



STATE OF INDIANA
OFFICE OF THE ATTORNEY GENERAL

INDIANA GOVERNMENT CENTER SOUTH, FIFTH FLOOR
302 W. WASHINGTON STREET • INDIANAPOLIS, IN 46204-2770
www.AttorneyGeneral.IN.gov

TELEPHONE: 317.232.6201
FAX: 317.232.7979

GREG ZOELLER
INDIANA ATTORNEY GENERAL

September 3, 2015

OFFICIAL OPINION 2015-01

Hon. James W. Merritt, Jr.
Majority Caucus Chairman
Indiana State Senate
200 West Washington Street
Indianapolis, IN 46204

RE: Standing Orders by Indiana Prescribers under “Aaron’s Law”

Dear Sen. Merritt:

You requested the Attorney General’s opinion regarding certain applications of “Aaron’s Law,” Indiana Code § 16-42-27 *et. seq.* This statute was enacted through Senate Enrolled Act 406, effective upon the Governor’s signature on April 17, 2015. You sought clarification particularly with regard to the use of standing orders by Indiana prescribers to authorize the dispensing of naloxone to entities, including non-health care entities, and bystanders.

The specific questions raised regarding SEA 406 are as follows:

1. Can a non-health care entity obtain naloxone based on a standing order from an Indiana prescriber?
2. Can such a non-health care entity distribute naloxone to those that may be in a position to render assistance to an imperiled person suffering from an opioid overdose?
3. Is the prescriber required to have a direct relationship with the recipient of the naloxone issued or the person that may experience the opioid-related overdose via a standing order protocol?
4. If a pharmacy or other healthcare provider distributes naloxone under a standing order, must they register with the Indiana State Department of Health as an “entity”?

BRIEF ANSWERS

1. An Indiana prescriber, as defined by I.C. § 16-42-27-1, may issue a standing order allowing a pharmacy or a non-health care entity which registers pursuant to I.C. § 16-42-27-2(e) to be dispensed opioid intervention drugs.
2. Under a standing order, an Indiana prescriber can authorize a registered entity to distribute opioid intervention drugs to a person that may be in a position to assist an individual experiencing an opioid-related overdose.
3. Under a standing order, a prescriber may authorize a person or entity to receive naloxone without a relationship to the person that is dispensed the opioid intervention drugs or the person whose overdose is attempted to be reversed by the opioid intervention drugs.
4. A pharmacy may dispense opioid intervention drugs pursuant to the authority of a standing order written to another “entity” without the pharmacy itself registering as an “entity”. If the pharmacy wishes to dispense opioid intervention drugs directly to a person that may be in a position to assist an individual experience an opioid-related overdose as authorized by a standing order, that pharmacy must register as an “entity”.

LEGAL ANALYSIS

Background

Indiana’s inherent police powers entitle the state to regulate the practice of medicine within its borders. State statute defines legend drugs¹, the licensing requirements to prescribe legend drugs², and the licensing requirements of those who may dispense legend drugs³. The code also authorizes who can perform medical procedures and provides civil immunity from liability for certain acts.

While most medical procedures are restricted to physicians, nurses, paramedics, and other health care providers, the law allows some acts to be performed by the general public. The state allows lay people to perform medical procedures by balancing the potential harm a lay person may cause the patient in rendering the assistance, the skill required to provide the intervention, and the emergent need of the patient.

Medical Procedures Allowed for Layperson Administration

Cardiopulmonary resuscitation (CPR) is a procedure widely promoted to the public since the 1970s as a means for a lay person to render time-critical emergency medical care. In 1998, the General Assembly extended civil immunity to non-health care providers with CPR training that

¹ I.C. § 16-42-16 *et. seq.*

² I.C. § 16-42-16-5

³ *Id.*

attempt resuscitation, as long as their acts or omissions don't arise to gross negligence or willful or wanton misconduct⁴.

Automatic External Defibrillators (AEDs) are a newer technology which gives an electrical shock to correct cardiac arrhythmias. Similar to non-health care providers that give CPR in an emergency, the legislature provided immunity to those that use AEDs, as long as they also call for ambulance services⁵. However, unlike CPR immunity, AED immunity doesn't require the lay person to have any training.

While CPR can be performed without equipment and AEDs have been made available in a number of public places, some lay person medical interventions authorized by the legislature require legend drugs to be performed.

Authorization for an Indiana Prescriber to Prescribe Epinephrine to a School Entity

Countering the onset of anaphylaxis requires epinephrine to be administered quickly. While potentially fatal, anaphylaxis can be reversed with a simple injection. Auto-injectable epinephrine, commonly marketed as an EpiPen[®], is a device with a spring-loaded needle that provides a standard dose of epinephrine through intramuscular injection designed to be used by lay people.

Recognizing that students, staff, and visitors of Indiana schools may suffer anaphylaxis and require epinephrine, the legislature authorized licensed health care providers whose scope of practice includes prescribing medication to write a prescription, drug order, or protocol for auto-injectable epinephrine to a school⁶. Further, the school nurse or trained school employees receive civil immunity for damages resulting from the administering epinephrine, unless the act or omission constitutes gross negligence or willful or wanton misconduct⁷.

A prescriber can write a standing order for a pharmacist to dispense auto-injectable epinephrine to a school, define the parameters under which the drug is to be administered, and authorize an individual to administer the drug on the physician's authority without ever examining the patient that requires the treatment.

Authorization for an Indiana Prescriber to Allow Pharmacists to Administer Immunizations under the Prescriber's Standing Drug Order

Under a drug order, prescription, or protocol, Indiana law allows a pharmacist to administer an immunization for eight defined diseases⁸, a medical procedure previously restricted to health care providers⁹.

⁴ I.C. § 34-30-12-2

⁵ I.C. § 34-30-12-1 and § 16-31-6.5-6

⁶ I.C. § 20-34-4.5-3

⁷ I.C. § 20-34-4.5-2 and § 20-34-4.5-4

⁸ Influenza, Shingles (herpes zoster), Pneumonia, Tetanus, Diphtheria, and Acellular Pertussis (Whooping Cough), Human papillomavirus (HPV) infection, and Meningitis. I.C. § 25-26-13-31.2(b)

⁹ I.C. § 25-26-13-31.2

The law defines requirements of the prescriber's drug order, prescription, or protocol; but allows a standing order to authorize a pharmacist to administer an immunization and notify the prescriber no later than 14 days after the procedure takes place¹⁰.

As exemplified by the epinephrine and pharmacist-administered immunization examples *supra*, an Indiana prescriber using a standing order can prescribe certain courses of treatment to patients the prescriber has not examined or assessed, by specifying the conditions the patient must satisfy for that treatment. Further, the standing order can be implemented by non-health care providers.

“Aaron’s Law”

Under “Aaron’s Law”, Indiana Code § 16-42-27 *et. seq.*, the General Assembly explicitly authorized prescribers to use standing orders to dispense naloxone to any individual or entity that may be in a position to assist a person experiencing an opioid-related overdose¹¹. Naloxone is an opioid antagonist which can counter the effects of an opioid overdose¹².

A prescriber’s standing order to an individual or entity must contain three things:

1. instructions to summon emergency services immediately before or after administering the drug,
2. education and training on drug overdose response and treatment, including the administration of naloxone, and
3. information and referrals to drug addiction treatment and programs, including local programs that offer medication assisted treatment¹³.

“Aaron’s Law” also authorizes a prescriber to write a standing order to authorize an entity to receive naloxone and distribute it to those individuals that may be in a position to assist a person experiencing an opioid-related overdose. The authorizations for receipt and distribution are valid as long as the entity registers with the Indiana State Department of Health (ISDH) or the local health department in the county where the services will be provided, in a manner prescribed by ISDH, and provides the same education and training described *supra*¹⁴. The parameters for qualifying as an entity are flexible and broad so that organizations such as community health centers, jails, counseling and recovery centers, and other groups could qualify and register as entity for this purpose. These authorizations parallel the ability of a prescriber to write a standing order for epinephrine to be dispensed to a school, and they were intended to remove actual or perceived barriers to promoting broad access and use where appropriate of naloxone to help save lives of those experiencing opioid-related overdoses.

The law also allows a pharmacy to register as an entity and receive standing order authority to dispense naloxone directly to a person that may be in a position to assist a person experiencing

¹⁰ I.C. § 25-26-13-31.2(c)(3)

¹¹ I.C. § 16-42-27-2(a) P.L. 32-2015

¹² I.C. § 16-18-2-263.9

¹³ I.C. § 16-42-27-2(a) P.L. 32-2015

¹⁴ I.C. § 16-42-27-2(e) P.L. 32-2015

an opioid-related overdose. This is similar to the authority allowing pharmacists to act under an order or prescription to dispense and administer immunizations, as allowed under I.C. § 25-26-13-31.2.

The law designates that an entity must annually register with the state department or local health department in a manner prescribed by the state department¹⁵. The law allows the state department to define what information they require for registration.

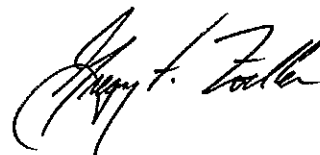
Similar to the immunity provided to those that administer CPR, use AEDs, or use auto-injectable epinephrine, "Aaron's Law" provides individuals or entities immunity from civil liability for obtaining naloxone, administering it in good faith, or acting under a standing order, as long as the individual or entity does not act grossly negligent or commit willful misconduct¹⁶. These immunity provisions apply so long as the entity and the ultimate recipients are acting in accordance with a standing order, and further distribution of naloxone is conducted by an entity registered with the ISDH, to family members or friends who may be in a position to assist a person experiencing an overdose.

"Aaron's Law" also provides prescribers who prescribe naloxone¹⁷ and prescribers, pharmacists, and registered entities who dispense naloxone civil immunity from all but acts of gross negligence or willful misconduct¹⁸. Additionally, the legislation makes it clear that individuals and entities that receive and administer naloxone to an individual experiencing an apparent opioid-relating overdose may not be considered to be practicing medicine without a license, so long as the actions were taken in good faith and the naloxone was obtained from a prescriber pursuant to a standing order.¹⁹

CONCLUSION

Based on the foregoing and with respect to your specific questions, it is my opinion that "Aaron's Law" allows Indiana prescribers to authorize entities to be dispensed naloxone and to distribute naloxone to individuals that may be in a position to render assistance to a person suffering from an opioid overdose.

Sincerely,



Gregory F. Zoeller
Attorney General

¹⁵ *Id.*

¹⁶ I.C. § 16-42-27-3(c) P.L. 32-2015

¹⁷ I.C. § 16-42-27-3(a) P.L. 32-2015

¹⁸ I.C. § 16-42-27-3(b) P.L. 32-2015

¹⁹ I.C. § 16-42-27-2(d) P.L. 32-2015