 0018, 0021,	(b)(4)	
OPTION PERIOD CLINs 0007, 0010, 0013, 0016, 0019, 0022		
OPTION PERIOD CLINs 0008, 0011, 0014, 0017, 0020, 0023		

Additional detailed information and requirements for the CLINs are as follows:

1. CLIN 0001 Manage the program per USG standards.
 - a. Maintain a Contractor Work Plan (CWP) that describes the activities to be performed in response to the Request for Proposal (RFP) requirements and a single Gantt chart to include all activities described in the CWP with a time-phased and task-linked budget. The level of detail contained in the CWP and the corresponding Gantt chart shall be sufficient to facilitate management and execution of the contract by the successful Contractor. This CLIN will also include any program management

activities related to the sharing of technologies with the ASPR Foundry and other industry entities.

b^(b)(4)



2. CLIN 0002 Procure and Manufacture Essential medicines and their ingredients, including generic medicines in shortage, used for the treatment of COVID-19 hospitalized patients
 - a. The essential medicines purchased, stored and distributed under this agreement shall be manufactured under a current establishment and product licensure issued by the Food and Drug Administration.
 - b. Contractor shall indicate number below:
 - i. Name of Medicine:
 - ii. License Number:
 - c. The Contractor agrees to comply with cGMP guidelines (21 CFR Parts 210-211, 600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents.
 - d. The Contractor agrees to advise the HHS CO and COR immediately of any relocation of any of their manufacturing facilities or the relocation of any sub Contractor's facility, funded under this contract. Contractor also agrees to advise the HHS CO and Contracting Officer's Representative immediately if at any time during the life of the contract, the items under this contract fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483)
 - e. Distribution of Medicines: The government may elect to require shipment of the essential medicines, API's or precursor materials to US Government facilities or to state and local health agencies and/or other providers.
 - i. The Government may direct the Consortium to destroy all quantities remaining in storage at a charge to be negotiated between the parties. Such charges shall not exceed the actual costs incurred by the Consortium, and agreed to by the Government in advance of the destruction and/or disposal.
 - ii. The contractor cannot reclaim title to product upon acceptance.
 - f. MANUFACTURING STANDARDS: The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of this therapeutic product.
 - i. If at any time during the life of this contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CBER and CDER, the Contractor shall have thirty (30) calendar

days from the time such material failure is identified to cure such material failure. If the Contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

3. CLIN 0003 Acquisition of the process knowledge and the technical package from an existing manufacturer of the APIs from an existing manufacturer, Technology Transfer of Process and Process Validation to rapidly manufacture APIs for essential APIs of Strategic National Health Security interest. (b)(4)

(b)(4)

- a. Development of APIs: Develop API's with the objective of identifying the appropriate continuous manufacturing or batch technology to ensure successful scale up to commercial batches. It is expected that the API manufacturing processes will be developed, bulk manufactured and (b)(4) API manufacturing prioritization and selection may be revised based on HHS/BARDA recommendations.
- b. The Contractor specifically plans to partner with the ASPR Foundry on continuous process technological innovations that arise from the proposed work previously described in the technical proposal. The Contractor will provide a technology transfer process to transfer continuous processes to ASPR Programs focused on building a Network of Distributed Pharmacies to add Resilience and Redundancy to the Supply Chain (e.g. The Pharmacy and Medicines on Demand Programs). Specifically, following the completion route scouting and process development activities, the Contractor will provide the Foundry with all technical information that has been obtained for the development of the continuous manufacturing processes for the drug targets that have been identified in both CLIN0003 and CLIN0005. These efforts will be performed at no additional cost to the USG as the work involved is already being done through CLIN0001, CLIN0003 and CLIN0005 where the efforts are included in their proposed funding request.

4. CLIN 0004 Build facility, store and maintain Strategic Reserve of Essential APIs, Precursor Chemical Ingredients, and Select Finished Products for National Public Health Security. The SAPIR will also be managed under an FDA Part 11 compliant validated Warehouse Management System, under Current Good Manufacturing Practices (CGMP) (b)(4)

(b)(4)

- a. Draft Manufacturing Facility Plan

Prepare a detailed Manufacturing Facility Plan describing the design, permit approval, retrofit/renovation, commissioning, qualification and validation of a U.S.-based facility(s) to store the Contractor's proposed SAPIR and Finished products. The Plan(s) shall contain the following elements:

- i) Architectural/structural plans that include concept functional designs, descriptions, and diagrams of space requirements, adjacency plans, floor plans, mechanical/electrical/plumbing, equipment layouts, material, product and personnel flows, solid, liquid contaminated and other waste flows, and an air balance description or diagram detailing zoning, pressurization, air flows and air quality classification.
- ii) Process and building/mechanical engineering including energy balances, utility flow diagrams, automation plan, equipment lists and a preliminary layout.
- iii) A proposed retrofit/renovation schedule including permitting, installation, commissioning and installation/ operational/ performance qualification and a risk mitigation analysis.
- iv) A description of the warehouse facility quality assurance and regulatory acceptance including quality systems, the validation master plan (VMP), and regulatory milestones towards facility approval as a cGMP storage facility.
- v) Provide a comprehensive Business Continuity Plan.

5. CLIN 0005 (b)(4)

(b)(4)

a. Draft Manufacturing Facility Plan

Prepare a detailed Manufacturing Facility Plan describing the design, permit approval, retrofit/renovation, commissioning, qualification and validation of a U.S.-based facility(s) to produce the Contractor's proposed APIs. The Plan(s) shall contain the following elements:

- i) Architectural/structural plans that include concept functional designs, descriptions, and diagrams of space requirements, adjacency plans, floor plans, mechanical/electrical/plumbing, equipment layouts, material, product and personnel flows, solid, liquid contaminated and other waste flows, and an air balance description or diagram detailing zoning, pressurization, air flows and air quality classification.
- ii) Process and building/mechanical engineering including energy balances, utility flow diagrams, automation plan, equipment lists and a preliminary layout.
- iii) A proposed retrofit/renovation schedule including permitting, installation, commissioning and installation/operational/performance qualification and a risk mitigation analysis.

- iv) A description of the manufacturing facility quality assurance and regulatory acceptance including quality systems, tech transfer plan, the validation master plan (VMP), and regulatory milestones towards facility approval.
 - v) Provide a comprehensive Business Continuity Plan.
- b) Draft Facility Operation Feasibility Plan
- i) Prepare an operational plan to manufacture the API's that includes:
 - 1. Detailed process descriptions, including a summary of process data that describes the yield and purification efficiencies of key process steps.
 - 2. Integration plans that outlines the addition of new/retrofitted facility(s) within the Contractor's product franchise.
 - 3. Comparison of process data that describes the significance of process scale-up and strain variability on production capacity.
 - 4. Proposed production schedules including detailed timelines for each production step from accessibility API manufacturing process through development, and scale up to full scale mfg.
 - 5. Detailed bulk upstream, bulk downstream, formulation, fill, and finish manufacturing capacity analysis for each API.
 - 6. Operational cost structure for API lot production that includes the anticipated cost breakdown for a specified quantity (ie kg or ton) of the finished product.
 - 7. Description of ongoing and/or anticipated process optimization activities.
 - 8. Dose calculations and contingency plans to address the need for higher dosages of the active product ingredient.
 - 9. Pre-pandemic facility management plans including a pandemic preparedness plan.
 - 10. Pandemic facility management plans including change procedures to pandemic operations in a declared emergency.
- c) Draft Security Plan
- i. The Contractor shall submit a Draft Security Plan addressing Security of Contract Operations. The plan shall include, at a minimum:
 - ii. Personnel Security Policies and Procedures including, but not limited to: Recruitment of new employees; Interview process; Personnel background checks; Suitability/adjudication policy; Access determination; Rules of behavior/conduct; Termination procedures; Non-disclosure agreements.

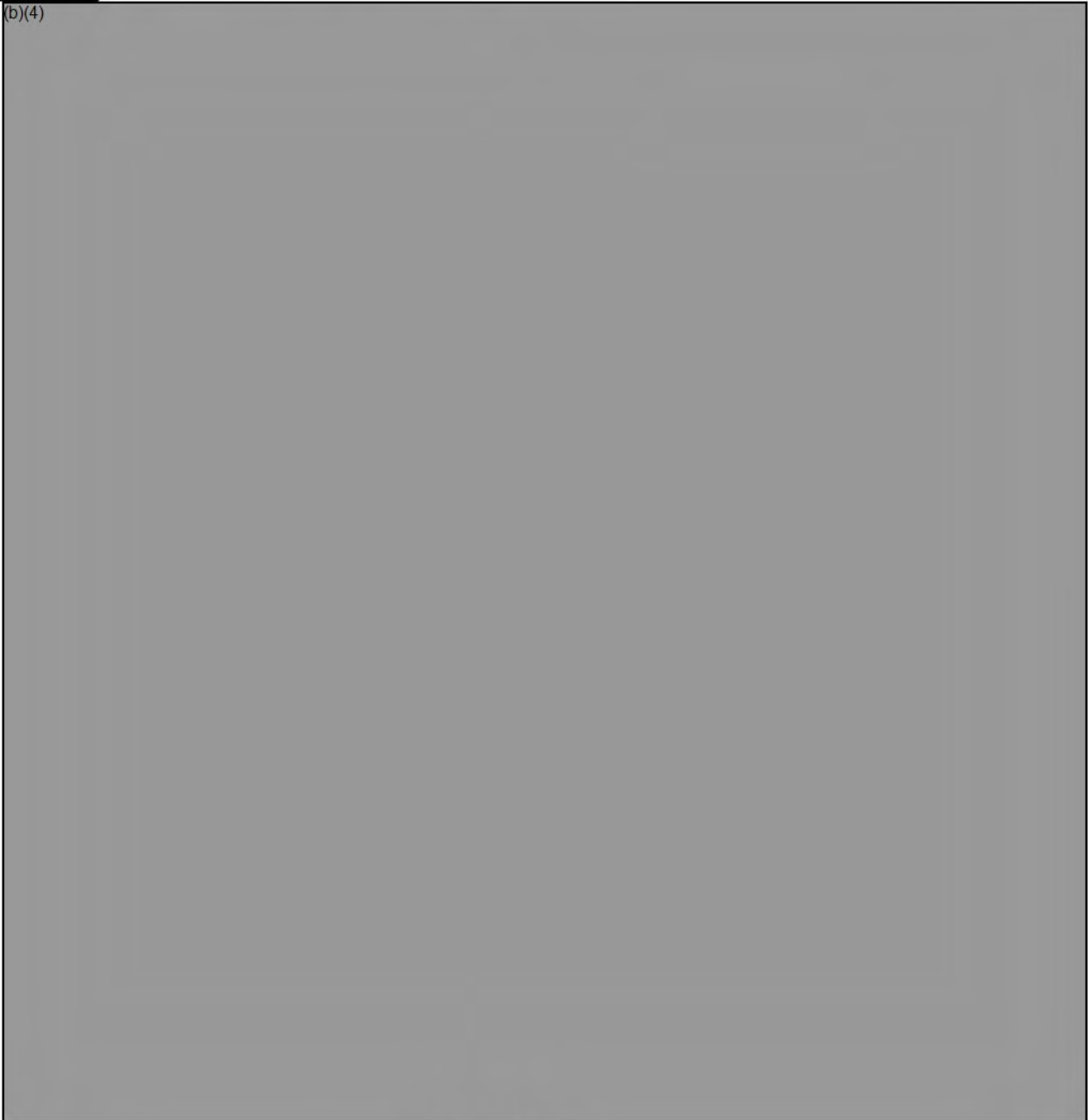
- iii. Physical Security Policies and Procedures including, but not limited to: Internal/external access control; Identification/badge requirements; Facility visitor access; Parking areas and access; Barriers/perimeter fencing; Shipping, receiving and transport (on and off-site); Security lighting; Restricted areas; Signage; Intrusion detection systems; Closed circuit television; Other control measures.
 - iv. General Information Security Policies and Procedures including, but not limited to: Identification of sensitive information; Access control/determination; Secured storage infrastructure; Document control; Retention/destruction requirements.
 - v. Information Technology Security Policies and Procedures including, but not limited to: Intrusion detection and prevention systems; Encryption systems; Identification of sensitive information/media; Passwords; Removable media; Laptop policy; Media access control/determination; Secure storage; System document control; System backup; System disaster recovery.
 - vi. The following instruction/intent shall be incorporated in the Draft Security Plan: Security Reporting Requirement - Violations of established security protocols shall be reported to the Contracting Officer (CO) and Project Officer (PO) upon discovery. The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. BARDA will determine if the severity of the violation requires further U.S. Government intervention.
- d) Occupancy and Retrofit/Renovation Close-Out
- i. Following the successful completion of facility commissioning and validation, and the product/process consistency/validation campaign, the Contractor shall submit a certificate of occupancy and a final retrofit/renovation technical close-out report for these activities.
- e) As mentioned in CLIN0003 and repeated here, the Contractor specifically plans to partner with the ASPR Foundry on continuous process technological innovations that arise from the proposed work previously described in the technical proposal. The Contractor will provide a technology transfer process to transfer continuous processes to ASPR Programs focused on building a Network of Distributed Pharmacies to add Resilience and Redundancy to the Supply Chain (e.g. The Pharmacy and Medicines on Demand Programs). Specifically, following the completion route scouting and process development activities, the Contractor will provide the Foundry with all technical information that has been obtained for the development of the

continuous manufacturing processes for the drug targets that have been identified in both CLIN0003 and CLIN0005. These efforts will be performed at no additional cost to the USG as the work involved is already being done through CLIN0001, CLIN0003 and CLIN0005 where the efforts are included in their proposed funding request.

6. CLINs 0006 through 0023: Optional CLINS for (b)(4)

(b)(4)

(b)(4)



(b)(4)



C.4 RETROFIT/RENOVATION – GENERAL

C.4.1 The General Contractor/Subcontractor (GC) proposed by the Contractor, for the retrofit portion of the anticipated contract, shall comply with the current edition of all applicable practices, codes, methods and standards as prepared by technical societies and associations, and other applicable laws, statutes, ordinances, rules and regulations. In case of conflict between codes and standards of the organizations, the more stringent regulations shall govern.

C.4.2 The GC shall provide all labor, materials, equipment, tools, supplies, supervision, and general retrofit/renovation services for the retrofit portion of the anticipated contract. The GC shall accomplish the retrofit objectives as described in the Contractor-proposed basis of design, as well as the detailed design plan, drawings and specifications developed during the design stage of the contract.

C.5 EARNED VALUE MANAGEMENT (EVM) SYSTEM REQUIREMENTS

The Contractor shall use an Earned Value Management (EVM) System for all retrofit and new construction activities of the anticipated requirement, that is consistent with the “*7 Principles of Earned Value Management Tier 2 System Implantation Intent Guide*” attached to this contract. Alternative systems may be submitted to the Contracting Officer for consideration and approval.

C.6 PERSON-IN-PLANT

With seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor’s facility, who shall be subject to the Contractor’s policies and procedures regarding security and facility access at all times while in the Contractor’s facility.

C.7 SECURITY REQUIREMENTS

Provide appropriate plans that demonstrate how the Contractor will meet and adhere to the security requirements outlined in attachment labeled Appendix D: BARDA Security Requirements.

C.8 PROGRAM MANAGEMENT

The overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities. The Contractor shall provide for the following program management activities as outlined below:

a. A listing of employees and subcontractors required to complete the objectives, including labor categories and descriptions, hourly rates, and estimated labor hours. Positions shall include, but are not limited to the following Program Manager, Quality Control and Inspection staff, Support Staff.

b. Program Director (PD)

Responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors. The contract deliverables list in Section F identifies all contract deliverables and reporting requirements for this contract.

c. Project Managers (PM)

Responsible for monitoring and tracking day-to-day progress and timelines, coordinating communication, project activities, costs incurred and other program management duties.

d. Administrative and Legal

Will provide development of compliant subcontractors (if applicable), consulting, and other legal agreements, and ensure timely acquisition of all proprietary rights, including IP rights, and reporting all inventions made in the performance of the project. Additionally, administrative staff with responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractors.

C.9 REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

Performance of the contract will be monitored by the Contracting Officer (CO)/Contracting Officer's Representative (COR) on a regular basis. The CO will be responsible for inspection and acceptance of deliverables and services. Monitoring of the contract will be based on periodic reporting by the Contractor.

C.10 SITE VISITS AND INSPECTIONS

At the discretion of the Government and independent of activities conducted by the Contractor, with five (5) business days' notice to the Contractor, the Government reserves the right to conduct site visits and inspections on an as needed basis. DCMA/BARDA reserves the right to conduct unannounced site visit inspections in circumstances where safety concerns are involved.

Contractor shall accommodate periodic or ad hoc site visits by the Government. If the Government, the Contractor, or other parties identify any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

SECTION D – PACKAGING, MARKING AND SHIPPING

Unless otherwise specified by the Contracting Officer, all deliverable items to be furnished to the Government under this contract (including invoices) shall be made by first class mail, overnight carrier, or email as described in Section F.

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E – INSPECTION AND ACCEPTANCE

1. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
2. For the purpose of this SECTION, the Contracting Officer's Representative is the authorized representative of the Contracting Officer.
3. Inspection and acceptance will be performed at:

Department of Health and Human Services (DHHS)
Assistant Secretary for Preparedness and Response (ASPR)
Biomedical Research and Development Authority (BARDA)
O'Neill House Office Building, 2nd Floor
Washington, DC 20515

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt. Inspection and acceptance of drug product may be performed at the Contractor's and/or Subcontractor's location, as approved by the Contracting officer or the Contracting Officer's Representative.

E.1 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://acquisition.gov/far/>

The following FAR clauses, pertinent to Section E, are hereby incorporated by reference:

Table D.1

FAR Clause	Title	Date
52.246-3	Inspection of Supplies – Cost Reimbursement	May 2001
52.246-5	Inspection of Services – Cost Reimbursement	Apr 1984

E.2 All work under this contract may be subject to inspection and final acceptance by the CO or the duly authorized representative of the Government. The Contracting Officer's Representative (COR) is a duly authorized representative of the Government and is responsible for the inspection and acceptance of all items/activities to be delivered and or completed under this contract.

SECTION F – DELIVERABLES/PERFORMANCE

F.1 Federal Acquisition Regulation Clause Incorporated by Reference

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address:

<http://acquisition.gov/far/>

The following FAR clause, pertinent to Section F, is hereby incorporated by reference:

Table F.1

FAR Clause	Title	Date
52.242-15	Stop-Work Order, Alternate I (Apr 1984)	Aug 1989

F.2 PERIOD OF PERFORMANCE

The base period of performance, for CLINs 0001 through 0005 of this contract, is four (4) years, from **May 18, 2020 through May 17, 2024**. Each option period, if CLINS are exercised, may extend the period of performance by one (1) year, to provide the U.S. Government full access to the Contractor’s capacity. Should all options under this contract be exercised (CLINs 0006 through 0023), the period of performance may be ultimately extended to ten (10) years with the contract end being **no later than May 17, 2030**.

F.3 DELIVERABLES

The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with the date(s) specified below:

Table F.2

Item	Description	Delivery Method & Addressee	Delivery Schedule
(1)	Reporting of Financial Conflict of Interest	Electronically to CO & COR	In accordance with 45 CFR Part 94
(2)	Invention Reporting Requirement – Annual Utilization Report	Electronically to CO	Annually on contract anniversary date
(3)	Invention Reporting Requirement – Final invention Statement	Electronically to CO	On or before contract expiration
(4)	Inventory of Government Owned Property	Electronically to CO & COR	Per Article G.7

Successful performance of the final contract shall be deemed to occur upon performance of the work described in Section C of this RFP, and upon delivery and acceptance of the items

described in Sections F.4 through F.6, by the Contracting Officer or their duly authorized representative.

F.4 CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

As applicable under the aforementioned CLINS and BARDA's discretion for frequency of meetings.

F.4.1 Submission of Contract Deliverables:

Documents shall be delivered electronically via email to the Contracting Officer (CO) and the Contracting Officer's Representative (COR), listed in Section G.1 and G.2. When electronic deliverables are not preferred by the Contracting Officer, deliverables and reports furnished to the Government under the potential resultant contract (including invoices) shall be addressed as indicated in Section G.3.

F.4.2 Reporting Requirements and Meetings:

The Contractor shall submit, to the CO and the COR, technical progress reports as identified in the anticipated contract. These reports shall be subject to the technical inspection and requests for clarification by the COR, and approval by the CO. These reports shall be brief, factual, and prepared in accordance with the following:

F.4.3 Monthly Progress Reports:

The Contractor shall submit a Monthly Progress Report on the 15th of each month or earlier, to the COR and CO/CS, summarizing all contractor work performed during the previous month, and an overall status of the project.

These reports shall include, but shall not be limited to: Contract number and title, Contractor's name and address, report author, date of submission, period of time being reported on, breakdown of any/all other direct costs by line item; assessment of technical progress, schedule status, travel conducted; and any Contractor concern or problems encountered and their recommended solutions. This report shall also provide an estimate of work to be completed and billed in the subsequent invoicing period.

F.4.4 Kick-off Meeting:

The Contractor shall accommodate for a meeting with HHS personnel, to kick-off the project. The meeting shall be scheduled within fourteen (14) calendar days after contract award. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval, within five (5) business days of the meeting or as otherwise authorized by the Contracting Officer. Location of the kick-off meeting is TBD.

F.4.5 Monthly Meetings (Retrofit & Development):

The Contractor shall plan and execute a monthly meeting, for each, the retrofit portion and the development portion of the contract (i.e. two meetings per month, at bi-weekly intervals during the retrofit period; once retrofit is complete, one monthly meeting for ongoing development updates). The meetings shall include the onsite Program Manager, Retrofit/Renovation Manager, COR, Contracting Officer/Specialist and any other pertinent personnel, unless otherwise directed by the COR and CO. The Contractor shall submit a meeting agenda, prior to the meeting that shall include, but not be limited to, the following items:

- Contract administration and funding
- Detailed current work status (retrofit and development, as applicable)
- Contractor general issues/concerns

The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval, within three (3) business days of the meeting or as otherwise authorized by the Contracting Officer.

F.4.6 Quarterly Site Visits:

The Contractor shall accommodate for quarterly site visits by the USG. The Contractor shall submit a meeting agenda, at least five (5) business days prior to the meeting, for the USG's input. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within five (5) business days after each site visit, or as otherwise authorized by the Contracting Officer.

F.4.7 Ad hoc Site Visits / BARDA Audits:

The Contractor shall accommodate for periodic site visits by the USG on an ad hoc basis. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within five (5) business days after each site visit, or as otherwise authorized by the Contracting Officer. If the Government, the Contractor, or other party identifies any issues during an audit, the Contractor shall document the finding(s), identify potential solutions, and provide a report to the COR and CO detailing the finding(s) and proposed corrective action(s) within 10 business days of the audit. The COR and CO will review the report and provide a response to the Contractor with 10 business days. Once corrective action is completed, the Contractor will provide a final report to COR and CO.

(b)(4)



(b)(4)

F.5 OTHER REPORTING REQUIREMENTS/DELIVERABLES

F.5.1 Risk Management Plan:

The Contractor shall develop a risk management plan within ninety (90) calendar days of contract award, highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. The plan shall clearly identify the applicability of each potential risk, and how it could directly impact the retrofit and the development portions of the contract. This plan should reference relevant WBS elements where appropriate. Updates to this plan shall be included every three months (quarterly) in the monthly Project Status Report.

F.5.2 Final Retrofit/Renovation Report & Certificate of Occupancy:

The Contractor shall submit a Final Retrofit/Renovation Report, that shall include, but not be limited to, a summary of all retrofit/renovation activities performed during the base period of performance, details of the increased capacity and capabilities resulting from the retrofit, and an accounting of any equipment/materials procured, operations, maintenance security, safety, insurances, and warranties under the Contract. In addition, the Certificate of Occupancy shall be submitted within ten (10) business days after receipt by the Contractor or with the Final Retrofit/Renovation Report, whichever comes first.

F.5.3 Draft Final and Final Progress Report:

These reports are to include a summation of the work performed and results obtained for execution of various studies and/or technical work packages during the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Progress Report shall be due forty-five (45) calendar days prior to the expiration date of the contract and the Final Progress Report shall be due no later than thirty (30) calendar days following the expiration date of the contract.

F.5.4 Reporting Interactions with the FDA:

See section H for requirements on reporting/documenting interactions with the FDA within five (5) business days of meeting with the FDA.

F.5.5 Incident Reporting:

Contractor shall document all critical programmatic concerns, risks, or potential risks, as well as accidents and safety violations, and communicate to the COR and CO within forty-eight (48) hours of the activity or incident (within 24 hours for a security activity/incident). Further updates shall be due to the COR and CO within forty-eight (48) hours, if additional issues arise. The Contractor shall submit a Corrective Action Plan within five (5) business days, if deemed necessary by either party, to address the circumstances. If corrective action is deemed necessary, the Contractor must address its considerations of concerns raised by the Government. All incident communications shall be documented in writing via e-mail. Telephone notifications will be acceptable during severe emergencies, followed by written correspondence.

F.5.6 Standard Operating Procedures:

The Contractor shall make their own internal Standard Operating Procedures (SOPs) and, to the extent possible, their Subcontractors' SOPs available for review by the Government, upon request from the COR or CO. SOPs within five (5) business days and may be provided electronically.

F.5.7 Manufacturing Campaign Reports:

Contractor shall provide Manufacturing Campaign Reports to the COR and CO, for review and comment. The Government reserves the right to request unredacted Manufacturing Campaign Reports for distribution within the USG. The Contractor shall submit said reports at least fifteen (15) business days prior to any FDA submission. If corrective action is recommended, the Contractor must address in writing, all concerns raised by the COR and CO. The Contractor shall take the Government's concerns and recommendations into consideration, when revising Manufacturing Campaign Reports, prior to FDA submission. Final FDA submissions shall be provided to the COR and CO concurrently, or no later than five (5) business day after submission to the FDA.

F.5.8 Quality Assurance (QA) Audit Reports for Subcontractor Audits / Site Visits:

The Government reserves the right to participate in QA audits. The Contractor shall notify the COR and CO, 10 days in advance of an upcoming, ongoing or recent audit/site visit of Subcontractor(s), as part of ongoing communications. Upon completion of the audit/site visit, the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the Subcontractor. If action is requested of a Subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the COR and CO. The Contractor shall provide responses from the Subcontractor, to address concerns and plans for corrective action execution. The report shall be provided to the COR and CO within 5 business days of report completion. If corrective action is recommended, the Contractor must address, in writing, concerns raised by the COR and CO.

F.5.9 Raw Data or Data Analysis / Product Transition Report:

Upon request by the Government, the Contractor shall provide raw data or data analysis. The Contractor shall provide a Product Transition Strategy to support transition of the product(s), ninety 90 days prior to the end of the (base/option) POP.

F.5.10 Draft and Final Validation Protocols:

The Contractor shall provide all Draft and Final Validation Protocols for API manufacturing to the Government for evaluation. The CO and COR reserve the right to request unredacted Validation Protocols, within the period of performance, for distribution within the USG. The Contractor shall submit all proposed Validation protocols to the COR and CO at least ten (10) business days prior to the validation start date. If corrective action is required before study execution, the Contractor shall address in writing, to the satisfaction of the Government, all concerns raised by BARDA, and provide the COR and CO a revised Validation Protocol that addresses the Government's comments and requested changes. The Contractor shall not proceed with any Validation protocol until the Contractor has provided BARDA with a final Validation Protocol and the CO provides approval. Once the validation protocols have been executed, the final validation reports will be made available to the USG and provided with 60 days of execution completion.

F.5.11 Supply Chain Resiliency Plan:

The partner contractor shall have a comprehensive Supply Chain Resiliency Program that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, medical device components and work-in-process through to finished goods. A critical component is any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

Identification of key equipment suppliers and their locations, local resources and the associated planning and control processes at the time of award is important to the security of the medical countermeasure supply chain. These processes shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product. Where multi-site manufacturing is integral to the delivery of contractual materials, it should be included as part of the planning and scheduling process.

Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.

As part of the contractor’s Supply Chain Resiliency Program, the partner, Contract Manufacturing Organization CMO/Contract Development Manufacturing Organization (CDMO), or Third Part Logistics (3PL) shall include a production plan that demonstrates how they will adhere to deliveries at the time of the contract award for review and approval by BARDA.

The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries. For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities. The contractor for medical devices shall address consumable supplies, the sourcing thereof and the ability to identify constraining manufacturing activities and the planned timing of resolution.

The partner contractor shall communicate the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries. For critical items these processes should provide visibility for key items over an adequate planning horizon that ensures effective control of the established supply chain for contractual deliveries. Production rates and lead times shall be understood and communicated to the HHS/ASPR/BARDA Contracting Officer or the Contracting Officer’s Representative as necessary.

Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items may be summarized with the following template:

Critical Material Name	Vendor	Supplier, Manufacturing / Distribution Location	Supplier Lead Time	Shelf Life	Transportation / Shipping restrictions
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F.5.12 Miscellaneous Technical Documents:

Upon request by the Contracting Officer, the Contractor and their subcontractors shall provide the USG with deliverables from contract funded activities, including but not limited to the following when requested by BARDA within five (5) business days from the request:

- Process Development Reports;
- Assay Qualification Plan/Report;

- Assay Validation Plan/Report;
- Assay Technology Transfer Report;
- Batch Records;
- SOPs or test method procedures;
- Master Production Records;
- Release testing laboratory records,
- Certificate of Analysis;
- Environmental monitoring tests records and results
- Utility testing and maintenance records
- Clinical and/or Nonclinical Studies Data/Reports;
- Animal Model or Other Technology Transfer Package;
- Regulatory documentation as required by HHS.
- Purchasing agreements and invoices

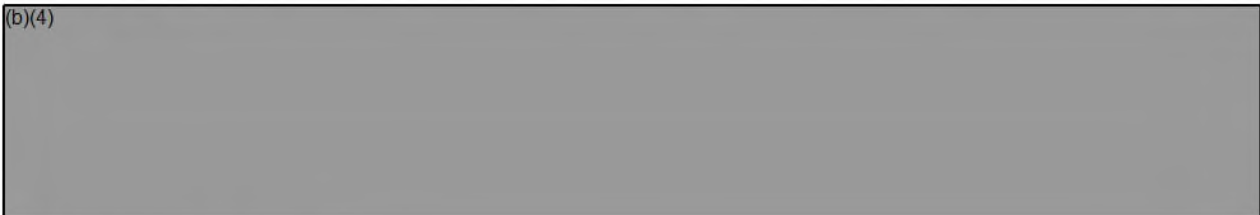
The CO and COR reserve the right to request unredacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

F.5.13 Publications and Presentations:

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission. Reports shall be due within thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts. The Contractor must address in writing all concerns raised by the COR and CO in writing. Final publications shall be submitted to the COR and CO concurrently or no later than one (1) calendar day of its submission.

F.5.14 Press Releases:

The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the Contracting Officer and Contracting Officer's Representative have received and approved an advanced copy of any press release no less than five (5) business days prior to the issuance of any potential press release.



F. 6 DELIVERY SCHEDULE:

Table F.3

No.	Deliverable	Format	Delivery Date
1	Kick-off Meeting	N/A	Within 14 calendar days after award.
2	Risk Management Plan	Electronic copy	Within 90 calendar days after award.
3	Monthly Reports	Electronic copy	15 th day of each month
4	Monthly Meetings	Teleconference	Within 5 days of Monthly Report submission.
5	Quarterly Site Visits	Site visit	To be scheduled in coordination with the USG.
6	Ad hoc Site Visits	Site visit	To be scheduled in coordination with the USG.
7	Final Contractor Defined Work Plan	Electronic copy	3 months after contract award
8	Final Manufacturing Facility Plan	Electronic copy	6 months after contract initiation
9	Final Facility Operation Feasibility Plan	Electronic copy	9 months after contract initiation
10	Security Plan	Electronic copy	9 months after contract initiation
11	Final Retrofit/Renovation Report	1 hard copy and electronic copy	<u>Draft</u> : 60 calendar days prior to end of Option Period 1. <u>Final</u> : 10 calendar days prior to end of Option Period 1.
12	Certificate/Permit(s) of Occupancy	1 hard copy and electronic copy	Within 10 business days after receipt by the Contractor.
13	Draft Final and Final Progress Report	1 hard copy and electronic copy	<u>Draft</u> : 45 calendar days prior to contract expiration; <u>Final</u> : within 30 calendar days of contract expiration.
15	Manufacturing Campaign Reports for items covered in contract CLINS	Electronic copy	<u>Draft</u> : 15 days prior to FDA submission. <u>Final</u> : concurrently or 1 business day after submission.
16	Raw Data / Data Analysis / Product Transition Report	Electronic copy	90 days prior to contract expiration.

18	Draft and Final Report on Evaluation of Fill Finish Alternatives	Electronic copy	<u>Draft</u> : 30 days after completion of analysis <u>Final</u> : 30 days after receiving BARDA comments.
19	Supply Chain Resiliency Plan	Electronic copy	9 months after contract initiation.
20	Commissioning and Validation Plan	Electronic copy	<u>Draft</u> : within 15 months of contract award. <u>Final</u> : at least 60 days prior to facility turnover.
21	Pandemic Readiness Operational Report	Electronic copy	<u>Minimum annually, maximum quarterly</u> , during 'Sustainment' option periods, starting with Option Pd. 1.
22	Sustainability Costs Report	Electronic copy	<u>Annually</u> during 'Sustainment' option periods, starting with Option Pd. 1.
23	Final Technical Proposal Revision	Electronic copy	<u>Within 30 days of contract award- to include all negotiated changes and responses to USG questions</u>
24	Final Business Proposal Revision	Electronic copy	<u>Within 30 days of contract award- to include all negotiated changes and responses to USG questions</u>

SECTION G – CONTRACT ADMINISTRATION DATA

G.1 CONTRACTING OFFICER

The Contracting Officer (CO) is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this Contract.

The CO is the only individual with authority to act as agent of the Government under this Contract, with authority to (1) direct or negotiate any changes in the statement of work, (2) modify or extend the period of performance, (3) authorize reimbursement to the Contractor for any costs incurred during the performance of this Contract and/or (5) otherwise change any terms and conditions of this Contract.

No information, other than that which may be contained in an authorized modification to this contract duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

James Harris
Chief Contracting Officer, DCMA, BARDA
(202) 805-3479
james.harris2@hhs.gov

G.2 CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) and alternate COR will represent the Government for the purpose of this contract:

Primary COR:

Arlene Joyner
Branch Chief, PCI Division, BARDA
(202) 205-8691
arlene.joyner@hhs.gov

Alternate COR:

Tim Belski
Branch Chief, PCI Division, BARDA
(202) 205-4235
Timothy.Belski@hhs.gov

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing

technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The alternate COR is responsible for carrying out the duties of the COR only in the event that the COR delegates his/her authority, or can no longer perform his/her duties as assigned.

The Government may unilaterally change the COR designation.

G.3 KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days' notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individual(s) is/are considered to be essential to the work being performed hereunder:

(b)(6)



G.4 INVOICE SUBMISSION

Invoices for payment shall be submitted to the Contracting Officer and Contracting Officer's Representative, as one (1) hard copy and one (1) electronic copy addressed in the format indicated below, shall follow the detailed invoicing instructions listed in Section J, and include an SF-1034.

The electronic version of the invoice can be submitted via e-mail or uploaded through HHS' eRoom (shared access may be provided to the Contractor after award).

The Government may request additional information (timecards, receipts, etc.) to support costs claimed in the Contractor's invoices. Incomplete invoices may be suspended by the Contracting Officer if the Contractor's claimed costs cannot be substantiated.

G.5 DELIVERIES

All deliveries of physical documents shall be addressed in the following format:

Table G.2

UPS/FedEx/USPS
U.S. Department of Health & Human Services <i>Insert Recipient's Name</i> HHS/ASPR/BARDA <i>Insert Office Number</i> – O'Neill House Office Building, 2 nd Floor Washington, DC 20515 <i>Insert Recipient's Telephone Number</i>

G.6 PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

- a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
- b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.
- c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

G.7 INDIRECT COST RATES

- a. The following provisional rates are established and incorporated into the contract for interim reimbursement of indirect costs (include specific CLINS or Base period if needed) pending the establishment of final indirect cost rates in accordance with FAR 52.216-7. The provisional rates may be revised during contract performance by mutual agreement of the contracting officer and the contractor at either party's request, to prevent substantial overpayment or underpayment. Use of the provisional rates does not change any cost ceilings or specific obligations in the contract.

(b)(4)

- b. The above indirect cost rates are also established as ceiling rates in the contract. The Government will not be obligated to pay any additional amounts should the final indirect cost rates exceed the ceiling rates, and in the event the final indirect cost rates are less

than the above established ceiling rates, the negotiated final rates will be reduced to conform to the lower rates.

- c. In accordance with FAR Part 52.216-7(d), the contractor shall submit an adequate final indirect cost rates proposal to the contracting officer within the 6-months period following the end of its fiscal years during the period of contract performance.

G.8 GOVERNMENT PROPERTY

- a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated into this contract by reference. This document can be accessed at:
http://oamp.od.nih.gov/sites/default/files/appendix_q_hhs_contracting_guide.pdf.
Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.
Requests for information regarding property under this contract should be directed to the following office:

Amos Moore
Property Rep.
O'Neil Federal Office Building
BETHESDA MD 20892-7670
Amos.Moore@hhs.gov

- b. Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated in this contract in paragraph a. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

G.9 POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared in accordance with FAR Subpart 42.15.

Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted fourteen days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address: <http://www.cpars.gov>.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1 ACKNOWLEDGMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

H.2 RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

H.3 GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

H.4 INFORMATION SECURITY

- a. Baseline Security Requirements
 1. **Contract Documentation** – The Contractor shall use provided templates, policies, forms and other agency documents provided by the Contracting Officer and the Contracting Officer's Representative to comply with contract deliverables as appropriate.
 2. **Contractor Non-Disclosure Agreement (NDA)** – Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete an appropriate non-disclosure agreement as applicable. A copy of each signed and witnessed NDA shall be submitted to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

H.5 INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the program director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: <https://ecfr.io/Title-45/pt45.1.94>

As required by 45 CFR Part 94, the Institution shall, at a minimum:

- a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Included are payments and equity interests;
 2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
 3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
 2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any BARDA-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.
 - c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the BARDA-funded research.

- d. Require that each Investigator who is planning to participate in the BARDA-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for BARDA-funded research. Require that each Investigator who is participating in the BARDA-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.
- e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to BARDA-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to BARDA-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the BARDA-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research.
- f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).
- g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).
- h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
- i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the BARDA-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the

situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the BARDA-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

H.6 FDA AUDITS

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- (1) Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.
- (2) Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA or third party.
- (3) Within 10 business days of audit report, Contractor shall provide CO and COR with a plan for addressing areas of nonconformance, if any are identified.
- (4) The final responses to the FDA findings shall be submitted on time to meet the FDA deadline. A copy will be provided to the CO and COR within 3 days of submitting to the FDA.

H.7 PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Biomedical Advanced Research and Development Authority (BARDA), Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (DHHS), under Contract No. 75A50120D00007"

H.8 REPORTING MATTERS OF FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in HHS funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The website to file a complaint on-line is: <http://oig.hhs.gov/fraud/hotline/> and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

H.9 INTERACTIONS WITH REGULATORY AGENCIES

The obligations set forth in this paragraph shall apply to the Contractor and any subcontract at any tier thereunder.

(a) The Contractor shall prepare and submit initial draft minutes and final accepted minutes of all formal meetings with U.S. regulatory agencies, to include FDA, to BARDA.

(b) The Contractor shall prepare and submit initial draft minutes and the final accepted minutes of all informal meetings with U.S. regulatory agencies, to include FDA, to BARDA. Informal meetings are defined as scheduled teleconferences with such U.S. regulatory agencies. Updates from such informal meetings will be shared during monthly or quarterly meetings.

(c) The Contractor shall forward the dates and times of all scheduled meetings with U.S. regulatory agencies, to include FDA, to BARDA and make arrangements for appropriate BARDA staff to attend such U.S. regulatory agencies meetings.

(d) The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to U.S. regulatory agencies The Contractor shall provide BARDA with five (5) business days, or such shorter period as may be practicable in time-sensitive

situations, to review and provide comments to the contractor prior to its submittal to U.S. regulatory agencies.

(e) The Contractor shall furnish all findings of U.S. regulatory agencies inspections, including FDA form 482 and 483 inspection notice and observations and Establishment Inspection Reports (EIR) pertinent to the Contract, to BARDA within five (5) business days of receipt.

(f) The Contractor shall notify the USG of all site visits/audits by U.S. regulatory agencies to include FDA, within 24 hours of agency personnel's arrival.

(g) The Contractor shall include the USG in all scheduled meetings and teleconferences with U.S. regulatory agencies.

(h) Contractor is not obligated to notify the USG of non-HHS funded project related meetings.

H.10. SECURITY

The work to be performed under this Contract will involve access to sensitive Biomedical Advanced Research and Development Authority [BARDA] program information. Upon contract award, the Program Protection Officer (PPO) will review the Draft Security Plan (submitted as part of the Contractor's Technical Proposal) in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and if changes are required, submit a Final Security Plan to the U.S. Government within thirty (30) calendar days after receipt of the Program Protection Officer's (PPO) comments. The Final Security Plan shall include a timeline for compliance of all the required security measures. Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

The execution of the work under this Contract shall be in accordance with the approved Final Security Plan. As outlined above, the content of the Final Security Plan shall be a continuation of the Draft Security Plan submitted as part of the Contractor's Technical Proposal. The Security Plan should address facilities providing drug shortage capabilities. Therefore, at a minimum, the Final Security Plan shall address the following items:

Personnel Security Policies and Procedures including, but not limited to: Recruitment of new employees; Interview process; Personnel background checks; Suitability/adjudication policy; Access determination; Rules of behavior/conduct; Termination procedures; Non-disclosure agreements.

Physical Security Policies and Procedures including but not limited to: Internal/external access control; Identification/badge requirements; Facility visitor access; Parking areas and access; Barriers/perimeter fencing; Shipping, receiving and transport (on and off-site); Security lighting; Restricted areas; Signage; Intrusion detection systems; Closed circuit television; Other control measures. Information Security Policies and Procedures including but not limited to: Identification of sensitive information; Access control/determination; Secured storage infrastructure; Document control; Retention/destruction requirements.

Information Technology Security Policies and Procedures including but not limited to: Intrusion detection and prevention systems; Encryption systems; Identification of sensitive information/media; Passwords; Removable media; Laptop policy; Media access control/determination; Secure storage; System document control; System backup; System disaster recovery.

The following instruction/intent shall be incorporated:

Security Reporting Requirement - Violations of established security protocols shall be reported to the Contracting Officer (CO) and Contracting Officer's Representative (COR) upon discovery. The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations.

Contracting Officer will determine if the severity of the violation requires further U.S. Government (USG) intervention.

H.11. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant. This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

H.12. Special Clause - Intellectual Property

Execution of this contract will require that the prime contractor (Phlow) providing services to HHS possess sufficient rights to specific Intellectual Property (IP) required for the development effort and the services described in this contract. Phlow will be responsible for negotiating any IP rights between Phlow and its subcontractors or teaming partners and assuring that those IP rights are consistent with HHS's IP rights in the Federal Acquisition Regulations (FAR) clauses contained in the prime contract and enable Phlow to perform all services described in the contract. The contract must reflect the Parties' (HHS and Phlow) rights to all IP developed and/or IP used in performance of this contract. Prior to execution of this contract, and or anytime throughout its period of performance, Phlow shall provide the Contracting Officer with a written description of all IP necessary to develop generic drugs and provide all services in the contract. The Description must identify the basis for offering HHS less than unlimited rights to any pre-existing IP identified in the Description that will be utilized in performance of this contract. The Description shall also include written verification that Phlow will provide HHS with rights to any and all IP utilized or developed during performance of this contract as specified under FAR Clause 52.227-11, FAR Clause 52.227-11 as amended in any applicable subcontract and/or teaming agreement related to performance of this contract, FAR Clause 52.227-14 (Alt. II Dec. 2007) and FAR Clause 52.227-14 (Alt. II Dec. 2007) as amended in any applicable subcontract and/or teaming agreement (the "FAR Clauses"). Phlow and Phlow's subcontractors and /or Phlow's teaming partners will remain free to negotiate any agreement of their own regarding their use of any of the IP utilized or developed during performance of this contract, so long as the negotiated agreement complies with the requirements under the FAR Clauses, and the terms contained in the agreement do not otherwise adversely affect the performance of work under this contract. The agreement if applicable shall be furnished to the Contracting Officer within five (5) business days after the agreement is finalized. This contract and any subsequent modifications will specifically incorporate the FAR Clauses and also FAR Clause 52.227-1 Authorization and Consent (DEC 2007) and FAR Clause 52.227-3 Patent Indemnity (APR 1984).

H.13 PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES (JUL 1999)

The contractor is hereby notified of the restrictions on the use of HHS funding for lobbying of Federal, State and Local legislative bodies. Section 1352 of Title 10, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions: the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 – Limitations on the Payment of Funds to Influence Federal Transactions and FAR Clause 52.203-12 (Sep 2007). In addition, the current HHS Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes; for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress; or any State or Local legislative body itself. The current HHS Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

H.14. DISSEMINATION OF INFORMATION

No information related to data obtained under this Contract shall be released or publicized without the prior written consent of the Contracting Officer, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.15. ACCESS AND DISPOSITION OF DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all Contractor efforts; Subcontractor efforts; communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, and all Contractor commitments and responses. Contractor shall provide the government with an electronic copy of all correspondence with the FDA related to this contract and discussed during any routine or adhoc call within five (5) business days of receipt. The Government shall have unlimited rights to all animal and human data funded under

this Contract. The Contractor shall keep copies of all data required by the FDA relevant to this Contract for the time specified by the FDA.

H.16. INCORPORATION OF TECHNICAL PROPOSAL

The Contractor's Technical Proposal included in its Proposal dated **March 18, 2020** or as revised by the Final Proposal Revision dated no later than 30 days from date of award, submitted in response to **BAA-18-100-SOL-00003** is hereby incorporated into the Contract by reference. The Contractor shall perform the work substantially as set forth in the technical proposal. Any revisions to the technical proposal that would significantly alter the technical approach must be approved in writing by the Contracting Officer. Within 30 days after contract award, the Contractor is required to deliver to the Contracting Officer a consolidated copy of their full technical proposal. In the event of a conflict between Section C, SOO, and the Contractor's technical proposal, Section C will take precedence.

H.17. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

H.18. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice (cGMP) regulations (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packaging of this product. If at any time during the life of the Contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, and purity of the product (a material failure) as identified by the FDA, then the Contractor shall have thirty (30) calendar days from the time such material failure is identified to institute a comprehensive plan and obtain approval by the Contracting Officer to cure such material failure.

H.19. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to Executive Order 13224 and Public Law 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Contract.

H.20. CONTRACTOR PUBLICITY

Phlow, or any entity or representative acting on behalf of Phlow, may not refer to this contract or the services furnished pursuant to the provisions of this contract in any news release or commercial advertising, or in connection with any news release or commercial advertising, without first obtaining explicit written consent to do so from the Contracting Officer or the HHS Press Office.

At the time of signature on this contract, Phlow shall provide the name and contact information for a point of contact for a representative from its Press Office.

Should any reference to this contract be included in any news release or commercial advertising issued by or on behalf of Phlow without the required written consent, the Government will consider the institution of all remedies available under applicable law.

SECTION I – CONTRACT CLAUSES

I.1 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address:

<http://acquisition.gov/far/>

The following FAR clauses, pertinent to Section I, are hereby incorporated by reference:

Table I.1

FAR Clause	Title	Date
52.202-1	Definitions	Nov 2013
52.203-3	Gratuities	Apr 1984
52.203-5	Covenant Against Contingent Fees	May 2014
52.203-6	Restrictions on Subcontractor Sales to the Government	Sep 2006
52.203-7	Anti-Kickback Procedures	May 2014
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	May 2014
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	May 2014
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	Oct 2010
52.203-13	Contractor Code of Business Ethics and Conduct	Oct 2015
52.203-14	Display of Hotline Poster(s)	Oct 2015
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights	Apr 2014
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	Jan 2017
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	May 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	Oct 2018
52.204-13	System for Award Management Maintenance	Oct 2018

52.204-18	Commercial and Government Entity Code Maintenance	Jul 2016
52.204-19	Incorporation by Reference of Representations and Certifications	Dec 2014
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities	Jul 2018
52.209-6	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	Oct 2015
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	Oct 2018
52.209-10	Prohibition on Contracting with Inverted Domestic Corporations	Nov 2015
52.210-1	Market Research	Apr 2011
52.215-2	Audit and Records – Negotiation	Oct 2010
52.215-8	Order of Precedence - Uniform Contract Format	Oct 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	Aug 2011
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.	Aug 2011
52.215-12	Subcontractor Certified Cost or Pricing Data	Oct 2010
52.215-13	Subcontractor Certified Cost or Pricing Data—Modifications	Oct 2010
52.215-15	Pension Adjustments and Asset Reversions	Oct 2010
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions	Jul 2005
52.215-19	Notification of Ownership Changes	Oct 1997
52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications	Oct 2010
52.215-23	Limitations on Pass-Through Charges	Oct 2009
52.216-7	Allowable Cost and Payment	Aug 2018
52.216-7	Allowable Cost and Payment, Alternate I (Feb 1997)	Aug 2018
52.216-8	Fixed Fee	Jun 2011
52.219-8	Utilization of Small Business Concerns	Oct 2018
52.219-9	Small Business Subcontracting Plan	Aug 2018
52.219-16	Liquidated Damages -- Subcontracting Plan	Jan 1999
52.219-28	Post-Award Small Business Program Representation	July 2013
52.222-1	Notice to the Government of Labor Disputes	Feb 1997
52.222-2	Payment for Overtime Premiums [<i>*\$0.00</i>]	July 1990
52.222-3	Convict Labor	Jun2003
52.222-4	Contract Work Hours and Safety Standards -- Overtime Compensation	May 2018
52.222-6	Construction Wage Rate Requirements	Aug 2018
52.222-7	Withholding of Funds	May 2014
52.222-8	Payrolls and Basic Records	Aug 2018
52.222-9	Apprentices and Trainees	Jul 2005
52.222-10	Compliance with Copeland Act Requirements	Feb 1988
52.222-11	Subcontracts (Labor Standards)	May 2014
52.222-12	Contract Termination-Debarment	May 2014
52.222-13	Compliance with Construction Wage Rate Requirements and Related Regulations	May 2014
52.222-14	Disputes Concerning Labor Standards	Feb 1988

52.222-15	Certification of Eligibility	May 2014
52.222-16	Approval of Wage Rates	May 2014
52.222-21	Prohibition of Segregated Facilities	Apr 2015
52.222-26	Equal Opportunity	Sept 2016
52.222-29	Notification of Visa Denial.	Apr 2015
52.222-37	Employment Reports on Veterans	Feb 2016
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	Dec 2010
52.222-50	Combating Trafficking in Persons	Jan 2019
52.222-54	Employment Eligibility Verification	Oct 2015
52.222-55	Minimum Wages Under Executive Order 13658	Dec 2015
52.222-62	Paid Sick Leave Under Executive order 13706	Jan 2017
52.223-6	Drug-Free Workplace	May 2001
52.223-12	Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners	Jun 2016
52.223-18	Encouraging Contractor Policy to Ban Text Messaging While Driving	Aug 2011
52.224-1	Privacy Act Notification	April 1984
52.224-2	Privacy Act	April 1984
52.224-3	Privacy Training	Jan 2017
52.225-1	Buy American – Supplies	May 2014
52.225-13	Restrictions on Certain Foreign Purchases	Jun 2008
52.227-11	Patent Rights-Ownership by the Contractor	May 2014
52.227-14	Rights in Data – General	May 2014
52.227-14	Rights in Data – General, Alternate II (Dec 2007)	May 2014
52.228-7	Insurance – Liability to Third Persons	Mar 1996
52.228-15	Performance and Payment Bonds -- Construction	Oct 2010
52.230-2	Cost Accounting Standards	Oct 2015
52.230-6	Administration of Cost Accounting Standards	June 2010
52.232-9	Limitation on Withholding of Payments	Apr 1984
52.232-17	Interest	May 2014
52.232-20	Limitation of Cost	Apr 1984
52.232-23	Assignment of Claims	May 2014
52.232-25	Prompt Payment	Jan 2017
52.232-27	Prompt Payment for Construction Contracts	Jan 2017
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	Oct 2018
52.232-39	Unenforceability of Unauthorized Obligations	Jun 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	Dec 2013
52.233-1	Disputes	May 2014
52.233-3	Protest After Award, Alternate I (Jun 1985)	Aug 1996
52.233-4	Applicable Law for Breach of Contract Claim	Oct 2004
52.236-5	Material and Workmanship	Apr 1984
52.236-7	Permits and Responsibilities	Nov 1991
52.236-18	Work Oversight in Cost-Reimbursement Construction Contracts	Apr 1984
52.236-19	Organization and Direction of the Word	Apr 1984

52.242-1	Notice of Intent to Disallow Costs	Apr 1984
52.242-2	Production of Progress Reports	Apr 1991
52.242-3	Penalties for Unallowable Costs	May 2014
52.242-4	Certification of Final Indirect Costs	Jan 1997
52.242-5	Payments to Small Business Subcontractors	Jan 2017
52.242-13	Bankruptcy	Jul 1995
52.243-2	Changes—Cost-Reimbursement, Alternate II (Apr 1984)	Aug 1987
52.243-2	Changes—Cost-Reimbursement, Alternate III (Apr 1984)	Aug 1987
52.243-2	Changes—Cost-Reimbursement, Alternate V (Apr 1984)	Aug 1987
52.243-6	Change Order Accounting	Apr 1984
52.243-7	Notification of Changes	Jan 2017
52.244-2	Subcontracts, Alternate I (Jun 2007)	Oct 2010
52.244-5	Competition in Subcontracting	Dec 1996
52.244-6	Subcontracts for Commercial Items	Jan 2019
52.245-1	Government Property	Jan 2017
52.245-9	Use and Charges	Apr 2012
52.246-3	Cost-Reimbursement Supply Contract	May 2001
52.246-25	Limitation of Liability—Services	Feb 1997
52.248-3	Value Engineering—Construction	Oct 2015
52.249-6	Termination (Cost-Reimbursement)	May 2004
52.249-6	Termination (Cost-Reimbursement), Alternate I (Sep 1996)	May 2004
52.249-14	Excusable Delays	Apr 1984
52.253-1	Computer Generated Forms	Jan 1991

I.2 DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) CLAUSES

Full text of HHSAR clauses may be accessed electronically at this address:
<http://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar>

Table I.2

HHSAR Clause	Title	Date
352.203-70	Anti-Lobbying	Dec 2015
352.208-70	Printing and Duplication	Dec 2015
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations	Dec 2015
352.223-70	Safety and Health	Dec 2015
352.227-70	Publications and Publicity	Dec 2015
352.231-70	Salary Rate Limitation	Dec 2015
352.233-71	Litigation and Claims	Dec 2015
352.237-75	Key Personnel	Dec 2015

I.3 ADDITIONAL CONTRACT CLAUSES

I.3.1 Additional Federal Acquisition Regulation (FAR) Clauses in Full Text

52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days.

(End of Clause)

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within thirty (30) calendar days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least thirty (30) days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 10 years.

(End of clause)

52.222-35 Equal Opportunity Veterans (Oct 2015)

a) Definitions. As used in this clause—

“Active duty wartime or campaign badge veteran,” “Armed Forces service medal veteran,” “disabled veteran,” “protected veteran,” “qualified disabled veteran,” and “recently separated veteran” have the meanings given at FAR 22.1301.

b) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-300.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified protected veterans, and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans.

c) Subcontracts. The Contractor shall insert the terms of this clause in subcontracts of \$150,000 or more unless exempted by rules, regulations, or orders of the Secretary of Labor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs, to enforce the

terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate of identify properly the parties and their undertakings.

(End of Clause)

52.222-36 Equal Opportunity for Workers with Disabilities (Jul 2014)

- a) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60.741.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities.

- b) Subcontracts. The Contractor shall include the terms of this clause in every subcontract or purchase order in excess of \$15,000 unless exempted by rules, regulations, or orders of the Secretary, so that such provisions will be binding upon each subcontractor or vendor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs of the U.S. Department of Labor, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

(End of Clause)

SECTION J – LIST OF ATTACHMENTS

Attachment A: Standard Form 1034 – Public Voucher for Purchases and Services Other Than Personal

Attachment B: Invoicing Instructions for Cost Reimbursement Contracts

Attachment C: BARDA Security Requirements

Attachment D: 7 Principles of Earned Value Management Tier 2 System Implementation Intent Guide