DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2020-01530-FOIA-OS

June 28, 2022

Sent via email:

Mr. Aaron Siri
Siri & Glimstad LLP
New YorkNY11786
Foia@sirillp.comm

Dear Mr. Siri:

This letter is the final response to your July 17, 2020, Freedom of Information Act (FOIA) request. Specifically, you requested the following records: "A copy of all written agreements with AstraZeneca relating to COVID-19, including the agreements discussed in this press release:
https://www.hhs.gov/about/news/2020/05/21/trump-administration-accelerates-astrazeneca-covid-19-vaccine-to-be-available-beginning-in-october.html."

The Office of the Assistant Secretary of Preparedness and Response (ASPR) conducted a search and located 18 pages of responsive records. After a careful review of these pages, I am releasing 2 pages to you in their entirety, and I am further withholding 16 pages in part, with portions redacted, pursuant to Exemptions 4 and 6 of the FOIA (5 U.S.C. §552).

FOIA exemption (b)(4) permits the withholding of trade secrets and commercial or financial information that is privileged or confidential.

FOIA exemption (b)(6) permits a Federal agency to withhold information and records about individuals in "personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." The definition of "similar files" has historically been broadly interpreted to include a wide variety of files, and the United States Supreme Court has held that Congress intended the term "similar files" to be interpreted broadly, rather than narrowly. I have analyzed these records and find they meet the threshold requirement of this exemption. Additionally, I have reviewed and weighed the public interest in disclosure of this information against the privacy interest in nondisclosure, and found that the privacy interest outweighs the public's interest in disclosure.

If you believe the information withheld should not be exempt from disclosure, or this response constitutes an adverse determination, you may appeal. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Please mark the correspondence, "Freedom of Information Act Appeal." Your appeal must be transmitted within 90 days from the date of receipt of this letter to:

Ms. Carol Maloney
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services

Office of the Assistant Secretary for Public Affairs
HHS.ACFO@hhs.gov

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, you may contact the HHS FOIA Public Liaison for assistance at:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)
Telephone: (202) 690-7453
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

There are no charges in this instance because the billable costs are less than our threshold of $25.

Sincerely yours,

Garfield Daley

For Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division

Enclosure(s)

ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PAGES 18

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER: 05/24/2020	2. CONTRACT NO. (If any): HHSO100201200004I
3. ORDER NO.: 75A50120F33007	4. REQUISITION/REFERENCE NO.: OS258575

5. ISSUING OFFICE (Address correspondence to):
ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

6. SHIP TO:
a. NAME OF CONSIGNEE: HHS/OS/ASPR
b. STREET ADDRESS: 200 C St SW
WASHINGTON DC 20201
c. CITY: WASHINGTON
d. STATE: DC
e. ZIP CODE: 20201

7. TO:
a. NAME OF CONTRACTOR: EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC
b. COMPANY NAME:
c. STREET ADDRESS: EMERGENT MANUFACTURING OPERATIONS B
5901 E LOMBARD ST
d. CITY: BALTIMORE
e. STATE: MD
f. ZIP CODE: 212246824

f. SHIP VIA:

8. TYPE OF ORDER
☐ a. PURCHASE
REFERENCE YOUR:
Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.
☒ b. DELIVERY
Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA: 2020.199C001.25103	10. REQUISITIONING OFFICE: BARDA

11. BUSINESS CLASSIFICATION (Check appropriate box(es))
☐ a. SMALL ☒ b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED ☐ e. HUBZone
☐ f. SERVICE-DISABLED VETERAN-OWNED ☐ g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM ☐ h. EDWOSB

12. F.O.B. POINT:

13. PLACE OF		14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)	16. DISCOUNT TERMS
a. INSPECTION	b. ACCEPTANCE			
Destination	Destination		Multiple	

17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Tax ID Number: (b) (4) DUNS Number: 968316831 Task Order Title: "Emergent CIADM Manufacturing Capacity Reservation and Expansion" Continued ...					

SEE BILLING INSTRUCTIONS ON REVERSE

18. SHIPPING POINT	19. GROSS SHIPPING WEIGHT	20. INVOICE NO.	17(h) TOTAL (Cont. pages):

21. MAIL INVOICE TO:
a. NAME: PSC/FMS
b. STREET ADDRESS (or P.O. Box): PSC_invoices@psc.hhs.gov
c. CITY | d. STATE | e. ZIP CODE

$628,250,000.00

17(i) GRAND TOTAL: $628,250,000.00

22. UNITED STATES OF AMERICA BY (Signature): (b) (6)

23. (b) (6)

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION NOT USABLE

OPTIONAL FORM 347 (Rev. 2/2012)
Prescribed by GSA/FAR 48 CFR 53.213(f)

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER	CONTRACT NO.	ORDER NO.
05/24/2020	HHSO100201200004I	75A50120F33007

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	See attached. Appr. Yr.: 2020 CAN: 199C001 Object Class: 25103 Period of Performance: 05/13/2020 to 12/31/2021					
1	ASPR-20-02178 -- Emergent CIADM Manufacturing Capacity Reservation and Expansion (1 of 3) Delivery: 12/31/2021				(b) (4)	
2	ASPR-20-02178 -- Emergent CIADM Manufacturing Capacity Reservation and Expansion (2 of 3) Delivery: 12/31/2021				(b) (4)	
3	ASPR-20-02178 -- Emergent CIADM Manufacturing Capacity Reservation and Expansion (3 of 3) Delivery: 12/31/2021				(b) (4)	
	The total amount of award: $628,250,000.00. The obligation for this award is shown in box 17(i). Contractor to sign below:					

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H)) $628,250,000.00

B. COST / PRICE SCHEDULE

B.1 Prices

B.1.1 The total fixed price of this task order (sum of Task 1 and Task 2) is $628,250,000.

B.1.2 The total fixed price of Task 1: Capacity Reservation is $542,750,000.

B.1.3 The total fixed price of Task 2: Pharmaceutical Manufacturing Capacity Expansion is $85,500,000.

B.2 Task 1 Payment Schedule

Following delivery and acceptance of the work described in **SECTION C.3.1 Task 1: Capacity Reservation** and the deliverables described in **SECTION F**, and on submission of a proper invoice, the Government will pay the Contractor as follows:

Item Description	Reporting Period	Due Date	Unit Price
Monthly Report #1	05/13/2020 – 05/31/2020	06/15/2020	$27,137,500
Monthly Report #2	06/01/2020 – 06/30/2020	07/15/2020	$27,137,500
Monthly Report #3	07/01/2020 – 07/31/2020	08/15/2020	$27,137,500
Monthly Report #4	08/01/2020 – 08/31/2020	09/15/2020	$27,137,500
Monthly Report #5	09/01/2020 – 09/30/2020	10/15/2020	$27,137,500
Monthly Report #6	10/01/2020 – 10/31/2020	11/15/2020	$27,137,500
Monthly Report #7	11/01/2020 – 11/30/2020	12/15/2020	$27,137,500
Monthly Report #8	12/01/2020 – 12/31/2020	01/15/2021	$27,137,500
Monthly Report #9	01/01/2021 – 01/31/2021	02/15/2021	$27,137,500
Monthly Report #10	02/01/2021 – 02/28/2021	03/15/2021	$27,137,500
Monthly Report #11	03/01/2021 – 03/31/2021	04/15/2021	$27,137,500
Monthly Report #12	04/01/2021 – 04/30/2021	05/15/2021	$27,137,500
Monthly Report #13	05/01/2021 – 05/31/2021	06/15/2021	$27,137,500
Monthly Report #14	06/01/2021 – 06/30/2021	07/15/2021	$27,137,500
Monthly Report #15	07/01/2021 – 07/31/2021	08/15/2021	$27,137,500
Monthly Report #16	08/01/2021 – 08/31/2021	09/15/2021	$27,137,500
Monthly Report #17	09/01/2021 – 09/30/2021	10/15/2021	$27,137,500
Monthly Report #18	10/01/2021 – 10/31/2021	11/15/2021	$27,137,500
Monthly Report #19	11/01/2021 – 11/30/2021	12/15/2021	$27,137,500
Monthly Report #20	12/01/2021 – 12/31/2021	12/31/2021	$27,137,500
		Total =	$542,750,000

B.3 Task 2 Payment Schedule

Following delivery and acceptance of the work described in **SECTION C.3.2 Task 2: Pharmaceutical Manufacturing Capacity Expansion** and the deliverables described in **SECTION F**, and on submission of a proper invoice, the Government will pay the Contractor as follows:

Item Description	Due Date	Unit Price
(b) (4) [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
	Total =	$85,500,000

C. SCOPE OF WORK

C.1 Project Background

BARDA established a Center for Innovation in Advanced Development and Manufacturing (CIADM) with a subsidiary of Emergent BioSolutions Inc. (including all of its subsidiaries, "Emergent"), as a public-private partnership to ensure domestic vaccine manufacturing surge capacity to address national preparedness and response priorities. HHS/BARDA requires the services of Emergent to provide core advanced development ("industrialization") and manufacturing services to other commercial partners under contract to the U.S. Government (USG) for development of biopharmaceuticals against public health threats. Additionally, HHS/BARDA requires Emergent to provide manufacturing facilities utilizing flexible manufacturing and modem platform technologies to produce vaccines for outbreaks of an emerging infectious pathogens.

In December 2019, a novel (new) coronavirus known as SARS-CoV-2 ("the virus") was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Services (HHS) declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

Under the President's Operation Warp Speed Mission, HHS is leading a whole of nation effort with the primary goal to execute on a well-defined portfolio of COVID-19 vaccine candidates to maximize probability of having one or more safe and effective vaccines as fast as possible for mass distribution. As such, it is a national security concern to quickly make available safe and effective COVID-19 vaccines. To this end, BARDA must reserve existing manufacturing capacity and expand manufacturing capacity in order to ensure adequate domestic capabilities are established and ready.

C.2 Objectives

The objective of this task order is to expand the public-private partnership with Emergent to reserve and expand the capacities and capabilities at Contractor's CIADM facility, and its affiliated Camden, MD and Rockville, MD facilities.

C.3 Tasks

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the tasks described below and in Attachment 1 – Contractor Capacity and Pricing.

C.3.1 Task 1: Capacity Reservation

The Contractor shall reserve drug substance and drug product manufacturing capacity at the contractor's Bayview CIADM, Camden, MD, and Rockville, MD facilities for the exclusive use of the USG for the duration of the period of performance. The Contractor's facilities shall have the capability of producing the number of batches specified as follows in each applicable calendar month. In the event the Contractor is not tasked with producing batches in a given month, the capacity shall lapse and the unused batch production capacity cannot be allocated to a future period. Specifically, the areas to be reserved and number of batches over the period of performance associated with each area under the reservation, shall be as follows (number of batches is based upon a generic manufacturing process):

Area Description	Estimated Monthly Number of Batches	Total Number of Vials for Full Period of Performance
Bayview CIADM Area [redacted] Drug Substance		(b) (4) [redacted]
Bayview CIADM Area [redacted] Drug Substance		
Camden, MD Fill/Finish Line (b) (4)		
Camden, MD Fill/Finish Line (b) (4)		
Camden, MD Fill/Finish Line New		
Rockville, MD Fill/Finish Line Existing		
Rockville, MD Fill/Finish Line New		

Bayview CIADM, Baltimore, MD Facility

The reservation fee per batch for drug substance at Bayview shall include the space and manufacturing activities from batch record preparation through manufacturing execution, including batch readiness activities, labor, and available equipment to produce one batch. Reservation fee does not include tech transfer, process and analytical development, process development, raw materials and lot release testing of a batch; these costs will be paid for under

separate product development task orders/contracts/agreements. When the reserved capacity is utilized for manufacturing drug substance on behalf of the government, the contractor will credit the reservation fee according to the table in Section B to the manufacturing of the batch in the specific area. The government will be responsible for any cost difference between the applied reservation fee and the actual cost of performing the manufacturing of the batch.

Camden, MD and Rockville, MD Facilities

The reservation fee per batch of drug product at Camden and Rockville, MD facilities shall include the space and manufacturing activities from batch record preparation through manufacturing execution, including batch readiness activities, labor, and available equipment to produce one batch. Reservation fee does not include tech transfer, process and analytical development, process development, raw materials and lot release testing of a batch; these costs will be paid for under separate product development task orders/contracts/agreements. When the reserved capacity is utilized for manufacturing drug product on behalf of the government, the contractor will credit the reservation fee according to the table in Section B to the manufacturing of the batch in the specific area. The government will be responsible for any cost difference between the applied reservation fee and the actual cost of performing the manufacturing of the batch.

The contractor shall maintain the reserved capacities in a state of readiness to perform current good manufacturing practices (cGMP) manufacturing activities, approved by the USG, under separate task orders/contracts/agreements for the entirety of the period of performance. If no manufacturing occurs in reserved capacities, the fees paid to contractor will cover reservation activities for that specific reserved capacity.

On a monthly basis, the contractor shall provide a monthly report that includes capacity availability and utilization or non-utilization, as well as any issues that impact the operational availability of the reserved capacity.

C.3.2 Task 2: Pharmaceutical Manufacturing Capacity Expansion

The contractor shall expand its existing capacities and capabilities in drug product manufacturing on an accelerated timeline. Specifically, the contractor shall establish a fill/finish manufacturing line at the contractor's Camden, MD facility that is capable of filling approximately (b) (4) vials per batch based on vial specifications. The contractor will use it reasonable best efforts to ensure the expanded capacity at the Camden facility will be operational for at-risk manufacturing no later than (b) (4) . The contractor shall also establish a fill/finish manufacturing line at the contractor's Rockville, MD facility capable of filling approximately (b) (4) vials per batch based on vial specifications. The contractor will use its reasonable best efforts to ensure the expanded capacity

at the Rockville facility will be operational for at-risk manufacturing no later than (b) (4) . Both of the new capacities must be designed to be in compliance with FDA current good manufacturing practices (cGMP) regulations (21 CFR parts 210 and 211) or agreed upon at-risk manufacturing state. The Rockville facility must be able to manufacture drug product from viral drug substance. The contractor shall be responsible for management of all activities, subcontractors, etc. to meet the goals of the Task Order, including holding routine meetings with BARDA, and completion of meeting minutes. BARDA will assist in facilitating appropriate discussions with the FDA.

As a firm-fixed price arrangement, it is expected that all property acquired under this task order will be owned by contractor. To the extent any Contractor Acquired Property is deemed to be owned by the Government, such property shall transfer to the contractor upon completion of the applicable CLIN. In consideration for the government's funding for this capacity expansion, the contractor agrees to provide the government priority access to the new fill/finish lines for the period of performance. The contractor also agrees to fund any/all sustainment costs associated with maintaining the equipment/infrastructure paid for by the government. This maintenance includes compliance with FDA current good manufacturing practices (cGMP) regulations (21 CFR parts 210 and 211).

On a monthly basis, the contractor shall provide a monthly report that includes progress in establishing the expanded drug product capacities at the Camden and Rockville facilities, including updates to the IMS.

D. PACKAGING AND MARKING

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.

E. INSPECTION AND ACCEPTANCE

Inspection and acceptance of all work, performance, reports and other deliverables, under this task order, will be performed at the CIADM's facility or approved subcontractor facility, by the Contracting Officer 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 task order.

F. PERFORMANCE / DELIVERABLES

F.1 Period of Performance

The period of performance of this task order shall be from May 13, 2020 through December 31, 2021.

F.2 Deliverable Requirements

F.2.1 Manufacturing Schedule with Allocated Capacity through Period of Performance

A Manufacturing Schedule shall be provided quarterly that includes the utilization and non-utilization of the reserved manufacturing capacities (Bayview Areas (b) (4); Camden fill/finish lines (b) (4) and the new line; and Rockville existing and new fill/finish lines). The schedule shall include:

- Length of time for manufacturing in each area
- Name of the teaming partner (i.e. (b) (4), etc)
- Vaccine/product technical information (i.e. cell line expression system, live viral, subunit, etc.)
- Batch Size or Scale
- Number of batches

F.2.2 Integrated Master Schedule (IMS) for Camden and Rockville New Fill/Finish Lines

The Fill/Finish IMS shall include the time-phased activities to completely execute the Fill/Finish CWBS. Microsoft Project compatible file required and will result in a Gantt Chart for project tracking. The IMS will document the delivery date for each deliverable, critical path, major milestones, tasks/activities, duration, lead/lag/slack time, and schedule relationships, and will be directly traceable to the SOW and the WBS to a minimum of a level (b) (4)

F.2.3 Work Breakdown Structure (WBS) for Camden and Rockville New Fill/Finish Lines

The WBS shall extend to elements to completely define the entire effort proposed to establish the fill/finish capability as described in the SOW. The WBS shall be to a depth and breadth necessary to accurately describe the proposed effort, to a minimum of a level (b) (4)

F.2.4 Validation Master Plan (VMP)

The VMP shall include a list of the Standard Operating Procedures that will be used in the commissioning, qualification and validation (CQV) of the Camden and Rockville new fill/finish areas. The VMP shall also include a list of the equipment and facilities' systems and extent of their CQV (i.e. Commissioning, Facility Acceptance Testing, Site Acceptance Testing, Installation Qualification, Operational Qualification, Performance Qualification, etc.).

F.2.5 Monthly Report

Each monthly report must include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. Specific to Task 1, each monthly report must include a summary of capacity

availability and utilization / non-utilization, as well as any issues that impact the operational availability of the reserved capacity. Specific to Task 2, each monthly report must include a summary of the progress in establishing the expanded drug product capacities at the Camden and Rockville facilities, including updates to IMS.

F.3 Schedule of Deliverables

Satisfactory performance of the task order shall be deemed to occur upon performance of the work described in **SECTION C** of this task order and upon delivery and acceptance of the following items.

Item	Task	Deliverable	Delivery Method	Due Date
1	1	Manufacturing Schedule with Allocated Capacity through Period of Performance	Electronically to CO and COR	(b) (4) after TO award; every (b) (4) thereafter
2	2	Integrated Master Schedule	Electronically to CO and COR	(b) (4)
3	2	Work Breakdown Structure	Electronically to CO and COR	(b) (4)
4	2	Validation Master Plan	Electronically to CO and COR	(b) (4)
5	1 & 2	Monthly Report	Electronically to CO and COR	day of every month throughout the task order period of performance

F.4 Meeting Requirements

F.4.1 Routine Update Teleconferences

The Contractor shall participate in regular teleconferences with USG to discuss the performance of the task order. The frequency will be agreed upon by the Contractor and USG and may be dependent on the activities during that time of the task order. Typically, these meetings are held (b) (4). The Contractor is responsible for securing a suitable call in number for relevant participants and be responsible for moderating the meeting. The Contractor shall keep meeting minutes and forward a finalized copy to the CO and COR for approval within (b) (4) after each teleconference, or as otherwise authorized by the Contracting Officer.

F.4.2 Person-in-Plant

Contractor shall accommodate up to (b) (4) BARDA personnel at an agreed upon time throughout the performance of this task order. On-site BARDA

personnel will provide support of the work and technical consultation in alignment with Contractor and per guidance from the BARDA program office in Washington, D.C.

F.4.3 Periodic Site Visits

The Contractor shall accommodate for periodic site visits by BARDA on an ad hoc basis or as agreed upon, with at least (b) (4) prior written notice. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within (b) (4) after each site visit, or as otherwise authorized by the CO.

F.4.4 Quarterly Site Visits

The Contractor shall provide formal presentations summarizing all work accomplished in the previous calendar quarter at the Contractor's site on a quarterly basis. The Contractor shall keep meeting minutes and forward a finalized copy to the CO and COR for approval within (b) (4) after each site visit, or as otherwise authorized by the CO.

F.4.5 Kick-Off Meeting

The Contractor shall participate in a kick-off meeting, within (b) (4) of task order award; content, format, and location to be determined by the USG and the Contractor. The Contractor is responsible for securing a physical location or a suitable call in number for relevant participants and be responsible for moderating the meeting. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within (b) (4) after the meeting is held, or as otherwise authorized by the Contracting Officer.

G. CONTRACT ADMINISTRATION

G.1 Contracting Officer

The following CO will represent the Government for the purpose of this Contract:

(b) (6)

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

The CO is the only person with the authority to act as agent of the Government under this contract. Only the CO has authority to (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this Contract; and (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 CO, which may be received from any person employed by the Government, or otherwise, shall be considered grounds for deviation from any stipulation of this Contract.

The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

G.2 Contracting Officer's Representative

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

(b) (6)

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 Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

G.3 Key Personnel

Key personnel specified in this task order are considered to be essential to work performance. At least (b) (4) 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 (b) (4) 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; provided that the Contracting Officer may ratify in writing that such diversion and such ratification shall constitute the

consent of the Contracting Officer required by this clause. The task order will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individuals are determined to be key personnel.

Name	Title
(b) (6) [redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

G.4 Invoicing Instructions

Invoices for payment shall be submitted electronically and shall include an SF-1034 and all supporting documentation.

G.5 Evaluation of Contractor Performance

Purpose: In accordance with FAR 42.1502(a), past performance evaluations shall be prepared at least annually and at the time the work under a contract or order is completed, via CPARS, the Government-wide evaluation tool (www.cpars.gov).

Evaluators: The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.

Performance Evaluation Factors: Per FAR 42.1503(b)(2), evaluation factors for each assessment shall include, at a minimum: technical (quality of product or service); cost control; schedule/timeliness; management and business relations; small business subcontracting; other (as applicable).

Contractor Review: A copy of the evaluation will be electronically sent to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within (b) (4) [redacted] after receipt of the evaluation.

Resolving Disagreements between the Government and the Contractor: Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.

Release of Contractor Performance Evaluation Information: The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.

Source Selection Information: Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

Retention Period: The agency will retain past performance information for a maximum period of (b) (4) after completion of contract performance for the purpose of providing source selection information for future contract awards.

H. SPECIAL REQUIREMENTS

H.1 Advance Understandings

H.1.1 The Government recognizes that Contractor's operations are essential as a matter of national security and, as such, Contractor is directed to maintain operations to the extent practicable regardless of state or local restrictions to the contrary. In addition, all Contractor employees, independent contractors, and subcontractors are considered essential personnel supporting critical infrastructure as set forth in DHS CISA Memorandum dated March 19, 2020.

H.1.2 Government confirms that all activities conducted by Contractor, any independent contractors and subcontractors under the task order as well as all general operations necessary to ensure execution of activities under the task order are subject to that certain declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) issued by the Secretary of Health and Human Services on March 10, 2020.

H.1.3 Government reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System. Emergent BioSolutions agrees that the Government's right to exercise priorities and allocations authority with respect to this order, to include the use of directives in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System, constitutes a no-cost change to this order.

H.1.4 Contractor will act as the Contract Development Manufacturing Organization (CDMO) for priority targets as determined by the Government and the scope will encompass Drug Substance and Drug Product within above network.

H.1.5 Upon approval of a direct relationship between Contractor and priority target, the Government will release the associated capacity to Contractor to deploy and contract with identified by the Government.

H.1.6 Contractor will negotiate pricing with the identified party for full scope of activities including manufacturing and raw materials.

H.1.7 Contractor may retain a reasonable quantity of vaccine manufactured at is facilities, not to exceed (b) (4) courses of therapy, to vaccinate Contractor's

employees and critical subcontractors, and their respective immediate families. Any such retained product will be at the Contractor's cost.

H.2 Intellectual Property

Execution of a subsequent task order for utilization of capacity reserved under this task order may require a relationship between HHS, the firm that possesses rights to specific Intellectual Property (IP) required for the development effort (the "MCM IP Holder"), and the firm providing the Core Services under the task order (the "CIADM"). The relationship must reflect the Parties' rights to all IP developed and/or IP used in performance of the task order, and be consistent with HHS' IP rights per the Federal Acquisition Regulations (FAR) clauses described in the base contract. Prior to any performance of work, the MCM IP Holder and/or the CIADM shall provide the Contracting Officer with a written description of all IP necessary to develop (the "Description"). 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 the task order. The Description shall also include written verification of the rights provided to HHS to any and all IP utilized or developed during performance of the task order 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 the task order, FAR Clause 52.227-14 and FAR Clause 52.227-14 as amended in any applicable subcontract and/or teaming agreement (the "FAR Clauses").

The MCM IP Holder and the CIADM will remain free to negotiate any agreement of their own regarding their use of any of the IP utilized or developed during performance of an task order, 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 the task order. The agreement shall be furnished to the Contracting Officer within (b) (4) after the agreement is finalized. In addition, this task order incorporates FAR Clause 52.227-1 Authorization and Consent (DEC 2007) and FAR Clause 52.227-3 Patent Indemnity (APR 1984).

H.3 Consultants and Sub-Contractors

As a commercial-item, firm fixed price arrangement, BARDA acknowledges that Contracting Officer authorization is not required for use of subcontractors or consultants.

H.4 Non-Personal Services and Inherently Governmental Functions

Pursuant to FAR 37.1, 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.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently Governmental actions 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.

The Contractor shall ensure that all of 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.

I. CONTRACT CLAUSES

Only the clauses incorporated in the base contract that are applicable to fixed price contracts and task orders (i.e., 52.212-4 – Contract Terms & Conditions – Commercial Items) are in full effect at the task order level. This section or other parts of this TO may incorporate 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. In addition, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/.

J. ATTACHMENTS

Attachment 1 – Contractor Capacity and Pricing

Attachment 1 – Contractor Capacity and Pricing

Emergent CIADM Manufacturing Capacity Reservation and Expansion

The Government secures the below capacity at the specified pricing:

1. Drug Substance – Baltimore, MD (Bayview – CIADM)
   a. (b) (4)
      i. Estimated timeframe: (b) (4) in total, (b) (4) through (b) (4)
      ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to [redacted] batches
      iii. Estimated pricing: (b) (4) / batch for a total of (b) (4). This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
   b. (b) (4)
      i. Estimated timeframe: (b) (4) in total, (b) (4) through (b) (4)
      ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to [redacted] batches
      iii. Estimated pricing: (b) (4) / batch for a total of (b) (4). This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
   c. Total for Drug Substance: (b) (4) (excluding raw materials)

2. Drug Product – Baltimore, MD (Camden)
   a. Existing Line (b) (4) ((b) (4) vials / batch)
      i. Estimated timeframe: (b) (4) in total, (b) (4) through (b) (4)
      ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to (b) (4) batches, (b) (4) units
      iii. Estimated pricing: (b) (4) / batch for a total of (b) (4). This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
   b. Existing Line (b) (4) ((b) (4) / batch)
      i. Estimated timeframe: (b) (4) in total, (b) (4) through (b) (4)
      ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to (b) (4) batches, (b) (4) units

iii. Estimated pricing: (b) (4) / batch for a total of (b) (4). This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.

c. New Line ((b) (4) vials / batch)
   i. Estimated timeframe: (b) (4) in total, (b) (4) through (b) (4)
   ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to (b) (4) batches, (b) (4) units
   iii. Estimated CAPEX Acceleration Fee: (b) (4) (best estimate, actual numbers may vary)
   iv. Estimated pricing: (b) (4) / batch for a total of (b) (4). This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.

ci. Total for Drug Product: (b) (4) (excluding raw materials) + Capex Acceleration of approximately (b) (4)

3. Drug Product – Rockville, MD
   a. Existing Line ((b) (4) vials / batch)
      i. Estimated timeframe: (b) (4) in total, (b) (4) through (b) (4)
      ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to (b) (4) batches, (b) (4) units
      iii. Estimated pricing: (b) (4) / batch for a total of (b) (4). This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
   b. New Line ((b) (4) vials / batch)
      i. Estimated timeframe: (b) (4) in total, (b) (4) through (b) (4)
      ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to (b) (4) batches, (b) (4) units
      iii. Estimated CAPEX Installation / Acceleration Fee: (b) (4) (best estimate, actual numbers may vary)
      iv. Estimated pricing: (b) (4) / batch for a total of (b) (4). This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.

c. Total for Drug Product: (b) (4) (excluding raw materials) + Capex Installation / Acceleration of approximately (b) (4)

4. Total Value for Drug Substance and Drug Product Capacity Commitment & Manufacturing:$542.75 million, excluding raw materials

5. Total Value for Capex: approximately $85.5M (best estimate, actual numbers may vary)