Over the past decade, the incidence rate of opioid abuse in the United States has substantially increased. According to the Centers for Disease Control, 44 people die every day from the misuse and abuse of prescription painkillers (CDC, 2016). In fact, by 2009, people in the United States accounted for 99% of the world’s consumption of hydrocodone and 81% of oxycodone (Kenan, Mack, & Paulozzi, 2012). Data compiled from the National Vital Statistics System suggests that the age adjusted rate of opioid analgesic poisonings increased from 1.4 per 100,000 in 1999 to 5.4 per 100,000 in 2011 (Chen, et al., 2014). Additional research from the CDC indicates that almost three out of every four overdoses related to prescriptions were the result of narcotic pain relievers (CDC, 2012).

An additional reason for this continued upward trend of opiate overdose deaths and abuse in the United States has been the rise in heroin use. Many young people who inject heroin report misuse of prescription opioids before starting to use heroin (SAMHSA, 2015). In 2013, over 16,000 Americans died as a result of prescription drug abuse, equating to nearly one death every 25 minutes (CDC, 2016). Approximately 1.9 million Americans meet the criteria for prescription painkillers use disorder based on their use of prescription painkillers within the past year (SAMHSA, 2015). In Indiana, prescription pain relievers and Heroin make up the top two drugs related to overdose deaths.

While many states and communities have taken steps to reduce the quantity of prescription opiates available through regulatory reform and other actions, the rate of opioid abuse and misuse continues to be a significant public health issue facing states and local communities. One tool that is crucial to combatting the opioid epidemic is Naloxone, whose brand name is Narcan®. Naloxone, an antidote for opioid overdoses, can now be distributed by pharmacists.

Who is at Risk for Opioid Abuse and Overdose? Anyone using opioids!

- High Risk Populations
- Have multiple prescriptions from multiple sources
- Take high doses at multiple times through the day
- Large single dose
- Have mental illness
- Have a history of alcohol or other substance abuse (including family history)
- Live in rural areas
- Low income

If you would like any additional information related to the opioid epidemic, please visit us at www.BitterPill.IN.Gov
Educational Goals

- Naloxone is an antidote for opioid overdose (opioid antagonist).
- This toolkit provides educational information on opioids, the antidote naloxone, methods of administration, in-depth information on brand name naloxone nasal spray (Narcan®) and its use, as well as examples of standing orders for dispensing naloxone.
- Naloxone can now be distributed without a prescription in pharmacies which are registered with the Department of Health and have a standing order from a physician. Ensure that anyone who may need naloxone (patient, family members and friends) has access to it.

Naloxone Indication

- Naloxone is an opioid antagonist for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression by both natural and synthetic opioids, as well as some mixed agonist-antagonist analgesics.
- Administer naloxone as quickly as possible if a patient is unresponsive and an opioid overdose is suspected, even when in doubt, because prolonged respiratory depression may result in damage to the central nervous system or death.
- The onset of action of naloxone is almost immediate, appearing within minutes, and may produce opiate withdrawal symptoms.

High Dose Effects and Overdose

The most adverse serious effect from high doses of opioids is *respiratory depression*. Individuals may experience signs and symptoms such as:

- Unusual drowsiness; difficulty waking from sleep
- Mental confusion
- Slurred speech and/or intoxicated behavior
- Slow or shallow breathing
- Pinpoint pupils
- Slow heart rate
- Low blood pressure

During an overdose, signs and symptoms may include:

- Pale and clammy face
- Limp body
- Blue/purple lips or fingernails
- Vomiting or gurgling
- Unresponsive or cannot wake from sleep
- Very little or undetectable breathing
- Very slow or undetectable heart rate
**Common Signs of Overdose**

- Pinpoint pupils
- Paraphernalia near the victim
- Blue fingers
- Undetectable pulse or heartbeat
- Blue mouth
- Unresponsive to stimuli

**Potential Adverse Reactions**

- Hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. Excessive doses of naloxone hydrochloride in post-operative patients have resulted in significant reversal of analgesia, and have caused agitation.

- Replace naloxone products before the expiration date or after use.
Naloxone Administration Steps & Description

Naloxone hydrochloride is a white to slightly off-white powder, and is soluble in water, dilute acids, and in strong alkali. It is slightly soluble in alcohol and practically insoluble in ether and chloroform.

Naloxone is sold under both generic and brand names. Naloxone rescue kits may be designed for nasal or intramuscular administration. The brand name Narcan® is a nasal spray and Evzio® is an auto-injector intended for intramuscular or subcutaneous use in the thigh.

Examples Include:

1. **Intranasal naloxone via Narcan® Nasal Spray**

   Narcan® Nasal Spray is a pre-filled, single 4 mg dose of naloxone hydrochloride in a 0.1 mL intranasal spray.

**Narcan® Nasal Spray Administration**

- **Step 1**
  - Open the box and peel back the package to remove the device.
  - Do not prime the unit.

- **Step 2**
  - Lay the patient on their back with head tilted back and place the nozzle tip in either (one) nostril until your fingers touch the bottom of the patient’s nose.

- **Step 3**
  - Using your thumb press the plunger firmly to release the dose into the patient’s nose.

Administer a single spray to adults or pediatric patients into one nostril. Administer an additional dose to the alternate nostril if the patient does not respond within 2-5 minutes, or responds and then relapses into respiratory depression. Each Narcan® Nasal Spray contains
only a single dose of naloxone and cannot be reused. A new dose may be given every 2 to 3 minutes. Rescue breathing should be provided while waiting for naloxone to take effect.

The duration of action of most opioids exceeds that of naloxone (30-90 minutes depending on dose and route of naloxone administration), therefore immediately seek emergency medical assistance and keep watch on the patient until emergency personnel arrive. Administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

2. Intramuscular naloxone via syringe:

3. Intramuscular naloxone via Evzio® auto injector:

4. Generic Assembly Naloxone Spray:
Following Naloxone Administration

You may see:

- Increased breathing and heart rate
- Blue color return to normal
- Precipitation of Severe Opioid Withdrawal
  - Naloxone may precipitate withdrawal in patients who are opioid dependent, resulting in body aches, diarrhea, increased heart rate, fever, runny nose, sneezing, goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.
  - Withdrawal is not life-threatening and naloxone is safe even in individuals who have not taken opioids.

PLACE THE VICTIM IN THE RECOVERY POSITION

Note: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Therefore, repeat doses may be required.

Refer to the Narcan® Nasal Spray package insert for considerations in special populations, such as patients with heart problems, those who are pregnant or breastfeeding.
Registration with the Indiana Department of Health

In order for an organization to administer and distribute naloxone, registration is required with the Indiana Department of Health by visiting https://optin.in.gov/.

Registration criteria include affirmation to/of:

1. Provide education and training on drug overdose response and treatment, including the administration of an overdose intervention drug to everyone that the program serves.
2. Not distribute an overdose intervention drug that is past its expiration.
3. Current standing order or prescription for an overdose intervention drug from a licensed Indiana Prescriber (Prescriber means Physician, Physician Assistant or Advanced Practice Nurse) and that during all times of performance as an Entity, a current standing order or prescription will be maintained.
4. Instruction by the Prescriber, and so too will instruct those receiving the overdose intervention drug from the Entity.
5. Inform how to summon emergency services immediately before, or immediately after, administration of the drug.
6. Inform how to administer the overdose intervention drug.
7. Provide drug addiction treatment information and referrals to drug treatment programs (including programs in the local area and programs that offer medication-assisted treatment that includes a federal Food and Drug Administration approved long-acting, non-addictive medication for the treatment of opioid or alcohol dependence).

Entities such as treatment centers, overdose prevention organizations, and community corrections can also dispense and train lay persons to administer naloxone. Requirements include a standing order from a medical prescriber.

Legality of Naloxone Use

A prescriber may, directly or by standing order, prescribe or dispense an overdose intervention drug without examining the individual to whom it may be administered if all of the following conditions are met:

1. The overdose intervention drug is dispensed or prescribed to:
   a. a person at risk of experiencing an opioid-related overdose; or
   b. a family member, a friend, or any other individual or entity in a position to assist an individual who, there is reason to believe, is at risk of experiencing an opioid-related overdose.
2. The prescriber instructs the individual receiving the overdose intervention drug or prescription to summon emergency services either immediately before or immediately after
administering the overdose intervention drug to an individual experiencing an opioid-related overdose.

3. The prescriber provides education and training on drug overdose response and treatment, including the administration of an overdose intervention drug.

4. The prescriber provides drug addiction treatment information and referrals to drug treatment programs, including programs in the local area and programs that offer medication assisted treatment that includes a federal Food and Drug Administration approved long acting, non-addictive medication for the treatment of opioid or alcohol dependence.
   a. A prescriber may provide a prescription of an overdose intervention drug to an individual as a part of the individual's addiction treatment plan.
   b. An individual may administer an overdose intervention drug to an individual who is suffering from an overdose.
   c. An individual may not be considered to be practicing medicine without a license in violation of IC 25-22.5-8-2, if the individual, acting in good faith, does the following:
      i. Obtains the overdose intervention drug from a prescriber.
      ii. Administers the overdose intervention drug to an individual who is experiencing an apparent opioid-related overdose.
      iii. Attempts to summon emergency services by calling 911 either immediately before or immediately after administering the overdose intervention drug.

Civil Immunity

Aarons Law, SB 406, provides civil immunity for lay persons, law enforcement, and prescribers/pharmacists who administer naloxone, except:

1. For an act of gross negligence or willful misconduct, a prescriber who dispenses/prescribes an overdose intervention drug or a pharmacist who dispenses an overdose intervention drug, in compliance with this chapter is immune from civil liability.
2. For an act of gross negligence of willful misconduct, an individual or entity is immune from civil liability for the following actions:
   a. Obtaining an overdose intervention drug under this chapter.
   b. Administering an overdose intervention drug in good faith.

Insurance Information

Naloxone reimbursement is provided by both Medicaid and HIP 2.0 when it is prescribed to either the user directly or the person receiving/picking up naloxone. Therefore, a family member or friend may purchase a naloxone toolkit for another individual who might need it and submit to insurance. Please contact the Family and Social Services Administration at their Consumer Service line at 1-800-901-1133 for billing information (Monday – Friday, 8:30 am – 5:00 pm).
The codes for Screening, Brief Intervention, and Referral to Treatment (SBIRT) can be used to bill time for counseling a patient about how to recognize overdose and how to administer naloxone. Billing codes for SBIRT are as follows:

- Commercial Insurance: CPT 99408 (15 to 30 minutes)
- Medicare: G0396 (15 to 30 minutes)
- Medicaid: H0050 (per 15 minutes)

**Helpful Resources**

- The Indiana Prescription Drug Abuse Prevention Task Force  
  [www.BitterPill.IN.gov](http://www.BitterPill.IN.gov)
- To search for treatment centers by zip code visit the SAMHSA Treatment Center Information  
  [https://findtreatment.samhsa.gov/](https://findtreatment.samhsa.gov/)
- Indiana 2-1-1 Help Center & Website  
  [http://www.in211.org/](http://www.in211.org/)
- Indiana State Department of Health  
  [http://www.in.gov/isdh/index.htm](http://www.in.gov/isdh/index.htm)
- The Centers for Disease Control Injury and Prevention  
  [http://www.cdc.gov/drugoverdose/](http://www.cdc.gov/drugoverdose/)
- Indiana Narcotics Anonymous  
- IU Health Chemical Dependency  
- SB187 – Overdose Intervention Drugs  

- Effective July, 1, 2016. This bill requires an entity acting under a standing order issued by a prescriber for an overdose intervention drug to report annually certain information to the state department of health (state department). Requires the state department to ensure that a statewide standing order for the dispensing of an overdose intervention drug is issued for Indiana. Allows the state health commissioner or a public health authority to issue a statewide standing order for the dispensing of an overdose intervention drug. Requires certain emergency ambulance services responsible for submitting the report to report the number of times an overdose intervention drug has been administered. Requires the ambulance service to include the information in the emergency ambulance service’s report to the emergency medical services commission under the emergency medical services system review. Provides that, if certain conditions are met, an individual who aided an individual in need of medical assistance due to an opioid related overdose is immune from certain criminal prosecution.
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<th>Phone</th>
<th>City/County</th>
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<td>Life Springs</td>
<td>(812) 280-2080</td>
<td>Jeffersonville</td>
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<tr>
<td>Porter Starke</td>
<td>(219) 531-3500</td>
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<td>Adult Rehab Center (ARC)</td>
<td>(317) 638-6585</td>
<td>Indianapolis</td>
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<tr>
<td>Aspire</td>
<td>(877) 574-1254</td>
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<tr>
<td>Centerstone of Indiana</td>
<td>(812) 339-1691</td>
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<td>Cummins Behavioral Health</td>
<td>(317) 247-8900</td>
<td>Indianapolis</td>
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<td>Hamilton Center</td>
<td>(317) 937-3712</td>
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<td>Eskenazi Health Midtown</td>
<td>(317) 880-8491</td>
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<td>(317) 572-9396</td>
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<td>Park Center Inc.</td>
<td>(260) 481-2800</td>
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<td>Valle Vista</td>
<td>(800) 447-1348</td>
<td>Greenwood</td>
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<td>Indianapolis Counseling Center</td>
<td>(317) 549-0333</td>
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<td>Edge-Water</td>
<td>(219) 885-4264</td>
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<td>Life Recovery Center</td>
<td>(317) 887-3290</td>
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<td>Pathway to Recovery</td>
<td>(317) 926-8557</td>
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<td>Amethyst House</td>
<td>(812) 401-3415</td>
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<td>St. Vincent Stress Center</td>
<td>(317) 338-4600</td>
<td>Indianapolis</td>
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<tr>
<td>Tara Treatment Center</td>
<td>(812) 526-2611</td>
<td>Franklin</td>
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<td>Sycamore Springs</td>
<td>(765) 743-4400</td>
<td>Lafayette</td>
</tr>
<tr>
<td>Volunteers of America of Indiana</td>
<td>(844) 455 –4673</td>
<td>Indianapolis</td>
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SAMPLE STANDING ORDER #1

Standing Order for the Prescription and Distribution of Naloxone to an Indiana Entity

This order authorizes __________________________________________ (hereafter: “Entity”) to be dispensed and to maintain naloxone, mucosal atomizer devices (MADs), syringes, and other components of opioid rescue kits, as defined infra, for the purpose of assembling and distributing kits to those that may be in a position to assist an individual suffering an opioid-related overdose. This standing order conforms to Indiana Code §16-42-27 et. seq.

Entity must annually register with the Indiana State Department of Health or the local health department in the county where services will be provided, in the manner the Department prescribes.

**Naloxone Overview:**

Naloxone is an opioid antagonist indicated to reverse central nervous system depression in an individual suffering from an opioid-related oversedation, poisoning or overdose. Naloxone is the generic form of Narcan®. Naloxone does not cause euphoric effects, is non-addictive, and is not a drug of abuse. Since 1971, naloxone has been successfully used to reverse opioid overdoses. Naloxone is a legend drug, but not a controlled substance.

**Naloxone Effects:**

Naloxone reverses opioid-related over sedation, poisoning or overdose by replacing and blocking agonists from attaching to the brain’s opioid receptors. Naloxone has a stronger affinity to the opioid receptors than do agonists. When administered to a person with opioids in their system, naloxone neutralizes the opioids’ effect, allowing the body to return to more normal function. Because the opioids remain in the person’s system, naloxone cannot be used to sabotage a urine screen. However, because naloxone has a shorter half-life than many opioids, rebound toxicity is a rare, but possible concern. For this reason and pursuant to the Indiana Code, seeking medical assistance should be part of overdose response education.

Naloxone does not produce an effect in people without opioids in their system and does not interact with any medications other than opioids. The only contraindication to administering naloxone is if the recipient has a known sensitivity or allergy to naloxone or its components, which is rare.

The most common side effect of naloxone is opioid withdrawal symptoms, including tachycardia, increased blood pressure, body aches, diarrhea, fever, and irritability. Withdrawal symptom likelihood can be reduced by administering small doses of naloxone over time instead of one large dose. Each dose contained in the opioid rescue kit is designed to reverse the overdose gradually.
Symptoms of Opioid Overdose:
A person suffering an opioid overdose may present with some or all of the following symptoms:

- Decreased level of consciousness,
- Pinpoint pupils,
- Gurgling or choking noises,
- Body is limp,
- Breathing slows or stops,
- Heart rate slows or stops,
- Blue lips and/or nail beds,
- Clammy skin,
- Caused by insufficient oxygen in the blood, or
- Can’t be woken or can’t speak, even after:
  - Shaken, or
  - Sternal rub.

Environmental Signs of an Opioid Overdose:
In addition to the symptoms an imperiled person presents indicating an opioid overdose, the following items may indicate an opioid overdose:

- Needles,
- Spoons (especially bent spoons),
- Lighters,
- Tourniquets,
- Balloons or baggies,
- Pill bottles, or
- Pills (whole or crushed).

Naloxone Administration:
If you believe that a person is suffering from an opioid overdose:

1. Confirm your belief by checking for the symptoms and signs of opioid overdose,
2. Call 911,
3. Conduct rescue breathing by clearing the airway and give a breath every 5 seconds,
4. Give naloxone,
5. If they do not have a pulse, give CPR,
6. If there is no change in 3-5 minutes after giving naloxone, administer another dose, and
7. Stay with the person until first responders arrive.

How to Give Naloxone:
Naloxone kits may be designed for nasal or muscular administration. Follow the instructions for the type of naloxone in your opioid rescue kit.
Intranasal Naloxone:

**How to Give Nasal Spray Naloxone**

1. Pull or pry off yellow caps from the syringe.
2. Pry off red cap from the spray capsule.
3. Grip the clear plastic wings of the capsule of naloxone.
4. Gently screw the capsule of naloxone into the barrel of the syringe.
5. Insert white cone into nostril: give a short, vigorous push on end of capsule to spray naloxone into the nasal cavity; one half of the capsule into each nostril.
6. If no reaction in 2-5 minutes, give the second dose.

Intramuscular Naloxone via syringe (1 mL):

Intramuscular Naloxone via Auto-injector Naloxone:
TREATMENT INFORMATION:
Prevention works, treatment is effective, people recover. Information on local drug addiction treatment programs can be found at: https://findtreatment.samhsa.gov/

You can also search for the Community Mental Health Center in your area.

ORDER TO DISPENSE:
This order authorizes a dispenser to provide Entity with the following materials:

The contents of Nasal Naloxone Rescue Kits should contain the following at a minimum:
- A prefilled 2 mL vial of Naloxone and a needleless luer-lock syringe,
- A mucosal atomizer device, and
- A quick guide of opioid overdose symptoms and assembly instructions.

The contents of Muscular Naloxone Rescue Kits (syringe) should contain the following at a minimum:
- A 1 mL vial of Naloxone,
- A syringe with an intramuscular needle.
- A quick guide of opioid overdose symptoms and assembly instructions.

The contents of Muscular Naloxone Rescue Kits (auto-injector) should contain the following at a minimum:
- A naloxone auto-injector.

This order authorizes a dispenser to provide Entity with replacement naloxone rescue kits.

This order authorizes each kit to include, at a minimum, one dose of naloxone. Studies have demonstrated that in as many of 40% of opioid overdoses, rescuers have needed two doses. The prescriber, dispenser, or entity may choose to include at least two doses of naloxone and administration devices per opioid rescue kit.

__________________________________________________________________________
Prescriber’s Signature & License No.                                      Date
__________________________________________________________________________
Prescriber’s Name (Print)                                                  Order’s Expiration Date
I, the Undersigned Physician:

(a) for the purpose of facilitating the prescribing of opioid antagonists to combat the effects of opioid overdose;

(b) in compliance with the statutes and regulations of the State of Indiana (the “Law”), including the rules and regulations of the Indiana Board of Pharmacy, including Indiana statutes governing the practice of pharmacy and any rules and regulations promulgated under Indiana law regulating the practice of pharmacy; and

(c) in association with pharmacists licensed in the State of Indiana (“Pharmacists”) employed by (INSERT YOUR COMPANY NAME) and its subsidiaries (collectively, the “Company”):

Issue this Standing Order to Dispense Opioid Antagonists (“Standing Order”) on the following terms:

1. I represent that I:

   (a) am licensed to prescribe legend drugs in the State of Indiana;

   (b) practice medicine in the State of Indiana;

   (c) am in good standing with the appropriate Indiana professional licensing board.

2. Prior to dispensing an opioid antagonist pursuant to this Standing Order, a Pharmacist shall complete any applicable training as required by the Law.

3. This Standing Order constitutes my prescription and order authorizing a Pharmacist to dispense opioid antagonists (including any supplies necessary for the administration of opioid antagonists) to any of the following individuals (each a “Recipient”):

   a) A person at risk of experiencing an opioid overdose;

   b) A family member, friend, or other individual or entity in a position to assist a person at risk of an opioid related overdose.

4. A Pharmacist may dispense an opioid antagonist to a Recipient in any of the following formulations:

   a) Intramuscular Naloxone;

   b) Intranasal Naloxone;

   c) Naloxone Auto-Injector;

   d) Any other opioid antagonist formulation permitted under the Law.

A Pharmacist may also dispense any other items necessary for the administration of opioid antagonists as determined by the Pharmacist.
5. At the time of dispensing, the Pharmacist shall provide the Recipient with counseling in accordance with the Law. Such counseling shall include:

a) The importance of contacting emergency services either immediately before or immediately after administering an opioid antagonist;

b) Education and training on drug overdose response and treatment, including the administration of an opioid antagonist;

c) Drug addiction treatment information and referrals for drug treatment programs.

6. I, the Undersigned Physician, authorize Pharmacists dispensing opioid antagonists under this Standing Order to issue prescriptions in my name for the opioid antagonist and any supplies necessary for the administration of the opioid antagonist. The dispensing Pharmacist shall document and retain each prescription created pursuant to this Standing Order in accordance with the Law.

7. I, the Undersigned Physician, acknowledge that the Law may change or may conflict with the terms of this Standing Order from time to time which such changes or conflicts may result from legislative or emergency rule changes to existing statutes and/or regulations. I authorize Pharmacists to exercise their discretion to dispense opioid antagonists in accordance with and to the fullest extent permitted by any applicable Law, effective as of the date of any amendment or modification to the Law.

8. A copy of this Standing Order shall be maintained at the pharmacy during the term of the Standing Order. Company pharmacies that dispense opioid antagonists pursuant to this Standing Order shall register with the Indiana State Department of Health in accordance with the Law. Such registration may be completed online at https://optin.in.gov and shall be renewed annually.

9. Company pharmacies that dispense opioid antagonists pursuant to this Standing Order shall annually report to the Indiana State Department of Health the number of doses of opioid antagonists dispensed by the pharmacy.

10. This Standing Order may be terminated by the Physician or the Company at any time upon delivery of written notice to the other party. This Standing Order has no expiration date and will remain in full effect unless terminated by one of the parties.

Effective this ____ day of ________ 201___.

________________________________________________________________________
Physician Name (printed/typed) Date Signed

________________________________________________________________________
Physician Name (signature) License Number

________________________________________________________________________
Address NPI

________________________________________________________________________
City, State and Zip Code DEA Number Phone Number UPIN
References