**XXXXX Tribal Health Center**

ADRESS

City, State, Zip

Phone

Policy and Protocol

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| Subject: Naloxone Distribution at XXXX Tribal Health Center |
| Effective Date: | Review Date: |
| Signature of Health Care Director:  |
| COPIES DISTRIBUTED TO:  |
| REFERENCES:  |

Policy:

In an effort to reduce overdose mortality in LOCATION, XXX Tribal Health Center’s Harm Reduction Program will provide overdose prevention education and distrubute naloxone to persons at risk for having or witnessing an opiod overdose. This policy serves as a standing order for those providing care for patient’s that utilize the harm reduction services and Harm Reduction Program at XXX Tribal Health Center to administer naloxone to clients who are experiencing an opiod overdose. It serves as a standing order to provide overdose prevention education and naloxone kits to XXXXX clients who are at risk of having or witnessing an opioid overdose.

Overview:

INSERT Opioid overdose statistics (e.g. Opioid overdose is the leading cause of accidental death in XXX state. Opioid-related deaths in XXX state have significantly increased over the past decade, and are preventable through education and naloxone intervention. XXX State Good Samaritan Law (Revised Code of XXX (RCW) XXXX) passed in XXX legalizes the administering, dispensing, prescribing, purchasing, acquisition, possession and use of naloxone for persons at risk of experiencing or witnessing an opioid-related overdose. Additionally, XXXX State is supportive of making naloxone available to high-risk populations such as syringe-exchange clients, and collaborative drug therapy agreements that allow pharmacists to education friends of potential opioid overdose victims and provide them with naloxone. Naloxone distribution is recommended by the Center of Disease Control and XXXX State Department of Health as a promising strategy to prevent overdose deaths. The American Medical Association and American Public Health Association both have policies supporting the availability of take-home naloxone. Nationwide, naloxone distribution programs have reported over 10,000 overdose reversals, and economic evaluations show that naloxone distributions to heroine users are highly cost-effective.

Definition of Terms:

**Administer**: direct application of a prescription drug to the body of a patient by a practitioner

**Dispense**: the interpretation of prescription or order for a legend drug and, pursuant to the prescription order, the proper selection, labeling, or packaging necessary to prepare that prescription or order for delivery. Practitioners with prescriptive authority such as physicians and advanced registered nurse practitioners are authorized to dispense the drugs which they prescribe

**Distribute:** to deliver medications other than by administering or dispensing a legend drug

Legend: drugs which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only

**Naloxone:** prescription medicine that reverses the effect of an opioid overdose

**RCW**: Revised Code of XXXX State

Standing Order: XXXXX

Procedure Guidelines:

1. The Harm Reduction Coordinator, under direction of the Health Officer, shall be responsible for training staff and volunteer on overdose prevention and naloxone use. XXX Tribal Health Center’s staff and volunteers who have completed training shall be qualified as Overdose Prevention Educators.
2. XXX Tribal Health Center’s Harm Reduction Staff shall be responsible for receiving shipments, monitoring inventory, and maintaining log details of dispensed kits and client enrollment forms
3. All Overdose Prevention Educators (including staff and volunteers) shall be authorized to deliver the Overdose Prevention and Naloxone Training, and distribute take-home naloxone kits.
4. All Overdose Prevention Educators will be eligible for additional training with the Harm Reduction coordinator to recognize overdose and administer naloxone to clients experiencing overdose at the Harm Reduction Center.
5. Overdose Prevention Educator shall identify syringe exchange clients at least 14 years of age, at risk of experiencing or witnessing opioid overdose as eligible Overdose Responder candidates, who fulfill the following criteria:
	* Current opoioid users, individuals with a history of opioid use, or someone with frequent contact with opioid users, age 14 years of older
	* Risk of overdose or likelihood of contact with someone at risk, by report or history
	* Able to understand and willing to learn the essential components of overdose prevention, management, and naloxone administration
6. Overdose Prevention Educators shall be responsible for delivering the “Overdose Prevention and Naloxone Training” educational curriculum to Overdose Responder candidates. The overdose Prevention Educator will complete an enrollment form for each participant. The training will take from 20 minutes up to 1 hour, depending on questions asked by candidates, and will include:
	* Overdose prevention techniques
	* Recognizing signs and symptoms of overdose
	* Calling 911 and the Good Samaritan Law
	* Rescue breathing
	* Naloxone storage, carrying, and administration
	* Post-overdose follow-up and care
7. Upon completion of the training, the Overdose Prevention Educator will assess the candidates on their understanding of the information and their comfort with the basic components of overdose response. Successful candidates shall be certified as Overdose Responders. A take-home naloxone kit will be dispensed to Overdose Responders who shall be authorized to possess and administer naloxone to any persons (friend, family, partner, etc) experiencing an opioid overdose.

Appendix A. Naloxone Package Insert

**Naloxone – Clinical Pharmacology**

**Complete or partial reversal of opioid depression**

Naloxone prevents or reverses the effects of opoioids including respiratory depression, sedation and hypotension. Also, naloxone can reverse the psychotomimetic and dysphoric effects of agonist-antagonists, such as pentazocine.

Naloxone is an essentially pure opioid antagonist, i.e., it does not possess the “agonistic” or morphine-like properties characteristic of other opioid antagonists. When administered in usual doses and in the absence of opioids or agonistic effects of other opioid antagonists, it exhibits essentially no pharmacologic activity.

Naloxone has not been shown to produce tolerance or cuase physical or psychological dependence. In the presence of physical dependence on opioids, naloxone will preoduce withdrawal symptoms. However, in the presence of opioid dependence, opioid withdrawal symptoms may appear within minutes of naloxone administration and will subside in about 2 hours. The severity and duration of the withdrawal syndrome are related to the dose of naloxone and to the degree and type of opioid dependence.

While the mechanism of action of naloxone is not fully understood, *in vitro* evidence suggests that naloxone antagonizes opioid effects by competing for the mu, kappa, and sigma opioid receptor sites in the CNS, with the greatest affinity for the mu receptor.

When naloxone hydrochloride is administered intravenously, the onset of action is generally apparent within two minutes; the onset of action is slightly less rapid when it is administered subcutaneously or intramuscularly. The duration of action is dependent upon the dose and route of administration of naloxone hydrochloride. Intramuscular administration produces a more prolonged effect than intravenous administration. Since the duration of action of naloxone may be shorter than that of some opioids, the effects of the opioid may return as the effects of Naloxone dissipate. The requirement for repeat doses of naloxone, however, will also be dependent upon the amount, type and route of administration of the opioid being antagonized.

**Indications and Usage for Naloxone**

Naloxone hydrochloride injection is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids including propoxyphene, methadone, and certain mixed agonist-antagonist analgesics: nalbuphine, pentazocine, butorphanl and cyclazocine. Naloxone hydrochloride is also indicated for the diagnosis or suspected or known acute opioid overdose.

**Contraindications**

Naloxone hydrochloride injection is contraindicated in patients known to be hypersensitive to naloxone hydrochloride or to any of the other ingredients contained in the formulation.

**Warnings**

***Drug Dependence***

Naloxone hydrochloride injection should be administered cautiously to persons, including newborns of mothers who are know or suspected to be physically dependent on opioids. In such cases, an abrupt and complete reversal of opioid effects may precipitate an acute withdrawal syndrome. The signs and symptoms of opioid withdrawal in a patient physically dependent on opioids may include but are not limited to the following: body aches, diarrhea, vomiting, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In the neonate, opioid withdrawal may also include: convulsions, excessive crying, and hyperactive reflexes.

***Repeat Administration***

The patient who has satisfactorily responded to naloxone should be kept under continued surveillance and repeated doses of naloxone should be administered, as necessary, since the duration of action of some opioids may exceed that of Naloxone.

***Repiratory Depression Due to Other Drugs***

Naloxone is not effective against repiratory depression due to non-opioid drugs and in the management of acute toxicity caused by levopropoxyphene. Reversal of repiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete or require higher dose of naloxone. If an incomplete response occurs, respirations should be mechanically assisted as clinically directed.

**Precautions**

***General***

In addition to naloxone, other resuscitive measures such as maintenance of free airway, artificial ventilation, cardiac massage, and vasopressor agents should be available and employed when necessary to counteract acute opioid poisoning.

***Drug Interactions***

Large doses of naloxone are required to antagonize buprenorphine since the latter has a long duration of action due to its slow rate of binding and subsequent slow disassociation from the opioid receptor. Buprenorphine antagonism is characterized by a gradual onset of the reversal effects and a decreased duration of action of the normally prolonged respiratory depression. The barbiturate methohexital appears to block the acute onset of withdrawal symptoms induced by naloxone in opioid addicts.

***Carcinogenesis, Mutagenesis, Impairment of fertility***

Studies in animals to assess the carcinogenic potential of naloxone have not been conducted. Naloxone was weakly positive in the Ames mutagenicity and in the *in vitro* human lymphocyte chromosome aberration test but was negative in the *in vitro* Chinese hamster V79 cell HGPRT mutageicity assy and in the *in vivo* rat bone marrow chromosome aberration study. Reproduction studies conducted in mice and rats at doses 4-times and 8-tmes, respectively, the dose of a 50kg human given 50mg/day (when based on surface area or mg/m2), demonstrated no embryotoxic or teratogenic effects due to naloxone.

**Use in Pregnancy**

***Teratogenic Effects: Pregnancy category C***

Teratology studies conducted in mice and rats at doses 4-times and 8-tmes, respectively, the dose of a 50kg human given 50mg/day (when based on surface area or mg/m2), demonstrated no embryotoxic or teratogenic effects due to naloxone. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, naloxone hydrochloride should be used during pregnancy only if clearly needed.

***Non-teratogenic effects***

Risk-benefit must be considered before Naloxone is administered to a pregnant woman who is known or suspected to be opioid-dependent since maternal dependence may often be accompanied by fetal dependence. Naloxone crosses the placenta, and may precipitate withdrawal in the fetus as well as in the mother. Patients with mild to moderate hypertension who receive naloxone during labor should be carefully monitored as severe hypertension may occur.

**Nursing Mothers**

It is not known whether naloxone is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when naloxone hydrochloride is administered to a nursing woman.

**Geriatric Use**

Clinical studies of naloxone hydrochloride injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

**Adverse Reactions**

***Opioid dependence***

Abrupt reversal of opioid effects in persons who are physically dependent on opioids may precipitate an acute withdrawal syndrome which may include, but limited to, the following: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irratibility, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure and tachycardia.

**Drug Abuse and Dependence**

Naloxone hydrochloride injection is an opioid antagonist. Physical dependence associated with the use of naloxone hydrochloride injection has not been reported. Tolerance to the opioid antagonist effct or naloxone is not known to occur.

**Naloxone Dosage and Administration**

Naloxone hydrochloride injection, USP may be administered intravenously, intramuscularly, or subcutaneously. The most rapid onset of action is achieved by intravenous administration and it is recommended in emergency situations. Since the duration of action of some opioids may exceed that of naloxone, the patient should be kept under continued surveillance. Repeated doses of naloxone should be administered as necessary.

