

AGREEMENT

between

and

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

AREA INDIAN HEALTH SERVICE

for

NALOXONE ACCESS FOR FIRST RESPONDERS

I. **Purpose of Agreement.** This Agreement is made between the _____ Area Indian Health Service on behalf of _____ (IHS Facility) and the _____ (Tribe) on behalf of its _____ (First Responders). The purpose of this Agreement is to establish guidelines for the transfer of Naloxone Hydrochloride (naloxone), the opioid overdose reversal agent, to First Responders, who are Tribal employees designated to immediately respond to an emergency. The mutual goals of the IHS Facility and the Tribe are to increase access to naloxone in the field in order to reduce morbidity and mortality from opioid overdose.

II. **Identification Number.** For purposes of Indian Health Service (IHS) internal administrative needs, this Agreement will carry the following identification number _____ and an official IHS file will be maintained by the Area Coordinator for Collaborative Agreements.

III. **Authority.** The IHS is an agency of the United States Department of Health and Human Services. IHS, as authorized by the United States Congress in the Snyder Act (25 U.S.C. § 13), provides a range of health services to eligible American Indians and Alaska Natives. The parties acknowledge that health services are provided to the extent resources are available and are provided free of charge, in order to carry out a long-recognized Congressional mandate to improve the general health status of American Indians and Alaska Natives. IHS is specifically authorized in the Indian Health Care Improvement Act to carry out comprehensive programs and initiatives for behavioral health prevention and treatment. 25 U.S.C. §§ 1665a and 1665c.

IV. **State Authority.** Historically, naloxone was previously limited as a prescription medication given to those only within a physician-patient relationship. In 2001, however, New Mexico became the first state to enact legislation to increase access to naloxone. Since then, every state has enacted a law to broaden access to naloxone. The majority of these laws provide immunity to health care providers who prescribe or dispense naloxone or individuals who possess or administer naloxone and the majority allow for third-party prescribing. IHS pharmacists acting within the scope of their position description are not subject to state laws; however, IHS will not require IHS pharmacists to dispense naloxone to a third party, such as a First Responder, against his/her wishes if they hold a license in a state that prohibits dispensing naloxone to a third party.

V. IHS Facility's Responsibilities

A. **Naloxone Purchase and Delivery.** The IHS Facility's Pharmacy will coordinate procurement and storage of all naloxone products and delivery devices, or related opioid overdose reversal agents. All items will be stored in accordance with normal pharmacy stock using established policies and procedures to ensure product integrity and access.

B. **Training.** The IHS Facility will direct First Responders to a Medical Control Provider-approved instructor-led training prior to program implementation on the use of naloxone devices, including how to identify an opioid overdose, how to use naloxone, and how to refer individuals to treatment options. The IHS Facility will confirm that the First Responder has attended the approved training prior to dispensing naloxone.

C. **Standing Order.** A Medical Control Provider (MCP), designated by the IHS Facility, will (1) act as the prescribing physician, (2) monitor the dispensing of naloxone to the First Responders, and (3) prepare a standing order authorizing the dispensing of naloxone to trained First Responders and allow First Responders to administer naloxone to individuals with an opioid overdose. See Appendix A, Standing Order for Naloxone.

D. **Data Collection.** The IHS Facility will coordinate all data collection and program evaluation efforts in coordination with First Responders. Data collection will include, at a minimum, patient name, date of administration, condition at presentation to IHS Facility's Emergency Department or other treatment center, substance of abuse if known, if referral to treatment occurred, and patient disposition. To the extent there is any individually identifiable information, the IHS Facility and First Responders agree to hold all such information obtained, learned or developed under, or in connection with, this agreement confidential in accordance with applicable federal laws and regulations.

E. **Treatment.** The IHS Facility may, in coordination with the First Responders, develop mechanisms for the IHS Facility and First Responders to refer individuals who experience an overdose to a treatment center or other appropriate treatment options.

VI. Tribe's Responsibilities.

A. **First Responder Identification and Training.** The Tribe shall identify and ensure all First Responders complete training and demonstrate competency prior to carrying a naloxone device. The Tribe shall also require all new First Responders to complete training. In addition, all First Responders are required to complete refresher training and competency assessment every two (2) years to obtain and administer naloxone. First Responders are required to provide to the MCP evidence or documentation of having completed a MCP-approved training. The Tribe shall maintain a training log identifying the name and date of all First Responders, who have completed the training, and provide a copy of the training log to the IHS Facility upon routine request to ensure training upon restock request.

B. **Initial Acquisition.** Initial issuance of naloxone will be dispensed by the IHS pharmacist after documentation is provided that the First Responder has completed the required training. The First Responder and pharmacist will sign the IHS Naloxone Acquisition Form (Appendix B) acknowledging the pharmacist is dispensing naloxone under the standing order and the naloxone is now the responsibility of the First Responder. The form will be collected and stored by the issuing IHS pharmacy.

C. Resupply Requests. The Tribe shall ensure that all First Responder requests for restock of naloxone devices shall be coordinated directly with the IHS Facility Pharmacy. It is the responsibility of the Tribe to replace expired or damaged naloxone at the IHS Facility pharmacy. If the naloxone device was used, the First Responder shall complete the IHS Naloxone Deployment Reporting Form (Appendix C) prior to obtaining another naloxone device.

D. Maintenance and Inspections. The Tribe agrees to properly store and maintain its inventory of naloxone. The Tribe shall conduct routine monthly inspections of naloxone devices to ensure product integrity and to ensure that the naloxone devices have not expired. The Tribe shall return any damaged or expired naloxone devices to the IHS Facility Pharmacy for appropriate disposal. The Tribe will maintain a count of missing or lost doses and report the need for replacement doses. The First Responders shall conduct an inspection of the naloxone device at the beginning of each shift to ensure that it is intact and ready for use.

E. Data Collection. The Tribe shall ensure First Responders collect and provide the following information to the IHS Facility: patient name, date of administration, location, disposition, and any additional comments (device worked, etc.). To the extent there is any individually identifiable information, the IHS Facility and the Tribe agree to hold all such information obtained, learned or developed under, or in connection with, this agreement confidential in accordance with applicable federal laws and regulations. The First Responders will complete the Naloxone Deployment Reporting Form (Appendix C) following the administration of naloxone intervention.

F. Treatment. First Responders may, in coordination with the IHS Facility and any mechanisms developed by the IHS Facility, refer individuals who experience an overdose to a treatment center or other appropriate treatment options.

G. Education. The First Responders shall coordinate with the IHS Facility to communicate and educate the community regarding the increased naloxone access to First Responders.

VII. General Provisions.

A. Availability of Appropriations. IHS obligations under this agreement are limited to the availability of appropriations and the IHS allocation of its appropriation. Further, all activities under this agreement are subject to the availability of sufficient appropriated federal funds and no provision shall be interpreted to require obligation or payment of federal funds in advance or excess of appropriations.

B. Confidentiality of Records. The content of all patient medical records shall be held in confidence and in accordance with the Privacy Act of 1974, 5 U.S.C. § 552a; Privacy Act Regulations, 45 C.F.R. Part 5b; Drug Abuse Prevention, Treatment, and Rehabilitation Act, as amended, 42 U.S.C. § 290dd-2; Confidentiality of Alcohol and Drug Abuse Patients Records, 42 C.F.R. Part 2; and Health Insurance Portability and Accountability Act of 1996, 45 C.F.R. Parts 160 and 164.

C. Disputes. The Director of the IHS shall make final decisions concerning any disputes resulting from this Agreement. Notwithstanding the foregoing, both parties retain their rights to pursue disputes through the judicial process.

D. **Effect of Agreement.** This Agreement will not result in, nor is it intended to, displace employees or impair existing contracts for services.

E. **Employment Status.** First Responders are not considered employees, officers, or agents of the IHS.

F. **Entirety of Agreement.** It is expressly agreed that this written Agreement represents the entire understanding between the parties and supersedes any prior agreements or understanding with respect to the subject matter herein. Any changes or modifications to this Agreement must be in writing and be signed by both parties.

G. **Law.** The parties agree that Federal law shall apply to any problem or dispute arising out of this Agreement. In the event of a conflict between this Agreement and applicable Federal law, the parties acknowledge that Federal law shall prevail and supersede the terms of this Agreement.

H. **Limitation of Liability.** This Agreement shall not be construed as altering or affecting in any way the responsibilities for, or any liability associated with, the provision of health care to American Indians beyond that which is currently governed by Federal law and regulation, including the Federal Tort Claims Act. IHS does not assume any liability under this Agreement for the Tribe's failure, if any, to comply with laws and regulations regarding care for individuals treated with naloxone.

I. **Non-exclusive.** This agreement does not restrict either party from participating in similar activities or arrangements with other entities.

J. **Notices.** All notices and requests under this agreement by either party shall be in writing and directed to the address of the parties as follows

K. **Supervision.** The First Responders remain under the authority, control, and employment of the Tribe. IHS' employees do not supervise the First Responders using naloxone.

L. **Third Parties.** Nothing in this Agreement, expressed or implied, is intended to confer any rights, remedies, claims, or interests upon an individual or entity not a party hereto. Neither party shall have the right to assign or transfer its rights to any third party under this Agreement.

M. **Termination.** This Agreement may be terminated with or without cause at any time by either party upon thirty (30) days written notice to the other party. Either party may terminate this Agreement immediately in the event that the other party is in breach of its terms or the IHS Facility no longer has a supply of naloxone.

N. **Term.** This Agreement will be effective upon the latest signatory date below and will be in effect for one year from that date unless modified in accordance herewith. Thereafter, this Agreement shall automatically renew for two (2) additional one (1) year terms unless either party provides written notice to the other party at least thirty (30) days in advance of the end of the term. The terms and conditions of this Agreement shall survive the expiration or termination of the Agreement.

IN WITNESS WHEREOF: The parties hereto have duly executed this Agreement in accordance with the terms and provisions contained herein. The persons signing this Agreement warrant that they have full authority to do so and that their signatures shall bind the parties for which they sign.

For the Tribe:

By: _____

Name: _____

Title: _____

Date: _____

For the _____ Area Indian Health Service:

By: _____

Name: _____

Title: _____

Date: _____

Appendix A

**U.S. Department of Health and Human Services
Indian Health Service
Standing Order for Naloxone**

This serves as the Standing Order authorizing the dispensing and administration of naloxone as indicated below:

1. The Indian Health Service facility, _____, is authorized to dispense _____ to trained First Responders for emergency use in the field.
2. The _____ contains:
 - a. _____ doses of naloxone to be given by _____; and
 - b. The toolkit additionally includes: _____
3. Trained First Responders are authorized to administer naloxone to individuals whom they believe, in good faith, are suffering from opioid overdose.
4. Address where naloxone training records will be located:
Indian Health Service Facility: _____
Address: _____
City, State, and Zip Code: _____

List any restrictions to this Medical Authorization, if applicable: _____

Medical Control Provider (MCP) / Clinical Director Name: _____
Indian Health Service Federal Facility: _____
Address: _____
City, State Zip Code: _____
Phone Number: _____ Date: _____
Medical Control Provider (MCP) / Clinical Director Signature: _____

File Form in Pharmacy Program:
Indian Health Service Federal Facility: _____
Pharmacist-in-Charge: _____
Address: _____
City, State Zip Code: _____
Phone Number: _____ Date: _____
Pharmacist-in-Charge Signature: _____

The completed form will be filed in the IHS Pharmacy.

Appendix B

**U.S. Department of Health and Human Services
Indian Health Service
Naloxone Acquisition Form**

Date of Issuance: _____

1. The Indian Health Service (IHS) facility, _____, under the direction of, _____, the local Medical Control Provider (MCP) will dispense Opioid Overdose Kits containing naloxone to the _____, First Responder.

2. The pharmacist (or designee), _____, has confirmed that the First Responder, _____, has completed the MCP-approved naloxone and opioid overdose training and competency.

3. First responders are instructed to:

- Store naloxone out of direct light and keep at room temperature (59 to 86 degrees Fahrenheit);
- Visually inspect naloxone and check for expiration prior to each shift;
- Replace expired or damaged naloxone at an IHS Pharmacy; and
- If the naloxone is deployed in an incident, the First Responder should return to the IHS pharmacy for a refill and complete the Naloxone Deployment Reporting Form.

4. The Opioid Overdose Kit contains at least one of the following (select all that apply):

- Intranasal naloxone
- Auto-Injector naloxone for intramuscular or subcutaneous administration
- Naloxone injection syringe and mucosal atomizer device for intranasal administration

5. The Opioid Overdose Kit may also contain the following (select all that apply):

- Naloxone administration instructions
- Gloves
- Face shield to provide rescue breathing

Other: _____

6. Reason for Replacement Kit (select one):

- Used for an emergency (must also complete the Naloxone Administration Reporting Form)
- Expired
- Damaged (describe) _____
- Lost (describe) _____

7. Lot Number: _____

Expiration Date: _____

(Print)

(Print)

(Signature)
Pharmacist (or designee)

(Signature)
First Responder
Contact Phone No.: _____

The completed form will be filed in the IHS Pharmacy.

Appendix C

U.S. Department of Health and Human Services Indian Health Service Naloxone Administration Report

Date of Report: _____ Date and Approximate Time of Incident: _____

1. Location of Incident (select one):

- Private residence
- Hotel or motel
- Substance abuse treatment center
- Shelter
- Sidewalk or street
- Nursing home or assisted living
- In BIA custody
- Other: _____

2. Did someone administer naloxone before you arrived (select one)? Yes No

3. What physical clues indicated need for naloxone (select all that apply)?

- Person looked blue
- Person was not breathing or had very shallow breathing
- Person did not respond to sternal rub or other attempts to be awakened
- Drugs or drug paraphernalia at the scene
- Known history of drug use
- Report of drug use by a bystander
- Other: _____

4. What type of naloxone was administered (select all that apply)?

- Intranasal naloxone
- Auto-Injector naloxone by intramuscular administration
- Auto-Injector naloxone by subcutaneous administration
- Naloxone injection with mucosal atomizer by intranasal administration

5. How many doses were administered? _____

6. What happened after you gave the person naloxone (select all that apply)?

- Person woke up from overdose
- Person vomited
- Person was agitated or had violent behavior
- Person went to hospital
- Person did not wake up from the overdose and died
- Other: _____

First Responder Name: _____ Signature: _____

Once completed, please give to the IHS Pharmacy.