

<b>AWARD/CONTRACT</b>		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE 1 OF 43 PAGES		
2. CONTRACT (Procurement, Instruction, Identification) NUMBER 75D30121C11172		3. EFFECTIVE DATE 07/08/2021		4. REQUISITION/PURCHASE REQUEST/PROJECT NUMBER 00HCBCD9-2021-57021			
5. ISSUED BY Centers for Disease Control and Prevention (CDC) Office of Acquisition Services (OAS) 2900 Woodcock Blvd, MS TCU-4 Atlanta, GA 30341-4004		CODE 8219		6. ADMINISTERED BY (If other than Item 5) Centers for Disease Control and Prevention (CDC) Office of Acquisition Services (OAS) 2900 Woodcock Blvd, MS TCU-4 Atlanta, GA 30341-4004			
7. NAME AND ADDRESS OF CONTRACTOR (Number, Street, County, State and ZIP Code) EAGLE HEALTH ANALYTICS, LLC 111 W 16TH AVE STE 424  ANCHORAGE, AK 99501-5169		8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)		9. DISCOUNT FOR PROMPT PAYMENT  Net 30			
CODE 081341367		FACILITY CODE		10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:			
11. SHIP TO/MARK FOR  <b>SBA Requirement Number: YZ1621447283Z</b>		CODE		12. PAYMENT WILL BE MADE BY Centers for Disease Control and Prevention (FMO) PO Box 15580 404-718-8100  Atlanta, GA 30333-0080			
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c)( ) <input checked="" type="checkbox"/> 41 U.S.C. 3304(a)(5)		14. ACCOUNTING AND APPROPRIATION DATA 9390GLY 2512 2021 75-2124-0943 C5B8111101					
15A. ITEM NUMBER	15B. SUPPLIES/SERVICES "See Section B"	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT		
<b>15G. TOTAL AMOUNT OF CONTRACT →</b>					(b)(4)		
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<b>CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE</b>							
17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. <input type="checkbox"/> SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)			
19A. NAME AND TITLE OF SIGNER (Type or print)				20A. NAME OF CONTRACTING OFFICER Sarah Turner			
19B. NAME OF CONTRACTOR BY _____ (Signature of person authorized to sign)		19C. DATE SIGNED		20B. UNITED STATES OF AMERICA BY _____ (Signature of Contracting Officer)		20C. DATE SIGNED	

Eagle Health Analytics: (b)(4)  
 CDC COR: John Wuichet, [uw12@cdc.gov](mailto:uw12@cdc.gov)  
 CDC Contract Specialist: Sarah Turner, [kwp9@cdc.gov](mailto:kwp9@cdc.gov)

*“HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.”*

## Section B - Supplies Or Services and Prices/Costs

TOTAL FUNDED AMOUNT OF CONTRACT: \$5,925,388.58

TOTAL CONTRACT AMOUNT (INCLUDING ALL OPTIONS): \$7,077,054.90

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	NOT TO EXCEED
0001	Medical officer/epidemiologist support services for the VAERS program  <i>Period of Performance: July 8, 2021 - January 7, 2022</i>  <i>Monthly invoicing in arrears</i>  Labor Hour CLIN  Severable Services		(b)(4)	
	Line(s) Of Accounting: 9390GLY 2512 2021 75-2124-0943 C5B8111101	(b)(4)		
0003	Clinician/medical officer support for the CISA Project  <i>Period of Performance: July 8, 2021 - July 7, 2022</i>  <i>Monthly invoicing in arrears</i>  Labor Hour CLIN  Severable Services		(b)(4)	
	Line(s) Of Accounting: 9390GLY 2512 2021 75-2124-0943 C5B8111101	(b)(4)		

**Option 1 (Option 1) Items:**

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	NOT TO EXCEED
0002	VAERS Option  Medical officer/epidemiologist support services for the VAERS program  <i>Period of Performance: January 8, 2022 - July 7, 2022</i>  <i>Monthly invoicing in arrears</i>  This is an Optional CLIN  Labor Hour CLIN  Severable Services		(b)(4)	

\*\*\*Please note: Authorizations to Proceed with candidate pre-screening were issued via e-mail by Contracting Officers Alan Sims on May 28, 2021 and Kris Lemaster on June 9, 2021\*\*\*

**B.1 LABOR CHART**

LABOR CATEGORY & ESTIMATED LEVEL OF EFFORT					
Line Item	Year	Estimated Labor Categories	Hourly Rate (fully burdened)	Estimated Level of Effort	Estimated Labor Cost
(b)(4)					

**NOTATION REGARDING LABOR HOUR VARIANCE:** Performance under this Time and Materials/Labor Hour Contract is in accordance with FAR 52.232-7, "Payments under Time and Materials and Labor Hour Contracts," incorporated by reference in Section I, which requires the vendor to manage to the ceiling price in the contract and the ceiling price of the line items. The number of hours per labor category are estimates. The CO and the COR must be notified of any variance from the estimated hours shown in the Level of Effort/Labor Categories chart.

## **Section C - Description/Specification/Work Statement**

### **Title: Supporting Vaccine Task Force on Vaccine Adverse Event Reporting and Clinical Immunization Safety Assessments**

#### **C.1 Background and Need –**

The Centers for Disease Control and Prevention's (CDC) mission is to promote the health and quality of life by preventing and controlling disease, injury, and disability. As part of this mission, CDC is tasked with implementing programs to ensure that people will live safer, healthier lives through protecting Americans from health threats via a prevention, detection and response network and establishing CDC as the trusted and effective resources for health development. CDC addresses critical public health challenges through working with a diverse set of partners to support the development and implementation of public health interventions.

CDC provides leadership to improve the health of people in all life stages and in all settings. It carries out this role by monitoring health, developing health improvement strategies, providing financial and technical assistance to partners and conducting other activities. There are major programs that have been implemented globally within the last several years that have greatly expanded the global mission of the CDC and have prompted the need for increased services and staffing domestically to support those activities. As more health crises are identified, the mission and response of CDC's operating divisions have expanded.

In part of the response to the global COVID-19 pandemic, the United States has introduced a national mass COVID-19 vaccination program. Over a 100 million American citizens already vaccinated and there is a goal of vaccinating the U.S. population by early summer. As vaccine safety monitoring is a critical component to any vaccination program, for COVID-19 vaccine safety monitoring efforts are the most intense and comprehensive in U.S. history. CDC is relying on established monitoring programs including the Vaccine Adverse Event Reporting System (VAERS) and the Clinical Immunization Safety Assessment (CISA) Project to offer . Because of these efforts, additional staffing is needed to support CDC's efforts in VAERS and v-safe safety activities.

#### **Vaccine Adverse Event Reporting System (VAERS)**

VAERS is a mandated program sponsored jointly by the Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA). The purpose of this project as authorized by the National Childhood Vaccine Injury Act (NCVIA), P.L. 99-660, is to provide a single nationwide mechanism to report, analyze and monitor vaccine adverse events (VAEs) that occur after receipt of vaccines. It also provides a vehicle for disseminating vaccine safety information to vaccines, family members, health care providers, vaccine manufacturers, government agencies, and other partners.

VAERS contains reports of VAEs based on two criteria, mandated and voluntary reports. The events mandated for healthcare provider and vaccine manufacturer reporting are listed in the Reportable Adverse Events Table (RET) available at [https://vaers.hhs.gov/docs/VAERS\\_Table\\_of\\_Reportable\\_Events\\_Following\\_Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf)



US- manufacturers of vaccines are mandated by 21 CFR Part 600.80 (Attachment 3) to submit reports routinely on a periodic basis, as well as in an expedited manner for more serious events. In addition, healthcare providers are encouraged to report all other clinically significant VAEs following the administration of any US vaccine in all age groups. For all reports, the impetus for reporting is not a presumed causal relationship between the vaccination and the event but may be based simply on the occurrence of the event temporally following vaccination and the lack of other obvious causes.

From 2015 through 2019, VAERS received an annual average of 58,000 reports, of which 49,000 were US reports. Of the US reports, 5.3% were classified as serious (i.e., associated with disability, hospitalization, prolongation of existing hospitalization, life-threatening illness, congenital anomaly/birth defect, or death [21 CFR 600.80]). Since 1990 to 2019, VAERS has received over 810,000 reports, most of which describe mild and self-limited adverse events such as injection site reactions and fever. (VAERS government data archive January 29, 2021.) VAERS helps to identify important new safety concerns and thereby can help inform vaccine policymakers and healthcare providers. In addition, the data are valuable for regulatory actions and vaccine research studies. The US Government considers post-licensure/authorization surveillance for any licensed and new vaccines through VAERS to be a nationally critical function, and the US Government considers the requirements of the VAERS activity to constitute essential services for which any lapse in coverage of services would be unacceptable.

The current COVID-19 pandemic and COVID-19 vaccination program have created additional requirements for VAERS. Specifically, as part of a mass immunization program with a goal to immunize every adult by May 2021, VAERS has had a surge in reporting of adverse events as compared to previous years and to other vaccines. In addition, CDC reviews reports that are coded as Adverse Events of Special Interest (AESI). These AESI include: acute myocardial infarction, anaphylaxis, coagulopathy, death, Guillain-Barré Syndrome, Kawasaki Disease, Multisystem Inflammatory Syndrome (in adults and in children), myopericarditis, narcolepsy, pregnancy, seizure, stroke, transverse myelitis, Bell's palsy, and appendicitis. Additional outcomes are added, as potential concerns following COVID-19 vaccination are identified.

### **Clinical Immunization Safety Assessments (CISA)**

CISA Project is a national network of vaccine safety experts from CDC's Immunization Safety Office (ISO) and seven medical research centers. CISA conducts clinical research, assesses complex adverse events following vaccination, and provides consultations to United States healthcare providers and public health partners.

During the United States COVID-19 vaccine program, CISA is operating a 24/7 on-call clinical consultation service for COVID-19 vaccine safety (CISA COVIDvax). Healthcare providers or health departments in the United States can request a consultation from CISA COVIDvax for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or Advisory Committee on Immunization Practices (ACIP) guidelines.

<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>

**CISA COVIDvax** is a partnership between CDC clinicians and vaccine safety and infectious disease expert physicians from medical research centers participating in the CISA Project. In addition, participating medical centers provide expertise in multiple clinical areas (including allergy/immunology, neurology, geriatric medicine, and obstetrics and gynecology).

## **C.2 Project Objective**

The objective of this contract is to provide CDC's vaccine safety activities with a ready source of clinical, scientific, and technical services for emergency response.

## **C.3 Scope of Work**

Independently and not as an agent of the Government, the Contractor shall provide all personnel and services necessary to perform the following tasks as listed in this SOW. This work will support the U.S. COVID-19 vaccination program's vaccine safety programs conducted by CDC.

## **C.4 Tasks and Technical Requirements**

### **Working Hours**

The contractor shall provide services during normal working hours, which are defined as Monday through Friday, 9 a.m. to 5 p.m. Because this is an emergency response effort, it is highly likely that some of the contractor's services will also be required outside of normal working hours, including on weekends. The Contracting Officer's Representative (COR) will provide contractor management with instruction and authorization when services outside of normal working hours are required and when the contractor is needed work over 40 hours per week. A requirement for work outside of normal working hours and additional hours may be given on short notice.

### **Technical Requirements**

The contractor shall perform the following tasks:

Task 1: The contractor shall organize a kick off meeting with the CDC within 1 week of contract award.

Task 2: The contractor shall provide medical officer/epidemiologist support services for the VAERS program. Tasks include:

- A. The contractor will sign a CDC VAERS Rules of Behavior (ROB) form.
- B. Working with CDC staff, the contractor will gain access to the VAERS VPN and the internal CDC VAERS abstraction website.
- C. The contractor will be trained by CDC staff on VAERS, using the VAERS VPN, how to review VAERS reports, how to conduct medical record abstraction, and how to enter data into the internal CDC VAERS abstraction website.
- D. Working with CDC staff, the contractor will review VAERS AESI reports. Up to 25 VAERS reports will be assigned per day for review.
- E. The contractor shall perform a review of available VAERS reports and associated medical records, if available, for each assigned report.

- F. The contractor shall perform data entry from the assigned reviews. These reviews will be via CDC electronic form, consisting mostly of check boxes and free text fields. The medical record review will determine if the reported AESI meets a published case definition (if available). Medical record reviews will follow CDC VAERS Standard Operating Procedures. All published case definitions will be provided to the contractor.
- G. The contractor shall request medical records from health care providers/systems located in the United States on behalf of VAERS.
- H. The contractor shall conduct literature reviews on new vaccine safety outcomes of concern or AESI.
- I. The contractor shall respond to inquiries received by the public, health departments, and providers. This may include reviewing the VAERS database, conducting literature reviews to provide published data as it pertains to the inquiry, and drafting a response to the inquiry. The response will be shared with the CDC VAERS inquires lead and the VAERS team lead or designee.
- J. The contractor shall work with CDC VAERS staff to resolve any questions or concerns related to VAERS reviews.
- K. The contractor shall attend up to 3 meetings per week.

Task 2 Requirements:

- 1. Contractors shall have a clinical background (e.g. physician, physician assistant, nurse practitioner); contractor does not need to be a licensed MD.
- 2. Contractors shall have good interpersonal and communication skills (written and oral).
- 3. Contractors shall have the ability to prioritize tasks and function in a potentially fast-paced, dynamic environment.
- 4. Prior experience with medical abstraction and knowledge of and experience with vaccine safety or infectious diseases is preferred.

Task 3. The contractor shall provide clinician/medical officer support for the CISA Project

- A. The contractor shall receive and respond to requests of assistance for COVID-19 vaccine safety emergencies or inquiries from healthcare providers and health departments. Requests may come in the form of phone calls or emails from the CDC Emergency Operations Center or other CDC public facing inquiry response services.
- B. The contractor shall monitor, triage, and assist with responding to emails and clinical inquiries that CISA receives daily.
- C. Using clinical expertise, the contractor shall triage calls and inquiries to determine the need for escalation to CISA's nationwide network of vaccine experts and others such as allergists.
- D. Contractor will attend daily morning and afternoon CISA team conference calls in addition to a daily conference call with CISA's national network of vaccine experts. Contractors will attend CISA meetings that urgently occur to assist inquirers. In addition, contractors will attend CISA consultation conference calls with inquirers.
- E. The contractor shall contribute to the investigation of adverse events including allergic reactions after COVID-19 vaccine in collaboration with state health departments and other partners.



- F. The contractor shall request medical records from health care providers/systems located in the United States on behalf of CISA.
- G. The contractor shall review, abstract, and summarize medical records pertinent to COVID-19 vaccine safety consults or evaluations. Inquires will be tracked in a CDC database. The contractor shall perform data entry from these reviews. Data entry will be via CDC electronic database, consisting mostly of check boxes and free text fields. The contractor will be trained by CDC CISA staff on how to input data into the database.
- H. The contractor shall work with CDC CISA staff to resolve any questions or concerns related to CISA inquiries, medical record reviews, or data entry into the electronic database.
- I. The contractor will sign a CDC VAERS Rules of Behavior (ROB) form.
- J. Working with CDC staff, the contractor will gain access to the VAERS VPN.
- K. The contractor shall search VAERS database for vaccine safety information.
- L. The contractor shall conduct literature reviews informing vaccine safety issues, including literature reviews about COVID-19 vaccines and clinical conditions.
- M. The contractor shall provide COVID-19 vaccine safety technical assistance to the response efforts and contribute to COVID-19 vaccine safety educational activities.
- N. The contractor shall maintain subject matter expertise pertinent to CDC COVID-19 response activities.
- O. The contractor shall contribute to the development of daily, weekly, and long-term team priorities and progress report updates.
- P. The contractor shall assist with research needs of the CISA team, including writing and editing scientific products (manuscripts, abstracts, scientific posters).
- Q. The contractor shall assist with the preparation of and/or give presentations on complex vaccine safety issues concerning individual patients/groups of patients and the results of scientific research.
- R. The contractor shall educate other team members on scientific and technical aspects of team activities and function.
- S. The contractor shall support the operational needs for the clinical service and contribute to clinical consultation tracking database activities for ISO.

#### Task 3 Requirements:

- 1. The contractor shall have a valid US Medical License (unrestricted).
- 2. The contractor shall have completed an ACGME Medical Residency program.
- 3. The contractor shall have medical knowledge in the areas of Adult and/or Pediatric Medicine.
- 4. The contractor shall have the ability to actively reach out and contact providers and partners on the phone.
- 5. The contractor shall have the flexibility to work across multiple disciplines of medicine and public health.
- 6. The contractor shall have familiarity with Microsoft Office products (e.g., MS Word and Excel).
- 7. Additional desired skills include: preferred Board Certification, including but not limited to Infectious Diseases, Emergency Medicine, Internal Medicine, Family Practice, and Pediatrics; knowledge and experience with COVID-19 patient care or public health and/or vaccines; comfort in working in 100% virtual environment; and experience with RedCap and Microsoft Teams.



Task 4: The contractor shall provide Project Coordinator Support Services for the VAERS program. Tasks include:

1. The contractor shall work with the CDC VAERS team to ensure monitoring and evaluation processes are followed per established standard operating procedures (SOPs).
2. The contractor shall assist the VAERS team lead manage activities, including medical record reviews and reports of adverse events of special interest (AESI).
3. The contractor shall coordinate assignments of VAERS AESI medical records reviews into CDC-based data entry systems (REDCap and VAERS Abstraction Website) with CDC and contract-based clinical staff.
4. The contractor shall provide reports to the VAERS team lead on status of AESI medical record reviews on a daily basis.
5. The contractor shall assist the VAERS team lead and CDC VAERS team members to write SOPs.
6. The contractor shall schedule meetings as required.
7. The contractor will sign a CDC VAERS Rules of Behavior (ROB) form.
8. Working with CDC staff, the contractor will gain access to the VAERS VPN and the internal CDC VAERS abstraction website.
9. The contractor will be trained by CDC staff on VAERS, using the VAERS VPN, how to review VAERS reports, how to conduct medical record abstraction, and how to enter data into the internal CDC VAERS abstraction website.
10. The contractor shall respond in writing to inquiries received by the public, health departments, and providers. This may include reviewing the VAERS database, conducting literature reviews to provide published data as it pertains to the inquiry, and drafting a response to the inquiry. The response will be shared with the CDC VAERS inquiries lead and the VAERS team lead, or designee.
11. The contractor shall work with CDC VAERS staff to resolve any questions or concerns related to VAERS reviews
12. The contractor shall assist the VAERS team responding to ad-hoc requests related to COVID-19 vaccine safety outcomes or concerns.
13. The contractor shall participate in up to 15 meetings per week.

#### **C.5 Deliverable Schedule –**

<b>Task</b>	<b>Deliverable</b>	<b>Quantity/Format</b>	<b>Due Date</b>	<b>Due To</b>
Task 1	Kick-off Meeting Notes	1 Word Document by Email	Within 2 weeks of award	COR
Tasks 2-4	Provide CDC with monthly status report for all tasks	1 Word Document by Email	15th of each month	COR

**C.6 Special Considerations** – The contractor must protect the confidentiality of proprietary, sensitive, and Personally Identifiable Information (PII). All staff under this contract working with VAERS and CISA will have access to PII and will be required to obtain a CDC Public Trust level-5 background clearance.

**C.7 Government Furnished Property** -- The government will provide badge access and laptops.

## **C.8 Clearances**

### **Information Security**

#### **Standard-1: Procurements Requiring Information Security and/or Physical Access Security**

##### **1. 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](mailto:fisma@hhs.gov).
- d. Comply with the Privacy Act requirements and tailor FAR clauses as needed.

- 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:

<b>Confidentiality:</b>	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> High
<b>Integrity:</b>	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> High
<b>Availability:</b>	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> High
<b>Overall Risk Level:</b>	<input type="checkbox"/> Low <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> High

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      ☒ 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 ☒ Moderate ☐ High

- 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. 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.

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], 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 <http://csrc.nist.gov/publications/>. Encryption keys shall be provided to CDC Cybersecurity Program Office (CSPO).

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.

#### T. Training

- 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) **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.

**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.

#### U. 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.

#### V. Incident Response

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

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized

user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose.

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

**Definition of an Incident:**

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

**Definition of a Breach:**

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

It further adds:

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

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

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

- 1) The contractor shall cooperate with and exchange information with CDC officials, as deemed necessary by the CDC Breach Response Team, to report and manage a suspected or confirmed breach.
- 2) All contractors and subcontractors shall properly encrypt PII in accordance with OMB Circular A-130 and other applicable policies, including CDC-specific policies, and comply with HHS-specific policies for protecting PII. To this end, all contractors and subcontractors shall protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
- 3) All contractors and subcontractors shall participate in regular training on how to identify and report a breach.
- 4) All contractors and subcontractors shall report a suspected or confirmed breach in any medium as soon as possible and no later than 1 hour of discovery, consistent with

applicable CDC IT acquisitions guidance, HHS/CDC and incident management policy, and United States Computer Emergency Readiness Team (US-CERT) notification guidelines. To this end, the Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC) or CDC Computer Incident Response Team (CSIRT) within 24 hours via email at csirt@cdc.gov or telephone at 866-655-2245, whether the response is positive or negative.

- 5) All contractors and subcontractors shall be able to determine what Federal information was or could have been accessed and by whom, construct a timeline of user activity, determine methods and techniques used to access Federal information, and identify the initial attack vector.
- 6) All contractors and subcontractors shall allow for an inspection, investigation, forensic analysis, and any other action necessary to ensure compliance with HHS/CDC Policy and the HHS/CDC Breach Response Plan and to assist with responding to a breach.
- 7) Cloud service providers shall use guidance provided in the FedRAMP Incident Communications Procedures when deciding when to report directly to US-CERT first or notify CDC first.
- 8) Identify roles and responsibilities, in accordance with HHS/CDC Breach Response Policy and the HHS/CDC Breach Response Plan. To this end, the Contractor shall NOT notify affected individuals unless and until so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, all notifications must be pre-approved by the appropriate CDC officials, consistent with HHS/CDC Breach Response Plan, and the Contractor shall then send CDC- approved notifications to affected individuals; and,
- 9) Acknowledge that CDC will not interpret report of a breach, by itself, as conclusive evidence that the contractor or its subcontractor failed to provide adequate safeguards for PII.

#### w. 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).

#### x. Homeland Security Presidential Directive (HSPD)-12

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*.

**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.

Y. Contract Initiation and Expiration

- 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).
- 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](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.

Z. 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.

In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS policies.

## **Standard-2: Requirements for Procurements Involving Privacy Act Records**

### **A. Privacy Act**

It has been determined that this contract is subject to the Privacy Act of 1974, because this contract provides for the design, development, or operation of a system of records on individuals.

The System of Records Notice (SORN) that is applicable to this contract is: 09-20-0136

The design, development, or operation work the Contractor is to perform is described in this Statement of Work and includes data collection and data management.

The disposition to be made of the Privacy Act records upon completion of contract performance is: *VAERS does not have an individual record schedule in NCEZID record schedule document. According to CDC MASO website, VAERS compliance with CDC record schedule "CDC-04-4-66" which is maintain at least six years, but no longer than ten years after the retirement of the system depending upon program need for scientific, legal, or business reference then delete/destroy .*

## **Section D - Packaging And Marking**

Not Applicable

## Section E - Inspection And Acceptance

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

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

<https://acquisition.gov>

(End of Clause)

FAR SOURCE	TITLE AND DATE
52.246-6	Inspection-Time-and-Material and Labor-Hour (May 2001)



## Section F - Deliveries Or Performance

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

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

(End of Clause)

FAR SOURCE	TITLE AND DATE
52.242-15	Stop-Work Order (Aug 1989)

## **Section G - Contract Administration Data**

### **G.1 Contract Representative**

#### **Contracting Officer (CO) responsible for this contract:**

Sarah Turner  
Office of Acquisition Services (OAS)  
Office of Financial Resources (OFR)  
Office of the Chief Operating Officer (OCOO)  
Centers for Disease Control and Prevention (CDC)  
KWP9@cdc.gov | 404-498-5613

#### **Contracting Officer's Representative (COR) responsible for this contract:**

John Wuichet  
[uw12@cdc.gov](mailto:uw12@cdc.gov)  
404.639.7052

(End of Clause)

### **G.2 CDCP\_G009 Contracting Officer (Jul 1999)**

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

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

(End of Clause)

### **G.3 CDC0\_G008 Contracting Officer's Representative (COR) (Jul 2017)**

Performance of the work hereunder shall be subject to the technical directions of the designated COR for this contract.

As used herein, technical directions are directions to the Contractor which fill in details, suggests possible lines of inquiry, or otherwise completes the general scope of work set forth herein. These technical directions must be within the general scope of work, and may not alter the scope of work or cause changes of such a nature as to justify an adjustment in the stated contract price/cost, or any stated limitation thereof.

In the event that the Contractor believes full implementation of any of these directions may exceed the scope of the contract, he or she shall notify the originator of the technical direction and the Contracting Officer, immediately or as soon as possible, in a letter or e-mail separate of any required report(s). No technical direction, nor its fulfillment, shall alter or abrogate the rights and obligations fixed in this contract.

The Government COR is not authorized to change any of the terms and conditions of this contract. Contract changes shall be made only by the Contracting Officer by properly written modification(s) to the contract.

The Government will provide the Contractor with a copy of the COR delegation memorandum upon request.

(End of Clause)

#### **G.4 CDC0\_G018 Payment by Electronic Funds Transfer (Feb 2018)**

(a) The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer –System for Award Management, in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

(b) In the case that EFT information is not within the System of Award Management, FAR 52.232-34 requires mandatory submission of Contractor's EFT information directly to the office designated in this contract to receive that information (hereafter: "designated office"); see below. The contractor shall submit the EFT information within the form titled "ACH Vendor/Miscellaneous Payment Enrollment Form" to the address indicated below. Note: The form is either attached to this contract (see Section J, List of Attachments) or may be obtained by contacting the Contracting Officer or the CDC Office of Financial Resources at 678-475-4510.

(c) In cases where the contractor has previously provided such information, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form is not required unless the designated financial institution has changed.

(d) The completed form shall be mailed after award, but no later than 14 calendar days before an invoice is submitted, to the following address:

The Centers for Disease Control and Prevention  
Office of Financial Resources (OFR)  
P.O. Box 15580  
Atlanta, GA 30333  
Or – Fax copy to: 404-638-5342

(End of Clause)

#### **G.5 CDCA\_G001 – Invoice Submission (March 2021)**

(a) The Contractor shall submit the original contract invoice/voucher in one of the following

ways: 1) mail, 2) facsimile, 3) email:

##### **Mailing Address:**

The Centers for Disease Control and Prevention  
Office of Financial Resources (OFR)  
P.O. Box 15580  
Atlanta, GA  
30333

Fax: 404-638-5324

Email: [cpbapinv@cdc.gov](mailto:cpbapinv@cdc.gov)

NOTE: Submit only one Invoice in PDF format per attachment.

- (b) Subject Line must contain the word "Invoice" Example: Subject: Invoice SAM12345 for Contract 75D30121\*\*\*\*\*
- (c) The content/details of the email must include the below information provided in the body of the email:
  - Contract or PO Number:
  - Invoice Number:
  - Amount:
  - Vendor Name:

Only one invoice can be sent to the mailbox with the above relevant details in the body (multiple invoices need to be sent in multiple emails)

- (d) The contractor shall submit 2 copies of the invoice to the cognizant contracting office previously identified in this contract. These invoice copies shall be addressed to the attention of the Contracting Officer.
- (e) Do not send Links, Zip Files, or .DAT files containing PDF Invoices
- (f) The Contractor ☒ is ☐ , is not required to submit a copy of each invoice directly to the Contracting Officer's Representative (COR) concurrently with submission to the Contracting Officer.
- (g) In accordance with 5 CFR part 1315 (Prompt Payment), CDC's Office of Financial Resources is the designated billing office for the purpose of determining the payment due date under FAR 32.904.

- (h) The Contractor shall include (as a minimum) the following information on each invoice:

- (1) Contractor's Name & Address
- (2) Contractor's Tax Identification Number (TIN)
- (3) Purchase Order/Contract Number and Task Order Number, if Appropriate
- (4) Invoice Number
- (5) Invoice Date
- (6) Contract Line Item Number and Description of Item
- (7) Quantity
- (8) Unit Price & Extended Amount for each line item



- (9) Shipping and Payment Terms
- (10) Total Amount of Invoice
- (11) Name, title and telephone number of person to be notified in the event of a defective invoice
- (12) Payment Address, if different from the information in (c)(1).
- (13) DUNS + 4 Number
- (14) Electronic funds transfer (EFT) banking info

For the status of invoices, please contact the OFR Service desk at [ofrservicedesk@cdc.gov](mailto:ofrservicedesk@cdc.gov)

NOTE: If your invoice has supporting documents, please combine the invoice and supporting documents as one PDF file. Do not submit the invoice and its supporting documents separately.

## **Section H - Special Contract Requirements**

### **H.1 CDC0\_H049 Non-Disclosure Agreement for Contractor and Contractor Employees (Jun 2020)**

- (a) The contractor and contractor employees shall prepare and submit Non-Disclosure Agreements (NDA) to the Contracting Officer prior to access of government information or the commencement of work at CDC.
- (b) The NDAs, at Exhibit I and II, are required in service contracts where contractor's employees will have access to non-public and procurement-sensitive information while performing functions in support of the Government. The NDA also requires contractor's employees properly identify themselves as employees of a contractor when communicating or interacting with CDC employees, employees of other governmental entities, and members of the public (when communication or interaction relates to the contractor's work with the CDC). The Federal Acquisition Regulation (FAR) 37.114 (c), states "All contractor personnel attending meetings, answering Government telephones, and working in other situations where their contractor status is not obvious to third parties are required to identify themselves as such to avoid creating an impression in the minds of members of the public or Congress that they are Government officials, unless, in the judgment of the agency, no harm can come from failing to identify themselves. They must also ensure that all documents or reports produced by contractors are suitably marked as contractor products or that contractor participation is appropriately disclosed."
- (c) The contractor shall inform contractor employees of the identification requirements by which they must abide and monitor employee compliance with the identification requirements.
- (d) During the contract performance period, the contractor is responsible to ensure that all additional or replacement contractors' employees sign an NDA and it is submitted to the Contracting Officer prior to commencement of their work with the CDC.
- (e) Contractor employees in designated positions or functions that have not signed the appropriate NDA shall not have access to any non-public, procurement sensitive information or participate in government meetings where sensitive information may be discussed.
- (f) The Contractor shall prepare and maintain a current list of employees working under NDAs and submit to the Contracting Officer upon request during the contract period of performance. The list should at a minimum include: contract number, employee's name, position, date of hire and NDA requirement.

**EXHIBIT I**  
Centers for Disease Control and Prevention (CDC)  
Contractor Non-Disclosure Agreement

**I. Non-public Information**

[Name of contractor] understands that in order to fulfill the responsibilities pursuant to [contract name and number] between the Centers for Disease Control and Prevention and [Name of CDC contractor] dated [date], employees of [contractor] will have access to non-public information, including confidential and privileged information contained in government-owned information technology systems. For purposes of this agreement, confidential information means government information that is not or will not be generally available to the public. Privileged information means information which cannot be disclosed without the prior written consent of the CDC.

In order to properly safeguard non-public information, [contractor] agrees to ensure that prior to being granted access to government information or the commencement of work for the CDC, whichever is applicable, all contractor employees will sign a Non-Disclosure Agreement (NDA) provided by the CDC prior to beginning work for the CDC. Contractor agrees to submit to the Contracting Officer the original signed copies of NDAs signed by the contractor's employees in accordance with the instructions provided by the Contracting Officer. Failure to provide signed NDAs in accordance with this agreement and instructions provided by the Contracting Officer could delay or prevent the employee from commencing or continuing work at the CDC until such agreement is signed and returned to the Contracting Officer.

Contractor further agrees that it will not cause or encourage any employee to disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee any non-public information that the employee may obtain in connection with the performance of the employee's responsibilities to the CDC.

**II. Procurement-Sensitive Information**

Contractor further agrees that it will not cause or encourage any employee to disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual, other than an authorized Government employee, any procurement-sensitive information gained while in connection with fulfilling the employee's responsibilities at the CDC. For purposes of this agreement, procurement-sensitive information includes, but is not limited to, all information in Statements of Work (SOW), Procurement Requests (PR), and Requests for Proposal (RFP); Responses to RFPs, including proposals, questions from potential offerors; non-public information regarding procurements; all documents, conversations, discussions, data, correspondence, electronic mail (e-mail), presentations, or any other written or verbal communications relating to, concerning, or affecting proposed or pending solicitations or awards; procurement data; contract information plans; strategies; source selection information and documentation; offerors' identities; technical and cost data; the identity of government personnel involved in the solicitation; the schedule of key technical and procurement events in the award determination process; and any other information that may provide an unfair competitive advantage to a contractor or potential contractor if improperly disclosed to them, or any of their employees.

Contractor understands and agrees that employee access to any procurement-sensitive information may create a conflict of interest which will preclude contractor from becoming a competitor for any acquisition(s) resulting from this information. Therefore, if an employee participates in any discussions relating to procurement-sensitive information, assists in developing any procurement-sensitive information, or otherwise obtains any procurement-sensitive information while performing duties at the

CDC, contractor understands and agrees that contractor may be excluded from competing for any acquisition(s) resulting from this information.

### III. Identification of Non-Government Employees

Contractor understands that its employees are not agents of the Government. Therefore, unless otherwise directed in writing by the CDC, contractor agrees to assist and monitor employee compliance with the following identification procedures:

- A. At the beginning of interactions with CDC employees, employees of other governmental entities, and members of the public (when such communication or interaction relates to the contractor's work with the CDC), contractors' employees will identify themselves as an employee of a contractor.
- B. Contractors' employees will include the following disclosures in all written communications, including outgoing electronic mail (e-mail) messages, in connection with contractual duties to the CDC:

*Employee's name*  
*Name of contractor*  
*Center or office affiliation*  
Centers for Disease Control and Prevention

- C. At the beginning of telephone conversations or conference calls, contractors' employees will identify themselves as an employee of a contractor.
- D. Contractors' employees should not wear any CDC logo on clothing, except for a CDC issued security badge while carrying out work for CDC or on CDC premises. The only other exception is when a CDC management official has granted permission to use the CDC logo.
- E. Contractors' employees will program CDC voice mail message to identify themselves as an employee of a contractor.

I understand that federal laws including, 18 U.S.C. 641 and 18 U.S.C. 2071, provide criminal penalties for, among other things, unlawfully removing, destroying or converting to personal use, or use of another, any public records. Contractor acknowledges that contractor has read and fully understands this agreement.

Name of contractor: \_\_\_\_\_

Signature of Authorized Representative of Contractor: \_\_\_\_\_

Date: \_\_\_\_\_

Copies retained by: Contracting Officer and contractor



## **EXHIBIT II**

### **Centers for Disease Control and Prevention (CDC) Contractors' Employee Non-Disclosure Agreement**

#### **I. Non-Public Information**

I understand that in order to fulfill my responsibilities as an employee of [Name of CDC contractor], I will have access to non-public information, including confidential and privileged information contained in government-owned information technology systems. For purposes of this agreement, confidential information means government information that is not or will not be generally available to the public. Privileged information means information which cannot be disclosed without the prior written consent of the CDC.

I, [Name of Employee], agree to use non-public information only in performance of my responsibilities to the CDC. I agree further that I will not disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee, any non-public information that I may obtain in connection with the performance of my responsibilities to the CDC.

#### **II. Procurement-Sensitive Information**

I further agree that unless I have prior written permission from the CDC, I will not disclose, publish, divulge, release, or make known in any manner or to any extent, to any individual other than an authorized Government employee, any procurement-sensitive information gained in connection with the performance of my responsibilities to the CDC. I specifically agree not to disclose any non-public, procurement-sensitive information to employees of my company or any other organization unless so authorized in writing by the CDC. For purposes of this agreement, procurement-sensitive information includes, but is not limited to, all information in Statements of Work (SOW), Procurement Requests (PR), and Requests for Proposal (RFP); Responses to RFPs, including proposals, questions from potential offerors; non-public information regarding procurements; all documents, conversations, discussions, data, correspondence, electronic mail (e-mail), presentations, or any other written or verbal communications relating to, concerning, or affecting proposed or pending solicitations or awards; procurement data; contract information plans; strategies; source selection information and documentation; offerors' identities; technical and cost data; the identity of government personnel involved in the acquisition; the schedule of key technical and procurement events in the award determination process; and any other information that may provide an unfair competitive advantage to a contractor or potential contractor if improperly disclosed to them, or any of their employees.

I understand and agree that my access to any procurement-sensitive information may create a conflict of interest which will preclude me, my current employer, or a future employer from becoming a competitor for any resulting government acquisition derived from this information. Therefore, if I participate in any discussions relating to procurement-sensitive information, assist in developing any procurement-sensitive information, or otherwise obtain any procurement-sensitive information while performing my duties at the CDC, I understand and agree that I, my current employer, and any future employer(s) may be excluded from competing for any resulting acquisitions.

#### **III. Special Non-Disclosure Agreement for Contractors with Access to CDC Grants Management and Procurement-Related Information Technology Systems**

In addition to complying with the non-disclosure requirements and safeguards stated above, I understand that my authorization to use CDC's grants management and procurement systems is strictly limited to the access and functions necessary for the performance of my responsibilities to the CDC and which have been approved in advance by the CDC. I understand that I am not authorized to enter procurement requests for any requirements pertaining to contracts or subcontracts held by me or my employer.

#### **IV. Identification as a Non-Government Employee**

I understand that as an employee of a government contractor, I represent an independent organization and I am not an agent of the Government. Therefore, I agree that unless I have prior written authorization from the CDC, I will, at the beginning of interactions with CDC employees, employees of other governmental entities, members of the public (when such communication or interaction relates to the contractor's work with the CDC), identify myself as an employee of a contractor. I further agree to use the following identification procedures in connection with my work at the CDC:

**A.** I will include the following disclosures in all written communications, including outgoing electronic mail (e-mail) messages:

*Employee's name*  
*Name of contractor*  
*Center or office affiliation*  
Centers for Disease Control and Prevention

**B.** I will identify myself as an employee of a contractor at the beginning of telephone conversations or conference calls;

**C.** I will not wear any CDC logo on clothing, except for a CDC issued security badge while carrying out work for CDC or on CDC premises; the only other exception is when a CDC management official has granted permission to use the CDC logo.

**D.** I will program my CDC voice mail message to identify myself as a contractors' employee.

I understand that federal laws including, 18 U.S.C. 641 and 18 U.S.C. 2071, provide criminal penalties for, among other things, unlawfully removing, destroying or converting to personal use, or use of another, any public records. I acknowledge that I have read and fully understand this agreement.

Name of contractor: \_\_\_\_\_

Name of Employee: \_\_\_\_\_

Signature of Employee: \_\_\_\_\_

Date: \_\_\_\_\_

Copies retained by: Contracting Officer, contractor, and Contractor Employee

## **H.2 CDC37.0001 Non-Personal Services (Jun 2020)**

(a) Personal services shall not be performed under this contract. Although the Government may provide sporadic or occasional instructions within the scope of the contract, the Contractor is responsible for control and supervision of its employees. If the Contractor (including its employees) believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

(b) The contractor shall comply with, and ensure their employees and subcontractors comply with, CDC Policy titled "Contractor Identification and Safeguarding of Non-Public Information". No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. The contractor is limited to performing the services identified in the contract statement of work and shall not interpret any communication with anyone as a permissible change in contract scope or as authorization to perform work not described in the contract. All contract changes will be incorporated by a modification signed by the Contracting Officer.

(c) The Contractor shall ensure that all of its employees and subcontractor employees working on this contract are informed of the terms and conditions herein. The Contractor agrees that this is a non-personal services contract; and that for all the purposes of the contract, the Contractor is not, nor shall it hold itself out to be an agent or partner of, or joint venture with, the Government. The Contractor shall notify its employees that they shall neither supervise nor accept supervision from Government employees. The substance of the terms herein shall be included in all subcontracts at any tier.

(d) The terms and conditions above do not limit the Government's rights under other terms of the contract, including those related to the Government's right to inspect and accept or reject the services performed under this contract.

(End of Clause)

## **H.3 CDC0\_H022 Smoke Free Working Environment (May 2009)**

In compliance with Department of Health and Human Services (DHHS) regulations, all contractor personnel performing work within CDC/ATSDR facilities shall observe the CDC/ATSDR smoke-free working environment policy at all times. This policy prohibits smoking in all CDC/ATSDR buildings and in front of buildings which are open to the public. This policy is also applicable to contractor personnel who do not work full-time within CDC/ATSDR facilities, but are attending meetings within CDC/ATSDR facilities.

(End of Clause)

## **H.4 Telework by Contractor (Feb 2015)**

Telework is the movement of contract performance from a CDC facility to a teleworker's residence or alternate work site. The Contractor's organizational decision to participate in telework is voluntary, and telework shall not increase the contract price. After contract award, telework arrangements shall be



mutually agreed to in advance by the Contractor, the Contracting Officer, and the Project Officer. The Contractor shall submit written telework requests to the Contracting Officer in accordance with instructions provided by the Contracting Officer. The Contractor shall ensure the continuity of performance by Teleworkers and the monitoring of Teleworkers' time. CDC staff do not supervise contractor employees and do not approve or monitor contractor employees' telework. Only the Contracting Officer has authority to approve telework arrangements on behalf of CDC.

Teleworkers shall use Government-Furnished Equipment (GFE) that has been properly configured for security by CDC's Information Technology Services Office (ITSO). The Government's inability to provide GFE for telework shall preclude the use of telework but shall not constitute an excusable delay. The Government shall provide maintenance and technical support for GFE used by Teleworkers. A Teleworker's use of GFE and government information shall be for contractual performance only, and shall be protected from unauthorized access, disclosure, sharing, transmission, or loss. Teleworkers shall comply with CDC Policy No. CDCGA- 2005-02, "Use of CDC Information Technology Resources" (see <http://aops-masiis.cdc.gov/Policy/Doc/policy90.pdf> ).

All GFE used for telework shall be removed from and returned to CDC facilities in accordance with CDC Policy CDC-MM-2005-01 "Controls for Government Property and Guidance on Removing Government Property from CDC Facilities" ( see <http://aops-mas-iis.od.cdc.gov/Policy/Doc/policy480.htm> ). Prior to removing GFE from CDC facilities, Teleworkers shall obtain written approval from the CDC Property Custodian. Teleworkers shall return all GFE to the CDC Property Custodian when he/she separates from the Contract or ceases to telework.

Teleworkers shall exercise due care in transporting and storing non-public information, to ensure it is safeguarded. Controlled unclassified information – formerly called sensitive but unclassified (SBU) information under CDC Policy No. CDC-IS-2005-02, "Sensitive by Unclassified Information" (see <http://aops-mas-iis.cdc.gov/Policy/Doc/policy464.htm> ) - including personally identifiable information (PII) and Privacy Act information shall be transported and stored only in encrypted form. Nonpublic government information shall not be stored on personally-owned equipment, devices, or storage media. Teleworkers shall comply with additional information security requirements established by CDC's Office of the Chief Information Security Officer (see <http://intranet.cdc.gov/ociso/> ). Teleworkers shall apply approved safeguards to protect government equipment, records, and non-public information from unauthorized access, disclosure, sharing, transmission, or damage, and shall comply with Privacy Act requirements (Privacy Act of 1974, P.L. 93-579, 5 USC 552a). Violation may result in adverse action, fines, and/or criminal prosecution.

For purposes of accelerated implementation of telework, the Contracting Officer may immediately elect to commence teleworking upon concurrence from the Project Officer and Contractor, with submission of the Contractor's supporting telework request and formal contract modification to follow within 30 calendar days. If the Contracting Officer and Project Officer determine that telework has adversely impacted contract performance, the Contracting Officer may immediately suspend telework arrangements upon written notification to the Contractor

(End of clause)

## **H.5 CDCA\_H037 Observance of Legal Holidays and Administrative Leave (Government Facilities Performance) (Jun 2020)**

### **(a) Holidays**



Government personnel observe the following listed days as holidays:

Washington's Birthday  
Memorial Day  
Independence Day  
Labor Day  
Veterans' Day  
Thanksgiving Day  
Christmas Day  
New Year's Day  
Columbus Day  
Martin Luther King Day

Any other day designated by Federal Statute  
Any other day designated by Executive Order  
Any other day designated by Presidential proclamation

For purposes of contract performance, the Contractor shall observe the above holidays on the date observed by the Government. Observance of such days shall not be cause for an additional period of performance or entitlement to compensation except as otherwise set forth in the contract. No form of holiday or other premium compensation will be reimbursed, however this does not preclude reimbursement for overtime work authorized in writing by the Contracting Officer.

**(b) Unscheduled Facility Closures**

In the event Government facilities are closed due to inclement weather, potentially hazardous or unsafe conditions, or other special circumstances, contractor personnel assigned to work within those facilities are automatically dismissed. Notwithstanding the terms herein, the contractor shall comply with any specific contract terms that require a level of ongoing support for critical operations during times of facility closure. The contractor may also continue to provide support under a scheduled telework arrangement in accordance with the terms of the contract if the contract expressly authorizes telework in writing.

**(c) Cost Impact**

Accounting for costs associated with an unscheduled facility closure is unique to each contract and depends upon a number of factors such as:

- i) Contract type, e.g. Fixed Price, Time and Materials, or Cost Reimbursement.
- ii) Contractor's established management and accounting practices for unproductive time.
- iii) The inclusion and applicability of other contract terms & conditions.
- iv) The ability of the contractor to mitigate costs by reassigning employees to work on other contracts, to work from a different facility, or to work remotely from home in accordance with contract telework provisions.

**H.6 CDC0\_H030 Contract Administration for 8(a) Contracts (Sep 2009)**

(a) This contract is issued as a direct award between the contracting activity and the 8(a) contractor pursuant to the Memorandum of Understanding between the Small Business Administration (SBA) and the Department of Health and Human Services. SBA does retain responsibility for 8(a) certification, 8(a)

eligibility determinations and related issues, and providing counseling and assistance to the 8(a) contractor under the 8(a) program. The cognizant SBA district office is:

**U.S. SMALL BUSINESS ADMINISTRATION**

*8(a) Business Development Office*

Seattle District Office

2401 Fourth Avenue, Suite 450

Seattle, WA 98121-3412

[www.sba.gov/wa](http://www.sba.gov/wa)

206-553-7310 voice

206-553-7099 fax

206-553-7049 tdd

(b) The contracting activity is responsible for administering the contract and taking any action on behalf of the Government under the terms and conditions of the contract. However, the contracting activity shall give advance notice to the SBA before it issues a final notice terminating performance, either in whole or in part, under the contract. The contracting activity shall also coordinate with SBA prior to processing any novation agreement. The contracting activity may assign contract administration functions to a contract administration office.

(c) The contractor agrees:

(1) to notify the Contracting Officer, simultaneous with its notification to SBA (as required by SBA's 8(a) regulations), when the owner or owners upon whom 8(a) eligibility is based plan to relinquish ownership or control of the concern. Consistent with 15 U.S.C. 637(a) (21), transfer of ownership or controls shall result in termination of the contract for convenience, unless SBA waives the requirement for termination prior to the actual relinquishing of ownership and control.

(2) it will adhere to the requirements of 52.219-14, Limitations on Subcontracting.

(End of Clause)

**H.7 CDCA\_H040 Government Property (July 2017)**

(a) Government-Furnished Property (GFP). In accordance with the terms of FAR 52.245-1, Government Property, the Government reserves the right to supply the Contractor, as Government-furnished property, any additional supplies, equipment, and materials determined by the Contracting Officer to be necessary and in the best interest of the Government.

(b) Contractor-Acquired Property (CAP). The Contractor must receive written consent from the Contracting Officer prior to purchase of any CAP not expressly identified in the contract, and as defined in FAR 52.245-1.

(c) Accountable and Sensitive Government Property. The Government will provide property labels and other identification for contractor-acquired Government property that is considered Accountable as defined in the [HHS Logistics Management Manual](https://intranet.hhs.gov/about/hhs/manuals/lmm/index.html) (LMM) <https://intranet.hhs.gov/about/hhs/manuals/lmm/index.html> or considered Sensitive as defined in [CDC's Sensitive Items List](https://intranet.cdc.gov/ofr/documents/contracts/Authorized-Prohibited-List.pdf) (<https://intranet.cdc.gov/ofr/documents/contracts/Authorized-Prohibited-List.pdf>)

(d) The contractor shall be responsible for the control and accountable record keeping of any Government property used in the performance of this contract predominately outside the confines of a Government controlled workspace in accordance with the HHS Contracting Guide found on the [OSSAM Government Property and Contractors Property intranet page](http://intranet.cdc.gov/ossam/property-shipping-receiving/property-management/government-property-contractors/index.html). (<http://intranet.cdc.gov/ossam/property-shipping-receiving/property-management/government-property-contractors/index.html>)

(e) The Chief of the Office of Safety, Security and Asset Management (OSSAM), Asset Management Services Office, Centers for Disease Control and Prevention (CDC), is hereby designated as the Property Administrator for this contract. The Contractor shall identify each item of equipment furnished by the Government to the Contractor or acquired by the Contractor using contract funds, with a suitable decal, tag, or other marking, as prescribed by the Property Administrator, and shall follow the guidance set forth in the HHS Contracting Guide.

(End of Clause)

## **H.8 CDCA\_H042 Records Management Obligations (Jun 2020)**

### *A. Applicability*

The following applies to all Contractors whose employees create, work with, or otherwise handle Federal records, as defined in Section B, regardless of the medium in which the record exists.

### *B. Definitions*

“Federal record” as defined in 44 U.S.C. § 3301, includes all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them.

The term Federal record:

1. includes Centers for Disease Control and Prevention (CDC) records.
2. does not include personal materials.
3. applies to records created, received, or maintained by Contractors pursuant to their CDC contract.
4. may include deliverables and documentation associated with deliverables.

### *C. Requirements*

1. Contractor shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to the Federal Records Act (44 U.S.C. chs. 21, 29, 31, 33), NARA regulations at 36 CFR Chapter XII Subchapter B, and those policies associated with the safeguarding of records covered by the Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all records, regardless of form or characteristics, mode of transmission, or state of completion.
2. In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under the legal control of, the Government are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552), as



amended, and the Privacy Act of 1974 (5 U.S.C. 552a), as amended and must be managed and scheduled for disposition only as permitted by statute or regulation.

3. In accordance with 36 CFR 1222.32, Contractor shall maintain all records created for Government use or created in the course of performing the contract and/or delivered to, or under the legal control of the Government and must be managed in accordance with Federal law. Electronic records and associated metadata must be accompanied by sufficient technical documentation to permit understanding and use of the records and data.
4. CDC and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Records may not be removed from the legal custody of CDC or destroyed except for in accordance with the provisions of the agency records schedules and with the written concurrence of the Head of the Contracting Activity. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. In the event of any unlawful or accidental removal, defacing, alteration, or destruction of records, Contractor must report to the Contracting Officer and the Contracting Officer's Representative. The agency must report promptly to NARA in accordance with 36 CFR 1230.
5. The Contractor shall immediately notify the appropriate Contracting Officer upon discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records or equipment. Disclosure of non-public information is limited to authorized personnel with a need-to-know as described in the contract. The Contractor shall ensure that the appropriate personnel, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of this information, data, documentary material, records and/or equipment is properly protected. The Contractor shall not remove material from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the Head of the Contracting Activity. When information, data, documentary material, records and/or equipment is no longer required, it shall be returned to CDC control or the Contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the Contracting Officer or address prescribed in the contract. Destruction of records is EXPRESSLY PROHIBITED unless in accordance with Paragraph (4).
6. The Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, contracts. The Contractor (and any sub-contractor) is required to abide by Government and CDC guidance for protecting sensitive, proprietary information, classified, and controlled unclassified information.
7. The Contractor shall only use Government IT equipment for purposes specifically tied to or authorized by the contract and in accordance with CDC policy.
8. The Contractor shall not create or maintain any records containing any non-public CDC information that are not specifically tied to or authorized by the contract.
9. The Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected from public disclosure by an exemption to the Freedom of Information Act.
10. Training. All Contractor employees assigned to this contract who create, work with, or otherwise handle records are required to take CDC-provided records management training. The Contractor is responsible for confirming training has been completed according to agency policies, including initial training and any annual or refresher training.



*D. Flowdown of requirements to subcontractors*

1. The Contractor shall incorporate the entire substance of the terms and conditions herein, including this paragraph, in all subcontracts under this contract, and must require written subcontractor acknowledgment of same.
2. Violation by a subcontractor of any provision set forth herein will be attributed to the Contractor.

**H.8 CDCA\_H005 Data Subject to Privacy Act Requirements (Jul 2017)**

(a) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act.

(b) In accordance with HHSAR Clause 352.224-70, Privacy Act, which has been incorporated into this contract, certain data provided to the Contractor under this contract shall be treated confidentially. The type(s) of data subject to this clause are as follows:

(c) Following are the requirements for handling this data and the disposition to be made of this data upon completion of contract performance:

(d) The Contracting Officer's Representative (COR) is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.:

## Section I - Contract Clauses

### Section I-1 - Clauses Incorporated By Reference

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

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

<https://acquisition.gov>

(End of Clause)

FAR SOURCE	TITLE AND DATE
52.202-1	Definitions (June 2020)
52.203-3	Gratuities (Apr 1984)
52.203-5	Covenant against Contingent Fees (May 2014)
52.203-6	Restrictions on Subcontractor Sales to the Government (June 2020)
52.203-7	Anti-Kickback Procedures (June 2020)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (May 2014)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (May 2014)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (June 2020)
52.203-13	Contractor Code of Business Ethics and Conduct (June 2020)
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights (June 2020)
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017)
52.204-4	Printed or Copied Double-Sided on Recycled Paper (May 2011)
52.204-9	Personal Identity Verification of Contractor Personnel (Jan 2011)
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020)
52.204-13	System for Award Management Maintenance (Oct 2018)
52.204-14	Service Contract Reporting Requirements (Oct 2016)
52.204-18	Commercial and Government Entity Code Maintenance (Aug 2020)
52.204-19	Incorporation by Reference of Representations and Certifications (Dec 2014)
52.204-23	<u>Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018)</u>
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (AUG 2020)
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Jun 2020)
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018)
52.209-10	Prohibition on Contracting with Inverted Domestic Corporations. (Nov 2015)
52.215-2	Audit and Records -- Negotiation (Jun 2020)
52.215-8	Order of Precedence - Uniform Contract Format (Oct 1997)

52.215-10	Price Reduction for Defective Certified Cost or Pricing Data (Aug 2011)
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data - Modifications (Jun 2020)
52.215-12	Subcontractor Certified Cost or Pricing Data (Jun 2020)
52.215-13	Subcontractor Certified Cost or Pricing Data - Modifications (Jun 2020)
52.215-15	Pension Adjustments and Asset Reversions (Oct 2010)
52.215-17	Waiver of Facilities Capital Cost of Money (Oct 1997)
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions. (Jul 2005)
52.215-19	Notification of Ownership Changes (Oct 1997)
52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications (Jun 2020)
52.219-12	Special 8(a) Subcontract Conditions (Oct 2019)
52.219-14	Limitations on Subcontracting (May 2020)
52.222-3	Convict Labor (Jun 2003)
52.222-4	Contract Work Hours and Safety Standards Act - Overtime Compensation (May 2018)
52.222-21	Prohibition of Segregated Facilities (Apr 2015)
52.222-26	Equal Opportunity (Sep 2016)
52.222-35	Equal Opportunity for Veterans (Jun 2020)
52.222-36	Equal Opportunity for Workers with Disabilities (Jun 2020)
52.222-37	Employment Reports on Veterans (Jun 2020)
52.222-40	Notification of Employee Rights Under the National Labor Relations Act (Dec 2010)
52.222-50	Combating Trafficking in Persons (Oct 2020)
52.222-54	Employment Eligibility Verification (Oct 2015)
52.223-5	Pollution Prevention and Right-to-Know Information (May 2011)
52.223-6	Drug-Free Workplace (May 2001)
52.223-10	Waste Reduction Program (May 2011)
52.223-18	Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020)
52.224-1	Privacy Act Notification (Apr 1984)
52.224-2	Privacy Act (Apr 1984)
52.225-13	Restrictions on Certain Foreign Purchases (Feb 2021)
52.226-1	Utilization of Indian Organizations and Indian-Owned Economic Enterprises (Jun 2000)
52.227-1	Authorization and Consent (Jun 2020)
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (Jun 2020)
52.227-3	Patent Indemnity (Apr 1984)
52.227-14	Rights in Data – General (May 2014)
52.232-7	Payments under Time-and-Materials and Labor-Hour Contracts (Aug 2012)
52.232-9	Limitation on Withholding of Payments (Apr 1984)
52.232-11	Extras (Apr 1984)
52.232-17	Interest (May 2014)

52.232-23	Assignment of Claims (May 2014)
52.232-25	Prompt Payment (Jan 2017)
52.232.33	Payment by Electronic Funds Transfer-- System for Award Management (Oct 2018)
52.232-39	Unenforceability of Unauthorized Obligations (Jun 2013)
52.232-40	Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)
52.233-1	Disputes (May 2014)
52.233-3	Protest after Award (Aug. 1996)
52.233-4	Applicable Law for Breach of Contract Claim (Oct 2004)
52.237-2	Protection of Government Buildings, Equipment, and Vegetation (Apr 1984)
52.237-3	Continuity of Services (Jan 1991)
52.237-7	Indemnification and Medical Liability Insurance (Jan 1997)
52.239-1	Privacy or Security Safeguards (Aug 1996)
52.242-13	Bankruptcy (Jul 1995)
53.243-3	Changes - Time-and-Materials or Labor-Hours (Sept 2000)
52.243-7	Notification of Changes (Jan 2017)
52.244-2	Subcontracts (Jun 2020)
52.244-5	Competition in Subcontracting (Dec 1996)
52.244-6	Subcontracts for Commercial Items (Nov 2020)
52.245-1	Government Property (Jan 2017)
52.245-9	Use and Charges (Apr 2012)
52.246-25	Limitation of Liability - Services (Feb 1997)
52.248-1	Value Engineering (Jun 2020)
52.249-6	Termination (Cost-Reimbursement) (May 2004), Alternate IV (May 2004)
52.249-14	Excusable Delays (Apr 1984)
<b>HHSAR SOURCE</b>	<b>TITLE AND DATE</b>
352.203-70	Anti-Lobbying (December 18, 2015)
352.208-70	Printing and Duplication (December 18, 2015)
352.211-3	Paperwork Reduction Act (December 18, 2015) if requires a contractor to collect the same information from 10 or more persons
352.222-70	Contractor Cooperations in Equal Employment Opportunity Investigations (December 18, 2015)
352.224-70	Privacy Act (December 18, 2015)
352.224-71	Confidential Information (December 18, 2015)
352.231-70	Salary Rate Limitation (December 18, 2015)
352.233-71	Litigation and Claims (December 18, 2015)
352.237-75	Key Personnel (December 18, 2015)



## Section I-2 - Clauses Incorporated In Full Text

### I.2 - FAR 52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 10 days.

(End of Clause)

### I.3 - FAR 52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 15 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

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

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 1 year.

(End of clause)

### I.4 - 52.219-17 SECTION 8(A) AWARD (OCT 2019)

(a) By execution of a contract, the Small Business Administration (SBA) agrees to the following:

(1) To furnish the supplies or services set forth in the contract according to the specifications and the terms and conditions by subcontracting with the Offeror who has been determined an eligible concern pursuant to the provisions of section 8(a) of the Small Business Act, as amended ([15 U.S.C.637\(a\)](#)).

(2) Except for novation agreements, delegates to the *Centers for Disease Control and Prevention* the responsibility for administering the contract with complete authority to take any action on behalf of the Government under the terms and conditions of the contract; provided, however that the contracting agency shall give advance notice to the SBA before it issues a final notice terminating the right of the subcontractor to proceed with further performance, either in whole or in part, under the contract.

(3) That payments to be made under the contract will be made directly to the subcontractor by the contracting activity.

(4) To notify the Centers for Disease Control and Prevention Contracting Officer immediately upon notification by the subcontractor that the owner or owners upon whom 8(a) eligibility was based plan to relinquish ownership or control of the concern.

(5) That the subcontractor awarded a subcontract hereunder shall have the right of appeal from decisions of the cognizant Contracting Officer under the "Disputes" clause of the subcontract.

(b) The offeror/subcontractor agrees and acknowledges that it will, for and on behalf of the SBA, fulfill and perform all of the requirements of the contract.

(End of clause)

#### **I.5 CDC42.0002 Evaluation of Contractor Performance Utilizing CPARS (Apr 2015)**

In accordance with FAR 42.15, the Centers for Disease Control and Prevention (CDC) will review and evaluate contract performance. FAR 42.1502 and 42.1503 requires agencies to prepare evaluations of contractor performance and submit them to the Past Performance Information Retrieval System (PPIRS). The CDC utilizes the Department of Defense (DOD) web-based Contractor Performance Assessment Reporting System (CPARS) to prepare and report these contractor performance evaluations. All information contained in these assessments may be used by the Government, within the limitations of FAR 42.15, for future source selections in accordance with FAR 15.304 where past performance is an evaluation factor.

The CPARS system requires a contractor representative to be assigned so that the contractor has appropriate input into the performance evaluation process. The CPARS contractor representative will be given access to CPARS and will be given the opportunity to concur or not-concur with performance evaluations before the evaluations are complete. The CPARS contractor representative will also have the opportunity to add comments to performance evaluations.

The assessment is not subject to the Disputes clause of the contract, nor is it subject to appeal beyond the review and comment procedures described in the guides on the CPARS website. Refer to: [www.cpars.gov](http://www.cpars.gov) for details and additional information related to CPARS, CPARS user access, how contract performance assessments are conducted, and how Contractors participate. Access and training for all persons responsible for the preparation and review of performance assessments is also available at the CPARS website.

The contractor must provide the CDC contracting office with the name, e-mail address, and phone number of their designated CPARS representative who will be responsible for logging into CPARS and reviewing and commenting on performance evaluations. The contractor must maintain a current representative to serve as the contractor representative in CPARS. It is the contractor's responsibility to notify the CDC contracting office, in writing (letter or email), when their CPARS representative information needs to be changed or updated. Failure to maintain current CPARS contractor representative information will result in the loss of an opportunity to review and comment on performance evaluations.

[End of Clause]

#### **I.6 HHSAR 352.239-74 Electronic and Information Technology Accessibility (December 18, 2015)**

(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at



<http://www.hhs.gov/web/508>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.

(b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see [FAR 2.101](#)) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) The Section 508 accessibility standards applicable to this contract are: 1194

- 205 WCAG 2.0 Level A & AA Success Criteria
- 302 Functional Performance Criteria
- 502 Inoperability with Assistive Technology
- 504 Authoring Tools
- 602 Support Documentation
- 603 Support Services

(d) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS website:

(<http://www.hhs.gov/web/508>). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://www.hhs.gov/web/508>. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>			1. CONTRACT ID CODE	PAGE 1 OF 12 PAGES
2. AMENDMENT/MODIFICATION NO. C0001	3. EFFECTIVE DATE 10/29/2021	4. REQUISITION/PURCHASE REQ. NO. 00HCBCD9-2021-60110	5. PROJECT NO. (If applicable)	
6. ISSUED BY Centers for Disease Control and Prevention (CDC) Office of Acquisition Services (OAS) 2900 Woodcock Blvd, MS TCU-4 Atlanta, GA 30341-4004	CODE 8219	7. ADMINISTERED BY (If other than Item 6) Centers for Disease Control and Prevention (CDC) Office of Acquisition Services (OAS) 2900 Woodcock Blvd, MS TCU-4 Atlanta, GA 30341-4004		
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) EAGLE HEALTH ANALYTICS, LLC 111 W 16TH AVE STE 424  ANCHORAGE, AK 99501-5169		(√)	9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (See Item 11)	
			10A. MODIFICATION OF CONTRACT/ORDER NO. 75D30121C11172	
		X	10B. DATED (See Item 13) 07/08/2021	
CODE C81341367	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 ACKNOWLEDGMENT 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)**

9390GLY 2512 2021 75-2124-G943 C5B8111101 Increase (b)(4)

**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: IAW FAR 43.103(a) Bilateral Modification
	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.)**

Eagle Health Analytics: (b)(4)

CDC COR: John Wuichet, [uw12@cdc.gov](mailto:uw12@cdc.gov)

CDC Contract Specialist: Sarah Turner, [kwp9@cdc.gov](mailto:kwp9@cdc.gov)

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) (b)(4)	16A. NAME OF CONTRACTING OFFICER Sarah Turner
15B. CONTRACTOR/OFFEROR (b)(4) (Signature of person authorized to sign)	15C. DATE SIGNED 11/3/2021
16B. UNITED STATES OF AMERICA Digitally signed by Sarah H. Turner BY Sarah H. Turner -S Date: 2021.11.04 13:05:51-04'00' (Signature of Contracting Officer)	16C. DATE SIGNED



***“HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.”***

## Section 2

The purpose of this modification is to:

- A. Increase the level of effort of CLIN 0001 Physicians by 4,333 hours to a total of 19,933 hours as reflected in Table B.1 below;
- B. Increase the total funded amount of CLIN 0001 by (b)(4) from (b)(4) to (b)(4)
- C. Increase the level of effort of optional CLIN 0002 Physician by 12,480 hours to a total of 20,800 hours as reflected in Table B.1 below;
- D. Increase the total amount of optional CLIN 0002 by (b)(4) from (b)(4) to (b)(4)
- E. Modify the Statement of Work to add Tasks 5 and 6 related to the v-safe pregnancy registry program;
- F. Create and fully fund CLIN 0004 in the amount of (b)(4) with a period of performance of November 1, 2021 - July 7, 2022;
- G. Increase the total funded amount of the contract by (b)(4) from (b)(4) to (b)(4) and
- H. Increase the total contract amount (including all options), by (b)(4) from (b)(4) to (b)(4)

## Section B - Supplies Or Services and Prices/Costs

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	VAERS	(b)(4)		
	Medical officer/epidemiologist support services for the VAERS program			
	Period of Performance: July 8, 2021 - January 7, 2022			
	Labor Hour CLIN Severable Services			
	Line(s) Of Accounting: 9390GLY 2512 2021 75-2124-0943 C5B8111101 (b)(4)			
0003	CISA	(b)(4)		
	Clinician/medical officer support for the CISA Project			
	Period of Performance: July 8, 2021 - July 7, 2022			
	Labor Hour CLIN Severable Services			

0004	Pregnancy Clinician Clinician/medical officer support for the v-safe pregnancy registry program	(b)(4)		
	Period of Performance: November 1, 2021 - July 7, 2022  Labor Hour CLIN Severable Services			
Line(s) Of Accounting: 9390GLY 2512 2021 75-2124-0943 C5B8111101		(b)(4)		

**Option 1 (Option 1) Items:**

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0002	VAERS Option Medical officer/epidemiologist support services for the VAERS program	(b)(4)		
	Period of Performance: January 8, 2022 - July 7, 2022 This is an Optional CLIN Labor Hour CLIN Severable Services			

**B.1 LABOR CHART**

LABOR CATEGORY & ESTIMATED LEVEL OF EFFORT					
Line Item	Year	Estimated Labor Categories	Hourly Rate (fully burdened)	Estimated Level of Effort	Estimated Labor Cost
(b)(4)					

**NOTATION REGARDING LABOR HOUR VARIANCE:** Performance under this Time and Materials/Labor Hour Contract is in accordance with FAR 52.232-7, "Payments under Time and Materials and Labor Hour Contracts," incorporated by reference in Section I, which requires the vendor to manage to the ceiling price in the contract and the ceiling price of the line items. The number of hours per labor category are estimates. The CO and the COR must be notified of any variance from the estimated hours shown in the Level of Effort/Labor Categories chart.

## **Section C - Description/Specification/Work Statement**

**Updated 10/25/2021**

### **Title: Supporting Vaccine Task Force on Vaccine Adverse Event Reporting and Clinical Immunization Safety Assessments**

#### **C.1 Background and Need**

The Centers for Disease Control and Prevention's (CDC) mission is to promote the health and quality of life by preventing and controlling disease, injury, and disability. As part of this mission, CDC is tasked with implementing programs to ensure that people will live safer, healthier lives through protecting Americans from health threats via a prevention, detection and response network and establishing CDC as the trusted and effective resources for health development. CDC addresses critical public health challenges through working with a diverse set of partners to support the development and implementation of public health interventions.

CDC provides leadership to improve the health of people in all life stages and in all settings. It carries out this role by monitoring health, developing health improvement strategies, providing financial and technical assistance to partners and conducting other activities. There are major programs that have been implemented globally within the last several years that have greatly expanded the global mission of the CDC and have prompted the need for increased services and staffing domestically to support those activities. As more health crises are identified, the mission and response of CDC's operating divisions have expanded.

In part of the response to the global COVID-19 pandemic, the United States has introduced a national mass COVID-19 vaccination program. Over a 100 million American citizens already vaccinated and there is a goal of vaccinating the U.S. population by early summer. As vaccine safety monitoring is a critical component to any vaccination program, for COVID-19 vaccine safety monitoring efforts are the most intense and comprehensive in U.S. history. CDC is relying on established monitoring programs including the Vaccine Adverse Event Reporting System (VAERS) and the Clinical Immunization Safety Assessment (CISA) Project to offer. Because of these efforts, additional staffing is needed to support CDC's efforts in VAERS and v-safe safety activities.

**Vaccine Adverse Event Reporting System (VAERS)** VAERS is a mandated program sponsored jointly by the Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA). The purpose of this project as authorized by the National Childhood Vaccine Injury Act (NCVIA), P.L. 99-660, is to provide a single nationwide mechanism to report, analyze and monitor vaccine adverse events (VAEs) that occur after receipt of vaccines. It also provides a vehicle for disseminating vaccine safety information to vaccines, family members, health care providers, vaccine manufacturers, government agencies, and other partners.

VAERS contains reports of VAEs based on two criteria, mandated and voluntary reports. The events mandated for healthcare provider and vaccine manufacturer reporting are listed in the Reportable Adverse Events Table (RET) available at

[https://vaers.hhs.gov/docs/VAERS Table of Reportable Events Following Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS%20Table%20of%20Reportable%20Events%20Following%20Vaccination.pdf)

US manufacturers of vaccines are mandated by 21 CFR Part 600.80 (Attachment 3) to submit reports routinely on a periodic basis, as well as in an expedited manner for more serious events. In addition,



healthcare providers are encouraged to report all other clinically significant VAEs following the administration of any US vaccine in all age groups. For all reports, the impetus for reporting is not a presumed causal relationship between the vaccination and the event but may be based simply on the occurrence of the event temporally following vaccination and the lack of other obvious causes.

From 2015 through 2019, VAERS received an annual average of 58,000 reports, of which 49,000 were US reports. Of the US reports, 5.3% were classified as serious (i.e., associated with disability, hospitalization, prolongation of existing hospitalization, life-threatening illness, congenital anomaly/birth defect, or death [21 CFR 600.80]). Since 1990 to 2019, VAERS has received over 810,000 reports, most of which describe mild and self-limited adverse events such as injection site reactions and fever. (VAERS government data archive January 29, 2021.) VAERS helps to identify important new safety concerns and thereby can help inform vaccine policymakers and healthcare providers. In addition, the data are valuable for regulatory actions and vaccine research studies. The US Government considers post-licensure/authorization surveillance for any licensed and new vaccines through VAERS to be a nationally critical function, and the US Government considers the requirements of the VAERS activity to constitute essential services for which any lapse in coverage of services would be unacceptable.

The current COVID-19 pandemic and COVID-19 vaccination program have created additional requirements for VAERS. Specifically, as part of a mass immunization program with a goal to immunize every adult by May 2021, VAERS has had a surge in reporting of adverse events as compared to previous years and to other vaccines. In addition, CDC reviews reports that are coded as Adverse Events of Special Interest (AESI). These AESI include: acute myocardial infarction, anaphylaxis, coagulopathy, death, Guillain-Barré Syndrome, Kawasaki Disease, Multisystem Inflammatory Syndrome (in adults and in children), myopericarditis, narcolepsy, pregnancy, seizure, stroke, transverse myelitis, Bell's palsy, and appendicitis. Additional outcomes are added, as potential concerns following COVID-19 vaccination are identified.

**Clinical Immunization Safety Assessments (CISA)** CISA Project is a national network of vaccine safety experts from CDC's Immunization Safety Office (ISO) and seven medical research centers. CISA conducts clinical research, assesses complex adverse events following vaccination, and provides consultations to United States healthcare providers and public health partners.

During the United States COVID-19 vaccine program, CISA is operating a 24/7 on-call clinical consultation service for COVID-19 vaccine safety (CISA COVIDvax). Healthcare providers or health departments in the United States can request a consultation from CISA COVIDvax for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or Advisory Committee on Immunization Practices (ACIP) guidelines. <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>

CISA COVIDvax is a partnership between CDC clinicians and vaccine safety and infectious disease expert physicians from medical research centers participating in the CISA Project. In addition, participating medical centers provide expertise in multiple clinical areas (including allergy/immunology, neurology, geriatric medicine, and obstetrics and gynecology).

**V-safe COVID-19 Pregnancy Registry** V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after people receive a COVID-19 vaccine. The v-safe COVID-19 Vaccine Pregnancy Registry is for v-safe participants who self-identify as pregnant at the time of vaccination or shortly thereafter (within 30 days of vaccination). The registry activities are in



addition to the v-safe after vaccination health check-ins that participants receive via text message. Pregnant participants in the registry are contacted to answer questions about their pregnancy and medical history. Participants are also asked for permission to contact their healthcare provider(s).

V-Safe is an active surveillance system for people who received a COVID-19 vaccine during pregnancy or in the periconception period (30 days within the start date of the last menstrual period). Call center staff conduct phone interviews with participants to collect data on demographics, past medical and obstetric history, gestational health conditions, pregnancy outcomes, delivery complications, and neonatal/infant health outcomes. As part of the interview, call center staff request consent from the participants for the release of medical records for both the participant and her infant(s) to verify diagnoses and supplement information obtained during the phone interview. If consent is granted, call center staff document the consent in the "V-safe Pregnancy Registry Call Center REDCap database" (Call Center database) and record the provider's name, name of the office/clinic, address, and phone number for all relevant providers. A separate "V-safe Pregnancy Registry Medical Record Abstraction REDCap database" (MRA database) was created to complete medical record abstractions for participants who consented to medical record release. CDC contractors will request medical records from medical offices/clinics and complete medical record abstraction.

## **C.2 Project Objective**

The objective of this contract is to provide CDC's vaccine safety activities with a ready source of clinical, scientific, and technical services for emergency response.

## **C.3 Scope of Work**

Independently and not as an agent of the Government, the Contractor shall provide all personnel and services necessary to perform the following tasks as listed in this SOW. This work will support the U.S. COVID-19 vaccination program's vaccine safety programs conducted by CDC.

## **C.4 Tasks and Technical Requirements**

### **Working Hours**

The contractor shall provide services during normal working hours, which are defined as Monday through Friday, 9 a.m. to 5 p.m. Because this is an emergency response effort, it is highly likely that some of the contractor's services will also be required outside of normal working hours, including [some evenings and weekends](#). The Contracting Officer's Representative (COR) will provide contractor management with instruction and authorization when services outside of normal working hours are required and when the contractor is needed work over 40 hours per week. A requirement for work outside of normal working hours and additional hours may be given on short notice.

### **Technical Requirements**

The contractor shall perform the following tasks:

**Task 1:** The contractor shall organize a kick off meeting with the CDC within 1 week of contract award.

**Task 2:** The contractor shall provide medical officer/epidemiologist support services for the VAERS program. Tasks include:

A. The contractor will sign a CDC VAERS Rules of Behavior (ROB) form.

- B. Working with CDC staff, the contractor will gain access to the VAERS VPN and the internal CDC VAERS abstraction website.
- C. The contractor will be trained by CDC staff on VAERS, using the VAERS VPN, how to review VAERS reports, how to conduct medical record abstraction, and how to enter data into the internal CDC VAERS abstraction website.
- D. Working with CDC staff, the contractor will review VAERS AESI reports. Up to 25 VAERS reports will be assigned per day for review.
- E. The contractor shall perform a review of available VAERS reports and associated medical records, if available, for each assigned report.
- F. The contractor shall perform data entry from the assigned reviews. These reviews will be via CDC electronic form, consisting mostly of check boxes and free text fields. The medical record review will determine if the reported AESI meets a published case definition (if available). Medical record reviews will follow CDC VAERS Standard Operating Procedures. All published case definitions will be provided to the contractor.
- G. The contractor shall request medical records from health care providers/systems located in the United States on behalf of VAERS.
- H. The contractor shall conduct literature reviews on new vaccine safety outcomes of concern or AESI.
- I. The contractor shall respond to inquiries received by the public, health departments, and providers. This may include reviewing the VAERS database, conducting literature reviews to provide published data as it pertains to the inquiry, and drafting a response to the inquiry. The response will be shared with the CDC VAERS inquires lead and the VAERS team lead or designee.
- J. The contractor shall work with CDC VAERS staff to resolve any questions or concerns related to VAERS reviews.
- K. The contractor shall attend up to 3 meetings per week.

**Task 2 Requirements:**

- 1. Contractors shall have a clinical background (e.g. physician, physician assistant, nurse practitioner); contractor does not need to be a licensed MD.
- 2. Contractors shall have good interpersonal and communication skills (written and oral).
- 3. Contractors shall have the ability to prioritize tasks and function in a potentially fast-paced, dynamic environment.
- 4. Prior experience with medical abstraction and knowledge of and experience with vaccine safety or infectious diseases is preferred.

**Task 3.** The contractor shall provide clinician/medical officer support for the CISA Project

- A. The contractor shall receive and respond to requests of assistance for COVID-19 vaccine safety emergencies or inquiries from healthcare providers and health departments. Requests may come in the form of phone calls or emails from the CDC Emergency Operations Center or other CDC public facing inquiry response services.
- B. The contractor shall monitor, triage, and assist with responding to emails and clinical inquiries that CISA receives daily.
- C. Using clinical expertise, the contractor shall triage calls and inquiries to determine the need for escalation to CISA's nationwide network of vaccine experts and others such as allergists.
- D. Contractor will attend daily morning and afternoon CISA team conference calls in addition to a daily conference call with CISA's national network of vaccine experts. Contractors will attend CISA meetings that urgently occur to assist inquirers. In addition, contractors will attend CISA consultation conference calls with inquirers.

- E. The contractor shall contribute to the investigation of adverse events including allergic reactions after COVID-19 vaccine in collaboration with state health departments and other partners.
- F. The contractor shall request medical records from health care providers/systems located in the United States on behalf of CISA.
- G. The contractor shall review, abstract, and summarize medical records pertinent to COVID-19 vaccine safety consults or evaluations. Inquires will be tracked in a CDC database. The contractor shall perform data entry from these reviews. Data entry will be via CDC electronic database, consisting mostly of check boxes and free text fields. The contractor will be trained by CDC CISA staff on how to input data into the database.
- H. The contractor shall work with CDC CISA staff to resolve any questions or concerns related to CISA inquiries, medical record reviews, or data entry into the electronic database.
- I. The contractor will sign a CDC VAERS Rules of Behavior (ROB) form.
- J. Working with CDC staff, the contractor will gain access to the VAERS VPN.
- K. The contractor shall search VAERS database for vaccine safety information.
- L. The contractor shall conduct literature reviews informing vaccine safety issues, including literature reviews about COVID-19 vaccines and clinical conditions.
- M. The contractor shall provide COVID-19 vaccine safety technical assistance to the response efforts and contribute to COVID-19 vaccine safety educational activities.
- N. The contractor shall maintain subject matter expertise pertinent to CDC COVID-19 response activities.
- O. The contractor shall contribute to the development of daily, weekly, and long-term team priorities and progress report updates.
- P. The contractor shall assist with research needs of the CISA team, including writing and editing scientific products (manuscripts, abstracts, scientific posters).
- Q. The contractor shall assist with the preparation of and/or give presentations on complex vaccine safety issues concerning individual patients/groups of patients and the results of scientific research.
- R. The contractor shall educate other team members on scientific and technical aspects of team activities and function.
- S. The contractor shall support the operational needs for the clinical service and contribute to clinical consultation tracking database activities for ISO.

**Task 3 Requirements:**

- 1. The contractor shall have a valid US Medical License (unrestricted).
- 2. The contractor shall have completed an ACGME Medical Residency program.
- 3. The contractor shall have medical knowledge in the areas of Adult and/or Pediatric Medicine.
- 4. The contractor shall have the ability to actively reach out and contact providers and partners on the phone.
- 5. The contractor shall have the flexibility to work across multiple disciplines of medicine and public health.
- 6. The contractor shall have familiarity with Microsoft Office products (e.g., MS Word and Excel).
- 7. Additional desired skills include: preferred Board Certification, including but not limited to Infectious Diseases, Emergency Medicine, Internal Medicine, Family Practice, and Pediatrics; knowledge and experience with COVID-19 patient care or public health and/or vaccines; comfort in working in 100% virtual environment; and experience with RedCap and Microsoft Teams.

**Task 4:** The contractor shall provide Project Coordinator Support Services for the VAERS program. Tasks include:



1. The contractor shall work with the CDC VAERS team to ensure monitoring and evaluation processes are followed per established standard operating procedures (SOPs).
2. The contractor shall assist the VAERS team lead manage activities, including medical record reviews and reports of adverse events of special interest (AESI).
3. The contractor shall coordinate assignments of VAERS AESI medical records reviews into CDC-based data entry systems (REDCap and VAERS Abstraction Website) with CDC and contract-based clinical staff.
4. The contractor shall provide reports to the VAERS team lead on status of AESI medical record reviews on a daily basis.
5. The contractor shall assist the VAERS team lead and CDC VAERS team members to write SOPs.
6. The contractor shall schedule meetings as required.
7. The contractor will sign a CDC VAERS Rules of Behavior (ROB) form.
8. Working with CDC staff, the contractor will gain access to the VAERS VPN and the internal CDC VAERS abstraction website.
9. The contractor will be trained by CDC staff on VAERS, using the VAERS VPN, how to review VAERS reports, how to conduct medical record abstraction, and how to enter data into the internal CDC VAERS abstraction website.
10. The contractor shall respond in writing to inquiries received by the public, health departments, and providers. This may include reviewing the VAERS database, conducting literature reviews to provide published data as it pertains to the inquiry, and drafting a response to the inquiry. The response will be shared with the CDC VAERS inquiries lead and the VAERS team lead, or designee.
11. The contractor shall work with CDC VAERS staff to resolve any questions or concerns related to VAERS reviews
12. The contractor shall assist the VAERS team responding to ad-hoc requests related to COVID-19 vaccine safety outcomes or concerns.
13. The contractor shall participate in up to 15 meetings per week.

**Task 5: The contractor shall provide medical officer/epidemiologist support services for the v-safe pregnancy registry program**

- A. The contractor will sign a CDC v-safe pregnancy registry Rules of Behavior (ROB) form.
- B. The contractor will sign a CDC v-safe pregnancy registry Assurance of Confidentiality (AoC) form.
- C. Working with CDC staff, the contractor will gain access to the v-safe pregnancy registry shared drive files, REDCap databases, and other protected files as needed.
- D. The contractor will be trained by CDC staff on the v-safe pregnancy registry history and protocols, including scopes of work of the contracted companies supporting both the v-safe pregnancy registry call center and medical record abstraction activities. This will include being trained in how to support both the call center and medical record abstraction activities.
- E. Working with CDC staff, the contractor will review pregnancy outcome data including, but not limited to, birth defects, pregnancy losses, obstetric complications, and infant health issues. This will be done in the context of clinical reviews of identified cases with oversight by the Team Lead and Deputy.
- F. The contractor shall monitor, triage, and assist with responding to emails and inquiries that the pregnancy registry receives daily.
- G. The contractor shall assist in answering inquiries about the registry from participants, including about privacy-related issues or concerns. This may include reviewing a participant's record and related notes and consultation with the lead. The contractor shall also assist in answering public inquiries. The response will be shared with the CDC v-safe Pregnancy Registry team lead or designee for review prior to being sent.



H. The contractor shall work with the pregnancy registry call center contractor, providing support, answering questions, coordinating communication, participating in regular coordination meetings, conducting quality control oversight, and assisting with information and data exchange to facilitate accurate completion of participant interviews and data collection.

I. Working with CDC staff, the contractor will organize structured clinical reviews of data from both participant interviews and abstracted, related medical records for pregnancies and maternal and infant health conditions; when necessary, the contractor will review supporting medical documentation and assist in any structured adjudication processes to categorize outcomes for analytic purposes. These reviews will be conducted through existing secure databases and structured clinical review systems. The contractor will record decisions made during these reviews and be responsible for organization support of these reviews. Clinical reviews will follow CDC v-safe Pregnancy Registry Standard Operating Procedures. All supporting documentation will be provided to the Contractor.

J. Conduct literature reviews on vaccine safety outcomes of concern related to reproductive and infant health. Contribute to manuscripts and presentation of data from the pregnancy registry; this will involve co-authorship of manuscripts.

K. The contractor will provide clinical and epidemiologic expertise and input for data analyses and manuscript development.

L. The contractor will work closely and collaboratively with other team members to support the success of the pregnancy registry work.

M. The contractor shall work with CDC v-safe Pregnancy Registry staff to resolve any questions or concerns related to the above activities.

N. The contractor shall attend up to 15-20 meetings per week. Some of these will be regularly scheduled meetings with the team and with contracting company staff; others may be of a more urgent nature to address issues as they arise.

#### Task 5 Requirements

1. The contractor shall have a clinical background (physician, physician assistant, nurse practitioner) required; does not need to be a licensed physician. Medical knowledge in areas of Obstetrics-Gynecology and/or Pediatric Medicine.
2. Ability to prioritize tasks and function in a potentially fast-paced, dynamic environment.
3. Flexibility to work across multiple disciplines of medicine and public health.
4. Familiarity with Microsoft Office products is required (e.g., MS Word and Excel).
5. Additional desired skills: preferred Board Certification, including but not limited to Obstetrics-Gynecology, Family Practice, and Pediatrics; knowledge and experience with public health and/or vaccines; prior experience with medical abstraction and knowledge of and experience with pregnancy, maternal and infant health comfortable working in 100% virtual environment, experience with RedCap and Microsoft Teams.

**Task 6.** The contractor shall provide clinician/medical officer and leadership support for the v-safe Pregnancy Registry

A. The contractor will be assigned to work with the Immunization Safety Office (ISO) pregnancy subject matter expert.

B. The contractor will maintain status updates on all ISO pregnancy-related/maternal-infant COVID-19 related activities.

C. The contractor will serve as lead coordinator of the v-safe pregnancy registry ensuring that program processes, protocols, and data management activities are maintained to provide quality data from the



registry. The contractor shall serve as a main point of contact for clinical and non-clinical related questions related to the v-safe pregnancy registry.

D. Working with CDC staff, the contractor will synthesize v-safe or VAERS analyzed data and provide regular weekly updates to CDC vaccine safety leadership. The contractor will contribute to or lead v-safe and VAERS manuscripts and presentations.

E. The contractor shall review protocols and other products related to pregnancy, maternal, and infant COVID-19 vaccine safety and provide feedback to the ISO pregnancy subject matter expert or other CDC staff

F. The contractor shall respond in writing to inquiries received by the public, partners, or internal to CDC related to pregnancy, maternal, and infant COVID-19 vaccine safety.

G. The contractor will sign a CDC VAERS Rules of Behavior (ROB) form.

H. Working with CDC staff, the contractor will gain access to the VAERS VPN and the internal CDC VAERS abstraction website.

I. The contractor will be trained by CDC staff on VAERS, using the VAERS VPN, how to review VAERS reports, how to conduct medical record abstraction, and how to enter data into the internal CDC VAERS abstraction website.

J. Working with CDC staff, the contractor will review VAERS pregnancy related reports, but may be assigned to other adverse events of special interest. When assigned, the contractor shall review up to 25 VAERS reports per day for review.

K. The contractor shall perform a review of available VAERS reports and associated medical records, if available, for each assigned report.

L. The contractor shall perform data entry from the assigned reviews. These reviews will be via a CDC electronic form, consisting mostly of check boxes and free text fields. The medical record review will determine if the reported AESI meets a published case definition (if available). Medical record reviews will follow CDC VAERS Standard Operating Procedures. All published case definitions will be provided to the Contractor.

O. The contractor shall request medical records from health care providers/systems located in the United States on behalf of VAERS.

P. Conduct literature reviews on vaccine safety outcomes of concern related to reproductive and infant health. Contribute to manuscripts and presentation of data from the pregnancy registry; this will involve co-authorship of manuscripts.

Q. Conduct literature reviews on new vaccine safety outcomes of concern or AESI.

R. The contractor shall respond to inquiries received by the public, health departments, and providers. This may include reviewing the VAERS database, conducting literature reviews to provide published data as it pertains to the inquiry, and drafting a response to the inquiry. The response will be shared with the CDC VAERS inquiries lead and the VAERS team lead, or designee.

S. The contractor shall work with CDC VAERS staff to resolve any questions or concerns related to VAERS reviews

T. The contractor shall assist the ISO pregnancy SME on ad hoc requests related to pregnancy related, maternal, or infant vaccine safety outcomes or concerns.

U. The contractor shall attend up to 15-20 meetings per week. Some of these will be regularly scheduled meetings with the team and with contracting company staff; others may be of a more urgent nature to address issues as they arise.

#### Task 6 Requirements

1. The contractor shall have a clinical background (physician, physician assistant, nurse practitioner) required; does not need to be a licensed physician. Medical knowledge in areas of Obstetrics-Gynecology and/or Pediatric Medicine.

2. Ability to prioritize tasks and function in a potentially fast-paced, dynamic environment.
3. Flexibility to work across multiple disciplines of medicine and public health.
4. Familiarity with Microsoft Office products is required (e.g., MS Word and Excel).
5. Additional desired skills: preferred Board Certification, including but not limited to Obstetrics-Gynecology, Family Practice, and Pediatrics; knowledge and experience with public health and/or vaccines; prior experience with medical abstraction and knowledge of and experience with pregnancy, maternal and infant health comfortable working in 100% virtual environment, experience with RedCap and Microsoft Teams.

#### C.5 Deliverable Schedule

Task	Deliverable	Quantity/ Format	Due Date	Due To
Task 1	Kick-off Meeting Notes	1 Word Document by Email	Within 2 weeks of award	COR
Tasks 2-6	Provide CDC with monthly status report for all tasks	1 Word Document by Email	15th of each month	COR

**C.6 Special Considerations** – The contractor must protect the confidentiality of proprietary, sensitive, and Personally Identifiable Information (PII). All staff under this contract working with VAERS, CISA, and/or v-Safe will have access to PII and will be required to obtain a CDC Public Trust Level-5 background clearance.



<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>			1. CONTRACT ID CODE	PAGE 1 OF 2 PAGES
2. AMENDMENT/MODIFICATION NO. C0002	3. EFFECTIVE DATE 01/08/2022	4. REQUISITION/PURCHASE REQ. NO. 00HCBCD9-2022-61700	5. PROJECT NO. (If applicable)	
6. ISSUED BY Centers for Disease Control and Prevention (CDC) Office of Acquisition Services (OAS) 2900 Woodcock Blvd, MS TCU-4 Atlanta, GA 30341-4004	CODE 8219	7. ADMINISTERED BY (If other than Item 6) Centers for Disease Control and Prevention (CDC) Office of Acquisition Services (OAS) 2900 Woodcock Blvd, MS TCU-4 Atlanta, GA 30341-4004		
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) EAGLE HEALTH ANALYTICS, LLC 111 W 16TH AVE STE 424  ANCHORAGE, AK 99501-5169		(√)	9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (See Item 11)	
			10A. MODIFICATION OF CONTRACT/ORDER NO. 75D30121C11172	
		X	10B. DATED (See Item 13) 07/08/2021	
CODE C81341367	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 ACKNOWLEDGMENT 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)**

9390GLY 2512 2022 75-2124-G943 C5B8111101 Increase (b)(4)

**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 52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MARCH 2000)
	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.)**

Eagle Health Analytics: (b)(4)  
 CDC COR: John Wuichet, [uw12@cdc.gov](mailto:uw12@cdc.gov)  
 CDC Contract Specialist: Sarah Turner, [kwp9@cdc.gov](mailto:kwp9@cdc.gov)

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) (b)(4)	16A. NAME OF CONTRACTING OFFICER Sarah Turner
15B. CONTRACTOR/OFFEROR (b)(4) (Signature of person authorized to sign)	15C. DATE SIGNED 12/17/2021
16B. UNITED STATES OF AMERICA BY Sarah H. Turner -S (Signature of Contracting Officer)	16C. DATE SIGNED Digitally signed by Sarah H. Turner -S Date: 2021.12.17 14:43:01 -05'00'



## SECTION 2

The purpose of this modification is to:

- A. Exercise Option 1 with a period of performance of January 8, 2022 - July 7, 2022;
- B. Fully fund CLIN 0002 in the amount of (b)(4)
- C. Increase the contract funded amount by (b)(4) from (b)(4) to (b)(4) and
- D. The total contract amount remains (b)(4)

## SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

### Option 1 Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0002	VAERS Option Medical officer/epidemiologist support services for the VAERS program  Period of Performance: January 8, 2022 - July 7, 2022 This is an Optional CLIN Labor Hour CLIN Severable Services  Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B8111101		(b)(4)	

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>			1. CONTRACT ID CODE	PAGE 1 OF 3 PAGES
2. AMENDMENT/MODIFICATION NO. 00003	3. EFFECTIVE DATE 07/06/2022	4. REQUISITION/PURCHASE REQ. NO. 00HCBCD9-2022-68937	5. PROJECT NO. (If applicable)	
6. ISSUED BY Centers for Disease Control and Prevention (CDC) Office of Acquisition Services (OAS) 2900 Woodcock Blvd, MS TCU-4 Atlanta, GA 30341-4004	CODE 8219	7. ADMINISTERED BY (If other than Item 6) Centers for Disease Control and Prevention (CDC) Office of Acquisition Services (OAS) 2900 Woodcock Blvd, MS TCU-4 Atlanta, GA 30341-4004		
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) EAGLE HEALTH ANALYTICS, LLC 111 W 16TH AVE STE 424  ANCHORAGE, AK 99501-5169		(√)	9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (See Item 11)	
		X	10A. MODIFICATION OF CONTRACT/ORDER NO. 75D30121C11172	
CODE UCNERAQ7G8J3			10B. DATED (See Item 13) 07/08/2021	
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 ACKNOWLEDGMENT 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)  
9390GLY 2512 2022 75-2124-0943 C5B8111101 Increase (b)(4)

### 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 53.217-8 and 43.103(a)(3)
	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.)

The purpose of this modification is to extend the contract period by 2 months

Contracting Officer; Gordon D. Barritt, 770 488 2724, [ins4@cdc.gov](mailto:ins4@cdc.gov)

COR John Wuichet, 404 639 7052, [uw12@cdc.gov](mailto:uw12@cdc.gov)

Contractor: (b)(4)

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) (b)(4)		16A. NAME OF CONTRACTING OFFICER Gordon D Barritt	
15B. CONTRACTOR/OFFEROR (b)(4) (Signature of person authorized to sign)	15C. DATE SIGNED 7/7/2022	16B. UNITED STATES OF AMERICA Gordon D. Digitally signed by Gordon D. Barritt -S BY Barritt -S (Signature of Contracting Officer)	16C. DATE SIGNED 7/7/2022

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	VAERS Medical officer/epidemiologist support services for the VAERS program Period of Performance: July 8, 2021 - January 7, 2022 Labor Hour CLIN, Severable Services		(b)(4)	
0002	VAERS Option Medical officer/epidemiologist support services for the VAERS program Period of Performance: January 8, 2022 - July 7, 2022 Labor Hour CLIN, Severable Services		(b)(4)	
0003	CISA Clinician/medical officer support for the CISA Project Period of Performance: July 8, 2021 - July 7, 2022 Labor Hour CLIN, Severable Services		(b)(4)	
0004	Pregnancy Clinician/medical officer support Period of Performance: November 1, 2021 - July 7, 2022 Labor Hour CLIN, Severable Services		(b)(4)	
1001	VAERS Medical Support of VAERS program. Period of Performance 8 July 2022 - 7 Sep 2022 Labor Hours, Severable Services Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B8111101 (b)(4)		(b)(4)	
1003	CISA Medical Support of CISA Program Period of Performance 8 July 2022 - 7 Sep 2022 Labor Hours, Severable Services Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B8111101 (b)(4)		(b)(4)	
1004	V-SAFE Pregnancy Medical Support of V-Safe program Period of Performance 8 July 2022 - 7 Sep 2022 Labor Hours, Severable Services Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B8111101 (b)(4)		(b)(4)	

1. In accordance with FAR 52.217-8, Option to Extend Services for the period of 7/8/2022 – 9/7/2022. All terms, conditions, rates, and work requirements remain unchanged.

2. CLIN 1001, VAERS Support is established and fully funded in the amount of (b)(4) for labor hour services.

3. CLIN 1003, CISA Support is established and fully funded in the amount of (b)(4) for labor hour services.

5. The total amount and funded amount of the contract is increased by (b)(4) from (b)(4) to (b)(4)

6 A recap of funding actions on this contract is as follows:

	CLIN 0001 VAERS	CLIN 0002 VAERS	CLIN 0003 CISA	CLIN 0004 V- SAFE	CLIN 1001 VAERS	CLIN 1003 CISA	CLIN 1004 V- SAFE	Total
(b)(4)								