

State of Nevada Department of Health and Human Services Division of Public & Behavioral Health

(hereinafter referred to as the Division)

Agency Ref. #:	16642
Budget Account:	3219
Category:	33
GL:	8516
Job Number:	<mark>?????</mark>

NOTICE OF SUBAWARD

Office of Public Health Informatics & Epidemiology Washoe County Regional Medical Examiner's Office Address: 4126 Technology Way, Suite 200 Carson City, NV 89706-2009 Address: PO Box 11130 Reno, NV 89502 Subavard Period: September 1, 2018 through August 31, 2019 Subrecipient's: Po Box 11130 Vendor #: T40283400-D. Dux & Bradstreet: 07-378-6998 Purpose of Award: Abstract standardized case-level data from Medical Examiner/Coroner (ME/C) reports on fatal opioid overdoes Region(s) to be served: Statewisted: State						
4126 Technology Way, Suite 200 PO Box 11130 Carson City, NV 99706-2009 Reno, NV 995062 Subaward Period: Subrecipient's: September 1, 2018 through August 31, 2019 Subrecipient's: Purpose of Award; Abstract standardized case-level data from Medical Examiner/Coroner (ME/C) reports on fatal opioid overdoes Reno, NV 98706-2009 Tor378-6998 Purpose of Award; Abstract standardized case-level data from Medical Examiner/Coroner (ME/C) reports on fatal opioid overdoes Region(s) to be served: Statewide Specific county or countes: Carson City, Churchill, Douglas, Elko, Esmerelda, Eureka, Humbolt, Lander, Lyon, Mienal, Pershing, Storay, Washoe, and northem portal funds Award to Date: \$ 79,914.00 1. Personnel \$29,600.00 Total Neguried This Action: \$ 0.00 2. Travel \$4,000.00 Amount Required This Action: \$ 0.00 3. Supplies	Program Name: Office of Public Health Informatics	& Epidemiology	bidemiology Subrecipient's Name: Washoe County Regional Medical Examiner's Office			;
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Section B: Description of Services, Scope of Work and Deliverables;						
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Section C: Budget and Financial Reporting Requirements; Section D: Request for Reimbursement;	Ũ					
	Section E: Audit Information Re	auest;				

Section F: Current/Former State Employee Discla Section G: DPBH Business Associate Addendum		
Dr. Laura Knight Washoe County Chief medical Examiner	Signature	Date
Brian Parrish, Health Program Manager 2, OPHIE		
for Julie Kotchevar, PhD. Administrator, Division of Public & Behavioral Health		

SECTION A

GRANT CONDITIONS AND ASSURANCES

General Conditions

- Nothing contained in this Agreement is intended to, or shall be construed in any manner, as creating or establishing the relationship of employer/employee between the parties. The Grantee shall at all times remain an "independent contractor" with respect to the services to be performed under this Agreement. The Department of Health and Human Services (hereafter referred to as "The Department") shall be exempt from payment of all Unemployment Compensation, FICA, retirement, life and/or medical insurance and Workers' Compensation Insurance as the Grantee is an independent entity.
- The Grantee shall hold harmless, defend and indemnify the Department from any and all claims, actions, suits, charges and judgments whatsoever that arise out of the Grantee's performance or nonperformance of the services or subject matter called for in this Agreement.
- 3. The Department or Grantee may amend this Agreement at any time provided that such amendments make specific reference to this Agreement, and are executed in writing, and signed by a duly authorized representative of both organizations. Such amendments shall not invalidate this Agreement, nor relieve or release the Department or Grantee from its obligations under this Agreement.

The Department may, in its discretion, amend this Agreement to conform with federal, state or local governmental guidelines, policies and available funding amounts, or for other reasons. If such amendments result in a change in the funding, the scope of services, or schedule of the activities to be undertaken as part of this Agreement, such modifications will be incorporated only by written amendment signed by both the Department and Grantee.

4. Either party may terminate this Agreement at any time by giving written notice to the other party of such termination and specifying the effective date thereof at least 30 days before the effective date of such termination. Partial terminations of the Scope of Work in Attachment A may only be undertaken with the prior approval of the Department. In the event of any termination for convenience, all finished or unfinished documents, data, studies, surveys, reports, or other materials prepared by the Grantee under this Agreement shall, at the option of the Department, become the property of the Department, and the Grantee shall be entitled to receive just and equitable compensation for any satisfactory work completed on such documents or materials prior to the termination.

The Department may also suspend or terminate this Agreement, in whole or in part, if the Grantee materially fails to comply with any term of this Agreement, or with any of the rules, regulations or provisions referred to herein; and the Department may declare the Grantee ineligible for any further participation in the Department's Grant Agreements, in addition to other remedies as provided by law. In the event there is probable cause to believe the Grantee is in noncompliance with any applicable rules or regulations, the Department may withhold funding as outlined in the current Grant Instructions and Requirements.

Grant Assurances

A signature on the cover page of this packet indicates that the applicant is capable of and agrees to meet the following requirements, and that all information contained in this proposal is true and correct.

- 1. Adopt and maintain a system of internal controls which results in the fiscal integrity and stability of the organization, including the use of Generally Accepted Accounting Principles (GAAP).
- 2. Compliance with state insurance requirements for general, professional, and automobile liability; workers' compensation and employer's liability; and, if advance funds are required, commercial crime insurance.
- 3. These grant funds will not be used to supplant existing financial support for current programs.
- 4. No portion of these grant funds will be subcontracted without prior written approval unless expressly identified in the grant agreement.
- Compliance with the requirements of the Civil Rights Act of 1964, as amended, and the Rehabilitation Act of 1973, P.L. 93-112, as amended, and any relevant program-specific regulations, and shall not discriminate against any employee for employment because of race, national origin, creed, color, sex, religion, age, disability or handicap condition (including AIDS and AIDS-related conditions).

- Compliance with the Americans with Disabilities Act of 1990 (P.L. 101-136), 42 U.S.C. 12101, as amended, and regulations adopted there under contained in 28 CFR 26.101-36.999 inclusive, and any relevant program-specific regulations.
- 7. Compliance with Title 2 of the Code of Federal Regulations (CFR) and any guidance in effect from the Office of Management and Budget (OMB) related (but not limited to) audit requirements for grantees that expend \$750,000 or more in Federal awards during the grantee's fiscal year must have an annual audit prepared by an independent auditor in accordance with the terms and requirements of the appropriate circular. A COPY OF THE FINAL AUDIT REPORT MUST BE SENT TO:

Nevada State Division of Public and Behavioral Health Attn: Contract Unit 4150 Technology Way, Suite 300 Carson City, NV 89706-2009

This copy of the final audit must be sent to the Division within nine (9) months of the close of the Subrecipient's fiscal year. To acknowledge this requirement, Section E of this notice of subaward must be completed.

- Certification that neither the Grantee nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency. This certification is made pursuant to regulations implementing Executive Order 12549, Debarment and Suspension, 28 C.F.R. pt. 67 § 67.510, as published as pt. VII of May 26, 1988, Federal Register (pp. 19150-19211).
- 9. No funding associated with this grant will be used for lobbying.
- 10. Disclosure of any existing or potential conflicts of interest relative to the performance of services resulting from this grant award.
- 11. Provision of a work environment in which the use of tobacco products, alcohol, and illegal drugs will not be allowed.
- 12. Compliance with Grant Instructions and Requirements from the Office of Community Partnerships and Grants. (Online: <u>http://dhhs.nv.gov/uploadedFiles/dhhsnvgov/content/Programs/Grants/Forms/FY17%20GIRS.pdf</u>)
- An organization receiving grant funds through the Division of Public and Behavioral Health of the Nevada Department of Health and Human Services shall not use grant funds for any activity related to the following:
 - 1. Any attempt to influence the outcome of any Federal, State or local election, referendum, initiative or similar procedure, through in-kind or cash contributions, endorsements, publicity or a similar activity.
 - 2. Establishing, administering, contributing to or paying the expenses of a political party, campaign, political action committee or other organization established for the purpose of influencing the outcome of an election, referendum, initiative or similar procedure.
 - 3. Any attempt to influence:
 - (a) The introduction or formulation of Federal, State or local legislation; or
 - (b) The enactment or modification of any pending Federal, State or local legislation, through communication with any member or employee of Congress, the Nevada Legislature or a local governmental entity responsible for enacting local legislation, including, without limitation, efforts to influence State or local officials to engage in a similar lobbying activity, or through communication with any governmental official or employee in connection with a decision to sign or veto enrolled legislation.
 - 4. Any attempt to influence the introduction, formulation, modification or enactment of a Federal, State or local rule, regulation, executive order or any other program, policy or position of the United States Government, the State of Nevada or a local governmental entity through communication with any officer or employee of the United States Government, the State of Nevada or a local governmental entity, including, without limitation, efforts to influence State or local officials to engage in a similar lobbying activity.
 - 5. Any attempt to influence:
 - (a) The introduction or formulation of Federal, State or local legislation;
 - (b) The enactment or modification of any pending Federal, State or local legislation; or
 - (c) The introduction, formulation, modification or enactment of a Federal, State or local rule, regulation, executive order or any other program, policy or position of the United States Government, the State of Nevada or a local governmental entity, by preparing, distributing or using publicity or propaganda, or by urging members of the general public or any segment thereof to contribute to or participate in any mass demonstration, march, rally, fundraising drive, lobbying campaign or letter writing or telephone campaign.

- 6. Legislative liaison activities, including, without limitation, attendance at legislative sessions or committee hearings, gathering information regarding legislation and analyzing the effect of legislation, when such activities are carried on in support of or in knowing preparation for an effort to engage in an activity prohibited pursuant to subsections 1 to 5, inclusive.
- 7. Executive branch liaison activities, including, without limitation, attendance at hearings, gathering information regarding a rule, regulation, executive order or any other program, policy or position of the United States Government, the State of Nevada or a local governmental entity and analyzing the effect of the rule, regulation, executive order, program, policy or position, when such activities are carried on in support of or in knowing preparation for an effort to engage in an activity prohibited pursuant to subsections 1 to 5, inclusive.
- An organization receiving grant funds through the Division of Public and Behavioral Health of the Nevada Department
 of Health and Human Services <u>may, to the extent and in the manner authorized in its grant</u>, use grant funds for any
 activity directly related to educating persons in a nonpartisan manner by providing factual information in a manner that
 is:
 - 1. Made in a speech, article, publication, or other material that is distributed and made available to the public, or through radio, television, cable television or other medium of mass communication; and
 - 2. Not specifically directed at:
 - (a) Any member or employee of Congress, the Nevada Legislature or a local governmental entity responsible for enacting local legislation;
 - (b) Any governmental official or employee who is or could be involved in a decision to sign or veto enrolled legislation; or
 - (c) Any officer or employee of the United States Government, the State of Nevada or a local governmental entity who is involved in introducing, formulating, modifying or enacting a Federal, State or local rule, regulation, executive order or any other program, policy or position of the United States Government, the State of Nevada or a local governmental entity.

This provision does not prohibit a grantee or an applicant for a grant from providing information that is directly related to the grant or the application for the grant to the granting agency.

SECTION B

Description of Services, Scope of Work and Deliverables

The project intent with the Washoe County Regional Medical Examiner's Office (WCME) is to support data collection, entry, and reporting regarding opioid overdose deaths as required by the funding opportunity Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality (ESOOS) through the Centers for Disease Control and Prevention (CDC).

WCME, hereinafter referred to as Subrecipient, agrees to provide the following services and reports according to the identified timeframes:

Scope of Work for WCME

Goal 1: Abstraction of Opioid Overdoes Deaths as Prescribed by CDC

Object	ive	Activities	Due Date	Documentation Needed
1.	Abstract Data into CDC web- based National Violent Death Reporting System (NVDRS)	1. Within 180 days of the date of death, enter data to initiate opioid overdose cases with a target of entering 100% of identified cases each year into the NVDRS. a. This may include travel to local and state jurisdictions for case and record reviews.	Ongoing	 Monthly case reconciliation with ESOOS Division of Public and Behavioral health Program Coordinator
2.	Report to State and community partners the number of cases abstracted	 Update and maintain a Case Requesting Log of all opioid overdoes deaths within jurisdiction. Jurisdictional counties include Carson City, Churchill, Douglas, Elko, Esmerelda, Eureka, Humboldt, Lander, Lyon, Mineral, Pershing, Storey, Washoe, and the northern portion of Nye. 	Monthly	 Updated Case Requesting Log submitted to ESOOS Division of Public and Behavioral Health Program Coordinator
3.	Identify barriers to stakeholder data extraction	3. Compile reports on data extraction barriers and provide to ESOOS program coordinator to assist in resolution.	Ongoing	 Monthly call with ESOOS Division of Public and Behavioral Health Program Coordinator

Goal 2: Conduct timely and comprehensive toxicology testing of suspected drug overdose deaths.

<u>Objective</u>	Activities	Due Date	Documentation Needed
 Enhanced surveillance of opioid-involved mortality 	 Perform additional toxicology on suspected-opioid involved deaths and upload reports into NVDRS 	Ongoing	 Monthly case reconciliation with ESOOS Division of Public and Behavioral Health Program Coordinator

Compliance with this section is acknowledged by signing the subaward cover page of this packet.

Subaward Packet (BAA) Revised 7/18

Budget and Financial Reporting Requirements

 Identify the source of funding on all printed documents purchased or produced within the scope of this subaward, using a statement similar to: "This publication (journal, article, etc.) was supported by the Nevada State Division of Public and Behavioral Health through Grant Number 6NU17CE924901-02 from the Center for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Division nor the CDC."

Any activities performed under this subaward shall acknowledge the funding was provided through the Division by Grant Number 6NU17CE924901-02 from CDC.

Category	Total cost	Detailed cost	Details of expected expenses
1. Personnel	\$ 29,600		
		\$ 29,600	Data Collection Specialist (includes fringe) for 33 weeks at \$1,200 per week
2. Travel	\$ 4,000		
		\$ 2,500	In-state travel not to exceed \$2,500
		1,500	Out-of-State travel for one staff member to attend national opioid surveillance conference, location TBD, not to exceed \$1,500
3. Supplies	\$		
		\$	
4. Equipment	\$		
	·	\$	
5. Contractual	\$		
Consultant			
6. Training	\$		
		\$	
7. Other	\$ 46,314		
		\$ 46,314	Additional toxicology testing of suspected drug overdose deaths not to exceed \$46,314
8. Indirect	\$		
		\$	
Total Cost	\$ 79,914		

Subrecipient agrees to adhere to the following budget:

- Division of Public and Behavioral Health policy allows no more than 10% flexibility of the total not to exceed amount of the subaward, within the approved Scope of Work/Budget. Subrecipient will obtain written permission to redistribute funds within categories. Note: the redistribution cannot alter the total not to exceed amount of the subaward. Modifications in excess of 10% require a formal amendment.
- Equipment purchased with these funds belongs to the federal program from which this funding was appropriated and shall be returned to the program upon termination of this agreement.
- Travel expenses, per diem, and other related expenses must conform to the procedures and rates allowed for State officers and employees. It is the Policy of the Board of Examiners to restrict Contractors/Subrecipients to the same rates and procedures allowed State Employees. The State of Nevada reimburses at rates comparable to the rates established by the US General Services Administration, with some exceptions (State Administrative Manual 0200.0 and 0320.0).

The Subrecipient agrees:

To request reimbursement according to the schedule specified below for the actual expenses incurred related to the Scope of Work during the performance period.

- Total reimbursement through this subaward will not exceed \$79,914
- Requests for Reimbursement will be accompanied by supporting documentation, including a line item description of expenses incurred;
- Additional supporting documentation of invoices or receipts may be needed in order to request reimbursement;
- Additional expenditure detail will be provided upon request from the Division.

Additionally, the Subrecipient agrees to provide:

- A complete financial reconciliation of all expenditures is required to be submitted to the Division within <u>45 days</u> of the <u>CLOSE OF THE BUDGET PERIOD</u>. Any un-obligated funds remaining after the 45-day closing period <u>must</u> be returned to the Division at that time, or if not already requested, will be deducted from the final award.
 - Any work performed after the BUDGET PERIOD will <u>not</u> be reimbursed.
 - If a Request for Reimbursement (RFR) is received after the 45-day closing period, the Division may <u>not</u> be able to provide reimbursement.
 - If a credit is owed to the Division after the 45-day closing period, the funds <u>must</u> be returned to the Division within <u>30 days</u> of identification.

The Division agrees:

- To provide technical assistance, upon request from the Subrecipient;
- To provide prior approval of reports or documents to be developed;
- To forward a report to the CDC.

Both parties agree:

- Site-visit monitoring and/or audits may be conducted by the Division of Public and Behavioral Health or the Centers for Disease Control and Prevention or related staff of the Subgrantee's Violent Death Registry program in its entirety at any time. Program and fiscal audits shall occur annually or as needed.
- The Subrecipient will, in the performance of the Scope of Work specified in this subgrant, perform functions and/or activities that could involve confidential information; therefore, the Subrecipient is requested to fill out and sign Section F, which is specific to this subaward, and will be in effect for the term of this subaward.
- All reports of expenditures and requests for reimbursement processed by the Division are SUBJECT TO AUDIT.
- The Division reserves the right to hold reimbursement under this subaward until any delinquent forms, reports, and expenditure documentation are submitted to and accepted by the Division.
- This subaward agreement may be TERMINATED by either party prior to the date set forth on the Notice of Subaward, provided the termination shall not be effective until <u>30 days</u> after a party has served written notice upon the other party. This agreement may be terminated by mutual consent of both parties or unilaterally by either party without cause. The parties expressly agree that this Agreement shall be terminated immediately if for any reason the Division, state, and/or federal funding ability to satisfy this Agreement is withdrawn, limited, or impaired.

Financial Reporting Requirements

- A Request for Reimbursement is due on a <u>monthly or quarterly</u> basis, based on the terms of the subaward agreement, no later than the 15th of the month.
- Reimbursement is based on <u>actual</u> expenditures incurred during the period being reported.
- Payment will not be processed without all reporting being current.
- Reimbursement may only be claimed for expenditures approved within the Notice of Subaward.

HD #:	1626
Budget Account:	321

31

GL: _____ Draw #:

Subrecipient Name: Program Name: Office of Public Health Informatics & Epidemiology Washoe County Medical Examiner and Coroner's Office Address: Address: PO Box 11130 4126 Technology Way, Suite 200 Carson City, NV 89706 Reno, NV 89502 **Budget Period:** Subrecipient's: EIN: 88-6000138 September 1, 2018 through August 31, 2019 Vendor #: T40283400-D FINANCIAL REPORT AND REQUEST FOR FUNDS (must be accompanied by expenditure report/back-up) Month(s) Calendar year **Request for Reimbursement** С Α В D Ε F Approved Budget **Total Prior** Current Year to Date Budget Percent Approved Budget Requests Request Total Balance Expended Category 1. Personnel \$29,600.00 \$0.00 \$0.00 \$0.00 \$29,600.00 0.0% \$4,000.00 2. Travel \$4,000.00 \$0.00 \$0.00 \$0.00 0.0% 3. Supplies \$0.00 \$0.00 \$0.00 \$0.00 \$0.00 4. Equipment \$0.00 \$0.00 \$0.00 \$0.00 \$0.00 _ 5. Contractual/Consultant \$0.00 \$0.00 \$0.00 \$0.00 6. Training \$0.00 \$0.00 \$0.00 \$0.00 \$0.00 \$46,314.00 \$46,314.00 0.0% 7. Other \$0.00 \$0.00 \$0.00 8. Indirect \$0.00 \$0.00 \$0.00 \$0.00 \$0.00 Total \$79,914.00 \$0.00 \$0.00 \$0.00 \$79,914.00 0.0%

I, a duty authorized signatory for the applicant, certify to the best of my knowledge and belief that this report is true, complete and accurate; that the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the grant award; and that the amount of this request is not in excess of current needs or, cumulatively for the grant term, in excess of the total approved grant award. I am aware that any false, fictitious or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims, or otherwise. I verify that the cost allocation and backup documentation attached is correct.

Authorized Signature

Title FOR DIVISION USE ONLY Date

NOTICE OF SUBAWARD			
Is program contact required? Yes No	Contact Person:		
Reason for contact:			
Fiscal review/approval date:			
Scope of Work review/approval date:			
ASO or Bureau Chief (as required):			
		Date	

SECTION E

Audit Information Request

 Non-Federal entities that <u>expend</u> \$750,000.00 or more in total federal awards are required to have a single or program-specific audit conducted for that year, in accordance with 2 CFR § 200.501(a). Within nine (9) months of the close of your organization's fiscal year, you <u>must</u> submit a copy of the final audit report to division. <u>Electronic copies are preferred</u> and can be sent to <u>contractunit@health.nv.gov</u>. Mail hard copies to the following address:

	Nevada State Division of Public and Behavioral Health Attn: Contract Unit 4150 Technology Way, Suite 300 Carson City, NV 89706-2009			
2.	Did your organization expend \$750,000 or more in all federal awards durin organization's most recent fiscal year?	ng your	YES	
3.	When does your organization's fiscal year end?			
4.	What is the official name of your organization?			
5.	How often is your organization audited?			
6.	When was your last audit performed?			
7.	What time-period did your last audit cover?			
8.	Which accounting firm conducted your last audit?			

SECTION F

Notification of Utilization of Current or Former State Employee

For the purpose of State compliance with NRS 333.705, subrecipient represents and warrants that if subrecipient, or any employee of subrecipient who will be performing services under this subaward, is a current employee of the State or was employed by the State within the preceding 24 months, subrecipient has disclosed the identity of such persons, and the services that each such person will perform, to the issuing Agency. Subrecipient agrees they will not utilize any of its employees who are Current State Employees or Former State Employees to perform services under this subaward without first notifying the Agency and receiving from the Agency approval for the use of such persons. This prohibition applies equally to any subcontractors that may be used to perform the requirements of the subaward. The provisions of this section do not apply to the employees' Retirement System (PERS) during the duration of the subaward.

Are any current or former employees of the State of Nevada assigned to perform work on this subaward?

YES If "YES", list the names of any current or former employees of the State and the services that each person will perform.

NO Subrecipient agrees that if a current or former state employee is assigned to perform work on this subaward at any point after execution of this agreement, they must receive prior approval from the Division.

Name

Services

Subrecipient agrees that any employees listed cannot perform work until approval has been given from the Division.

SECTION G

Business Associate Addendum

BETWEEN

Nevada Division of Public and Behavioral Health

Hereinafter referred to as the "Covered Entity"

and

Washoe County Regional Medical Examiner's Office

Hereinafter referred to as the "Business Associate"

PURPOSE. In order to comply with the requirements of HIPAA and the HITECH Act, this Addendum is hereby added and made part of the agreement between the Covered Entity and the Business Associate. This Addendum establishes the obligations of the Business Associate and the Covered Entity as well as the permitted uses and disclosures by the Business Associate of protected health information it may possess by reason of the agreement. The Covered Entity and the Business Associate shall protect the privacy and provide for the security of protected health information disclosed to the Business Associate pursuant to the agreement and in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-5 ("the HITECH Act"), and regulation promulgated there under by the U.S. Department of Health and Human Services (the "HIPAA Regulations") and other applicable laws.

WHEREAS, the Business Associate will provide certain services to the Covered Entity, and, pursuant to such arrangement, the Business Associate is considered a business associate of the Covered Entity as defined in HIPAA, the HITECH Act, the Privacy Rule and Security Rule; and

WHEREAS, Business Associate may have access to and/or receive from the Covered Entity certain protected health information, in fulfilling its responsibilities under such arrangement; and

WHEREAS, the HIPAA Regulations, the HITECH Act, the Privacy Rule and the Security Rule require the Covered Entity to enter into an agreement containing specific requirements of the Business Associate prior to the disclosure of protected health information, as set forth in, but not limited to, 45 CFR Parts 160 & 164 and Public Law 111-5.

THEREFORE, in consideration of the mutual obligations below and the exchange of information pursuant to this Addendum, and to protect the interests of both Parties, the Parties agree to all provisions of this Addendum.

- I. DEFINITIONS. The following terms shall have the meaning ascribed to them in this Section. Other capitalized terms shall have the meaning ascribed to them in the context in which they first appear.
 - 1. **Breach** means the unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of the protected health information. The full definition of breach can be found in 42 USC 17921 and 45 CFR 164.402.

- 2. **Business Associate** shall mean the name of the organization or entity listed above and shall have the meaning given to the term under the Privacy and Security Rule and the HITECH Act. For full definition refer to 45 CFR 160.103.
- 3. **CFR** stands for the Code of Federal Regulations.
- 4. **Agreement** shall refer to this Addendum and that particular agreement to which this Addendum is made a part.
- 5. **Covered Entity** shall mean the name of the Division listed above and shall have the meaning given to such term under the Privacy Rule and the Security Rule, including, but not limited to 45 CFR 160.103.
- 6. **Designated Record Set** means a group of records that includes protected health information and is maintained by or for a covered entity or the Business Associate that includes, but is not limited to, medical, billing, enrollment, payment, claims adjudication, and case or medical management records. Refer to 45 CFR 164.501 for the complete definition.
- 7. **Disclosure** means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information as defined in 45 CFR 160.103.
- 8. Electronic Protected Health Information means individually identifiable health information transmitted by electronic media or maintained in electronic media as set forth under 45 CFR 160.103.
- Electronic Health Record means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff. Refer to 42 USC 17921.
- 10. **Health Care Operations** shall have the meaning given to the term under the Privacy Rule at 45 CFR 164.501.
- 11. **Individual** means the person who is the subject of protected health information and is defined in 45 CFR 160.103.
- 12. **Individually Identifiable Health Information** means health information, in any form or medium, including demographic information collected from an individual, that is created or received by a covered entity or a business associate of the covered entity and relates to the past, present, or future care of the individual. Individually identifiable health information is information that identifies the individual directly or there is a reasonable basis to believe the information can be used to identify the individual. Refer to 45 CFR 160.103.
- 13. Parties shall mean the Business Associate and the Covered Entity.
- 14. **Privacy Rule** shall mean the HIPAA Regulation that is codified at 45 CFR Parts 160 and 164, Subparts A, D and E.
- 15. **Protected Health Information** means individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. Refer to 45 CFR 160.103 for the complete definition.
- 16. Required by Law means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. This includes but is not limited to: court orders and court-ordered warrants; subpoenas, or summons issued by a court; and statues or regulations that require the provision of information if payment is sought under a government program providing public benefits. For the complete definition refer to 45 CFR 164.103.
- 17. **Secretary** shall mean the Secretary of the federal Department of Health and Human Services (HHS) or the Secretary's designee.
- 18. **Security Rule** shall mean the HIPAA regulation that is codified at 45 CFR Parts 160 and 164 Subparts A and C.
- 19. **Unsecured Protected Health Information** means protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary in the guidance issued in Public Law 111-5. Refer to 42 USC 17932 and 45 CFR 164.402.
- 20. **USC** stands for the United States Code.
- II. OBLIGATIONS OF THE BUSINESS ASSOCIATE.
 - Access to Protected Health Information. The Business Associate will provide, as directed by the Covered Entity, an individual or the Covered Entity access to inspect or obtain a copy of protected health information about the Individual that is maintained in a designated record set by the Business Associate or, its agents or subcontractors, in order to meet the requirements of the Privacy Rule, including, but not limited to 45 CFR 164.524 and 164.504(e) (2) (ii) (E). If the Business Associate maintains an electronic health record, the Business Associate or, its agents or subcontractors shall provide such information in electronic format to enable the Covered Entity to fulfill its obligations under the HITECH Act, including, but not limited to 42 USC 17935.

- Access to Records. The Business Associate shall make its internal practices, books and records relating to the use and disclosure of protected health information available to the Covered Entity and to the Secretary for purposes of determining Business Associate's compliance with the Privacy and Security Rule in accordance with 45 CFR 164.504(e)(2)(ii)(H).
- 3. Accounting of Disclosures. Promptly, upon request by the Covered Entity or individual for an accounting of disclosures, the Business Associate and its agents or subcontractors shall make available to the Covered Entity or the individual information required to provide an accounting of disclosures in accordance with 45 CFR 164.528, and the HITECH Act, including, but not limited to 42 USC 17935. The accounting of disclosures, whether electronic or other media, must include the requirements as outlined under 45 CFR 164.528(b).
- 4. Agents and Subcontractors. The Business Associate must ensure all agents and subcontractors to whom it provides protected health information agree in writing to the same restrictions and conditions that apply to the Business Associate with respect to all protected health information accessed, maintained, created, retained, modified, recorded, stored, destroyed, or otherwise held, transmitted, used or disclosed by the agent or subcontractor. The Business Associate must implement and maintain sanctions against agents and subcontractors that violate such restrictions and conditions and shall mitigate the effects of any such violation as outlined under 45 CFR 164.530(f) and 164.530(e)(1).
- 5. Amendment of Protected Health Information. The Business Associate will make available protected health information for amendment and incorporate any amendments in the designated record set maintained by the Business Associate or, its agents or subcontractors, as directed by the Covered Entity or an individual, in order to meet the requirements of the Privacy Rule, including, but not limited to, 45 CFR 164.526.
- 6. Audits, Investigations, and Enforcement. The Business Associate must notify the Covered Entity immediately upon learning the Business Associate has become the subject of an audit, compliance review, or complaint investigation by the Office of Civil Rights or any other federal or state oversight agency. The Business Associate shall provide the Covered Entity with a copy of any protected health information that the Business Associate provides to the Secretary or other federal or state oversight agency. The Business Associate and information to the Secretary or other federal or state oversight agency. The Business Associate and individuals associated with the Business Associate are solely responsible for all civil and criminal penalties assessed as a result of an audit, breach, or violation of HIPAA or HITECH laws or regulations. Reference 42 USC 17937.
- 7. Breach or Other Improper Access, Use or Disclosure Reporting. The Business Associate must report to the Covered Entity, in writing, any access, use or disclosure of protected health information not permitted by the agreement, Addendum or the Privacy and Security Rules. The Covered Entity must be notified immediately upon discovery or the first day such breach or suspected breach is known to the Business Associate or by exercising reasonable diligence would have been known by the Business Associate in accordance with 45 CFR 164.410, 164.504(e)(2)(ii)(C) and 164.308(b) and 42 USC 17921. The Business Associate must report any improper access, use or disclosure of protected health information by: The Business Associate or its agents or subcontractors. In the event of a breach or suspected breach of protected health information, the report to the Covered Entity must be in writing and include the following: a brief description of the incident; the date of the incident; the date the incident was discovered by the Business Associate; a thorough description of the unsecured protected health information that was involved in the incident; the number of individuals whose protected health information was involved in the incident; and the steps the Business Associate is taking to investigate the incident and to protect against further incidents. The Covered Entity will determine if a breach of unsecured protected health information has occurred and will notify the Business Associate of the determination. If a breach of unsecured protected health information is determined, the Business Associate must take prompt corrective action to cure any such deficiencies and mitigate any significant harm that may have occurred to individual(s) whose information was disclosed inappropriately.
- 8. **Breach Notification Requirements.** If the Covered Entity determines a breach of unsecured protected health information by the Business Associate has occurred, the Business Associate will be responsible for notifying the individuals whose unsecured protected health information was breached in accordance with 42 USC 17932 and 45 CFR 164.404 through 164.406. The Business Associate must provide evidence to the Covered Entity that appropriate notifications to individuals and/or media, when necessary, as specified in 45 CFR 164.404 and 45 CFR 164.406 has occurred. The Business Associate is responsible for all costs associated with notification to individuals, the media or others as well as costs associated with mitigating future breaches. The Business Associate must notify the Secretary of all breaches in accordance with 45 CFR 164.408 and must provide the Covered Entity with a copy of all notifications made to the Secretary.
- 9. Breach Pattern or Practice by Covered Entity. Pursuant to 42 USC 17934, if the Business Associate knows of a pattern of activity or practice of the Covered Entity that constitutes a material breach or violation of

the Covered Entity's obligations under the Contract or Addendum, the Business Associate must immediately report the problem to the Secretary.

- 10. Data Ownership. The Business Associate acknowledges that the Business Associate or its agents or subcontractors have no ownership rights with respect to the protected health information it accesses, maintains, creates, retains, modifies, records, stores, destroys, or otherwise holds, transmits, uses or discloses.
- 11. Litigation or Administrative Proceedings. The Business Associate shall make itself, any subcontractors, employees, or agents assisting the Business Associate in the performance of its obligations under the agreement or Addendum, available to the Covered Entity, at no cost to the Covered Entity, to testify as witnesses, or otherwise, in the event litigation or administrative proceedings are commenced against the Covered Entity, its administrators or workforce members upon a claimed violation of HIPAA, the Privacy and Security Rule, the HITECH Act, or other laws relating to security and privacy.
- 12. **Minimum Necessary.** The Business Associate and its agents and subcontractors shall request, use and disclose only the minimum amount of protected health information necessary to accomplish the purpose of the request, use or disclosure in accordance with 42 USC 17935 and 45 CFR 164.514(d)(3).
- 13. **Policies and Procedures.** The Business Associate must adopt written privacy and security policies and procedures and documentation standards to meet the requirements of HIPAA and the HITECH Act as described in 45 CFR 164.316 and 42 USC 17931.
- 14. **Privacy and Security Officer(s).** The Business Associate must appoint Privacy and Security Officer(s) whose responsibilities shall include: monitoring the Privacy and Security compliance of the Business Associate; development and implementation of the Business Associate's HIPAA Privacy and Security policies and procedures; establishment of Privacy and Security training programs; and development and implementation of an incident risk assessment and response plan in the event the Business Associate sustains a breach or suspected breach of protected health information.
- 15. Safeguards. The Business Associate must implement safeguards as necessary to protect the confidentiality, integrity, and availability of the protected health information the Business Associate accesses, maintains, creates, retains, modifies, records, stores, destroys, or otherwise holds, transmits, uses or discloses on behalf of the Covered Entity. Safeguards must include administrative safeguards (e.g., risk analysis and designation of security official), physical safeguards (e.g., facility access controls and workstation security), and technical safeguards (e.g., access controls and audit controls) to the confidentiality, integrity and availability of the protected health information, in accordance with 45 CFR 164.308, 164.310, 164.312, 164.316 and 164.504(e)(2)(ii)(B). Sections 164.308, 164.310 and 164.312 of the CFR apply to the Business Associate of the Covered Entity in the same manner that such sections apply to the Covered Entity. Technical safeguards set forth by the guidelines of the National Institute of Standards and Technology (NIST). The Business Associate agrees to only use or disclose protected health information as provided for by the agreement and Addendum and to mitigate, to the extent practicable, any harmful effect that is known to the Business Associate, of a use or disclosure, in violation of the requirements of this Addendum as outlined under 45 CFR 164.530(e)(2)(f).
- 16. **Training.** The Business Associate must train all members of its workforce on the policies and procedures associated with safeguarding protected health information. This includes, at a minimum, training that covers the technical, physical and administrative safeguards needed to prevent inappropriate uses or disclosures of protected health information; training to prevent any intentional or unintentional use or disclosure that is a violation of HIPAA regulations at 45 CFR 160 and 164 and Public Law 111-5; and training that emphasizes the criminal and civil penalties related to HIPAA breaches or inappropriate uses or disclosures of protected health information. Workforce training of new employees must be completed within 30 days of the date of hire and all employees must be trained at least annually. The Business Associate must maintain written records for a period of six years. These records must document each employee that received training and the date the training was provided or received.
- 17. **Use and Disclosure of Protected Health Information.** The Business Associate must not use or further disclose protected health information other than as permitted or required by the agreement or as required by law. The Business Associate must not use or further disclose protected health information in a manner that would violate the requirements of the HIPAA Privacy and Security Rule and the HITECH Act.
- III. PERMITTED AND PROHIBITED USES AND DISCLOSURES BY THE BUSINESS ASSOCIATE. The Business Associate agrees to these general use and disclosure provisions:

1. Permitted Uses and Disclosures:

a. Except as otherwise limited in this Addendum, the Business Associate may use or disclose protected health information to perform functions, activities, or services for, or on behalf of, the Covered Entity as

specified in the agreement, provided that such use or disclosure would not violate the HIPAA Privacy and Security Rule or the HITECH Act, if done by the Covered Entity in accordance with 45 CFR 164.504(e) (2) (i) and 42 USC 17935 and 17936.

- b. Except as otherwise limited by this Addendum, the Business Associate may use or disclose protected health information received by the Business Associate in its capacity as a Business Associate of the Covered Entity, as necessary, for the proper management and administration of the Business Associate, to carry out the legal responsibilities of the Business Associate, as required by law or for data aggregation purposes in accordance with 45 CFR 164.504(e)(2)(A), 164.504(e)(4)(i)(A), and 164.504(e)(2)(i)(B).
- c. Except as otherwise limited in this Addendum, if the Business Associate discloses protected health information to a third party, the Business Associate must obtain, prior to making any such disclosure, reasonable written assurances from the third party that such protected health information will be held confidential pursuant to this Addendum and only disclosed as required by law or for the purposes for which it was disclosed to the third party. The written agreement from the third party must include requirements to immediately notify the Business Associate of any breaches of confidentiality of protected health information to the extent it has obtained knowledge of such breach. Refer to 45 CFR 164.502 and 164.504 and 42 USC 17934.
- d. The Business Associate may use or disclose protected health information to report violations of law to appropriate federal and state authorities, consistent with 45 CFR 164.502(j)(1).

2. Prohibited Uses and Disclosures:

- a. Except as otherwise limited in this Addendum, the Business Associate shall not disclose protected health information to a health plan for payment or health care operations purposes if the patient has required this special restriction and has paid out of pocket in full for the health care item or service to which the protected health information relates in accordance with 42 USC 17935.
- b. The Business Associate shall not directly or indirectly receive remuneration in exchange for any protected health information, as specified by 42 USC 17935, unless the Covered Entity obtained a valid authorization, in accordance with 45 CFR 164.508 that includes a specification that protected health information can be exchanged for remuneration.

IV. OBLIGATIONS OF COVERED ENTITY

- 1. The Covered Entity will inform the Business Associate of any limitations in the Covered Entity's Notice of Privacy Practices in accordance with 45 CFR 164.520, to the extent that such limitation may affect the Business Associate's use or disclosure of protected health information.
- 2. The Covered Entity will inform the Business Associate of any changes in, or revocation of, permission by an individual to use or disclose protected health information, to the extent that such changes may affect the Business Associate's use or disclosure of protected health information.
- 3. The Covered Entity will inform the Business Associate of any restriction to the use or disclosure of protected health information that the Covered Entity has agreed to in accordance with 45 CFR 164.522 and 42 USC 17935, to the extent that such restriction may affect the Business Associate's use or disclosure of protected health information.
- 4. Except in the event of lawful data aggregation or management and administrative activities, the Covered Entity shall not request the Business Associate to use or disclose protected health information in any manner that would not be permissible under the HIPAA Privacy and Security Rule and the HITECH Act, if done by the Covered Entity.

V. TERM AND TERMINATION

1. Effect of Termination:

- a. Except as provided in paragraph (b) of this section, upon termination of this Addendum, for any reason, the Business Associate will return or destroy all protected health information received from the Covered Entity or created, maintained, or received by the Business Associate on behalf of the Covered Entity that the Business Associate still maintains in any form and the Business Associate will retain no copies of such information.
- b. If the Business Associate determines that returning or destroying the protected health information is not feasible, the Business Associate will provide to the Covered Entity notification of the conditions that make return or destruction infeasible. Upon a mutual determination that return, or destruction of protected health information is infeasible, the Business Associate shall extend the protections of this Addendum to such protected health information and limit further uses and disclosures of such protected health

information to those purposes that make return or destruction infeasible, for so long as the Business Associate maintains such protected health information.

- c. These termination provisions will apply to protected health information that is in the possession of subcontractors, agents, or employees of the Business Associate.
- 2. **Term**. The Term of this Addendum shall commence as of the effective date of this Addendum herein and shall extend beyond the termination of the contract and shall terminate when all the protected health information provided by the Covered Entity to the Business Associate, or accessed, maintained, created, retained, modified, recorded, stored, or otherwise held, transmitted, used or disclosed by the Business Associate on behalf of the Covered Entity, is destroyed or returned to the Covered Entity, or, if it not feasible to return or destroy the protected health information, protections are extended to such information, in accordance with the termination.
- 3. **Termination for Breach of Agreement**. The Business Associate agrees that the Covered Entity may immediately terminate the agreement if the Covered Entity determines that the Business Associate has violated a material part of this Addendum.

VI. MISCELLANEOUS

- 1. **Amendment.** The parties agree to take such action as is necessary to amend this Addendum from time to time for the Covered Entity to comply with all the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law No. 104-191 and the Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009, Public Law No. 111-5.
- 2. **Clarification.** This Addendum references the requirements of HIPAA, the HITECH Act, the Privacy Rule and the Security Rule, as well as amendments and/or provisions that are currently in place and any that may be forthcoming.
- 3. **Indemnification.** Each party will indemnify and hold harmless the other party to this Addendum from and against all claims, losses, liabilities, costs and other expenses incurred as a result of, or arising directly or indirectly out of or in conjunction with:
 - a. Any misrepresentation, breach of warranty or non-fulfillment of any undertaking on the part of the party under this Addendum; and
 - b. Any claims, demands, awards, judgments, actions, and proceedings made by any person or organization arising out of or in any way connected with the party's performance under this Addendum.
- 4. Interpretation. The provisions of the Addendum shall prevail over any provisions in the agreement that may conflict or appear inconsistent with any provision in this Addendum. This Addendum and the agreement shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HITECH Act, the Privacy Rule and the Security Rule. The parties agree that any ambiguity in this Addendum shall be resolved to permit the Covered Entity and the Business Associate to comply with HIPAA, the HITECH Act, the Privacy Rule and the Security Rule.
- 5. **Regulatory Reference.** A reference in this Addendum to a section of the HITECH Act, HIPAA, the Privacy Rule and Security Rule means the sections as in effect or as amended.
- 6. **Survival**. The respective rights and obligations of Business Associate under Effect of Termination of this Addendum shall survive the termination of this Addendum.