AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
	1		33

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
00005	9/1/2023	000HCVG1-2023-80795	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
Centers for Disease Control and Prevention (CDC) Office of Acquisition Services (OAS) 2900 Woodcock Blvd, MS TCU-4 Atlanta, GA 30341-4004	8219		8219

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*	(√)	9A. AMENDMENT OF SOLICITATION NO.
CVS PHARMACY, INC. 1 CVS DR WOONSOCKET, RI 02895-		9B. DATED *(See Item 11)*
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. 75D30122C13954
		10B. DATED *(See Item 13)* 06/01/2022

CODE TXNJU9N2PHJ7 FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers __ is extended, __ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:
(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
9390LR9 2512 2023 75-X-0140 C6R6111101 Increase $120,773,016.68

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(√)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103 (a)(3) Reflect other agreements of the parties modifying the terms of contracts
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Contractor POC: Jinali Desai, (b)(6)
COR: Mary Hoelscher mzr1@cdc.gov - 404.639.5446
Contract Specialist (OFR/OAS): Eric Lyons kpy2@cdc.gov 770.488.2949

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME OF CONTRACTING OFFICER
Jinali Desai	[redacted] Lauren Peel

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b)(6) *(Signature of person authorized to sign)*	09/15/2023	BY Lauren Peel -S *(Signature of Contracting Officer)* Digitally signed by Lauren Peel -S Date: 2023.09.15 16:52:16 -04'00'	

Section 2

In accordance with the Advance Agreement distributed on September 1, 2023, and pursuant to authority cited in Block 13C, this Modification serves to:

1. Update Contractor POC to Jinali Desai as detailed in Block 14.

2. Incorporate updated Section C - Statement of Work as set forth herein to add Vaccination Services.

3. Update Section B to add Vaccination Services as follows:

    a. Add Option Period 1.1 (09/01/2023 – 09/30/2024) Items:

        i. CLIN 1003 Vaccination Services, is added and funded with extended price and funded amount of (b)(4)

        ii. CLIN 1004 Vaccination Services: Startup Costs is added and funded with extended price and funded amount of (b)(4)

        iii. CLIN 1005 Vaccination Services: Program Management and Reporting is added and funded with extended price and funded amount of (b)(4)

        iv. CLIN 1006 Vaccination Services: Marketing is added and funded with extended price and funded amount of (b)(4) and

        v. Optional CLIN 1007 Additional Vaccination Services is added with extended price of (b)(4) and funded amount of (b)(4)

    b. Add Option Period 2.1 (10/01/2024 – 12/31/2024) Items:

        i. CLIN 2003 Vaccination Services, is added with extended price of (b)(4) and funded amount of (b)(4)

        ii. CLIN 2004 Vaccination Services: Program Management and Reporting is added with extended price of $ (b)(4) and funded amount of (b)(4)

4. Update Section J – List of Attachments to add: Attachment J.1.b – Vaccination Data Reporting Requirements; and Attachment J.1.c. – Summary of Outreach Conducted for Bridge Access Program..

5. Total contract funded amount is increased by $120,773,016.68 from (b)(4) to $ (b)(4)

6. Total contract value is increased by (b)(4) from (b)(4) to $ (b)(4)

All other terms and conditons of the contract remain unchanged and in full force and effect.

Section B - Supplies Or Services and Prices/Costs

Base Period (06/01/2022 – 11/30/2023) Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	ICATT Testing Services in accordance with the statement of work.	1 Job	(b)(4)	

Base Period Additional Testing (06/01/2022 – 11/30/2023) Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0002	ICATT Additional Testing This is an Optional Line Item that may be exercised at any point during the delineated period of performance, and may be exercised more than once so long as the total value does not exceed 250% of the referenced core task CLIN.	1 Job	(b)(4)	

Base Period NIH Recover Linkage (03/01/2023 – 11/30/2023) Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0003	Digital Link to NIH Recover Website Inclusion of link to NIH RECOVER website in appointment confirmation email	1 Job	(b)(4)	
0004	Change to NIH RECOVER website link, accompanying text or image (price/change) (b)(4) each	(b)(4	(b)(4)	

Option Period 1 (12/01/2023 – 05/31/2024) Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
1001	ICATT Testing Services in accordance with the statement of work.	1 Job	(b)(4)	
1002	ICATT Additional Testing This is an Optional Line Item that may be exercised at any point during the delineated period of performance, and may be exercised more than once so long as the total value does not exceed 250% of the referenced core task CLIN.	1 Job		

Option Period 1.1 Items:

ITEM	SUPPLIES / SERVICES	QTY/UNIT	UNIT PRICE	EXTENDED PRICE
1003	**Vaccination Services** Services in accordance with Section C Period of Performance: 09/13/2023 – 9/30/2024	1 Job	(b)(4)	
	Line(s) Of Accounting: 9390LR9 2512 2023 75-X-0140 C6R6111101 (b)(4)			

1004	**Vaccination Services: Startup Costs** Services in accordance with Section C Period of Performance: 09/01/2023 – 9/14/2023	1 Job	(b)(4)	
	Line(s) Of Accounting: 9390LR9 2512 2023 75-X-0140 C6R6111101 (b)(4)			
1005	**Vaccination Services: Program Management and Reporting** (b)(4) Services in accordance with Section C Period of Performance: 09/13/2023 – 9/30/2024	1 Job	(b)(4)	
	Line(s) Of Accounting: 9390LR9 2512 2023 75-X-0140 C6R6111101 (b)(4)			
1006	**Vaccination Services: Marketing** *Marketing Low Plan and Direct Mailer Outreach (1M at* (b)(4) *mailing)* Services in accordance with Section C Period of Performance: 09/13/2023 – 9/30/2024	1 Job	(b)(4)	
	Line(s) Of Accounting: 9390LR9 2512 2023 75-X-0140 C6R6111101 (b)(4)			
1007	**Option: Additional Vaccination Services** This is an Optional Line Item that may be exercised at any point during the delineated period of performance and may be exercised more than once so long as the total value does not exceed 230% of the referenced core task CLIN. Period of Performance: 09/13/2023 – 9/30/2024	1 Job	(b)(4)	

Option Period 2 (06/01/2024 – 11/30/2024) Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
2001	ICATT Testing Services in accordance with the statement of work.	1 Job	(b)(4)	
2002	ICATT Additional Testing This is an Optional Line Item that may be exercised at any point during the delineated period of performance, and may be exercised more than once so long as the total value does not exceed 250% of the referenced core task CLIN	1 Job	(b)(4)	

Option Period 2.1 (10/01/2024 – 12/31/2024) Items:

ITEM	SUPPLIES / SERVICES	QTY/UNIT	UNIT PRICE	EXTENDED PRICE
2003	**Vaccination Services** in accordance with Section C Period of Performance: 10/01/2024 – 12/31/2024	1 Job	(b)(4)	
2004	**Vaccination Services: Program Management and Reporting** Services in accordance with Section C (b)(4) Period of Performance: 10/01/2024 – 12/31/2024	1 Job	(b)(4)	

Option Period 3 (12/01/2024 – 05/31/2025) Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
3001	ICATT Testing Services in accordance with the statement of work.	1 Job	(b)(4)	
3002	ICATT Additional Testing This is an Optional Line Item that may be exercised at any point during the delineated period of performance, and may be exercised more than once so long as the total value does not exceed 250% of the referenced core task CLIN.	1 Job	(b)(4)	

B.1 Test & Testing Program Management Pricing

Test Type per Setting*	Price	Unit	Limitations and Pricing Assumptions
Swab and Send- Pharmacy / Retail	(b)(4)	Per Test	Price Valid & Test/Service Available Until May 11, 2023
Swab and Send- Non-Pharmacy/Retail		Per Test	Price Valid & Test/Service Available Until May 11, 2023
Swab and Send (b)(4) (b)(4)		Per Test	Price Valid & Test/Service Available Until May 11, 2023
Unobserved self-collection and testing – Distributed (optional)		Per Test	Price Valid & Test/Service Available Until May 11, 2023
Unobserved self-collection and testing – Resulted (optional)		Per Test	Price Valid & Test/Service Available Until May 11, 2023
POC NAAT- Pharmacy / Retail		Per Test	Price Valid & Test/Service Available Until May 11, 2023
POC NAAT- Pharmacy /Retail (test provided by USG)		Per Test	Price Valid & Test/Service Available Until May 11, 2023
POC NAAT- **Non-**Pharmacy/Retail		Per Test	Price Valid & Test/Service Available Until May 11, 2023
POC NAAT- **Non-**Pharmacy/Retail (test provided by USG)		Per Test	Price Valid & Test/Service Available Until May 11, 2023
Extended hour testing (in addition to the per test cost)		Additional Cost Per Test	Price Valid & Test/Service Available Until May 11, 2023
Sample Accessioning and Shipping for further characterization		Per Test	Price Valid & Test/Service Available Until May 11, 2023
Testing Support Services (environmental support for non-English speakers, elderly, young children, people with disabilities, etc.)		Per Test	Price Valid & Test/Service Available Until May 11, 2023
Point of Care Antigen Testing at Surge sites and Federally Supported Sites (test provided by USG)		Per Test	Price Valid & Test/Service Available Until May 11, 2023
Surge Site Infrastructure Management Fee		Per Site	Price Valid & Test/Service Available Until May 11, 2023
Point of Care Antigen Testing		Per Test	Price Valid & Test/Service Available Until May 11, 2023
Point of Care Antigen Testing (test provided by the USG)		Per Test	Price Valid & Test/Service Available Until May 11, 2023
Multiplex test (see definition table C.1 subsection A)		Per Test	Price Valid & Test/Service Available Until May 11, 2023
Point of Care Antigen Testing at MinuteClinic		Per Visit	CVS would pursue payment from patient for any services and tests not related to COVID-19 that may be provided at the time of the visit.
OTC test distribution (test provided by USG)		Per Visit	
Program Management Fee Type*†	**Price**	**Unit**	**Limitations and Pricing Assumptions**
Reporting - Standard	(b)(4)	Per Month	Includes the following reports: invoice reconciliations, monthly payer update, HHS Protect site maintenance and daily reporting, CVS planned workflow changes, OTC reporting
Reporting - Customized & Ad Hoc Reporting Requests		Per Report / Change Request	Level of effort shall be estimated in advance by CVSH: Low - 1 - 10 hours / Moderate - 11 - 40 hours / High - 41 - 60 hours / Major - 60+.

Screener Criteria Changes	(b)(4)	Per Change	Maximum of 1 change requested per month. CVS in its sole discretion may choose whether to accept the requested change. Any accepted changes shall be made in accordance with CVS's deployment schedule.
ICATT Program Management Fee		Per Month	PM/Overhead for testing program. Excludes activities/pricing included above. Includes maintaining digital screener capability (not inclusive of changes), and up to 2 meetings per week.
Transition to Post-PHE Testing Fee (transition into MinuteClinic setting).		One Time	Effective April 18, 2023

*All services selected for a given period of performance must run the entire period of performance unless otherwise mutually agreed to by the parties. ICATT Program Management and Reporting – Standard are required for ongoing performance.
† Program Management Fees, except for Transition to Post-PHE Testing Fee**, are valid and may be invoiced on the 12th of every month, starting May 12, 2023.
OTC tests shall not be considered Government Furnished Materials for purposes of or subject to any Contractor tracking or inventory management requirements.

Vaccination Services Pricing**

Vaccination Service	Price	Unit
Vaccine Administration (Pharmacy)	(b)(4)	per vaccination
Bridge Optimization Cost (Pharmacy)		per vaccination
Underinsured Vaccine (Pharmacy Only)		per vaccination
Vaccine Administration (Minute Clinic)		per vaccination
Bridge Optimization Cost (Minute Clinic)		per vaccination
Low Vaccination Area Payment (September 15, 2023 – December 31, 2023)		per vaccination
Low Vaccination Area Payment (January 1, 2024 – September 30, 2024)		per vaccination

**All services selected for a given period of performance must run the entire period of performance unless otherwise mutually agreed to by the parties. CLIN 1005: Vaccination Services – Program Management and Vaccination Reporting are required for ongoing performance.
** CLIN 1005 does not include vaccination screener, digital scheduler criteria changes, or vaccination reporting (customized or ad hoc reporting requests) – any such requests shall be subject to a seaparately priced bilateral modification.

B.1.1 ICATT Vulnerable Population Testing, Reimbursement Shift to Private or Public Insurance, and Low-Vaccination Coverage Population Payments

	Price	Unit
Vulnerable Population FFP Payment**	(b)(4)	Per Qualifying Test (b)(4)
Low-Vaccination Population Per-Dose Payment		Per Qualifying Vaccine Dose (b)(4)
		Per Qualifying Vaccine Dose (b)(4)

(b)(4)

B.1.2 ICATT Linkage to HHS RECOVER

	Price

Inclusion of link to HHS RECOVER website in appointment confirmation email		(b)(4)
Change to HHS RECOVER website link, accompanying text or image (price per each change for a maximum of two (2) changes)		

B.2 Options for Additional Services – Separately Priced Line Items

Upon mutual agreement of the parties, the Contractor may provide additional support if the Government has a requirement for it. Additional support is included as separately priced Contract Line Item Numbers (CLINs) identified in Schedule B and described below. The optional CLIN may be exercised more than once up to the total amount listed for each CLIN.

If Additional Services are required, the parties will mutually agree upon the estimated level of effort (LOE) that is needed and price associated with the LOE. The Contracting Officer may exercise the option by modification of this contract, signed by both parties within the period of performance of the CLIN associated with the option line item as shown in the schedule above. The exact period of performance for the option for Additional Services will be established in the contract modification and may be for a different period of time than other line items in this contract. The vendor will be notified in writing, by email, at least 30 days before the option is exercised. After that written notification, a funded, bilateral modification will be issued to formally exercise the option or options.

The Government reserves the right not to exercise any Additional Services CLINs if no Additional Services are required during the performance of this contract.

B.2.a. Additional Testing Services:

Additional Testing Services are included as separately priced Contract Line Item Numbers (CLINs) X002 identified in the Schedule B.

B.2.b. Additional Vaccination Services:

Additional Vaccination Services (period of performance 9/13/2023 – 09/30/2024) are included as separately priced Contract Line Item Number (CLIN) 1007 identified in Schedule B.

B.4 Contract Points of Contact

Vendor POC: Jinali Desai - (b)(6)
Contract COR: Mary Hoelscher – mzr1@cdc.gov - 404.639.5446
OFR/OAS: Eric Lyons - kpy2@cdc.gov - 770.488.2949
OFR/OAS secondary contact: Samantha Bily - qnb7@cdc.gov – 404.498.2150

Section C - Description/Specification/Work Statement

SECTION 1 – BACKGROUND

On March 13, 2020, the President declared a national emergency concerning COVID-19 under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act"). The novel coronavirus (SARS-CoV-2) is a highly contagious pathogen that is responsible for the current worldwide pandemic of COVID-19 disease. To aggressively address this disease, an immediate deployment of critical public health assets and support was required to decrease transmission of the virus and to provide medical care for impacted communities.

Initially, the federal government implemented new policies to streamline payment for pharmacy testing to more quickly diagnose individuals who may be infected with SARS-COV-2. Early diagnosis has a direct impact on saving lives and reducing the spread of COVID-19 disease. The support provided by the federal government allows private companies to scale operations and dramatically increase COVID-19 testing access and capacity by removing the complexity and uncertainty associated with billing.

In March 2020, under the Office of the Surgeon General, the US Government established the Community Based Testing Site (CBTS) program to support patient accessibility to no-cost diagnostic testing in pharmacies and community surge testing sites. This program was converted under the inter-agency Testing and Diagnostics Workgroup (TDWG) to the Increasing Community Access to Testing (ICATT) Program. ICATT provides no-cost testing in locations with a high social vulnerability index (SVI), elevated rates of COVID-19 incidence, and/or lower rates of COVID-19 vaccine uptake. Under this contract, patients do not receive a bill for the test and do not pay any fee related to test processing, evaluation, or handling. Evidence shows that when local no-cost opportunities are available there is an increase in the number of individuals who seek and receive testing.

Community pharmacy and surge testing sites are maintained through a public/private partnership with various national pharmacy chains, independent pharmacies, and laboratories. Between April 2020 and November 2021, through various contracting actions, the ICATT program has directly supported the performance of more than 25.5 million SARS-CoV-2 tests through the more than 10,000 pharmacies and community sites in all 50 states, Washington DC, and Puerto Rico. As of November 2021, 53% of the ICATT sites are in high SVI communities, and 40% of all ICATT tests performed are for racial and ethnic minorities. ICATT has supported over 790 surge sites since April 2020. As of December 2021, the program has 32 active surge sites. At present, the ICATT program performs an estimated 5% of all national testing and based on a recent Rockefeller Foundation survey, parents indicated that pharmacies are the most favored location for obtaining a test.

COVID-19 vaccinations are critical in preventing a surge in COVID-19 cases due to a variant strain. During the COVID-19 pandemic, the Federal Retail Pharmacy Program (FRPP) administered COVID-19 vaccines at no-cost to eligible patients under a federal vaccine procurement contract. On May 11, 2023, the public health emergency (PHE) ended, impacting testing and administration of vaccinations for the uninsured and underinsured, one of the most vulnerable populations. Manufacturers will commercialize the vaccines which will result in a sharp price increase for vaccines. Post-PHE, due to the reversion to pre-pandemic policies and authorities, the uninsured and underinsured may not have the ability to afford the unsubsidized cost of vaccinations.

SUBSECTION A – DEFINITIONS

Communities of Interest	Supporting communities of interest by providing no-cost access to COVID-19 testing is the primary mission of the ICATT Program. Communities of interest meet one or more of the following criteria: *For Testing Services:* • Are located in a moderate or high social vulnerability index (SVI) census tract (SVI rating is greater than 0.5); pharmacy locations that are not located in moderate- or high-SVI census tracts but serve moderate- or high-SVI census tracts are included in this consideration; • Greater than 36% of the demographic composition of the county identifies as non-white, or Hispanic • Are at a greater risk of SARS-CoV-2 transmission due to the 7-day case rate exceeding 25 per 100,000; • Are located in a testing desert (see definition); and/or • Are at greater risk of poorer health outcomes resulting from COVID-19 disease where vaccination rates are less than half the national average. *For Vaccination Services:* • Are located in a low-access area or low-vaccination coverage area (see definitions)

Cost Share	The process by which the Government covers copays normally owed by an insured patient to result in cost-free coverage for vaccinations.
End-To-End Testing Process	All aspects of testing and support services including patient registration/scheduling, application of screening criteria, ordering of the test by a licensed healthcare practitioner, operation of the testing site, transportation/delivery of test sample to lab (if needed based on testing model), conduct the test or cover payment for conducting the test, notification of results to patients, input as required into the HHS Protect system data, and report positive and negative cases as directed by the relevant state and local Departments of Health.
ESDTF	Expansion of Screening and Diagnostics Taskforce
Federally Supported Testing	Federally supported testing is a rapid stand-up of COVID-19 testing at sites where the federal government has determined that a testing need exists that otherwise is not covered by existing pharmacy testing capacity or surge sites sponsored by other public health jurisdictions.
HHS Protect	A secure platform for authentication, amalgamation, and sharing of healthcare information.
ICATT	Increased Community Access to Testing Team. Provides no-cost COVID-19 testing to Uninsured Individuals and no-cost COVID-19 vaccinations to Uninsured and Underinsured individuals. Operates in pharmacies, congregate settings, surge sites, hot spots, and priority locations.
Insurance Denial	(b)(4)
Insurance Discovery	The process the Contractor must undertake the steps set forth in Section 4(2)(K).
Low Vaccination Area	An area in which a significant number of uninsured and underinsured persons have not yet been vaccinated. The definition of low-vaccination area will be updated over time to include more recent COVID-19 vaccine uptake data. CDC will update a list of low-vaccination coverage areas each month and distribute it to participating vendors.
NAAT	Nucleic Acid Amplification Test
Outreach	Activity conducted by Contractor to reach Communities of Interest and that aim to improve vaccination coverage, access, and awareness in Communities of Interest.
PREP Act	The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a PREP Act declaration. The declaration provides immunity from liability (except for willful misconduct) for claims: • of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions • determined by the Secretary to constitute a present, or credible risk of a future public health emergency • to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures
Site Status	**Confirmed** – Testing site that has been approved but has not reached Go Live date.
	Inactive – Testing site that has not submitted results in HHS Protect for 30 days.
	Live – Testing site that is currently providing testing.
	Transition/Closed – Testing site identified by Contractor that is no longer providing testing. Contractors cannot bill for testing that occurs after the Close Date for closed sites.

SVI	Social Vulnerability Index. Social vulnerability refers to the potential negative effects on communities caused by external stresses on human health. Such stresses include natural or human-caused disasters, or disease outbreaks. SVI uses 15 U.S. census variables to help local officials identify communities that may need support before, during or after disasters. See:https://www.atsdr.cdc.gov/placeandhealth/svi/data_documentation_download.html for more information
STLT	State, Tribal, Local, or Territorial Public Health Agencies
TDWG	Testing and Diagnostics Working Group
Testing Desert	Census tract that is at least 10 miles away from a testing site.
Testing Sites	**Border** – Testing at migration related sites such as an airport, border station, or quarantine station.
	Community – Long term non-pharmacy testing site (may be a brick-and-mortar store or fixed site in a community)
	Congregate – Congregate facilities such as nursing homes or schools
	Pharmacy – Brick-and-mortar pharmacy testing sites including Pharmacy drive-thru locations
	Non-Pharmacy/Retail Sites - Off-site testing of a short duration to include surge, community, congregate, Federally Supported sites and or similar locations not associated with permanent structures.
	Pop-up/stand-up sites – see surge with management fee
	Surge Testing – Short-term remote testing events (e.g., parking lots or other public venues) that are held in response to an STLT public health agency's determination that a change in local case rates indicates a greater need increased testing in the area. Surge testing events are typically held for one to two weeks at a time.
	Surge with infrastructure management – Surge testing site with management fee. Fee is added when Contractor provides Surge Site Infrastructure Management services. (see section 4.11)
	Surge without infrastructure management – Surge testing site without management fee. Fee is not added if another entity provides infrastructure management (such as a generator, Wi-Fi, tent, tables, etc.)
Testing Methods	**Genomic Sequencing -** next generation sequencing performed to identify specific variants of SARS-CoV-2 in clinical specimens; in the context of this document, it can refer to sequencing done for genomic surveillance purposes (see CDC definition) or diagnostic purposes to detect variants of clinical relevance. Sequencing for diagnostic purposes must be performed using a method compliant with CLIA regulations. **Confirmatory Testing** - Confirmatory POC testing, typically PCR or NAAT, is performed to confirm the results of an antigen POC result that mismatches the patient's symptoms. Confirmatory Testing will be offered, as appropriate based upon clinician evaluation, to a patient who receives an antigen test. **Unobserved-self collection -** Samples are self-collected, without observation from a medical professional, returned to a drop-off location or mailed followed by laboratory PCR testing. **Multiplexed Testing –** Diagnostic tests which detect two or more targets in a single test; in the context of this document, it refers to two or more pathogens such as SARS-CoV-2 and influenza. **Over-the-counter (OTC) tests –** Diagnostic tests that have been authorized by FDA for use without a prescription. **Point-of-care (POC) Testing -** Diagnostic tests performed at or near the place of specimen collection, Test performed could be antigen based or NAAT based. **Polymerase Chain Reaction (PCR) –** Diagnostic tests that detect SARS-CoV-2 genetic material; in the

	context of this document and other solicitation materials, it includes both reverse transcription polymerase chain reaction and isothermal amplification POC or laboratory-based testing methods. **Pooled Sample Testing -** Combining the same type of specimen from several people and conducting one test on the combined pool of specimens to detect SARS-CoV-2. Pooled tests that return positive results require each specimen in the pool to be retested individually to determine which individual(s) are positive. The advantages of pooling include preserving testing reagents and resources, reducing the amount of time required to test large numbers of specimens (increasing throughput), and lowering the overall cost of testing. The optimal pooling strategy depends on the incidence of infection in the community, and pool size need to be adjusted accordingly. **Swab and Send** –Observed self-collection kit for sample collection followed by laboratory PCR testing.
Turnaround Time (TAT)	The difference between Date of Sample Collection and Date of Testing Result as recorded in HHS Protect or other required federal reporting systems.
Underinsured Individual	*Vaccination Services:* An adult, eighteen years of age or older, who meets the requirements set forth in Section 4.2.kK.b.4.a. Vaccine Services for Underinsured Individuals is not available at MinuteClinic.
Uninsured Individual	*Vaccination Services:* An adult, eighteen years of age or older, who meets the requirements set forth in Section 4.2.kK.b.4.a.
US Regions	For the purposes of the ICATT program, there are seven (7) US regions: 1. New England (Northeast): Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont 2. Mid-Atlantic: Delaware, Maryland, New Jersey, New York, Pennsylvania, and Washington, D.C. 3. South: Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia 4. Midwest: Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin 5. Southwest: Arizona, New Mexico, Oklahoma, and Texas 6. West: Alaska, Colorado, California, Hawaii, Idaho, Montana, Nevada, Oregon, Utah, Washington, and Wyoming 7. Other: U.S. territories, protectorates, or freely associated states.
Vaccination Services	The administration of COVID-19 vaccines, including boosters, to Uninsured Individuals and Underinsured Individuals
Voucher	a) A document or digital document (on a phone) that contains the patient information and scheduled testing time. The test taker presents the printed voucher to the Contractor to indicate that they have registered for a test. The test voucher is combined with the collected sample to link the patient to their sample and track the sample to the next step in the testing process, thereby serving as a laboratory requisition. The test voucher can be a digital document on a phone. In this case, the test taker presents the digital voucher, and the Contractor will print out a physical voucher to be combined with the test sample. The voucher has no monetary value. b) A test voucher can also be a piece of paper with a registration number that allows a test taker to register for a test using pharmacy sites that are not funded by the Government. In this way, the government can support testing in pharmacies to populations at higher risk of COVID-19 disease or poorer health outcomes that are not located in high SVI areas or supported by the Government. Using the registration number on the voucher, the test taker can register for a no cost test instead of charging the test to the patient's health care insurance. The voucher has no monetary value.
Wrap-around Services	A testing partner's (Contractor) ability to conduct both of the following at the time that the result is communicated to the patient: 1.) Connect patients who receive positive or indeterminant COVID-19 test results with care linkages and/or available therapeutic interventions 2.) Provide COVID-19 vaccination access and informational resources to patients who receive negative COVID-19 test results. 3.) Linkage to the HHS RECOVER website

SECTION 2 – PURPOSE

In this effort, the Expansion of Screening and Diagnostics Task force (ESDTF) at the U.S. Centers for Disease Control and Prevention (CDC), which supports the inter-agency TDWG, seeks to increase equitable access to COVID-19 testing and vaccination through contractual relationships with private sector partners.

SECTION 3 – SCOPE OF WORK

The ICATT program objectives are achieved through four (4) primary efforts:

1.) Testing in pharmacies to ensure equitable access to COVID-19 testing
2.) Establishing surge testing sites and provide testing to provide infection control to populations at elevated risk of SARS-CoV-2 transmission
3.) Establishing community testing sites and provide testing to increase access to COVID-19 testing in under-resourced communities
4.) Administering COVID-19 vaccines to Uninsured and Underinsured Individuals to ensure equitable access to vaccines in the period following commercialization.

Additionally, the ESDTF ICATT Program will continue to expand testing and vaccination outreach, availability, and effectiveness. As needed, the Government shall increase or decrease the number of testing sites supported to adapt to the pandemic response needs. However, at this time it is the intention of the Government to maintain approximately 20,000 ICATT testing sites and for participating vendors to offer vaccination services at their retail locations across the U.S at which COVID-19 vaccinations are currently offered. The number of sites that the ICATT program will maintain may be subject to change as the response to the COVID-19 pandemic continues to evolve.

The contractor shall sustain surge testing capabilities to deploy to disease outbreak zones, including flexible off-site testing models to rapidly reach communities of interest. Contractors shall use appropriate testing methodologies in accordance with state and federal regulations to provide quality and timely results as described in 4.8.F.

To provide patients access to wrap-around services in addition to testing provided under ICATT, the Contractor shall integrate ICATT testing services with other related COVID-19 vaccination and therapeutics delivery services to the greatest degree possible at each testing site to create a single point of access. These wrap-around services are intended to help reduce morbidity and transmission of this disease. The Contractor shall maintain the capability to provide wrap-around services under this contract. Distribution of informational resources may be offered upon mutual agreement of the parties. Actual distribution of therapeutics if required during performance will be added via a bilateral modification.

The Contractor shall track and report data on testing and vaccination sites and tests and vaccinations performed and billed to ICATT. All such data collected by the Contractor will be entered into HHS Protect.

The Contractor shall adapt and implement strategies in collaboration with the government to respond to the changing pandemic environment, employ maintenance strategies to ensure testing capabilities are up to date and relevant, and implement efficiencies over time for cost and timeliness of services provided.

SECTION 4 – TASKS TO BE PERFORMED

1. General Tasks and Responsibilities

The Contractor shall provide the below tasks/services in locations that have been approved by the Government to address the COVID testing and vaccination needs of individuals in communities of interest covered under the ICATT program. All services reimbursed under this contract shall be provided at no cost to Uninsured Individuals and, as applicable to Vaccination Services, Underinsured Individuals.

The Contractor, in accordance with the relevant laws and regulations of state Departments of Health and other state agencies, officials or community partners related to specific site, shall perform the following (collectively, "Services"):

i. ***Testing Services:***

1. Provide full end-to-end processing of tests including patient registration/scheduling, application of screening criteria, ordering of the test by a licensed healthcare practitioner, operation of the testing site, transportation/delivery of test sample to lab (if needed based on testing model), conduct the test or arrange for the conducting of the test, notification of results to patients, input required HHS Protect system data,

and report positive and negative cases as directed by the relevant state and local Departments of Health. See "Specific Tasks" for more details.
2. Test according to specific criteria determined by the Centers for Disease Control & Prevention (CDC) unless otherwise agreed to by the Government: https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html.
3. Implement standard diagnostic testing quality assurance and controls per test kit manufacturer guidelines.

ii. ***Vaccination Services:***

1. Provide vaccinations in accordance with protocols determined by the CDC: https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html and https://www.cdc.gov/vaccines/covid-19/index.html;
2. Implement standard vaccine quality assurance and controls per manufacturer guidelines and in accordance with protocols established by the CDC: https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html
3. Comply with Vaccine Adverse Event Reporting System (VAERS) reporting requirements: https://vaers.hhs.gov/reportevent.html; and
4. Administer Vaccinations in conformance with the CDC Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

Unless otherwise waived, and to the extent applicable, the Contractor shall abide by all Federal and State guidelines, (e.g., Health Insurance Portability and Accountability Act (HIPAA)), needed to protect personal identity information.

2. Program Management and Staffing

A. The Contractor shall provide program management for the operation of the contract and shall provide organization, control systems, quality assurance and reporting procedures.
B. The Contractor shall meet on a weekly basis with ICATT program representatives on all aspects of the (b)(4)
C. The Contractor shall provide, maintain, and use all information technology (IT) systems necessary for the full discharge of activities required under this contract. Such systems include patient screening and registration, scheduling, chain of custody of specimens and tests, fulfilling public health reporting obligations, patient notification of test results, logistical support (e.g., timely delivery of all required testing related supplies), and capacity to report on all elements described in Attachments J.1 "Data Reporting Requirements."
D. Contractor shall report all elements described in Attachment J.1 "Data Reporting Requirements" as indicated in Attachment J.1.
E. Contractor shall report Over-the-Counter (OTC) test sales on at least a weekly basis, in accordance with Attachment J.1 "Data Reporting Requirements", Section E.
F. When partnering with another entity (e.g., state and local stakeholders, bases, etc.) in providing surge site testing infrastructure management and operations of event sites, the Contractor shall work with the state and/or local stakeholders to determine the appropriate testing strategies, logistics, site management, and implementation timelines, and operating hours for the sites. The Contractor may coordinate with the state/local Department of Health or other state/local agencies for the purposes of setting up and operating the site to accomplish any of the following: scheduling patients, site logistics, augmenting personnel, augmenting supplies, and augmenting security.
G. For the purposes of establishing and operating approved testing sites for scheduling patients, site logistics, augmenting personnel, augmenting supplies, and augmenting security, the Contractor shall coordinate with appropriate state/local Department of Health or other governing state/local agencies to determine the required policies and regulations for conducting ICATT services within their jurisdictions. It is the Contractor's responsibility to assure all services under this contract comply to these policies and regulations.
H. (b)(4)
I. Contractor shall ensure that contractor's sites currently providing no-cost testing supported by other federal agencies and programs (e.g., HRSA and/or ELC) will be excluded from ICATT-participation to the extent such other programs cover testing services provided at those sites.
J. Contractor shall provide Services:
    i. In compliance with Clinical Laboratory Improvement Amendment (CLIA) (including CLIA Certificates or Certificates of Waiver, or CLIA violations and Food and Drug Administration (FDA) regulations (including FDA EUA submissions or amendments).
    ii. Using tests and vaccinations with appropriate FDA Emergency Use Authorization (EUA) and Biological License Application (BLA).
    iii. In compliance with any regulatory barriers or requirements required for successful performance of

services (including FDA EUA submissions or amendments, CLIA Certificates or Certificates of Waiver, or CLIA violations at proposed sites).

iv. While implementing the conversion to private/public insurance reimbursement as summarized in Section 8.

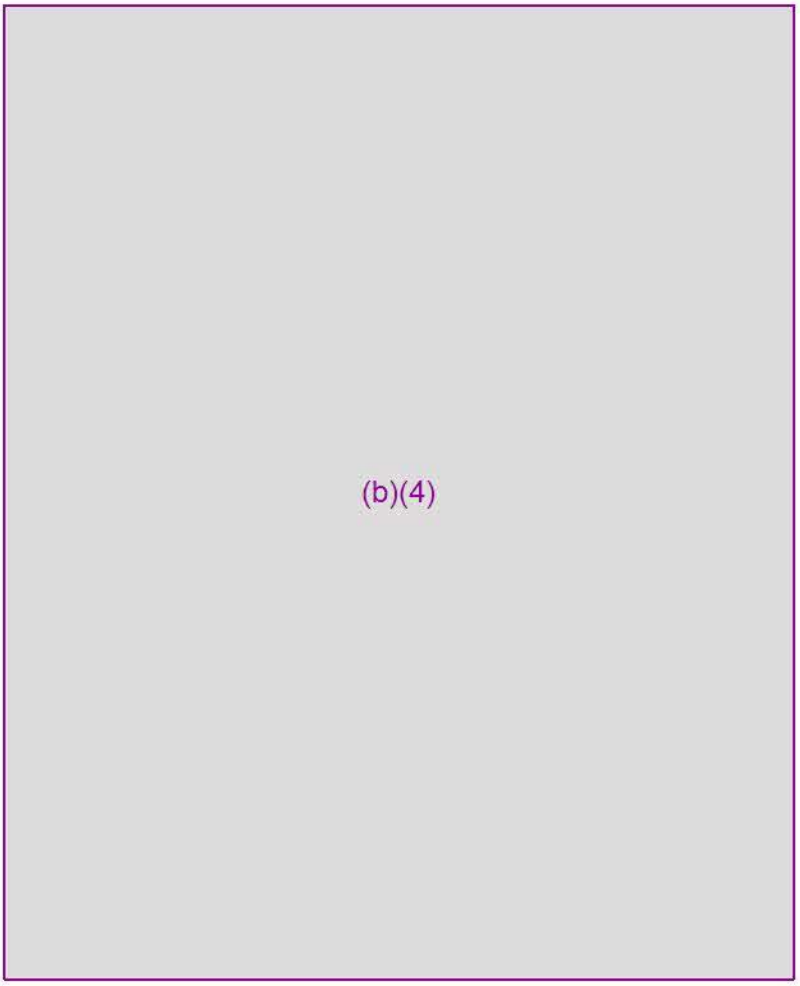
v. And while implementing the following the applicable Insurance Discovery/ process as set forth herein (below).

(b)(4)

K. Insurance Discovery:

Insurance Discovery – Vaccinations – Pharmacy: (b)(4)

(b)(4)



L. The Contractor shall provide, upon CDC request, ad hoc reports, mutually agreeable in number and scope, in order to clarify testing and vaccination data as required by the changing nature of COVID-19.

M. The contractor shall complete one final report for Testing Services and one final report for Vaccination Services and Outreach at the completion of each period of performance. The final reports shall include total testing and vaccination numbers for the period of performance. The reports should highlight areas of interest, trends, quality issues, and continuous improvement metrics. The reports should also include any challenges in the implementation of Section 8.

3. Site Locations

Testing Services Site Locations

A. The testing locations are sites that have been determined to benefit from enhanced access to testing, including pharmacies, community sites, and surge sites. It is the Government's desire to establish and maintain up to 20,000 approved test sites at locations covered by the ICATT program. From time to time, the Government may identify locations to be added, changed, and/or removed. When the Government requests a change and it is within the Contractor's locations covered under this Contract, upon mutual agreement of the Parties, the Contractor may make the change and/or add the location. The government will provide a one (1) week notice to expand or contract surge sites once all information to implement the site has been received by the contractor. (b)(4) (b)(4) The government will provide four (4) week notice for expansion or contraction of pharmacy sites. (b)(4) (b)(4) when mutually agreed upon the Contractor shall be able to scale up to this level with two weeks' notice if operating below the minimum at the direction of the Government. These sites shall meet the following criteria:

(b)(4)

(b)(4)

C. The Contractor shall also have the capability to conduct testing for periods of shorter duration (e.g., a couple of weeks) at offsite locations such as parking lots, aggregate settings, and population dense areas within two weeks of request and in inclement weather (temperate rain, heat, cold, wind), but not severe conditions where Contractor would be required to enact emergency actions plans as required under 29 CFR 1910.38 (https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.38).
D. The Contractor shall abide by all federal and state scope of practice laws, regulations, and policies. The parties expressly acknowledge that, in the event the provisions relating to the scope of practice of pharmacists, pharmacy interns, and pharmacy technicians set forth in the PREP Act Declaration (as amended) issued by the Secretary of HHS expire or are terminated, Contractor may not be able to provide the testing services described in this contract. In such event, the parties may meet and confer to determine a mutually acceptable solution.
E. The Contractor shall provide communications indicating that HHS funds the no-cost program and instructing patients how they should proceed to be tested.

Vaccination Services Site Locations

(b)(4)

B. The Contractor shall abide by all federal and state scope of practice laws, regulations, and policies. The parties expressly acknowledge that, in the event the provisions relating to the scope of practice of pharmacists, pharmacy interns, and pharmacy technicians set forth in the PREP Act Declaration (as amended) issued by the Secretary of HHS expire, are modified, or are terminated, Contractor may not be able to provide the Services described in this contract. In such event, the parties may meet and confer to determine a mutually acceptable solution.
C. The Contractor shall include a statement on its COVID-19 vaccination landing page and app that the CDC Bridge Program is funded by HHS/CDC. Contractor shall provide information to patients about how they may determine if they are eligible for no-cost vaccination through the Bridge program

Site Selection and Other Requirements

A. The Contractor must notify Government of any new Testing Services site locations and hours of operation before the Contractor begins work to ensure appropriate distribution and prevent duplication with other Contractors. The Government will review Contractor-recommended site locations and hours within seven days of submitting recommended sites within HHS Protect for review and approval. Surge sites may also be identified or recommended by state and federal government in consultation and coordination with the

Contractor

B. The Contractor shall use the Facility ID #, as provided by HHS Protect for each site location, when reporting in HHS Protect or through the states Immunization Information System.
C. Contractor shall report new Testing sites and site updates in accordance with Attachment J.1, section D.
D. The Contractor shall notify the government and provide a list of sites that are added or no longer providing Testing Services each week via email or other electronic reporting system as agreed between the Contractor and Government.
E. The Contractor shall ensure that HHS Protect records Services Sites statuses, site locations, site number, site metadata, and ICATT participation status correctly with the Government monthly as described in Attachment J.1, Section F. All status changes are reported to HHS Protect, COR, and the project manager.
F. The Contractor shall notify the Government seven calendar (7) days in advance before closing a site.
G. The Contractor shall update their Services sites with Google and Vaccination Services Sites on www.vaccines.gov on a biweekly basis with additions and closures as appropriate to ensure the public can locate Services sites.

4. Patient Registration and Consent

A. The Contractor shall provide an online platform which is smartphone compatible where patients can perform initial registration. The website shall be section 508 compliant. The website shall provide:
    i. Clear step by step description of the Services process. Each step shall be described using clear and simple language that a member of the general public would be able to understand.
    ii. Align with CDC national priorities: https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html
    iii. Refer patients to CDC testing guidance
    iv. Clear eligibility criteria
    v. Detailed guidance on no-cost testing
    vi. Acknowledgement of HHS funding support
    vii. A testing site map showing testing type, appointment availability, and operating hours for each testing location
    viii. Answers to frequently asked questions about Services (developed and maintained by the Contractor)
    ix. Type of testing available at each location
    x. How and when results will be returned
    xi. Requirements for testing children
    xii. Toll free point of contact for additional information
    xiii. Explanation if a pharmacy rejects testing according to CDC guidance
    xiv. Whether a doctor's referral is necessary for patient receipt of Services
B. Through the registration process or at the Services site, the Contractor shall request patient information through a screening process compliant with Attachment J.1, Exhibit A in Attachment J.1, and an informed consent for Services.
C. The Contractor shall implement screening criteria as provided by the Government (see Exhibit A in Attachment J.1, for current screening questions). The Contractor shall adopt a screening protocol that is consistent with the CDC priorities and guidelines for Services. The Government may change the criteria for Services; however, the Contractor shall have a reasonable amount of time to design, test, and implement new or revised screening questions in electronic interface used by the Contractor. The Contractor shall obtain approval from the Government to change any criteria. CDC publishes priorities for COVID-19 Services. This guidance can change periodically. It is the Contractor's responsibility to check the CDC website periodically for updates.
D. If the screening criteria are met, the Contractor shall, if applicable, arrange for a licensed healthcare practitioner to review and order the test. The Contractor shall have an integrated system for collecting information, tracking specimens, and reporting Services results. The Contractor may offer a standing order for Services if it complies with all federal and state laws and regulations.
E. The Contractor shall be capable of uploading a group of test takers from a digital list when testing in congregate settings.
F. The Contractor's registration process shall be available and efficient for walk-up test takers.
G. In addition to an electronic registration process, the Contractor shall provide for a paper registration process to allow for Services in environments where the electronic registration process would be less expedient than a paper registration process (e.g., registration of foreign nationals for whom the electronic registration process in English may present a barrier). The Contractor is responsible for subsequently capturing paper registrations in their electronic system.
H. The Contractor shall provide clear website communications that publicize the availability of no cost COVID-19 testing for Uninsured Indiviudals and no-cost COVID-19 vaccination for Uninsured and Underinsured Individuals. All materials should be shared with HHS for review and acknowledge HHS as the funder.

5. Site Preparation – Standup Testing Sites

A. The Contractor may coordinate or enter into an agreement with state and local governments to supply items necessary to fulfill testing site needs, including supportive infrastructure.
B. When providing full-service testing sites the Contractor shall have prepared all necessary equipment (e.g., swabs, personal protective equipment (PPE), traffic flow management, and tents) prior to test takers' arrivals.
C. For all new locations or sites where testing services have not been performed for over one (1) week, the Contractor shall undergo a testing dry run where a small number of test takers or the testing staff are tested, prior to operating at full capacity. Any site preparation or testing performance issues not resolved during the testing dry run shall be communicated to the Government by the end of the business day.
D. Sites shall have the ability to properly store and monitor the storage of testing supplies to assure quality.

6. Patient Verification

A. The Contractor shall be responsible for matching patients that arrive to the Services location to the correct laboratory requisition documentation. After verification, Contractor staff shall provide the FDA EUA authorized or fully approved testing kit or vaccine lot number that is appropriately linked to the patient.
B. The Contractor shall implement processes that allow for sample tracking and transfer of sample collection kits to the laboratories (if required) while preventing or severely limiting, to the extent practicable, direct interaction between the Contractor testing staff and the patient.

7. Patient Testing – Testing Services

A. When self-swab specimen collection is not be feasible, the Contractor shall collect the testing specimen via nasopharyngeal or via other swab administered by Contractor staff.
B. The patient/test taker will be responsible for conducting self-swab testing. The Contractor shall ensure specimen collection is done in accordance with relevant CLIA regulations, FDA EUA, and manufacturer instructions. If the patient cannot perform a self-swab, the Contractor shall ensure that a member of Contractor staff perform the swabbing procedure in accordance with CLIA and manufacturer instructions. Contractor may include a telehealth option for specimen collection observation.
C. The Contractor shall ensure all tests are performed according to FDA and CMS regulations, guidelines, and Frequently-Asked-Questions available from the CDC, FDA, and CMS websites.
D. The Contractor shall maintain a safe distance between Contractor testing staff and patients as per CDC guidance. In the event a safe distance cannot be maintained, the Contractor shall ensure that contractor personnel are equipped with the necessary PPE to safely perform testing.
E. The Contractor shall provide a location for patients to deposit self-collected specimens that meets the test manufacturer's specimen storage criteria and is in accordance with federal and state regulations.
F. The Contractor shall provide the following test methods, as appropriate to the testing site, as proposed by the Contractor and approved by the Government at the point of site registration in HHS Protect; in limited circumstances the Government will provide OTC tests. While many tests listed below are optional to propose, the Contractor is encouraged to apply a broad mix of tests and sites to ensure resource and test manufacturing limitations do not impact contract performance. (see 1.A definitions)
    a. Swab and Send (Laboratory-based NAAT) testing
        i. The Contractor shall provide specimen collection kits at agreed-upon testing sites for the patient or Contractor to perform sample collection, and then the Contractor shall send the specimen to a laboratory for NAAT testing.
        ii. Self-collection kits may be provided by the Contractor, test site partner, state/local government, or the federal government. The source of test will be decided at the sole discretion of the Government. Contractor shall include pricing structure for test administration when the test kit is provided by the Government
    b. Unobserved self-sample collection & laboratory-based NAAT testing (optional)
        i. Upon sixteen (16) weeks advanced written notice, the Contractor shall provide self-collection kits for the patient to pick-up at agreed-up on sites or receive by mail, and then the patient returns the specimen to specified drop-off locations or mails it directly to a laboratory for testing. If returned to designated drop-off location, the Contractor shall send the specimen to a laboratory for NAAT testing.
        ii. Self-collection kits may be provided by the Contractor, test site partner, state/local government, or the federal government. The source of test will be decided at the sole discretion of the Government. Contractor shall include pricing structure for test administration when the test kit is provided by the Government
    c. Point-of-Care (POC) NAAT testing
        i. The Contractor shall provide POC NAAT testing at agreed-upon testing sites.
        ii. Test kits may be provided by the Contractor, test site partner, state/local government, or the federal government. The source of test will be decided at the sole discretion of the

Government based on response needs and market conditions. Contractor shall include pricing structure for test administration when the test kit is provided by the Government

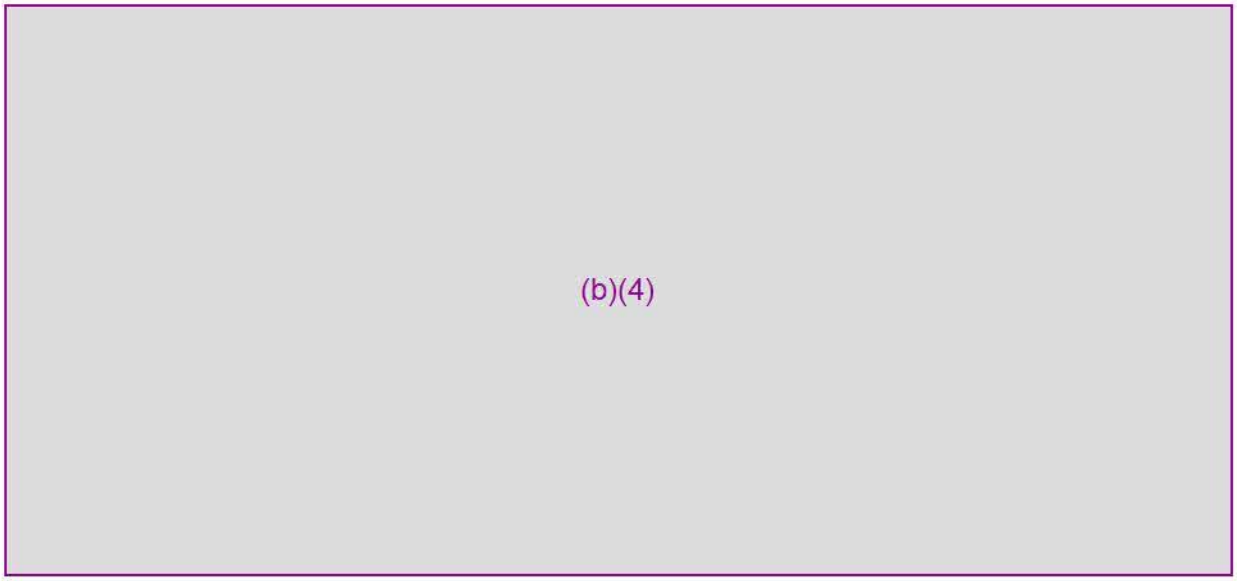
d. Point-of-Care (POC) Antigen testing
    i. The Contractor shall provide POC testing at agreed-upon testing sites.
    ii. Test kits may be provided by the Contractor, test site partner, state/local government, or the federal government. The source of test will be decided at the sole discretion of the Government based on response needs and market conditions. Contractor shall include pricing structure for test administration when the test kit is provided by the Government.
e. Confirmatory POC testing
    i. The Contractor shall provide POC testing at agreed-upon testing sites where antigen tests are used.
    ii. Test kits may be provided by the Contractor, test site partner, state/local government, or the federal government. The source of test will be decided at the sole discretion of the Government based on response needs and market conditions. Contractor shall include pricing structure for test administration when the test kit is provided by the Government.
    iii. Confirmatory testing will be offered, as appropriate based upon clinician evaluation, to a patient who receives a Contractor administered antigen test (excluding Lumira antigen tests) and receives a result that does not match symptoms.
f. Over-the-Counter Self-Testing
    i. To enhance access to COVID-19 testing and offer more options to those who choose not to get tested at sites or to focus testing on specific populations, the Contractor shall distribute self-testing over-the-counter kits. Self-Testing over-the-counter kits are those where the patient completes both the specimen collection and the testing of the specimen at home or other location using an approved specimen collection kit and testing device.
    ii. The Contractor track the number of tests distributed and the distribution location and send the data to the government using HHS Protect or other secured digital means as directed by the Government. If required by state regulations and not exempt by PREP Act or other federal authority, the Contractor shall ensure a licensed healthcare provider capable of providing guidance for the use of tests is available as part of the distribution of self-testing kits.
    iii. The Contractor shall develop a standard procedure to execute this task that may be optimized to suit different test distribution scenarios. The Contractor shall develop a plan, informational document, and playbooks for self-testing to be shared publicly. All such documents shall belong to the Government. Contractors shall have the right to unlimited access and use.
g. OTC COVID 19 Test Result Interpretation
    i. To support the use of cost effective over the counter home COVID 19 tests, Contractor shall be prepared in certain sites to offer consultations to assist patients in the interpretation of the results of such tests. Subject to the parties' mutual agreement, this may be expanded to non-OTC COVID 19 tests.
h. Multiplex Testing
    i. The Contractor shall provide specimen collection kits at agreed-upon testing sites for the patient or Contractor to perform sample collection, and then the Contractor shall send the specimen to a laboratory for NAAT testing (until 5/11/23).
    ii. Contractor may offer Multiplex testing to individuals who have onset of symptoms within three (3) days of their test appointment.

8. Specimen Security/Preparation, Storage, Shipping, and Testing – Testing Services

A. After the patient has deposited the used test kit in the collection area, the Contractor shall ensure that test kits are placed in appropriate storage and stored until processing in accordance with manufacturer instructions.
B. The Contractor shall be responsible for ensuring all collected samples are tested in compliance with Center for Medicare and Medicaid Services' (CMS) Clinical Laboratory Improvement Amendments (CLIA). Consistent with the site selection and approval process identified in section 4.4.A, above, review of approval request shall occur with seven days of request submission.
C. If testing is done at an off-site commercial lab subcontractor, the Contractor shall abide by all shipping and handling guidance when shipping specimens to its commercial lab subcontractor. The Contractor is responsible for all contracts, relationships, and payment with commercial lab subcontractors.

9. Notification of Results – Testing Services

(b)(4)



C. The Contractor must comply with all state and local laws regarding reportable conditions, including but not limited to reporting to the relevant public health authorities with all data elements required by jurisdiction for submission of reportable results. The contractor shall ensure this compliance flows down to all subcontractors.

10. Surge Site Infrastructure Management – Testing Services

A. The Contractor shall be equipped to provide site management in the event that surge site partners (such as state, local governments, or federal agencies) are not able to provide these services. The Government will identify surge sites and provide surge site testing authorization based on ICATT program needs.

B. A mutual agreement between Contractor and the Government as to whether surge site infrastructure management is needed shall be made on a site-by-site basis.

C. Contractor surge site management responsibilities include:

i. Biohazardous waste management and disposal (e.g., gloves, masks)

ii. Physical management of the site to include:

1. Site interaction with site point of contact for all logistics coordination
2. Clinical staffing; traffic control within site; managerial staffing
3. Nonmedical equipment including tents, cones, tables, chairs, electric power, generator, heaters, porta potty (if restroom unavailable)
4. Storage of specimens in accordance with manufacturer instructions
5. An unarmed security guard who can contact local police and deescalate low level security concerns when conditions warrant security presence and/or at the recommendation of the local jurisdiction.

iii. Provision of laptops; printers; supplies for printing

iv. Subject Matter Expert (SME) on technology platform for registration, technology, and troubleshooting

v. Office supplies including Sharpies, pens, paper

vi. Wi-Fi access hot spots

vii. Printed informational materials (as needed)

viii. Managing storage; inventory/reporting and redistribution of supplies (laptops, test kits, PPE) from storage location to sites when required

ix. Coordination of returning unused supplies at the end of surge site events

x. Assignment of a POC per site for shipping or courier service driver/dispatch to contact upon arrival

xi. Daily delivery of specimens to an appropriate shipping or courier drop-off location when a site is not at a physical street address (e.g., a park and ride) or in rural areas that do not have regular pickup service.

xii. Staffing for registration/check-in for onsite patient registration and line management

xiii. Designated clinical staff assigned to be on point for medical emergencies

xiv. On-site advertising of the event

D. Surge sites established in the US Affiliated Pacific Islands and Territories may incur additional management fees due to increased logistical challenges with sample processing.

11. Drive Through-Independent Testing Approaches – Testing Services

A. The Contractor shall provide at least one testing approach independent of the need for a drive-through that can be implemented at pharmacy sites. These testing models may include testing in pharmacy parking lots or offsite locations and/or unobserved, self-sample collection and testing, as described below.

B. Parking Lot and Offsite Testing
   i. The model is intended to allow for testing of at least 100 people per day, whether walk up or drive up. Appropriate signage shall be displayed to promote and direct testing.
   ii. The site shall offer reasonable protection from weather so that the site can be operated year-round, including in inclement weather (reference section 4.3.C).
   iii. The contractor shall be able to move testing sites within two weeks' notice to mutually agreed upon locations.
   iv. Testing can be POC, laboratory based, or other suitable method and the testing fee should reflect the testing method. The contractor shall also develop the capability to conduct testing at offsite non-pharmacy locations, which may include non-parking lot sites, such as a stadium infield, school gymnasium, community center, or green space.

C. Unobserved, Self-Sample Collection and Drop-Off
   i. To improve the efficiency of COVID-19 testing and offer options to those who cannot be tested in a traditional setting (i.e., drive through testing), the Contractor shall provide a self-collection kit that can be performed at home or other location.
   ii. The patient is responsible for returning completed sample collection kits to drop off locations for testing, such as pharmacies drop boxes or smart lockers, for pick up and testing by the Contractor.
   iii. At drop-off sites, the Contractor shall continue to be responsible for the same specific tasks and technical requirements as outlined for other testing sites (reference sections 4.1 – 4.C).
   iv. Contractor shall ensure that all unobserved, self-sample collection and testing signage and other promotional paraphernalia clearly acknowledge HHS funding support.

12. Submission of Specimens of Interest for Further Characterization – Testing Services

A. The Contractor shall submit specific specimens for further characterization (e.g., genomic sequencing) to state or federal laboratories as identified by the Government.

B. The Contractor shall work with the testing laboratory to identify, aliquot and provide the necessary metadata to be shipped with each sample to the state or federal facility in accordance with International Air Transport Association (IATA), state, and federal guidelines.

13. Combined Testing/Wraparound Services

(b)(4)

14. Support Services

A. (b)(4)

15. Contract Additional Services Line Items

A. Given the uncertainty of changing testing and vaccination needs, the Government may elect to exercise a contract line-item option of varying percentages of the base task to support additional Testing or Vaccination Services as specified in Section B.

B. In addition, the Government may elect to exercise a separate optional line item for Additional Vaccination Services for the administration of additional doses of COVID-19 vaccines from October 1, 2024 to December 31, 2024.

16. Vaccination Services

A. The Contractor shall provide Vaccination Services as follows:
   i. The Contractor shall procure and store COVID-19 vaccinations.
   ii. The Contractor shall administer COVID-19 vaccinations, including booster doses, to Uninsured Individuals and Underinsured Individuals.
   iii. In the pharmacy setting, unless otherwise stated in this Agreement, the Contractor shall not charge any Cost-Sharing to Uninsured Individuals or Underinsured Individuals or seek reimbursement from the Government for Vaccination Services rendered under this contract except as outlined within this contract.
   iv. Notwithstanding the above, the parties expressly acknowledge that, in the event CVS is unable to procure a sufficient supply of vaccine on a net no-cost basis from Manufacturers, CVS may not be able to provide the Vaccine Services as described in this contract. In such event, the parties may meet and confer to determine a mutually acceptable solution.
   v. Notwithstanding the above, the parties expressly acknowledge that in the event there are changes to current vaccine regulations, procurement, storage, or handling requirements that are beyond CVS's control, CVS may not be able to provide the Vaccine Services as described in this contract. In such event, the parties may meet and confer to determine a mutually acceptable solution.

B. The Contractor shall provide necessary staff and licenses to perform all contracted vaccination services;

C. The Contractor shall procure, as specified, and ensure all necessary space, equipment, and storage is available for safe and secure administration and storage COVID-19 vaccines;

D. The Contractor shall perform Outreach as defined in Section C.1.A.

E. The Contractor shall participate in a weekly coordination call with CDC staff and other funded pharmacies, health centers, and health departments to coordinate procurement of vaccinations to meet the needs of areas with high numbers of uninsured and underinsured populations or low vaccination rates;

F. The Contractor shall leverage data and technical assistance, made available by CDC, to determine the locations that the uninsured, underinsured and unvaccinated populations, as well as to understand features and demographics of selected low-vaccinated areas;

G. The Contractor shall report the following data funded by this contract to CDC monthly and discuss during regular check-ins with CDC staff:
   i. Vaccination Data
   (b)(4)
   ii. Outreach Data
      a) (b)(4)
   iii. Other data elements to be reported, if applicable, (b)(4)
   (b)(4)

SECTION 5 – GOVERNMENT FURNISHED MATERIALS

To the extent applicable to the Services methodology utilized, the Government may, at its discretion:

1. Give access to playbooks, SOPs, one-pagers, and other informational resources.
2. Assist with sourcing (but not procuring) nasal swab test kits needed to operate the self-swab testing sites.
3. Assist with communicating to state and local Departments of Health where private sector partners (e.g., retailers, pharmacies, clinics) would like to operate these sites.
4. Assist by providing data and guidance on which counties, states, and regions to place self- swab sites.
5. Assist by providing data and technical assistance on where uninsured and underinsured people live and the locations if low-vaccination coverage areas, as well as to help understand features and demographics of selected low-vaccinated areas.
6. Provide testing materials (e.g., test kits, PPE) when pandemic response needs and market conditions require government provision in order ensure expedient and safe ICATT testing availability.
7. Give access to HHS Protect and state IIS systems for reporting purposes.
8. Training to HHS Protect and use of state IIS systems, as needed.

SECTION 6 – PERIOD OF PERFORMANCE

See Section B for period of performance dates.

SECTION 7 – DELIVERABLES/REPORTING SCHEDULE

Item	SOW Reference	Deliverable Description	Date of Delivery
1.a	See: Section 4 and Attachment J.1.a and J.1.b, Sections A – C	Daily Services Reports, including Patient Screening and Demographics and Services Encounter Data	Daily (Unless otherwise agreed upon by the Government)
1.c	Section 4 and Attachment J.1.c	Outreach Summary Data	Monthly
2	See: Section 4 and Attachment J.1, Section C	Services Site Data	Prior to Site Launch (Unless otherwise agreed upon by the Government)
3	See: Attachment J.1, Section E	Over-the-Counter COVID-19 Test Sales	Weekly (Unless otherwise agreed upon by the Government)
4	See: Section 4 and Attachment J.1, Section F	Testing Site Metadata	Monthly (Unless otherwise agreed upon by the Government
5	See: Section 4	Site Updates with Google for testing and www.vaccines.gov for vaccines	Biweekly (Unless otherwise agreed upon by the Government
6	See Section 4 and J.1.b	Vaccination Monthly Report, includes monthly percentage of Vaccinations by payor (private insurance, Medicaid, Medicare, and cash payments)	Monthly (Unless otherwise mutually agreed upon)
7.a	Section 4	Final Report Testing	Within 30 days preceding the end of the Period of Performance.
7.b	Section 4	Final Report Vaccinations	Within 30 days preceding the end of the Period of Performance.
8	Section 4	Insurance Audit Report	Monthly

SECTION 8 – ICATT Vulnerable Population Testing and Reimbursement Shift to Private or Public Insurance Payments, and Low-Vaccination Coverage Payments

Vulnerable Population Testing : (b)(4)

(b)(4)

(b)(4)

Billing Laboratory Tests to Public/Private Insurance

(b)(4)

Low-Vaccination Coverage Payments: To achieve program goals, the Contractor shall have an opportunity to receive separate, firm fixed price payments for vaccinations performed in census tracts that meet the definition of a "low-vaccination area."

(b)(4)

SECTION 9 – SPECIAL CONSIDERATIONS (Individual sections of this Section 9 that are not applicable are noted)

A. Baseline Security Requirements

1) Applicability. The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:

a. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.

b. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) employee will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

2) Not applicable - Safeguarding Information and Information Systems. In accordance with the Federal Information Processing Standards Publication (FIPS)199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall:

a. Protect government information and information systems in order to ensure:

• Confidentiality, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;

• Integrity, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and

• Availability, which means ensuring timely and reliable access to and use of information.

b. Provide security for any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor on behalf of HHS regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, within one (1) hour or less, bring the situation to the attention of the other party.

c. Adopt and implement the policies, procedures, controls, and standards required by the HHS Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the HHS Information Security Program security requirements, outlined in the HHS Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing fisma@hhs.gov.

d. Comply with the Privacy Act requirements and tailor FAR clauses as needed.

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3) Information Security Categorization. In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Appendix C, and based on information provided by the ISSO, CISO, or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Information Type	**Confidentiality**	**Integrity**	**Availability**
C.2.8.9 Personal Identity and Authentication	Moderate	Moderate	Moderate
D.14.1 Access to Care Information	Moderate	Moderate	Low
D14.2 Population Health Management and Consumer Safety	Moderate	Moderate	Low
D.14.3 Health Care Administration	Moderate	Moderate	Low
D.14.4 Health Care Delivery Services	Moderate	Moderate	Low
Overall Risk	Moderate	Moderate	Moderate

Based on information provided by the ISSO, Privacy Office, system/data owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:

[ ] No PII [X] Yes PII

4) Personally Identifiable Information (PII). Per the Office of Management and Budget (OMB) Circular A-130, “PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual.” Examples of PII include, but are not limited to the following: social security number, date and place of birth, mother‘s maiden name, biometric records, etc.

PII Confidentiality Impact Level has been determined to be: [ ] Low [X] Moderate [ ] High –Not applicable, system is not processing PII of any type.

5) Not applicable - Controlled Unclassified Information (CUI). CUI is defined as “information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information.” The Contractor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information,

(implemented at 32 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "handling" refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

a. marked appropriately;

b. disclosed to authorized personnel on a Need-To-Know basis;

c. protected in accordance with NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and

d. returned to HHS control, destroyed when no longer needed, or held until otherwise directed.

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Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

6) Not applicable - Protection of Sensitive Information. For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, Protection of Sensitive Agency Information by securing it with a FIPS 140-2 validated solution.

7) Confidentiality and Nondisclosure of Information. Any information provided to the contractor (and/or any subcontractor) by HHS or collected by the contractor on behalf of HHS shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any HHS records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and [CDC] policies. Unauthorized disclosure of information will be subject to the HHS/[CDC] sanction policies and/or governed by the following laws and regulations:

a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);

b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and

c. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

8) Internet Protocol Version 6 (IPv6). All procurements using Internet Protocol shall comply with OMB Memorandum M-05-22, Transition Planning for Internet Protocol Version 6 (IPv6). .

9) Not applicable - Government Websites. All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.

10) Contract Documentation. The Contractor shall use provided templates, policies, forms and other agency documents to comply with contract deliverables as appropriate.

Security baseline deliverables

Document Section	Deliverable Title/Description	Due Date
2 – Rules of Behavior	Signed ROB for all employees accessing HHS Protect	Initiation of contract and at least annually thereafter
2 – Personnel Security Responsibilities	List of Personnel with defined roles and responsibilities	Prior to performing any work on behalf of HHS

11) Not applicable - Standard for Encryption. The Contractor (and/or any subcontractor) shall:

a. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.

b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI],

CDC Implementation of HHS Security and Privacy Language for Information and Information Technology Procurements Language, Version 1.0 Page 13 Office of the Chief Information Security Officer (OCISO) proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.

c. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and CDC-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).

d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the COR.

e. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys.

12) Not applicable - Contractor Non-Disclosure Agreement (NDA). Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the CDC 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.

13) Not applicable - Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) – The Contractor shall assist the CDC Senior Official for Privacy (SOP) or designee with conducting a PTA for the information system and/or information handled under this contract in accordance with HHS policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

a. The Contractor shall assist the CDC SOP or designee in reviewing the PIA at least every three years throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the CDC SOP that a review is required based on a major change to the system (e.g., new uses of information collected, changes to the way information is shared or disclosed and for what purpose, or when new types of PII are collected that could introduce new or increased privacy risks), whichever comes first.

B. Training – Not Applicable to this Contract

1) Mandatory Training for All Contractor Staff. All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/CDC Contractor Information Security Awareness, Privacy, and Records Management training (provided upon contract award) before performing any work under this contract. Thereafter, the employees shall complete CDC Security Awareness Training (SAT), Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS training policies.

2) Role-based Training. All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training (RBT)

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at least annually in accordance with HHS policy and the HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum.

All HHS employees and contractors with SSR who have not completed the required training within the mandated timeframes shall have their user accounts disabled until they have met their RBT requirement.

3) Training Records. The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall be provided to the CO and/or COR within 30 days after contract award and annually thereafter or upon request.

C. Rules of Behavior

1) The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior.

2) All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least annually thereafter, which may be done as part of annual CDC Security Awareness Training. If the training is provided by the contractor, the signed ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

D. Not applicable - Incident Response

FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cybersecurity and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose.

OMB Memorandum M-17-12, "Preparing for and Responding to a Breach of Personally Identifiable Information" (03 January 2017) states:

Definition of an Incident:

An occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.

Definition of a Breach:

The loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose.

It further adds:

A breach is not limited to an occurrence where a person other than an authorized user potentially accesses PII by means of a network intrusion, a targeted attack that exploits website vulnerabilities, or an attack executed through an email message or attachment. A breach may also include the loss or theft of physical documents that include PII and portable electronic storage media that store PII, the inadvertent disclosure of PII on a public website, or an oral disclosure of PII to a person who is not authorized to receive that information. It may also include an authorized user accessing PII for an other than authorized purpose.

The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII".

Contracts with entities that collect, maintain, use, or operate Federal information or information systems on behalf of CDC shall include the following requirements:

1) The contractor shall cooperate with and exchange information with CDC officials, as deemed necessary by the CDC Breach Response Team, to report and manage a suspected or confirmed breach.

2) All contractors and subcontractors shall properly encrypt PII in accordance with OMB Circular A-130 and other applicable policies, including CDC-specific policies, and comply with HHS-specific policies for protecting PII. To this end, all contractors and subcontractors shall protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.

3) All contractors and subcontractors shall participate in regular training on how to identify and report a breach.

4) All contractors and subcontractors shall report a suspected or confirmed breach in any medium as soon as possible and no later than 1 hour of discovery, consistent with applicable CDC IT acquisitions guidance, HHS/CDC and incident management policy, and United States Computer Emergency Readiness Team (US-CERT) notification guidelines. To this end, the Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC) or CDC Computer Incident Response Team (CSIRT) within 24 hours via email at csirt@cdc.gov or telephone at 866-655-2245, whether the response is positive or negative.

5) All contractors and subcontractors shall be able to determine what Federal information was or could have been accessed and by whom, construct a timeline of user activity, determine methods and techniques used to access Federal information, and identify the initial attack vector.

6) All contractors and subcontractors shall allow for an inspection, investigation, forensic analysis, and any other action necessary to ensure compliance with HHS/CDC Policy and the HHS/CDC Breach Response Plan and to assist with responding to a breach.

7) Cloud service providers shall use guidance provided in the FedRAMP Incident Communications Procedures when deciding when to report directly to US-CERT first or notify CDC first.

8) Identify roles and responsibilities, in accordance with HHS/CDC Breach Response Policy and the HHS/CDC Breach Response Plan. To this end, the Contractor shall NOT notify affected individuals unless and until so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, all notifications must be pre-approved by the appropriate CDC officials, consistent with HHS/CDC Breach Response Plan, and the Contractor shall then send CDC- approved notifications to affected individuals; and,

9) Acknowledge that CDC will not interpret report of a breach, by itself, as conclusive evidence that the contractor or its subcontractor failed to provide adequate safeguards for PII.

E. Position Sensitivity Designations

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR).

Investigation	PositionRequirement
__ NAC	National Agency Check
__ Tier 1	Low-Risk Non-Sensitive, including HSPD-12 Credentialing
__ Tier 2s *(with subject interview)*	Moderate-Risk Public Trust (MRPT)
__ Tier 3	Non-Critical Sensitive, National Security, including Secret and "L" access eligibility
__ Tier 4	High-Risk Public Trust
__ Tier 5	Critical Sensitive and Special Sensitive, National Security, including Top Secret, SCI, and "Q" access eligibility
_X_ Not Applicable	No Requirement

F. Homeland Security Presidential Directive (HSPD)-12 – Not Applicable to this Contract

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; FIPS

201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.

For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12)

Roster. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO by the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted immediately upon change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member.

If the employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level.

G. Contract Initiation and Expiration – Not Applicable to this Contract

1) General Security Requirements. The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology and in accordance with the HHS Contract Closeout Guide (2012).

HHS EA requirements may be located here: https://www.hhs.gov/ocio/ea/documents/proplans.html

CDC EPC Requirements: https://www2a.CDC.gov/CDCup/library/other/eplc.htm

2) System Documentation. Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, Security Considerations in the System Development Life Cycle, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

3) Sanitization of Government Files and Information. As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

4) Notification. The Contractor (and/or any subcontractor) shall notify the CO and/or COR and system ISSO before an employee stops working under this contract.

5) Contractor Responsibilities Upon Physical Completion of the Contract. The contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or CDC policies.

6) The Contractor (and/or any subcontractor) shall perform and document the actions identified in the CDC Out-Processing Checklist (http://intranet.cdc.gov/od/hcrmo/pdfs/hr/Out_Processing_Checklist.pdf) when an employee terminates work under this contract. All documentation shall be made available to the CO and/or COR upon request.

H. Records Management and Retention

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS policies and shall not dispose of any records unless authorized by HHS.

Electronic and Information Technology Accessibility

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities,

unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access-aboard.gov/sec508/standards.htm.

(c) The Section 508 accessibility standards applicable to this contract are: 1194.
205 WCAG 2.0 Level A & AA Success Criteria
302 Functional Performance Criteria
502 Inoperability with Assistive Technology
504 Authoring Tools
602 Support Documentation
603 Support Services

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and documentation detail - whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://hhs.gov/web/508.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(e) Electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at http://508.hhs.gov/, or from the Section 508 Coordinator listed at https://www.hhs.gov/web/section-508/additional-resources/section-508-contacts/index.html. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Representative.

Vaccination Services, Government Monitoring:

(b)(4)

Section J – List of Attachments

Attachment J.1 – Testing Data Reporting Requirements
Attachment J.1.b – Vaccination Data Reporting Requirements
Attachment J.1.c. – Summary of Outreach Conducted for Bridge Access Program

Attachment J.1 Vaccination: Data Elements for Vaccines (Bridge Program)

Vaccination data enumerated in sections A through B below shall be reported daily to the HHS Protect system or other system designated by the Government. Site Data enumerated in section C shall be reported to the Government upon launch of a new site and then ongoing on a weekly basis.

CDC routinely collects patient demographic data to inform the equitable and efficient administration of our programs. The data will be uploaded and processed in a secured environment rate for PII. This data is being collected in compliance with 45C.F.R. part 46.102(l)(2), 21C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.

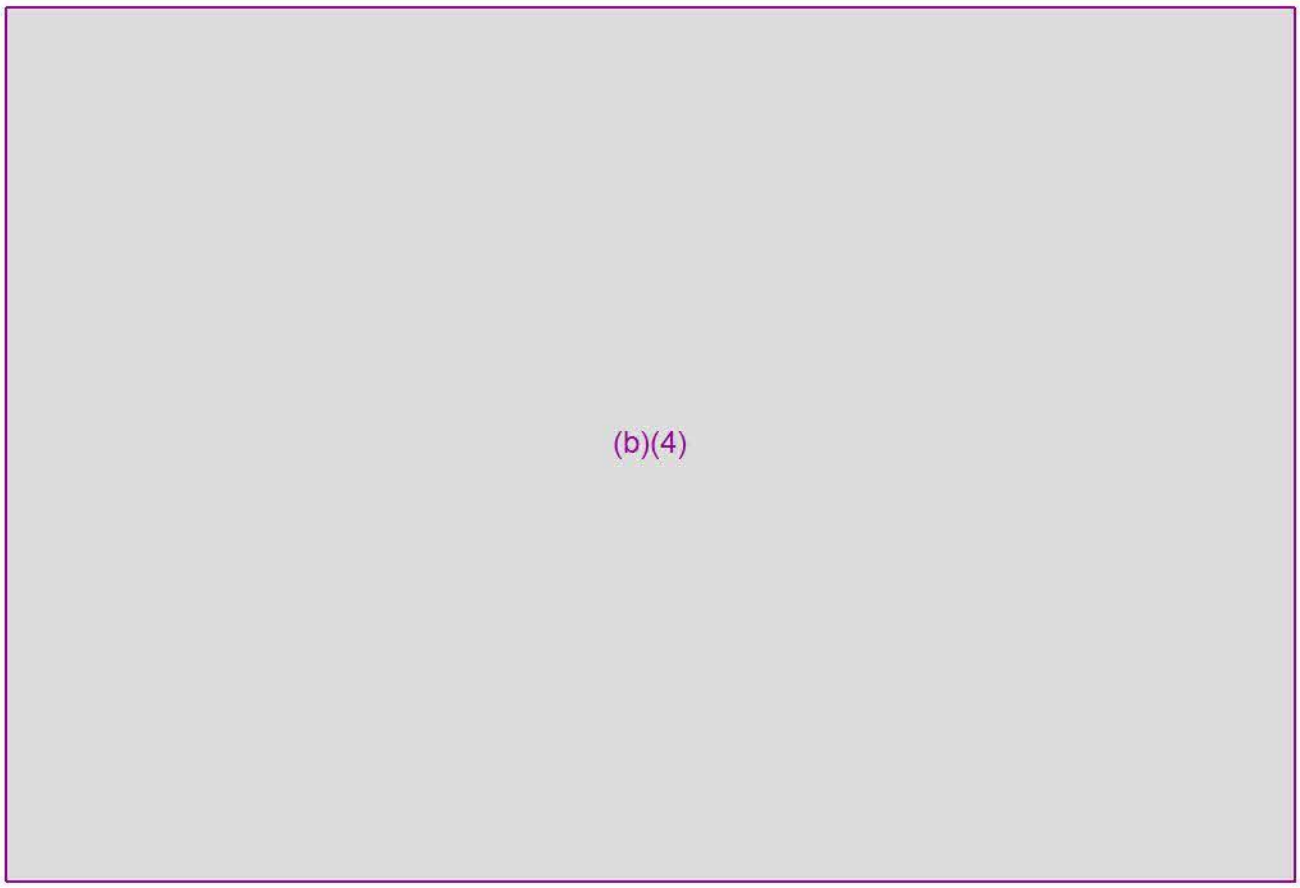
Fields present in pre-existing J1 document
New fields required

A. Vaccination Related Fields

Field Name	Format	Description/Options	Example	Vendor-Specific Notes
(b)(4)				

B. Patient-Related fields

Field Name	Format	Description/Options	Example	Vendor-Specific Notes
(b)(4)				



C. Vaccination Site Related Fields

Field Name	Format	Description/Options	Example	Vendor-Specific Notes
(b)(4)				

(b)(4)

(b)(4)

Attachment J.1 - Data Reporting Requirements

Testing data enumerated in sections A through C below shall be reported daily to the HHS Protect system or other system designated by the Government. Test result and patient data shall be reported in HHS Protect within 24 hours of receipt of result interpretation.

A. Test-Related Fields

Field Name	Format	Description/Options	Example
Resulted Date	MM/DD/YYYY	The date the sample is resulted.	11/01/2021
(b)(4)			

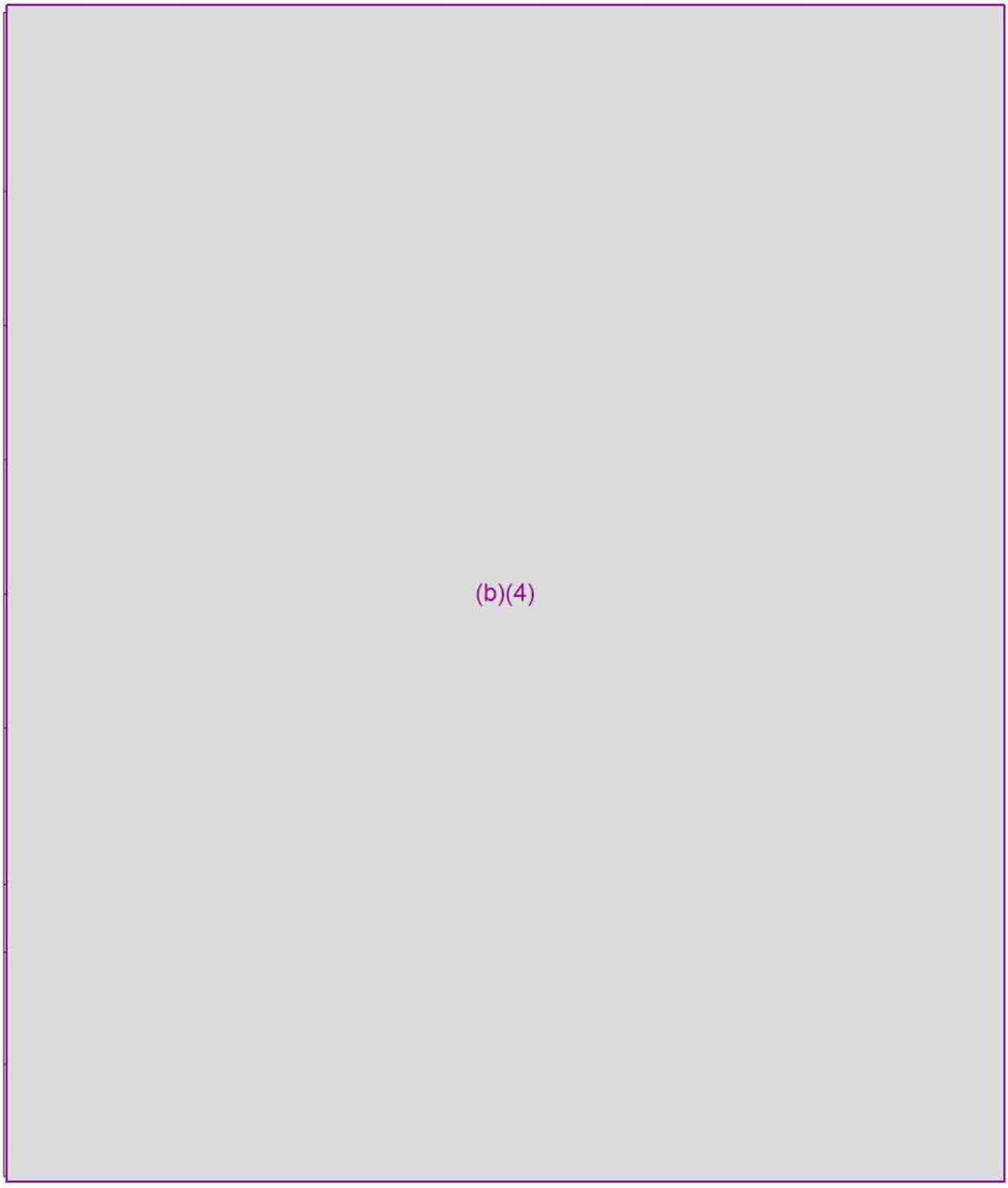
B. Patient-Related Fields

Field Name	Format	Description/Options	Example
(b)(4)			

C. Screening Questions Fields

Field Name	Format	Description/Options	Example
(b)(4)			

(b)(4)



A draft of the screening questions provided by the Government is included in this Statement of Work under Exhibit A, ICATT Pharmacy Screening Questions. The Contractor shall use these screening questions in the wording provided by the Government. However, the Contractor may consult with the Government on modifying question wording or response options to suit its testing circumstances.

The Contractor may ask additional screening questions subject to the following conditions:

- The Government-provided screening questions are the first screening questions asked.
- Additional questions are approved by the Government.

The Contractor may report additional fields upon Government approval. The Contractor is not required to report the results of additional questions that it may ask.

D. Testing Site Data

Testing site data shall be reported by the Contractor to the Government in advance of the site beginning testing. Testing at any site is subject to Government approval. Testing site data shall be reported by the Contractor to the HHS Protect system or other system designated by the Government.

Field Name	Format	Description/Options	Example
(b)(4)			