AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
	1		39

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
00006	9/13/2023	000HCVG1-2023-80748	

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.
WALGREEN CO. 200 WILMOT RD STE 2002 DEERFIELD, IL 60015-		9B. DATED *(See Item 11)*
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. 75D30122C13958
		10B. DATED *(See Item 13)* 06/01/2022

CODE	HRE3UMLEM2P5	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 $83600000.00

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.)*
See Section 2

Vendor POC: Anita Patel (b)(6)
Contract COR: Mary Hoelscher – mzr1@cdc.gov - 404.639.5446
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
Richard Gates, SVP, Chief Pharmacy Officer	Lauren Peel

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b)(6) *(Signature of person authorized to sign)*	9/15/23	BY Lauren Peel -S *(Signature of Contracting Officer)*	Digitally signed by Lauren Peel -S Date: 2023.09.15 19:52:06 -04'00'

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

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

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

    a. Add Option Period 1.1 (09/13/2023 – 09/30/2024) Items:

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

        ii. CLIN 1004 Option: 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)

3. Update Section J – List of Attachments to add: Attachment J.1.b – Vaccination Data Reporting Requirements and Attachment J.2 - Data Use Agreement.

4. Total contract funded amount is increased by $83,600,000.00 from (b)(4) to $ (b)(4)

5. 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 Section C.	1 Job	(b)(4)	
	Line(s) Of Accounting: 9390K12 2512 2022 75-X-0140 C6B3121101 (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 (02/13/2023 – 11/30/2023) Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0003	Digital Link to NIH Recover Website Link Website/Test Reports to NIH Recover Program Website	1 Job	(b)(4)	

Option Period 1 (12/01/2023 – 5/31/2024) Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
1001	ICATT Testing Services in accordance with Section C.	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 (9/13/2023 – 09/30/2024) Items:

ITEM	SUPPLIES / SERVICES	QTY/UNIT	UNIT PRICE	EXTENDED PRICE
1003	**Vaccination Services** Services in accordance with Section C Period of Performance: 9/13/2023 – 9/30/2024	1 Job	(b)(4)	
	Line(s) Of Accounting: 9390LR9 2512 2023 75-X-0140 C6R6111101 (b)(4)			
1004	**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. Services in accordance with Section B.2.b Period of Performance: 9/13/2023 – 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 Section C.	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		

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

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

Option Period 3 (12/01/2024 – 5/31/2025) Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
3001	ICATT Testing Services in accordance with Section C.	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.1.1 Unit Pricing

Testing Services Pricing

Test Type per Setting	Unit	Price
Swab and Send- Pharmacy / Retail insurance reimbursement	Per Test	(b)(4)
Swab and Send- Uninsured or US Territory	Per Test	
Swab and Send (test cost reimbursed by HRSA, CMS, or private insurance reimbursement)	Per Test	
Unobserved self-collection and testing	Per Test	
Unobserved self-collection and testing (test cost reimbursed by HRSA, CMS, or private insurance reimbursement) - Distributed	Per Test	
POC NAAT- Pharmacy / Retail Uninsured or Not Covered by insurance	Per Test	
POC NAAT- Pharmacy / Retail (test cost reimbursed by HRSA, CMS, or private insurance reimbursement)	Per Test	
POC NAAT- Pharmacy /Retail (test provided by USG)	Per Test	
POC NAAT- **Non-**Pharmacy/Retail	Per Test	
POC NAAT- **Non-**Pharmacy/Retail (test provided by USG)	Per Test	
Extended hour testing (in addition to the per test cost)	Additional Cost Per Test	
Sample Accessioning and Shipping for further characterization	Per Test	
Testing Support Services (environmental support for non-English speakers, elderly, young children, people with disabilities, etc.)	Per Test	
Confirmatory POC testing at Federally Supported Sites (test provided by USG)	Per Test	
Point of Care Antigen Testing at Surge sites and Federally Supported Sites (test provided by USG)	Per Test	
Surge Site Infrastructure Management Fee	Per Site	
Point of Care Antigen Testing	Per Test	
Point of Care Antigen Testing billed to insurance (80%)	Per Test	
Point of Care Antigen Testing (test provided by the USG)	Per Test	
Diagnostic Sequencing	Per sample	
Pooled Sample Testing	Per sample	
Multiplex test (see definition table C.1 subsection A)	Per Test	
OTC test distribution (test provided by USG)	Per Test	

Vaccination Services Pricing

Vaccination Service	Price	Unit
Vaccine Administration – Uninsured Individuals	(b)(4)	Per Vaccination
Vaccine Administration – Underinsured Individuals		Per Vaccination

B.1.2 ICATT Vulnerable Population Testing, Reimbursement Shift to Private or Public Insurance, Low Access Area, and Low Vaccination Area Payments*

	Price	Unit	Estimated Quantity/Ceiling
Vulnerable Population FFP Payment**	(b)(4)	Per Test (b)(4) (b)(4)	
ICATT FFP Payment for when Billing Laboratory Tests to Public/Private Insurance Rather than ICATT Program		(b)(4)	(b)(4)

Low Access Area Per Dose Payment	(b)(4)	Per Qualifying Vaccine	(b)(4)
Low Access Area Site Stand-Up Payment		Per New Site	
Low Vaccination Area Payment		Per Qualifying Vaccine	
Low Vaccination Area Site Stand-Up Payment		Per New Site	

(b)(4)

*Each Vaccination Service is only eligible for either the Low Access Area per dose payment or the Low Vaccination Area per dose payment, and each Vaccination Service site is only eligible for either the Low Access Area per site payment or the Low Vaccination Area per site payment. Site stand-up payments are only applicable to the establishment of new sites in those areas and existing sites would not qualify.
**The per qualifying test shall be invoiced at the end of each period of performance.

B.1.3 ICATT Linkage to other HHS Programs

	Price
Link Website to HHS Programs	(b)(4)

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

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

If such Additional Services are required, the Government will determine the estimated level of effort (LOE) that is needed. The estimated LOE will be provided to the Contractor for its confirmation of the total. The Contracting Officer may exercise the option by written notice to the Contractor 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 at the time it is exercised and may be for a different period of time than other line items in this contract. The vendor will be notified in writing, by letter or email, at least fifteen (15) days before the option is to be exercised. followed by a funded, bilateral modification 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:

B.2.b.1. Additional Vaccination Services (period of performance 09/13/2023 – 09/30/2024) are included as separately priced Contract Line Item Number (CLIN) 1004 identified in the Schedule B.

B.4 Contract Points of Contact

Vendor POC: Anita Patel - (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 supports 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 support 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 and impacted 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 access to COVID-19 testing and vaccination 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 Area as such terms are defined below. Notwithstanding the above, Vaccination Services will be available at all of Contractor's retail locations across the U.S.
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 testing to under-resourced populations. Operates in pharmacies, congregate settings, surge sites, hot spots, and priority locations.
Insurance Discovery	A process that identifies if a patient has valid insurance coverage if a patient self-reports no medical insurance coverage or if a patient provides incorrect medical insurance information.
Low Access Area	With respect to Vaccination Services, an area in which a significant number of Uninsured Individuals and Underinsured Individuals, as such terms are defined for Vaccination Services, are far enough from the closest pharmacy, health center, or health department site as to make it difficult for those persons to travel to the nearest site to access a vaccination service. For example, these areas may be defined as census tracts that are at least 1 mile in urban areas, 2 miles in suburban areas, and 10 miles in rural areas away from the nearest Vaccination Services site. CDC will update a list of Low-Access Areas each month and distribute it to Contractor fifteen (15) days prior to the date on which such updates will take effect. Notwithstanding the above, Contractor will provide Vaccination Services to

	Uninsured Individuals at all of its retail locations across the U.S. in accordance with the terms of this contract.
Low Vaccination Area	With respect to Vaccination Services, an area in which a significant number of Uninsured Individuals and Underinsured Individuals, as such terms are defined for Vaccination Services, have not yet received Vaccination Services. This will be defined, for example, as census tracts that are in the lowest 50th percentile of historical COVID-19 vaccination coverage and where more than 10% of the population is comprised of Uninsured Individuals. The definition of Low-Vaccination Area will be updated over time to include more recent Vaccination uptake data. CDC will update a list of Low Vaccination Areas each month and distribute it to Contractor fifteen (15) days prior to the date on which such updates will take effect. Notwithstanding the above, Contractor will provide Vaccination Services to Uninsured Individuals at all of its retail locations across the U.S. in accordance with the terms of this contract.
NAAT	Nucleic Acid Amplification Test
Outreach	Outreach includes communications, promotional materials, partnerships, and educational events conducted by Contractor to reach Communities of Interest. Outreach conducted by Contractor should aim to improve coverage, access, and awareness regarding Vaccination Services 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 NAAT, is performed to confirm the results of a POC result that mismatches the patient's symptoms. Used only in certain settings to guide patient care or processing. **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.
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.
Underinsured Individual	*Vaccination Services:* An adult, eighteen years of age or older, who meets the requirements set forth in Section 4.2.L of this contract.
Uninsured Individual	*Vaccination Services:* An adult, eighteen years of age or older, who meets the requirements set forth in Section 4.2.L of this contract.
Vaccination Services	The administration of COVID-19 vaccines, including boosters, to Uninsured Individuals and Underinsured Individuals as set forth in Section C of this contract.
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 2.) Provide COVID-19 vaccination access and informational resources to patients who receive negative COVID-19 test results. 3.) Linkage to the other HHS programs to support COVID testing programs.

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") or (the "Government"), which supports the inter-agency TDWG, seeks to increase equitable access to COVID-19 testing, and vaccination services 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 Vaccination Services to Uninsured Individual and Underinsured Individual populations to ensure equitable access to vaccines and treatment in the period following commercialization.

Additionally, the ESDTF ICATT Program will continue to expand testing, vaccination outreach, availability, and effectiveness. As needed, the Government shall increase or decrease the number of testing and Vaccination Services 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 to require participating vendors to offer Vaccination Services at all of their retail locations across the U.S. 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 and may differ in scope of participation for testing and vaccination.

In addition to the above, the Contractor shall sustain surge testing and Vaccination Services capabilities to deploy to disease outbreak zones, including flexible off-site testing and Vaccination Services models to rapidly reach communities of interest. Contractors shall use appropriate testing and vaccination 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 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 shall be required.

The Contractor shall track and report data on Services provided under this contract and as otherwise mutually agreed upon by the parties that enhances the analysis of HHS testing, and vaccination data and complements federal disease surveillance and research activities. Unless otherwise stated herein, all 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 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. In return, the Government will reimburse Contractor in accordance with the fees set forth in Table B.1. All Services rendered and reimbursed under this contract shall be provided at no cost to Uninsured and 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.
3. Implement standard diagnostic testing quality assurance and controls per test kit manufacturer guidelines.

ii. Vaccination Services:

1. Administer COVID-19 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 COVID-19 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 applicable to pharmacies: https://vaers.hhs.gov/reportevent.html
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, 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 ensure all necessary communication on at least a weekly basis with ICATT

program representatives on all aspects of the Services locations regarding Site Status changes, inventory and key staffing and leadership updates, site needs, testing metrics, and risks and issues.

C. The Contractor shall ensure adequate materials are available for operations.
D. 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."
E. Contractor shall report all elements described in Attachment J.1 "Data Reporting Requirements" on a once daily basis every business day.
F. 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.
G. When partnering with another entity (e.g., state and local stakeholders, bases, etc.) in providing surge site 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.
H. For the purposes of establishing and operating approved 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.
I. Contractor shall maintain sufficient staffing capacity sufficient to maintain hours of operation and service capacity described to meet applicable requirements of sections 1 and 4.3.A.
J. 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.
K. Contractor shall ensure the following:
    a. All Services performed under this contract shall be performed 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).
    b. To the extent applicable, all tests and vaccines used in performance of Services under this contract have appropriate FDA Emergency Use Authorization (EUA), FDA approval, or Biological License Application (BLA).
    c. Services are provided in compliance with any applicable regulations or requirements required for performance of Services (including, to the extent applicable, FDA EUA submissions or amendments, CLIA Certificates or Certificates of Waiver, or CLIA violations at proposed sites).
    d. Billing and reimbursement for Services are conducted in accordance with the terms set forth in Section 8 of this statement of work.
    e. Utilization of the insurance discovery processes that were developed, as required, by the end of the public health emergency (PHE).
L. Insurance Discovery:
    a. Prior to invoicing for Vaccination Services rendered under this contract, Contractor shall perform the following actions to confirm CDC is the payor of last resort:

        1. Contractor will collect demographic information from the patient.
        2. Contractor will request the patient provide their pharmacy benefits coverage information or Contractor will review to see if pharmacy benefits coverage information is already on file for the patient.
        3. Contractor runs a real-time eligibility check of the pharmacy benefit to

determine if patient has active pharmacy benefit coverage both before and after administration of the vaccination.

4. For Vaccination Services provided hereunder, Contractor runs a real-time eligibility check of medical benefit to determine whether patient has active medical coverage and whether that coverage is in-network or out-of-network.

5. *Eligibility Check Findings – Contractor shall invoice eligible claims as follows:*

    a. **Uninsured Individuals:** If the eligibility check is returned showing that the patient does not have active pharmacy benefit coverage, or if coverage is identified but does not cover COVID-19 vaccination, the patient is considered an Uninsured Individual and CDC will be invoiced the Vaccine Administration Fee set forth in Table B.1.1.

    b. **Insured Individuals:** If the patient's pharmacy benefit coverage is confirmed and an adjudicated claim is returned with no cost to the patient, the patient will be considered insured and both the vaccine ingredient fee and the fee for administration will be charged to the pharmacy benefit plan. If the patient's pharmacy benefit coverage is confirmed and an adjudicated claim is returned with a message to "Bill Medical Plan" and if Contractor is confirmed to be in network, the patient will be considered insured and both the fee for the vaccine and the fee for administration will be charged to the medical plan.

    c. **Underinsured Individuals:** If the patient's medical or pharmacy benefit coverage is confirmed, however an adjudicated claim is returned with any cost-sharing amount that must be collected from the patient at the time of service, the patient will be considered to be an Underinsured Individual. Any cost covered by the medical or pharmacy benefit coverage is applied to the vaccine ingredient fee and the cost share attributable to the patient will be invoiced to CDC up to the full value of the Vaccine Administration Fee – Cost Share as set forth in Table B.1.1.

    d. **Individuals with No Coverage at Walgreens**: If the patient's pharmacy or medical benefit coverage is confirmed, but the claim is rejected as out-of-network, the patient is presumed to have coverage elsewhere. In these instances, services rendered to the patient are not eligible to be invoiced under this contract. The patient will be offered alternative options including the option to self-pay or to follow up with their health plan to determine where the service may be covered.

    e. **Improper Processing:** Contractor shall not invoice the Government under this contract for claims not paid due to improper claims processing.

M. The Contractor shall provide monthly reports on the above activities including any challenges to implementation.
N. The Contractor shall provide upon request by CDC ad hoc reports to clarify data on ICATT Testing Services and Vaccination Services as required by the changing nature of COVID-19.
O. The Contractor shall complete a final report at the completion of each period of performance. The final report shall include total Testing and Vaccination Services billed under this contract for the period of performance, the report should highlight areas of interest, and trends, quality issues, and continuous improvement metrics. The final reports should also include any challenges in the implementation of Section 8 of the statement of work.

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. The Contractor shall operate and sustain a minimum of 1,000 pharmacy, community and / or retail testing sites concurrently. The government will provide four (4) weeks notice for expansion or contraction of pharmacy sites. While due to budget constraints and program needs the Government may permit Contractor to operate fewer than 1,000 sites, 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:
    i. A minimum of 200 sites shall be in each of any three US regions or a minimum of 100 sites in each of the contiguous U.S. regions (regions one through six; see "US Regions" in definitions)
    ii. At least 50% of sites should be located in intermediate to high social vulnerability index census tract areas or, if not feasible, at least 500 sites should be located in such areas
    iii. At least 10% of sites shall operate under extended hours based on testing demand. The Government defines extended hours as at least 3 hours before 9 AM or after 5 PM. These sites may provide any test method
    iv. During regular operations, the Contractor shall be prepared to meet a site capacity of at least 28 ICATT testing appointments per day for observed specimen collection on-site or at least 20 unobserved, self-sample collection kit pick-ups,
    v. At sites where appointments are not offered, during regular operations, the Contractor shall be prepared to meet a site capacity of at least 28 ICATT tests per day for observed specimen collection on-site or at least 20 unobserved, self-sample collection kit pick-ups, and
    vi. For pharmacy sites, testing hours shall coincide with pharmacy hours.
B. The Contractor shall have the ability to expand testing capacity to at least 42 ICATT tests per day in mutually agreed locations with two weeks' notice by modifying testing strategies, which may include extending operating hours, increasing the number of appointments per hour, and utilizing additional no-cost testing methodologies.
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.
E. The Contractor shall provide inside and outside communications/signage indicating that HHS funds the no-cost testing program instructing patients how they should proceed to be tested
F. Billing for Uninsured Individuals – Testing in US Territories and States: For testing in US Territories, such as Puerto Rico or US Virgin Islands, the swab and send fee will include reimbursement for scheduling, registration, sample collection, sample transport, laboratory-based PCR testing, and results reporting. The model shall only be deployed when the test taker presents with no valid insurance and insurance discovery is unsuccessful. For testing in the United States, this fee can also be applied only when the test taker presents with no valid insurance and insurance discovery is unsuccessful.

Vaccination Services Site Locations

A. The Contractor shall offer Vaccination Services at **all** current retail locations, where allowed by law, not just sites that are currently established for testing under this contract. Each location shall be assigned a Facility ID for payment and reporting purposes.
B. The Contractor shall set up additional sites to broaden the number of locations where Vaccination Services are available in Low Access Areas and Low Vaccination Areas. Many of these sites may be operated in partnership with community organizations (for example, in a place of worship or at a community center). Sites may be mobile, or set up for a few weeks. CDC will review and approve all sites and, upon two weeks advanced written notice from CDC, each physical location will be assigned a Facility ID before operating.
C. The Contractor shall also conduct Vaccination Services 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 Contractor-approved request by the Government 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). The Contractor shall review and mutually agree to the Government proposed site. Each off-site location should be assigned a Facility ID and CDC consent before operating.
D. The Contractor shall abide by all applicable federal and state scope of practice laws, regulations, and policies.
E. The Contractor shall indicate in all Program materials that reference the CDC Bridge Program and are distributed that the CDC Bridge Program is funded by HHS/CDC. Contractor shall provide information to patients about how to determine whether they are eligible for no-cost vaccination through the Program.

Site Location Selection, Other Requirements:

The following is applicable to Services site locations unless otherwise stated.

A. The Government must approve Contractor-recommended 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, to the extent applicable, 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 Services site location, when reporting in HHS Protect or through the state IIS.
C. Contractor shall report new Services 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 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 Site 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, the 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 Castlight Health and 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

The following is applicable to Services site locations unless otherwise stated.

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 Services priorities: https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html
   iii. Refer patients to CDC Services guidance
   iv. Clear eligibility criteria
   v. Detailed guidance on no-cost testing
   vi. Acknowledgement of HHS funding support
   vii. A site map showing appointment availability and operating hours for each location
   viii. Answers to frequently asked questions about Services (developed and maintained by the Contractor)
   ix. Type of Services 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 Services 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 testing 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 provision; 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 Services. This guidance can change periodically. It is the Contractor's responsibility to check the CDC website periodically for updates. If the screening criteria are met, the Contractor shall 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 applicable, and if it complies with all federal and state laws and regulations.
D. The Contractor shall be capable of uploading a group of test takers from a digital list when testing in congregate settings.
E. The Contractor's registration process shall be available and efficient for walk-up test takers.
F. 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.
G. The Contractor shall provide clear website communications that publicize the availability of no-cost Services for Uninsured Individuals and Underinsured Individuals, as applicable. All materials should be shared with HHS for review and acknowledge HHS as the funder.

5. Site Preparation

The following is applicable to Services site locations unless otherwise stated.

A. The Contractor may coordinate or enter into an agreement with state and local governments to supply items necessary to fulfill Services site needs, including supportive infrastructure.
B. When providing full-service Services sites, the Contractor shall have prepared all necessary

equipment (e.g., swabs, personal protective equipment (PPE), traffic flow management, and tents) prior to patient's arrivals.

C. For all new locations or sites where Services have not been performed for over one (1) week, the Contractor shall undergo a dry run where a small number of patients or the staff practice receiving Services, prior to operating at full capacity. Any site preparation or Services performance issues not resolved during the 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 Services supplies to assure quality.

6. Patient Verification

The following is applicable to Services site locations unless otherwise stated.

A. The Contractor shall be responsible for matching patients that arrive to the Services location to the correct laboratory requisition documentation. if applicable. After verification, Contractor staff shall provide the FDA EUA authorized or fully approved testing kit or Vaccination Service 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's 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.
    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

i. 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. For instance, if the Contractor supports Federally Supported Testing (optional to propose), then confirmatory POC testing is mandatory to offer.
   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 is performed in specific settings, i.e. Federally Supported Testing, to confirm the result of a POC test to expedite patient management and processing.
f. Multiplexed testing
   i. The Contractor shall provide multiplexed SARS-CoV-2 diagnostic tests which also include influenza and/or other respiratory pathogen targets at agree-upon sites. Multiplexed testing will be implemented at the sole discretion of the government based on the pandemic environment. Multiplex testing may be used in place of a singleplex test.
g. Pooled Testing
   i. Upon determination by the Government that pooling is the preferred testing approach, the Contractor may provide laboratory testing services for pooling of 5 to 10 samples or more. Pooled sample testing being performed under an FDA EUA shall be performed according to CDC, FDA, and CMS regulations and guidance. Pooled testing may be optionally awarded in support of congregate setting sample collection and testing or in federally supported testing arrangements.
   ii. Pooled testing may take the form of diagnostic, screening, or surveillance testing. Laboratories that conduct diagnostic or screening testing for COVID-19 shall also comply with Clinical Laboratory Improvement Amendments (CLIA) regulations. Laboratories should use an existing authorized nucleic acid assay.
   iii. If a pooled test result is negative, then all specimens can be presumed negative

with the single test and reported as such. If the pooled test result is indeterminate or positive, each of the samples in the pool will need to be tested individually to determine which sample(s) tested positive, and individual results should be reported accordingly. Individual diagnostic retests shall be billed to the Government as a separate test at the corresponding individual diagnostic test rate.

h. Genomic Sequencing
    i. As a function of public health activities in response to changing dynamics of the COVID-19 pandemic response (e.g., surveillance of The Contractor shall reflex a subset of samples for next generation sequencing for diagnostic purposes conducted under CLIA or other laboratory quality management systems. Sequencing shall be completed and data reported within one (1) week of request from the Government.
    ii. Samples may come from sites at which the Contractor currently obtains specimens from its pharmacy-based testing and surge testing sites as well as from other third-party state testing sites as designated by the HHS and agreed on by the parties.
    iii. The Contractor shall provide:
        1. Data and metadata management
        2. Secured delivery of genomic data to local, state, or federal partners
        3. The uploading of genomic data and associated metadata (provided in bulk upload format by the sample submitter) to GenBank, according to CDC's minimum data requirements from the Genomic Sequencing Laboratory.
    iv. Upon request, the Contractor shall ship a subset of samples to a designated state or federal public health laboratory within 48 hours of request for further testing.
    v. The Contractor shall provide accessioning services for samples submitted directly by surveillance partners. Sample submitters are responsible for providing metadata to the testing laboratory in a bulk upload format.

i. 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 shall 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.

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

4.4.3.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)

A. The Contractor shall make reasonable efforts to make test results available to test takers within 2 days after sample collection. Reasonable efforts are considered returning greater than 85% of total results per week (Monday through Sunday) within 2 days, ordering surge situations, where national percent positivity exceeds 10%, no more than 20% of test results being returned after 2 days or longer. Results made available to the test takers 3 days or longer after sample collection will be reimbursed at the government's discretion, if more than 20% of the total results for any given week exceed the 2-day deadline for more than 2 consecutive weeks. Prior to enacting discretion for reimbursement, the contractor shall have three weeks after notification by the government to make corrective actions such that no more than 10% of total results per week are made available 2 days or longer after sample collection. Upon notification from the Contractor that corrective action involves a change in laboratory partners, the Contractor and Government shall mutually agree upon a resolution period. The federal government will not execute reimbursement discretion, but may enact the option to request an improvement plan, if the contractor's one week turnaround time lies within one standard deviation of the mean ICATT program turnaround time (program average will be calculated by excluding the contractor turnaround time).
    i. Test results should be communicated to test takers (or their legal guardians) either at the site, or in a manner approved by the relevant STLT Departments of Health.
    ii. Test results should be in writing: a handout provided at the testing site, email, text, or through the registration portal/application are acceptable. Phone calls are acceptable to provide results immediately but shall be followed up in writing.

B. As described in section 4.16, the Contractor shall link any patient with a positive test result to relevant information about COVID-19 therapeutics. The Contractor shall link any individual with a negative test result to relevant information about COVID-19 vaccination. The Contractor shall regularly update therapeutics and vaccination information in their test results.

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

The following is applicable to Services surge site locations unless otherwise stated.

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 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. Federal and state partners will remain responsible for State/Federal Government Responsibilities in Section 4.13.F

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:
        a. Site interaction with site point of contact for all logistics coordination
        b. Clinical staffing; traffic control within site; managerial staffing
        c. Nonmedical equipment including tents, cones, tables, chairs, electric power,

generator, heaters, porta potty (if restroom unavailable)
d. Storage of specimens in accordance with manufacturer instructions
e. If necessary, 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. Federally Supported Testing (Testing Services)

A. The Contractor shall perform POC or equivalent using an authorized diagnostic test at agreed-upon federally supported locations.
B. POC tests 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. If the test provided by the government requires additional testing platform equipment (e.g., readers), the Government will supply this equipment as government-furnished property; the list of equipment will need to be confirmed as necessary by the government prior to procuring it.
C. The Contractor shall perform confirmatory POC testing to confirm rapid POC-positive tests in all people and negative tests in symptomatic people. The Contractor shall follow any other CDC recommendations for confirmation of POC tests (https://www.cdc.gov/coronavirus/2019-ncov/lab/). Confirmatory POC tests can be purchased by the Contractor or provided by the government; the source of the confirmatory test will be decided at the sole discretion of the government. If provided by the government, [redacted] will be subtracted from the cost of this provision of testing. Requirements for Confirmatory testing in this high-density setting are:
    i. Rapid time to results (<30 minutes)
    ii. Portable handheld instrument/reader/device that can be taken to the patient, rather than transport of specimen or patient to other testing location, appropriate for use as confirmatory test (no presumptive results).
D. The Contractor shall provide availability of staff and necessary equipment to conduct 24 hour, 7 days a week testing at agreed-upon federally supported locations. In the event the government is unable to provide a fixed structure where the testing will be performed, the Contractor shall provide an appropriate facility or unit for testing that is cost-beneficial to the government. Staff will be on call for screening testing at all hours and capable of testing at least 100 people per hour within one (1) hour of notification.
E. Specimens shall not be shipped; test results shall be available rapidly to make the quarantine decisions promptly. Tasks described in section 4.11.B will be included in the cost of Federally Supported Testing.

(b)(4)

F. State/Federal Government Responsibilities:
    i. Selection and coordination of site POC for logistics coordination of site locations; including any necessary permits
    ii. Biohazardous waste management and disposal (e.g., gloves, masks)
    iii. Media relations
    iv. Identification of state and local POCs
    v. Testing hours/days
    vi. Go live/closing dates
    vii. Identification of number of tests to be performed in total
    viii. Storage location for supplies

12. 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 will 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.
        a. At locations where remote sample drop-off occurs, Contractor shall ensure a capacity of at least 30 samples per day, per sample drop-off 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.

13. 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.

14. Combined Testing/Wraparound Services

The following is applicable to Services unless otherwise stated.

A. The Contractor shall connect any patient who receives ICATT Testing Services, and receives a

positive or indeterminant COVID-19 test result with appropriate information on how to receive such therapeutics at the testing location or other Services site. In addition, the Contractor shall link any individual with a negative test result to relevant information about COVID-19 vaccination and how to receive Vaccination Services at the testing location or other Services site. The Contractor shall regularly update Vaccination Services information in their test results.

~~B.~~ At pharmacy sites where Vaccination Services are available, the Contractor shall provide information on how to schedule a vaccination appointment or, if available, offer a walk-up Vaccination Service to any patient who receives a negative COVID-19 test result and who has not already been fully vaccinated against SARS CoV-2. Opportunity to receive Vaccination Services shall be offered at the time of negative result notification to the patient.

C. Contractor shall include linkage to the HHS Programs.
   a. To further the missions of the HHS programs and CDC ICATT programs, ICATT patients that receive testing services will be provided links to patient recruitment information. Outreach to ICATT patients will include posting links to the HHS program on the Contractor's website.
   b. The Contractor shall provide the following Outreach.
      i. DIGITAL

The Contractor shall provide electronic links and brief information about the program on their testing pages, i.e., the Contractor's website about getting a test through their system. Information may include written text and visual images and will include website links, phone numbers, and other necessary contact information. All necessary information about the program will be provided to the Contractor by the federal government to ensure this task is performed. The form, content, and size of the information that will be posted on Contractor's website will be jointly agreed upon by the Contractor and government. Program links and information will be aligned with the test recipient's information to ensure only test recipient within a specific distance or drive time from the study sites will have access to information about the program. The zip code alignment and strategy will be mutually agreed upon by the Contractor and the government. Study site testing locations and distance and drive time information will be provided by the government. The Contractor will provide mutually agreed upon digital metrics, i.e., key performance indicators, for the effectiveness of websites and digital test reports so that minor modifications can be made dynamically to optimize the process. Digital metrics will be calculated using the number of registered study participants over the number of tests performed from data provided by HHS programs.

15. Support Services

The following is applicable to Services site locations unless otherwise stated.

A. For patients who may require assistance (including non-English speakers; adults aged 65 years and older; children below the age of five; individuals with physical, learning, and/or cognitive disabilities; and individuals who are blind and/or deaf), the Contractor shall provide reasonable assistance to perform Services evaluation, maintain a reasonable speed of Services administration and transitioning patients to and from the Services areas. Reasonable assistance includes foreign or sign language interpretation; support services for the blind and visually impaired; ambulatory support (e.g., wheelchairs); physical assistance; and support for individuals requiring assistance reading and/or understanding directions.

16. Additional Services Line Items

A. Given the uncertainty of changing Services needs, the Government may elect to exercise a contract line-item option of varying percentages of the base task to support Additional 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 01, 2024, to December 31, 2024.

17. Vaccination Services:

A. **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. The Contractor shall bear all costs of COVID-19 vaccination procurement and storage without the use of Government funding.

iv. The Contractor shall not charge any cost-sharing to Uninsured Individual and Underinsured Individual patients or seek reimbursement from either the Government (except as outlined under this contract) or the vaccine manufacturer (except for through a Patient Assistance Program or use of donated vaccine for Underinsured Individuals only).

B. **General Requirements:**

a. The Contractor shall hire and retain necessary staff and licenses to perform all contracted functions;

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

c. The Contractor shall conduct Outreach.

d. The Contractor shall participate in regular coordination calls with CDC staff and other funded pharmacies, health centers, and health departments to coordinate delivery of Vaccination Services to meet the needs of areas with high numbers of Uninsured Individual and Underinsured Individual populations, Low Vaccination Areas, or Low Access Areas;

e. The Contractor shall leverage data and technical assistance, made available by CDC, to determine the locations for Uninsured Individuals and Underinsured Individuals, as well as to understand features and demographics of Low Access Areas and Low Vaccination Areas, and better conduct Outreach;

f. The Contractor shall track and monitor the results of Outreach for required monthly reporting to CDC and to improve impact over time;

g. Before Vaccination Services are administered the Contractor-shall conduct the insurance discovery process to ensure patients receiving such Vaccination Services under this contract meet the definition of Uninsured Individual or Underinsured Individual as applicable.

h. The Contractor shall discuss during regular check-ins with CDC staff:

1. Vaccination Data

1. Percent of Vaccination Services dispensed that are billed to this channel versus to other payors. Other data as specified in Table J.1.b.

2. Additional data elements may be requested by CDC and shall be mutually agreed upon by the parties.

3. Note that CDC may audit this documentation if the ratio of Vaccination Services dispensed under this contract significantly exceeds the rate of Uninsured Individuals in the community.

4. Outreach Summary Data:

i. Number and location of offsite clinics

ii. Number of doses administered at offsite clinics

3. Other data elements to be reported, such as patient screening and demographic data, and site location data, are included in Attachment J.1 and will be reported weekly.

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 Individuals and Underinsured Individuals live and the locations of Low Access Areas and Low Vaccination Areas, as well as to help understand features and demographics of selected Low Access Areas and Low Vaccination 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. For reporting purposes, give access to HHS Protect for ICATT Testing Services and state IIS systems, for Vaccination Services.
8. Training to HHS Protect for ICATT Testing Services and use of state IIS systems for Vaccination Services, as needed.

SECTION 6 – PERIOD OF PERFORMANCE

See Section B.

SECTION 7 – DELIVERABLES/REPORTING SCHEDULE

Item #	SOW Reference	Deliverable Description	Date of Delivery
1.a and 1.b	See: Section 4 and Attachment J.1a. and J.1b, Sections A – C	Daily Services Reports, Demographics and Services Encounter Data	Daily
1.c	Section 4	Outreach Summary Data (number and location of offsite clinics, doses administered at offsite clinics)	Monthly
2	See: Section 4 and Attachment J.1, Section D	Services Site Data	As Need, Prior to Site Launch
3	See: Attachment J.1, Section E	Over-the-Counter COVID-19 Test Sales	Weekly
4	See: Section 4 and Attachment J.1, Section F	Testing Site Metadata	Prior to Site Launch and at Least
5	See: Section 4	Site Updates with Castlight Health and Google and www.vaccines.gov	Weekly
6	See Section 4	Vaccination Monthly Report for Vaccination Services billed under this contract	Monthly
7.a	Section 4	Final Report Testing	Within 30 days preceding the end of the Period of Performance.

7.b	Section 4	Final Report Vaccination Services provided under this contract	Within 30 days preceding the end of the Period of Performance

SECTION 8 – ICATT Vulnerable Population Testing, Reimbursement Shift to Private or Public Insurance Payments, Low Access Area Payment, and Low Vaccination Area Payment

Vulnerable Population Testing: To achieve program goals, the Contractor will have an opportunity to receive a separate firm fixed price payment for exceeding testing goals. The Contractor shall provide a plan detailing how they will achieve this goal. At the end of each calendar month, tests performed above the 60% non-white, or Hispanic population goal will be paid a higher rate of payment. For instance, if 63% of total tests were reported in non-white, non-Hispanic populations, the contract would receive the base price per test and an payment per test for 3% of tests for that calendar month. This applies to any combination of tests provided or conducted at all locations. The sum of the payments will not exceed per calendar month.

Billing Laboratory Tests to Public/Private Insurance
To encourage sustainability of the testing program, during the base period of performance only, a ee will be added to the cost of the test fee listed in table B1. The additional firm fixed price payment will not cover the cost of the test or administering the test. The additional firm fixed price payment will apply to the development of procedures needed to support billing to third party payers. The contractor must present evidence of reimbursement to receive payment.
For laboratory-based tests performed in pharmacy, community, or retail locations under this contract billed to private insurance, HRSA, Medicare, or Medicaid. The Government will pay an additional fee of per test to cover the administrative, logistic, and management costs of performing the test, up to the lesser of 5% or 10,000 test

Low Access Area Payment: To achieve program goals, in addition to providing Vaccination Services to Uninsured Individuals at all of Contractor's retail location the Contractor shall have an opportunity to receive separate, firm fixed price payments for Vaccination Services performed in census tracts that meet the definition of Low Access Area ("Low Access Area Payment"). The Contractor should propose a monthly ceiling for Low Access Area Payments in their business proposal.

1. One payment will be an until December 31, 2023, and rom January 1, 2024, per vaccination administered. The contactor can invoice monthly as vaccines are administered.
2. The second payment will be a one-time payment per one-day site and per multi-day site, for each site established in a Low Access Area. The Contractor can invoice monthly as new sites are established.
3. Only sites approved by CDC are eligible for incentive payments.

Low Vaccination Area Payment: To achieve program goals, in addition to providing Vaccination Services to Uninsured Individuals at all of Contractor's retail location, the Contractor shall have an opportunity to receive separate, firm fixed price payments for Vaccination Services performed in census tracts that meet the definition of a "Low Vaccination Area". The Contractor should propose a monthly ceiling for Low Vaccination Area payments in their business proposal.

1. One payment will be an , until December 31, 2023, and from January 1, 2024, per Vaccination Service administered. The Contactor can invoice monthly as Vaccine Services are administered.
2. The second payment will be a one-time payment per one-day site and per multi-day site, for each site established in a Low Vaccination Area. The Contractor can invoice monthly as new sites are established.
3. Only sites approved by CDC are eligible for incentive payments.

Sites may only qualify for either the Low Vaccination Area Payment or Low Access Area Payment. This includes payments per new site set up and payments per dose administered.

As described in attachment J.1 and Section 4.18, CDC will **collect data on a regular basis** from the Contractor, to

capture site locations, Vaccination Services encounters, partnerships/Outreach, and patient demographics.

1. CDC will use the data to **create lists of locations** that qualify for the Low Access Area Payment and Low Vaccination Area Payment and provide an updated version of the list to the pharmacies each month. Areas included on each list would continue to qualify for these payments for approximately 3 months after they are included on a list, even if removed from the following month's list.

SECTION 9 – SPECIAL CONSIDERATIONS

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) 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) 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) 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) 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) 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) 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) 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).

CDC Implementation of HHS Security and Privacy Language for Information and Information Technology Procurements Language, Version 1.0 Page 14 within 60 days of assuming their new responsibilities. Thereafter, they shall complete RBT 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. 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 another 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	Position Requirement
__ 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.

Vaccination Services, Government Monitoring:

For Vaccination Services, CDC may implement processes to ensure appropriate use of government funds on Vaccination Services only for the Uninsured Individuals and Underinsured Individuals. Beyond the currently required patient insurance attestation, encounter data-level patient insurance status reporting, and insurance discovery processes, these processes may include periodic facility-level monitoring such as, for example:

a. Running weekly spot checks on facility-level data on Vaccination Services billed to this contract for a particular site and provided by that site, and ensuring the ratio is not significantly dissimilar from the overall Uninsured Individual rate in that census tract; or
b. Using either planned site visits or a “secret shopper” technique to ensure they are asking patients to attest to insurance status as required and that backend processes meet program requirements.

Section I-1 - Clauses Incorporated By Reference

Add:

FAR SOURCE	TITLE AND DATE
52.245-1	Government Property (Sept 2021)

Section J – List of Attachments

Attachment J.1 – Testing Data Reporting Requirements
Attachment J.1.b – Vaccination Data Reporting Requirements
Attachment J.2 - Data Use Agreement

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
Vaccination Event ID	String	Unique identifier for each vaccination to prevent duplicate result submission	578928889	
Vaccination Administered Date	MM/DD/YYYY	The date the vaccination was administered	11/01/2021	
Facility ID	String	Unique identifier for each site. Contractor shall obtain approval from the Government for the Facility ID.	P2000	
Vaccine manufacturer name	String	The manufacturer of the vaccine that was administered.	Pfizer, Moderna, etc.	
Vaccine product	String	NDC of product administered	80777-282-05	
Vaccine product	String	CVX of product administered	519 https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx	
Copay	String	Indicator whether copay applies	Yes/No	

B. Patient-Related fields

Field Name	Format	Description/Options	Example	Vendor-Specific Notes
Patient Zip Code	ZIP	5-digit ZIP code of patient residence	10000	
Patient Residence State	2-letter state abbreviation	The state where the patient resides.	TX	

Patient birth year	YYYY	The birth year of the patient	1978	
Patient Gender	String	Male, Female, Other, Not Reported	Female	
Patient Race	String	American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; White; Other; Not Reported	Black or African American	
Patient Ethnicity	String	Hispanic/Latino; Non-Hispanic/Latino; Not Reported	Hispanic/Latino	
Patient ID	String	Unique identifier for the patient, if available, subject to the condition that the identifier cannot be linked back to the patient		

C. Vaccination Site Related Fields

Field Name	Format	Description/Options	Example	Vendor-Specific Notes
Facility ID	Defined by Contractor or Government	Unique identifier for each site. Contractor shall obtain approval from the Government for the Facility ID.	P2000	
Site Description	String	Description of vaccination site to include relevant details at discretion of Government and Contractor.	Store #10000	
Address	Address	Address of vaccination site	100 S Main St	
City	City	City of vaccination site	Houston	
State	Two-letter state abbreviation	State of vaccination site	AK	
ZIP Code	ZIP	5-digit ZIP code of vaccination site	10000	
Go Live Date	MM/DD/YYYY	Date site began vaccination.	11/01/2021	
IIS ID	String	Identifier assigned by	State	

		IIS to the Provider Organization	specific ID used for IIS reporting	
Pharmacy NPI	String	National Provider Identification number for the pharmacy (i.e. not the pharmacist or the prescriber)	1528162450	

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)/AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)

DATA USE AGREEMENT

This data use agreement ("Agreement") is between the following parties:
Data Provider ("Provider"):
Walgreen Co.

Data Recipient ("Recipient"):
Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC)

These parties will collectively be considered the "Parties," or individually, a "Party." This Agreement will be effective as of the latest date signed below ("Effective Date") by the Provider and Recipient.

PURPOSE AND BACKGROUND

This Agreement establishes the terms and conditions under which the Provider will provide, and Recipient will receive and use, the data covered under this Agreement. This Agreement ensures adherence to guiding principles of accountability, privacy and confidentiality, stewardship, scientific practice, efficiency, and equity. Use and disclosure of the data must be consistent with this Agreement and with applicable law.

The Parties agree that the Recipient will use the data being shared for the purpose(s) of:

Sharing data reported by Data Source to the Data Collation and Integration for Public Health Event Responses (HHS PROTECT) platform in furtherance of the United States Government (USG) post-public health emergency (PHE) response to Coronavirus Disease 2019 (COVID-19). This data will assist CDC/ATSDR and the USG to ensure a common operating picture to address the needs of the public. To that end, CDC/ATSDR is working by and through a contractor, Palantir Technologies, who securely ingests data from the Data Source into HHS PROTECT. The HHS PROTECT platform will enable Authorized Users, as that term is defined herein, to integrate, model, and otherwise access and use the shared data to implement key public health surveillance activities.

Depending on their level of access, Authorized Users may use the data in furtherance of public health activities in general to include the execution of public health programs and public health surveillance, and post-response activities related to COVID-19. This includes, at a minimum, the following activities:

1. Use and redistribute the data provided herein or analyses thereof to official governmental health agencies or other agencies and entities conducting their public health responsibilities. This includes the sharing of vaccine administration data to manufacturers of COVID-19 vaccines (Pfizer, Moderna, etc.), consistent with applicable federal law. The data that the manufacturers shall access to will be limited to the data they need to review, perform analysis to support the USG's post-PHE COVID-19 and other public health efforts and validate invoices. The data will exclude PHI and PII and include only the manufacturer's

NDCs, ability to filter on uninsured administrations, date of the administrations to the uninsured, total # of doses administered to the uninsured by NDC and store information.

2. Analyze and visualize the data to improve the planning and execution of public health programs and support public health surveillance efforts.

3. Develop analytic methods to identify immediate public health events or concerns at the federal, state, and local level that warrant further follow-up public health investigation or immediate public health intervention actions.

4. Share the data and derivative analyses with appropriate governmental health agency jurisdictions for local or other actions that may be warranted.

5. Enable authorized public health officials to query the platform for additional data or information as may be necessary to carry out critical public health functions.

6. Validate vendor invoices, conduct payment procedures, and monitor for fraud; and

CDC/ATSDR and/or Authorized Users may publish findings and conclusions related to their analyses of the data provided and will acknowledge Data Source as the source of the data in any such publication.

CDC/ATSDR agrees that access to the data in the platform will be limited to those individuals necessary to review the data and perform analysis to support the USG's post-PHE COVID-19 and other public health efforts. To that end, Authorized Users will be required to comply with the defined Rules of Behavior and limited to their respective levels of access.

CDC/ATSDR may use the Covered Data, consistent with CDC/ATSDR's authorities under applicable federal law. CDC/ATSDR agrees that any such use will be on a need-to-know basis and will protect individual privacy and confidential business or financial information to the fullest extent allowed by applicable federal law. CDC/ATSDR further agrees that it will notify Provider of the need to use the Covered Data as soon as practicable prior to use of the data and, where practicable and appropriate, will work collaboratively with Provider to ensure appropriate coordination and access to developed analyses and reports.

COVERED DATA

This section will provide information about the data being shared per this Agreement.

The Parties acknowledge that Covered Data are limited to those data specified in the Appendix A, which identifies the complete set of data items to which the Recipient will have access to under this Agreement.

The Parties are permitted to transmit, access, receive, share and/or use any part of the Covered Data listed below as specified in the agreed purpose and uses, as set out herein.

Site, Testing, and Vaccine data collected under ICATT contract # 75D30122C13958.

Where CDC/ATSDR is the Recipient, the Parties acknowledge that in a public health emergency (PHE) or if an event is significantly likely to become a PHE, as provided in 42 U.S.C. §247d, certain data in the custody and control of CDC/ATSDR may be necessary to respond to the PHE.

In that event, CDC/ATSDR may use the Covered Data, consistent with CDC/ATSDR's authorities under applicable federal law. CDC/ATSDR agrees that any such use will be on a need-to-know basis, will be a minimum amount necessary to support a coordinated federal response, and will protect individual privacy and confidential business or financial information to the fullest extent allowed by federal law. CDC/ATSDR further agrees that it will notify Provider of the need to use the Covered Data as soon as practicable prior to use of the data for this purpose and, where practicable and appropriate, will work collaboratively with Provider throughout the response to ensure appropriate coordination and access to developed analyses and reports.

AGREEMENT ADMINISTRATION

Unless otherwise designated and agreed upon by Parties, the Recipient will act as the "Data Custodian" of the Covered Data once the data are transmitted. As Data Custodian, the Recipient is responsible for ensuring that the Covered Data are kept secured and that access to and use of the Covered Data is consistent with this Agreement and applicable law.

Where required by law, Recipient will ensure that the authorized users within Recipient's organization are deemed authorized to access the Covered Data will receive appropriate security training and be aware of the terms of this Agreement.

The Recipient designates the following individual(s) as the primary Data Custodian(s) point of contact:

Chare Brown (CDC/DDPHSIS/ORR/OD)
Associate Director for Information Resources
Centers for Disease Control and Prevention
ORR – Office of Readiness and Response
IRO – Information Resources Office | Atlanta, GA
CDC: 404.553.8861 | cos9@cdc.gov

Unless otherwise designated and agreed upon by Parties, the Provider will act as the "Data Administrator" of the Covered Data being transmitted. As Data Administrator, the Provider is responsible for the Covered Data being transmitted to the Recipient and/or granting appropriate access to authorized users for the Recipient.

To the extent allowed by law, the Provider will ensure that the Covered Data may be transmitted to Recipient's organization consistent with the purposes set forth under this Agreement.

The Provider designates the following individual(s) as the primary Data Administrator(s) point of contact:

Samantha Picking, Pharm D, Director of Immunizations

Walgreen Co.

200 Wilmot Rd, Deerfield, IL, 60015, (b)(6)

Processes for Communication

All notices or any other communication provided for herein shall be provided in writing through the following means:

- To the above identified Data Administrator/Custodian by email.
- To the above identified Data Administrator/Custodian by registered or certified mail, return receipt requested; by receipted hand delivery; by courier or other similar and reliable carrier. Notice by registered mail will only be used when necessary and when requested by CDC/ATSDR in writing.

Effective Date, Term of Data Use, and Termination Date

The term of this DUA will align with the term of Contract No. 75D30122C13958. This DUA shall be added to the underlying contract as [an addendum/exhibit/etc.], is incorporated by reference into the underlying contract, and shall be enforceable as part of the scope of work and deliverables as further provided therein. All terms and conditions not subsequently altered by addenda remain in full force and effect. The parties agree that any provision of funds for purposes of data collection, generation, or sharing expected under this DUA will be reflected in Contract and is subject to the terms of that Contract.

The DUA will remain in effect until two years after the end of the underlying contract, unless altered by written mutual agreement. The parties acknowledge that expiration of this DUA does not alter the access to and use of data transmitted to CDC/ATSDR prior to its expiration. The DUA may be renewed upon mutual written consent of the parties.

Except as otherwise expressly provided herein, this Agreement may be amended only by the mutual written consent of the signatories as the authorized representatives of each Party. Amendments to this Agreement must be requested in writing through the means above and must be signed by all Parties to be effective.

CONFIDENTIALITY, SECURITY, AND LEGAL REQUIREMENTS

The Parties will establish appropriate administrative, technical, procedural, and physical safeguards to assure the confidentiality and security of Covered Data. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by applicable law for the type of data provided under this Agreement.

Recipient agrees to the following:

Confidentiality: Where Covered Data provided pursuant to this Agreement are identifiable or potentially identifiable, Recipient agrees to maintain the confidentiality of the Covered Data to the fullest extent required by applicable law. Recipient further agrees to not disclose such Covered Data, including but not limited to names and other identifying information of persons who are the subject of such Covered Data, either during the term of this Agreement or longer,

except as consistent with this Agreement or as may be allowed or required by applicable law.

Where CDC/ATSDR is the Recipient, CDC/ATSDR will protect the privacy and confidentiality of the Covered Data consistent, where applicable, with the following federal laws: the Privacy Act of 1974; to the extent applicable, standards promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the Freedom of Information Act (FOIA). Where other more specific federal laws apply to the Covered Data; CDC/ATSDR as Recipient will comply with those laws, as well. CDC/ATSDR will seek to assert relevant exemptions to disclosure available under federal law, most critically, where applicable, for personal and/or private information, the disclosure of which would constitute an invasion of privacy; trade secret and commercial or financial information that is private and confidential; or information exempted from release by federal statute.

Except as may be provided for in this Agreement, Recipient shall not use the information from Covered Data to link to other data nor establish contact with any potentially identified person or his/her family nor establish contact with the persons represented in the data without prior written approval from the Provider.

Where required by law and/or where practicable, Recipient agrees to notify Provider before releasing Covered Data to a third party pursuant to a judicial, governmental, or other request under law, to allow Provider the opportunity to state any objection to the disclosure of the Covered Data.

Security: Recipient will use all reasonable administrative, technical, and physical measures to safeguard Covered Data once transmitted, and to protect Covered Data from unauthorized access, disclosure, use, or modification. This includes setting permissions to access or edit data commensurate with the level of sensitivity of the data. Should there be a data breach and unauthorized disclosure of Covered Data, consistent with applicable legal requirements, Recipient notify appropriate response teams and Provider of the incident.

Transfer: Where Covered Data provided pursuant to this Agreement are identifiable or potentially identifiable or are privileged, sensitive, or confidential, transmission of the Covered Data from the Provider to Recipient shall be done in accordance with acceptable practices for ensuring the protection, confidentiality, and integrity of the contents. The Parties may coordinate to implement methods to achieve these outcomes consistent with procedures already in place for similar data exchanges. If encrypted identifiable information is transferred electronically through means such as the Internet, then said transmissions will be consistent with the rules and standards promulgated by applicable legal requirements regarding the electronic transmission of identifiable information.

Storage: Covered Data will be maintained and stored in compliance with the Recipient's security policies and procedures and consistent with applicable law. Where Covered Data are identifiable or potentially identifiable or are privileged, sensitive or confidential, such records and data shall be secured in an encrypted, password-protected electronic folder with access restricted to project personnel for purposes as set forth in this Agreement.

Access: Where Covered Data provided pursuant to this Agreement are identifiable or potentially identifiable or are privileged, sensitive, or confidential, Recipient and its authorized users shall access Covered Data on secured devices only.

Recipient may provide Covered Data access to appropriate employees, contractors, and

other authorized users. Recipient agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized access to the Covered Data.

Data Maintenance, Deletion or Storage Requirements after Termination

Unless explicitly stated otherwise in the Agreement, ownership of Covered Data shall remain with the Provider. However, the Parties agree that the Covered Data provided under this Agreement and in the custody and control of the Recipient is subject to the laws applicable to the Recipient.

Accordingly, the Recipient agrees to maintain, store, protect, archive and/or dispose of Covered Data in accordance with applicable law. Obligations under law to maintain and secure Covered Data will survive termination of this Agreement. At a minimum, the Provider agrees that an archival copy of the Covered Data may be retained by Recipient to comply with relevant records retention requirements and/or for the purposes of research integrity and verification.

When CDC and/or ATSDR act as Recipient, as federal agencies, the disposition of records in their custody and control is governed by the Federal Records Act and may only be accomplished in accordance with schedules for destruction as provided under law.

APPLICABLE LEGAL AUTHORITIES

Applicable federal and/or state/jurisdiction or local laws that govern the collection, use, disclosure, and maintenance of the Covered Data may be cited as standard authorities related to the Covered Data, which includes project-specific authorities and regulations. Parties acknowledge that CDC and ATSDR, as federal agencies, are not subject to the application of state or local laws or regulations or the internal policies and/or procedures of the other party, except where consistent with federal law.

This Agreement is governed by applicable federal law.

Applicability of HIPAA

As applicable to the Covered Data and the Provider, CDC/ATSDR, as Recipient, is a “public health authority” as defined at 45 C.F.R. §164.501 and as used in 45 C.F.R. §164.512(b), Standards for Privacy of Individually Identifiable Health Information, promulgated under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). CDC/ATSDR, as a public health authority, is authorized by 45 CFR 164.512(b) to receive Protected Health Information (“PHI”).

REPORTING OF DATA USED IN PUBLICATIONS AND PRESENTATIONS

Notification

Recipient agrees to allow Provider no more than thirty (30) days to review and provide comments for consideration on papers, reports, publications, or presentations that Recipient plans to submit for publication or presentation. If publication needs to occur sooner than 30 days, Recipient agrees to notify Provider, who will expedite review consistent with the need to publish. However, notification shall not act to prevent the publication of information if there is an emergency need to publish meaningful, real-time information for a public health response. Appropriate privacy protections will be considered prior to any such emergency need to publish.

Attribution

Recipient agrees to factually acknowledge Provider in any paper, publication or presentation using the covered data.

Where CDC/ATSDR is the Provider, the citation must read as follows:

"Centers for Disease Control and Prevention/Agency for Toxic Substances and Drug Registry, [Name of data file, year(s)], as compiled from data provided through [Program/Study Name] "

Representation

Recipient agrees to assume full responsibility for the analysis, interpretation of the data, and provide a copy of the report, publication, or presentation to Provider.

Use

Where CDC/ATSDR is the Provider, per mutual agreement between Provider and Recipient, Provider grants full permission and a royalty-free, non-exclusive, irrevocable license to HHS, CDC/ATSDR to use, reproduce, publish, distribute, and exhibit materials arising from this Agreement for use in education, training, and other purposes consistent with CDC/ATSDR's mission.

ADDITIONAL TERMS AND CONDITIONS

- Entire Agreement: This Agreement, including any appendices related to data, specifications, or operations incorporating this Agreement by reference, and as amended from time to time, constitutes the entire agreement and understanding between the Parties and supersedes all prior oral or written agreements and understandings between them with respect to the Covered Data.

- Assignment: No Party may assign or transfer any or all of its rights and/or obligations under this Agreement or any part of it, nor any benefit or interest in or under it, to any third party without the prior written consent of all Parties, which shall not be unreasonably withheld.

- Mutual Representations: Each party to this Agreement represents to the other Party that, at all times during the term and at such other times as may be indicated, it shall comply with, and as applicable, shall require its directors, officers and employees to comply with its duties and obligations pursuant to applicable law and this Agreement, including but not limited to duties and obligations which survive the termination of this Agreement

- Use of Electronic Signatures and Electronic Records: The Parties may elect to establish processes for the use of Electronic Records in the management of and compliance with this Agreement. This may include for the addition of published policies, procedural information, notices, and any other documents arising from or pertaining to this Agreement, including this Agreement itself. Any such process must include the establishment of a mutually acceptable Electronic Signature process, which complies with federal and state laws.

- Disagreements: Disagreements between the Parties arising under or relating to this Agreement will be resolved by consultation between the Parties and referral of the dispute

to appropriate management officials of the Parties whenever possible.

- Public Document: This Agreement may be made publicly available.

- Funding: This Agreement is not an obligation or a commitment of funds, or a basis for the transfer of funds, and does not create an obligation or commitment to transfer data, but rather is a statement of understanding between the parties concerning the sharing and use of covered data. Expenditures by each party are subject to its budgetary processes and to the availability of funds and resources pursuant to applicable laws, regulations, and policies."

DISCLAIMERS

Disclaimers for Entity Providing the Data

It should be noted that as a Federal agency, CDC/ATSDR cannot agree to indemnification provisions. However, representations or disclaimers on the accuracy of the data may be appropriate.

- Intellectual property rights on material arising from the use of the data will be determined by applicable federal law.
- Interpretations, conclusions, and/or opinions that are reached as a result of analyses of the data are the Recipient's interpretations, conclusions, and/or opinions, and do not constitute the findings, policies, or recommendations of the Provider.

The data provided and covered under this Agreement are provided on an 'as is' basis. Except as expressly set forth herein, the data provider makes no representations, of any kind, either express or implied, with respect to the data set and expressly disclaims any and all representations of any kind with respect thereto, including any representations of data quality or fitness for a particular purpose. Metadata documents have been reviewed for accuracy and completeness. Unless otherwise stated, all data and related materials are considered to satisfy the quality standards relative to the purpose for which the data were collected. However, neither the author nor any part of the federal government can assure the reliability or suitability of the data for a particular purpose. The act of distribution shall not constitute any such warranty, and no responsibility is assumed for a user's application of t data or related materials.

SIGNATORIES

The undersigned individuals represent that they have competent authority on behalf of their respective agencies to enter into the obligations set out in this Agreement. Signature indicates that an understanding of the terms of this Agreement and an agreement to comply with its terms, to the extent allowed by law.

PROVIDER	RECIPIENT
Signature: (b)(6) Richard Gates, SVP, Chief Pharmacy Officer 200 Wilmot Road, Suite 2002 Deerfield, IL 60015 Walgreen Co. Date:9/15/2023	Signature: (b)(6) Printed Name: Joseph D Miller Title: Associate Director of Laboratory Science Organization: CDC/ATSDR Date:9/15/2023

APPENDIX A: DATA USE AGREEMENT DEFINITIONS

Terms used, but not otherwise defined, in this agreement shall have the same meaning as those terms in applicable laws and regulations, unless specifically stated otherwise.

- ***"Agreement"*** means this data use agreement, as amended from time to time in accordance with the terms and conditions set forth below.
- ***"Authorized User"*** for purposes of this Agreement, means an individual who, as part of directly supporting the Recipient activities, has a need for access to data provided under this Agreement and has been granted appropriate access, which may include executing necessary documentation for such access. Generally, authorized users will be employees, contractors, and/or other agents of the Recipient.
- ***"Effective date"*** is the date this agreement becomes valid, either on the date specified or the last date of signature.
- ***"Data Provider"*** or ***"Provider"*** refers to the party providing the data outlined in this Agreement.
- ***"Data Recipient"*** or ***"Recipient"*** refers to the party receiving the data outlined in this Agreement.
- ***"Data Administrator"*** is the data provider's individual who is responsible for the data and granting appropriate access to agreement parties.
- ***"Data Custodian"*** is the individual from a recipient agreement party responsible for the maintenance and protection of the data for their party.
- ***"Data Source"*** means an entity sending data to the HHS PROTECT platform. The Data Source entering into this DUA either agrees that it has the legal authority to share this data in the platform and/or will obtain consent from any external entities or individuals from whom it collects data.
- ***"Covered Data"*** shall mean the data provided to the Recipient by the Provider and any associated records, reports, copies, or databases.
- ***"Limited data set (LDS)",*** to the extent the term is used to define data elements being shared, is consistent with the term as defined in the Privacy Rule at 45 CFR Section 164.514(e).
- ***"Applicable law"*** means all laws, statutes and regulations promulgated by all regulatory authorities and all governmental authorities.
- ***"Project"*** refers to the specific research or analysis outlined in the purpose section of this agreement.
- ***"Results"*** means all normalized data and results generated in the performance of the Project.
- ***"Required by law"*** means as applicable federal laws require.
- ***"Protected health information (PHI)"*** is information is considered to be individually identifiable information relating to the past, present, or future health status of an individual that is created, collected, or transmitted, or maintained by a HIPAA-covered entity in relation to the provision of healthcare, payment for healthcare services, or use in healthcare operations.
- ***"Personally identifiable information (PII)"*** is any information about an individual maintained by an agency, including (1) any information that can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.

- ***"Agreement party" / "parties"*** or ***"signatory"*** refers to the representative for both the data provider and data recipient with the authority to sign this agreement into place.
- ***"Completed work"*** refers to any draft or final product of analysis, research, or project findings gleaned from the covered data set.

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.

A. Vaccination Related Fields

Field Name	Format	Description/Options	Example	Vendor-Specific Notes
Vaccination Event ID	String	Unique identifier for each vaccination to prevent duplicate result submission	578928889	
Vaccination Administered Date	MM/DD/YYYY	The date the vaccination was administered	11/01/2021	
Facility ID	String	Unique identifier for each site. Contractor shall obtain approval from the Government for the Facility ID.	P2000	
Vaccine manufacturer name	String	The manufacturer of the vaccine that was administered.	Pfizer, Moderna, etc.	
Vaccine product	String	NDC of product administered	80777-282-05	
Vaccine product	String	CVX of product administered	519 https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx	
Copay	String	Indicator whether copay applies	Yes/No	

B. Patient-Related fields

Field Name	Format	Description/Options	Example	Vendor-Specific Notes
Patient Zip Code	ZIP	5-digit ZIP code of patient residence	10000	
Patient Residence State	2-letter state abbreviation	The state where the patient resides.	TX	
Patient birth year	YYYY	The birth year of the patient	1978	
Patient Gender	String	Male, Female, Other, Not Reported	Female	
Patient Race	String	American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; White; Other; Not Reported	Black or African American	
Patient Ethnicity	String	Hispanic/Latino; Non-Hispanic/Latino; Not Reported	Hispanic/Latino	
Patient ID	String	Unique identifier for the patient, if available, subject to the condition that the identifier cannot be linked back to the patient		

C. Vaccination Site Related Fields

Field Name	Format	Description/Options	Example	Vendor-Specific Notes
Facility ID	Defined by Contractor or Government	Unique identifier for each site. Contractor shall obtain approval from the Government for the Facility ID.	P2000	
Site Description	String	Description of vaccination site to include relevant details at discretion	Store #10000	

		of Government and Contractor.		
Address	Address	Address of vaccination site	100 S Main St	
City	City	City of vaccination site	Houston	
State	Two-letter state abbreviation	State of vaccination site	AK	
ZIP Code	ZIP	5-digit ZIP code of vaccination site	10000	
Go Live Date	MM/DD/YYYY	Date site began vaccination.	11/01/2021	
IIS ID	String	Identifier assigned by IIS to the Provider Organization	State specific ID used for IIS reporting	
Pharmacy NPI	String	National Provider Identification number for the pharmacy (i.e. not the pharmacist or the prescriber)	1528162450	


CDC
CENTERS FOR DISEASE
CONTROL AND PREVENTION

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
Facility ID	Defined by Contractor or Government	Unique identifier for each site. Contractor shall obtain approval from the Government for the Facility ID.	P2000
Collected Date	MM/DD/YYYY	The date the sample was collected	11/01/2021
Test Results	String	Positive, Negative, Indeterminate	Positive
Test Type	String	Options to be defined by the Government	Swab and Send
Test ID	String	Unique identifier for each test to prevent duplicate result submission	
Budgetary Test Type	String	Options to be defined by the Government to aid in reconciling invoices submitted by the Contractor	Point-of-Care Test - Pharmacy
extended_hours	String	Yes or no if test was conducted outside pharmacy core hours; contractor-dependent.	Yes
test_provided	String	Yes or no if government provided the test.	Yes
site_management_fee	String	Yes or no if test incurs a surge site management fee.	Yes
support_services	String	Yes or no if vendor provided testing support services, contractor-dependent.	Yes

B. Patient-Related Fields

Field Name	Format	Description/Options	Example
Patient Residence County	County name	The county (not the city) where the patient resides.	Harris
Patient Residence State	2-letter state abbreviation	The state where the patient resides.	TX
Age	Single year age 0-120	The age of the patient at the time of the test. Ages 85+ will be aggregated upon ingestion to the data system.	32
Patient Gender	String	Male, Female, Other, Not Reported	Female
Patient Race	String	American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; White; Other; Not Reported	Asian
Patient Ethnicity	String	Hispanic/Latino; Non-Hispanic/Latino; Not Reported	Hispanic/Latino
Patient ID	String	Unique identifier for the patient, if available, subject to the condition that the identifier cannot be linked back to the patient	
insurance_status	String	Private Insurance, Medicaid, Medicare, Uninsured	Uninsured

C. Screening Questions Fields

Field Name	Format	Description/Options	Example
Patient Symptom Status	String	Result of patient screening question that	Asymptomatic

		enumerates a set of COVID-19-related symptoms. If the patient selects one or more symptoms, they are deemed Symptomatic. If not, they are deemed Asymptomatic.	
Patient Exposure	Yes/No	Result of patient screening question that seeks to identify if a patient is a close contact of a confirmed case of COVID-19.	Yes
Patient Travel	Yes/No	Result of patient screening question that seeks to identify if a patient has recently traveled or will travel in the near future.	No
Patient Underlying Conditions	Yes/No	Result of patient screening question that enumerates a set of underlying conditions that are thought to increase risk for severe COVID-19 infection. If the patient selects one or more conditions, the result is Yes. If not, the result is No.	No
Patient Immunocompromised Status	Yes/No	Result of patient screening question that enumerates a set of underlying conditions that are thought to indicate immunocompromised status. If the patient selects one or more conditions, the result is Yes. If not, the result is No.	Yes
Patient Pregnancy Status	Yes/No	Result of patient screening question that seeks to identify if the patient is pregnant.	Yes
Patient Vaccination Status	Yes/No	Result of patient screening question that seeks to identify if the patient has received one or more COVID-19 vaccination doses.	Yes
Patient Doses Received	1, 2, 3	Result of patient screening question that seeks to identify number of COVID-19 vaccination doses received. If patient is not vaccinated, field is left blank. The Government reserves the right to change the number of doses captured in this question subject to FDA and CDC guidance on booster doses.	2
First vaccine type	Pfizer-BioNTech, Moderna, J&J, Other	Result of patient screening question that seeks to identify the manufacturer of each vaccination dose. If patient is not vaccinated, field is left blank. The Government reserves the right to change the number of doses captured in this question subject to FDA and CDC guidance on approved vaccines.	Pfizer-BioNTech
Second vaccine type	Pfizer-BioNTech, Moderna, J&J, Other	Result of patient screening question that seeks to identify the manufacturer of each vaccination dose. If patient is not vaccinated, field is left blank. The Government reserves the right to change the manufacturers in this question subject to FDA and CDC guidance on approved vaccines.	Pfizer-BioNTech
Third vaccine type	Pfizer-BioNTech, Moderna, J&J, Other	Result of patient screening question that seeks to identify the manufacturer of each vaccination dose. If patient is not vaccinated, field is left blank. The Government reserves the right to change the manufacturers in this question subject to FDA and CDC guidance on approved vaccines.	Pfizer-BioNTech

Fourth vaccine type	Pfizer-BioNTech, Moderna, J&J, Other	Result of patient screening question that seeks to identify the manufacturer of each vaccination dose. If patient is not vaccinated, field is left blank. The Government reserves the right to change the manufacturers in this question subject to FDA and CDC guidance on approved vaccines.	Pfizer-BioNTech
First vaccination date	Month and year of vaccination	Result of patient screening question that seeks to identify the time of each vaccine dose. If patient is not vaccinated, field is left blank. The Contractor shall report this to the Government in the form of MM/01/YYYY.	10/01/2021
Second vaccination date	Month and year of vaccination	Result of patient screening question that seeks to identify the time of each vaccine dose. If patient is not vaccinated, field is left blank. The Contractor shall report this to the Government in the form of MM/01/YYYY.	10/01/2021
Third vaccination date	Month and year of vaccination	Result of patient screening question that seeks to identify the time of each vaccine dose. If patient is not vaccinated, field is left blank. The Contractor shall report this to the Government in the form of MM/01/YYYY.	10/01/2021
Fourth vaccination date	Month and year of vaccination	Result of patient screening question that seeks to identify the time of each vaccine dose. If patient is not vaccinated, field is left blank. The Contractor shall report this to the Government in the form of MM/01/YYYY.	10/01/2021
Two weeks since last dose?	Yes/No	Result of patient screening question that seeks to identify, when final dose of vaccination was received in the current or previous month, if the dose was at least two weeks in the past. If patient was vaccinated prior to the previous month or is unvaccinated, field is left blank.	Yes
Patient past positive test	Yes/No	Result of patient screening question that seeks to identify if the patient has tested positive for COVID-19 in the past.	No
Patient positive test within 90 days	Yes/No	Result of patient screening question that seeks to identify if the patient has tested positive for COVID-19 in the past 90 days. If patient has never tested positive for COVID-19, field is left blank.	Yes
Patient positive test prior to 90 days	Yes/No	Result of patient screening question that seeks to identify if the patient has tested positive for COVID-19 prior to the past 90 days. If patient has never tested positive for COVID-19, field is left blank.	Yes

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**
Facility ID	Defined by Contractor or Government	Unique identifier for each site. Contractor shall obtain approval from the Government for the Facility ID.	P2000
Subcontractor	String	If Contractor has a Subcontractor arrangement, the Contractor will identify their Subcontractor to the Government.	Topco-eTN
Site Description	String	Description of testing site to include relevant details at discretion of Government and Contractor.	Store #10000
Address	Address	Address of testing site	100 S Main St
City	City	City of testing site	Houston
State	Two-letter state abbreviation	State of testing site	AK
ZIP Code	ZIP	5-digit ZIP code of testing site	10000
Go Live Date	MM/DD/YYYY	Date site will begin testing.	11/01/2021

E. Over-the-Counter Test Sales

Under an executed data use agreement, the Contractor shall provide to the Government aggregate sales data related to over-the-counter COVID-19 tests. The Contractor shall provide at least aggregated national sales data on a weekly basis by count of item(s) sold. If available, the Contractor shall provide sales data at the state and/or distribution center level. If available, the Contractor shall provide data on inventory in stock. Over-the-counter sales data shall be reported via email to the Government or its designee, to the HHS Protect system, or to another system designated by the Government.

F. Site Metadata

The Contractor shall provide the Government with the operating hours of its testing sites. The Contractor shall provide the Government information on the testing capacity available at its sites, including, if available, information on the number or percentage of appointments dedicated to ICATT-funded tests. The Contractor shall provide the Government information on the tests available for patients at each of its testing sites (e.g. POC, lab-based PCR).

Exhibit A: ICATT Pharmacy Screening Questions

	Question	Response Options	Reporting Field Name	Reporting Field Options
1.	In the last 14 days, have you experienced any of these symptoms? Select all that apply.	fever cough shortness of breath recent loss of sense of smell or taste muscle pain fatigue chill headache, sore throat congestion/runny nose vomiting diarrhea (checkbox, select all that apply)	symptom_status	Asymptomatic Symptomatic Not Reported
2.	In the last 14 days, have you had contact with someone who has a suspected or confirmed case of COVID-19? Count any contact that lasted longer than 15 minutes, closer than 6 feet away.	Yes/No	recent_contact	Yes No Not Reported
3.	Are you seeking a COVID-19 test because you have either recently returned from travel or are planning on traveling soon?	Yes/No	traveling	Yes No Not Reported
4.	Has a healthcare worker ever diagnosed you with any of the following? Select all that apply.	Heart conditions High blood pressure Overweight or obesity Diabetes Current or former smoker Kidney failure or end stage renal disease Cirrhosis of the liver Chronic lung disease, such as COPD, moderate to severe asthma, cystic fibrosis, or pulmonary embolism Immunocompromised state, such as from immunocompromising medications, solid organ or blood stem cell transplant, HIV, or other immunocompromising conditions (checkbox, select all that apply)	underlying_conditions (If any box other than immunocompromised state checked)	Yes No Not Reported
			immunocompromised (If immunocompromised checked)	Yes No Not Reported
5.	Are you pregnant?	Yes/No	pregnant	Yes No Not Reported
6.	Have you had a COVID-19 vaccine?	Yes/No	has_received_vaccine	Yes No

				Not Reported
	If yes:			
6a.	How many doses have you received?	1 / 2 / 3 / 4 (bubbles)	received_doses	1 2 3 4 Not Reported
	For each dose:			
6b.	Which vaccine have you had?	Pfizer-BioNTech, Moderna, Johnson & Johnson / Janssen, Other (bubbles)	first_vaccine_type second_vaccine_type third_vaccine_type fourth_vaccine_type	Pfizer-BioNTech, Moderna, J&J, Other Not Reported
6c.	Time of shot	Month and year (drop downs)	first_vaccination_date second_vaccination_date third_vaccination_date fourth_vaccination_date	First of the month
	If final shot received in current or previous month:			
6d.	Has it been two weeks since your most recent dose?	Yes/No	two_weeks_since_dose	Yes No Not Reported
7.	Have you tested positive for COVID-19 in the past?	Yes/No	past_positive_test	Yes No Not Reported
	If yes:			
7a.	Did you receive this positive test…	Within the last 90 days, Prior to the last 90 days (checkbox, can select both)	past_positive_test_ within_90_days past_positive_test_ prior_to_90_days	Yes No Not Reported

Notes:

- Please continue to ask any other questions necessary for CARES Act reporting requirements or other state-mandated requirements.
- ICATT requests any data pharmacies have on completion rates of the existing screeners. ICATT will conduct an analysis of this data before and after implementation of the revised questions in partnership with each pharmacy partner if desired.
- ICATT requests that this screener be implemented as soon as possible and that the timeline of implementation be communicated to ICATT.