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July 7, 2016

OFFICIAL OPINION 2016-01

Hon. Jerry Torr and Hon. Sean Eberhart
State Representatives
Indiana House of Representatives
200 W. Washington Street
Indianapolis, Indiana 46204

RE: Civil liability protection for prescribers of auto-injectable epinephrine

Dear Reps. Torr and Eberhart:

You requested the Attorney General's opinion concerning prescriber liability protection under statutes referred to collectively as the "auto-injectable epinephrine laws." Specifically, you sought clarification about the scope of civil liability protection afforded physicians who prescribe auto-injectable epinephrine to schools under Indiana Code Chapter 20-34-4.5 *et seq.* Enacted through Senate Enrolled Act 245, P.L. 92-2014, this statute became effective on July 1, 2014.

Your letter also referenced two related laws: (1) House Enrolled Act 1323, P.L. 45-2014, (Indiana Code Article 21-44.5 *et seq.*), which became effective with the Governor's signature on March 24, 2014, and concerns auto-injectable epinephrine at post-secondary educational institutions; and (2) House Enrolled Act 1454, P.L. 59-2015, (Indiana Code Chapter 16-41-43 *et seq.*), which became effective July 1, 2015, and concerns auto-injectable epinephrine at businesses, associations, and governmental entities.

This Office has addressed prescriber liability in each of these three statutory contexts:

1. Does a physician who writes a prescription to a school or school district for auto-injectable epinephrine receive civil liability protection for damages resulting from administration of the auto-injectable epinephrine at the school?

2. Does a physician who writes a prescription to a post-secondary educational institution for auto-injectable epinephrine receive civil liability protection for damages resulting from administration of the auto-injectable epinephrine at the institution?
3. Does a physician who writes a prescription to a business, association, or governmental entity for auto-injectable epinephrine receive civil liability protection for damages resulting from administration of the auto-injectable epinephrine at the business, association, or governmental entity?

BRIEF ANSWERS

1. Yes. A licensed health care provider, whose scope of practice includes prescribing medication, and who writes a prescription, drug order, or protocol to a school or school district is not liable for civil damages resulting from the administration of auto-injectable epinephrine at the school, or for providing training to school personnel regarding administration of the drug.
2. Yes, *unless* the act or omission by the physician in relation to prescribing the drug constitutes gross negligence or willful or wanton misconduct. A licensed health care provider, whose scope of practice includes prescribing medication, and who writes a prescription, drug order, or protocol to a post-secondary educational institution is not liable for civil damages resulting from the administration of auto-injectable epinephrine at the institution by a licensed campus medical professional or trained designee. But the physician may not receive civil liable protection if the act or omission by the physician constitutes gross negligence or willful or wanton misconduct.
3. Yes. A licensed health care provider, whose scope of practice includes prescribing medication, and who writes a prescription, drug order, or protocol, or provides training to school personnel is not liable for civil damages resulting from administration of the auto-injectable epinephrine at a business, association, or governmental entity.

LEGAL ANALYSIS

Introduction

Indiana's inherent police powers allow it to regulate the practice of medicine within its borders by prescribing who may perform medical procedures and the training required to perform them. This power includes defining legend drugs¹ (such as epinephrine²), the licensing requirements to

¹ Ind. Code § 16-42-19-2.

² See Ind. Code § 16-18-2-199 (defining "legend drug" as "subject to 21 U.S.C. 353(b)(1)"; listed in certain documents published by the United States Department of Health and Human Services; or "insulin"). Epinephrine shall be dispensed only upon a written prescription pursuant to Ind. Code § 16-42-19-11(a)(1).

prescribe legend drugs,³ and the licensing requirements of those who may dispense such drugs.⁴ Likewise, the State determines the consequences for failing to meet certain medical standards; it has for example created a statutory mechanism for imposing civil liability upon physicians who commit medical malpractice.⁵

On the other hand, the legislature has authority to curtail civil liability by granting individuals “civil immunity”⁶ in some instances while specifying that an individual “is not liable for civil damages” in others.⁷ Using both immunity and liability protection, the General Assembly has limited physicians’ civil liability for damages arising from the acts of *third parties*—including lay persons—who relied upon the physician’s training or used a legend drug prescribed by the physician.

Physician Immunity for Training Third Parties

Automatic External Defibrillators (AEDs) give an electric shock to correct a cardiac arrhythmia. Recognizing that people may suffer heart attacks and need immediate assistance, the legislature has encouraged physicians to train lay persons in the administration of AEDs. Accordingly, a licensed physician who gives medical direction in the use of an AED is “immune from civil liability” for any act or omission of the licensed physician if it “involves training for or use of an automatic defibrillator” as long as it does not amount to gross negligence or willful or wanton misconduct.⁸ Beyond training, the legislature has also provided immunity to physicians who prescribe legend drugs for use by lay persons.

Civil Immunity for Prescribers of Overdose-Intervention Drugs

In *Official Opinion 2015-01*⁹ this Office addressed issues related to the disbursement of naloxone to certain entities under “Aaron’s Law.”¹⁰ Naloxone, a legend drug, works to counteract the effects

³ Ind. Code § 16-42-19-20 *et seq.*

⁴ Ind. Code § 16-42-19-5 *et seq.*

⁵ Ind. Code Article 34-18 *et seq.*; *see also* Ind. Code § 16-42-19-16(7) (making it unlawful to dispense a legend drug unless provided for in the Legend Drug Act).

⁶ *See generally, e.g.,* Ind. Code §§ 34-30-1-2, 34-30-2 *et seq.* (collecting civil-immunity provisions outside of Ind. Code title 34 as an aid to readers).

⁷ In similar situations the operative phrase “not liable for civil damages” removes civil liability as a matter of law. *See, e.g.,* Ind. Code § 7.1-5-10-15.5(b)(1), (2) (under the Indiana Dram Shop Act, a person who furnishes an alcoholic beverage to a person “is not liable in a civil action for damages” caused by the impairment or intoxication of the person furnishing the alcohol unless certain statutory exceptions are met); *see also Weida v. Dowden*, 664 N.E.2d 742, 748-49 (Ind.Ct.App.1996), *trans. denied* (noting that a defendant may not be held liable under the Dram Shop Act for “furnishing” an alcoholic beverage to another person unless the defendant had actual knowledge that the person served was visibly intoxicated). It should be noted that the General Assembly added a new section to Ind. Code Chapter 34-30-2, which “contains a list of references to other immunity from civil liability provisions outside IC 34” in P.L. 45-2014 (HEA 1323-2014), P.L. 92-2014 (SEA 245-2014), and P.L. 59-2015 (HEA 1454-2015), indicating that it views the operative effect as being the same.

⁸ Ind. Code § 34-30-12-1(e)(1), (2).

⁹ *Ind. Att’y Gen. Op. No. 2015-01* (Sept. 3, 2015), *available at* http://www.in.gov/attorneygeneral/files/ADMINISTRATIVE.Official_Opinion_2015-01.09.03.15.pdf.

¹⁰ Ind. Code § 16-42-27 *et seq.*

of an opioid overdose¹¹ but “has virtually no effect in people who have not taken opioids.”¹² *Opinion 2015-01* concluded that “Aaron’s Law” authorizes a physician to prescribe Naloxone by standing order to individuals or entities positioned to assist persons experiencing opioid-related overdoses.¹³ The Opinion also reasoned that prescribers of naloxone¹⁴ who dispense or prescribe the drug are afforded civil immunity from all but acts of gross negligence or willful misconduct.¹⁵ Thus, physicians receive immunity for both prescribing naloxone and training lay people in the use of AEDs.

The “Auto-Injectable Epinephrine Laws”

The legislature has explicitly limited civil liability for prescribers of auto-injectable epinephrine arising from administration of the drug by lay persons. When administered quickly, epinephrine counters the onset of anaphylaxis—a potentially fatal allergic reaction triggered in some people by foods, insect stings, medications, and latex. Anaphylaxis requires medical attention, including the immediate administration of epinephrine.

Auto-injectable¹⁶ epinephrine, commonly marketed as an EpiPen®, works rapidly by activating a spring-loaded needle that delivers a standard dose of epinephrine through an intramuscular injection designed for use by lay people. Auto-injectable epinephrine is most effective when it is available to be administered *quickly*. But unlike naloxone, epinephrine may have adverse consequences for individuals who are not in fact experiencing anaphylaxis—particularly individuals with certain heart conditions.¹⁷

Accordingly, the legislature has attempted to encourage decisive, good-faith administration of epinephrine while recognizing that adverse consequences may arise from its improper use. On one hand, the legislature recognizes that people may suffer anaphylaxis and require immediate access to epinephrine, so it has 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 school or school district,¹⁸ post-secondary educational institution,¹⁹ or other “entity”—defined by statute as “any business, association, or governmental entity.”²⁰ In each instance, a prescriber may write a standing order for a pharmacist to dispense auto-injectable epinephrine to the respective organization, define the parameters under which the drug is to be

¹¹ Ind. Code § 16-18-2-263.9.

¹² World Health Organization, *Information sheet on opioid overdose* (Nov. 2014), http://www.who.int/substance_abuse/information-sheet/en/.

¹³ Ind. Code § 16-42-27-2(a)(1)–(4) (listing the conditions required in the prescriber’s standing order).

¹⁴ Ind. Code § 16-42-27-3.

¹⁵ *Ind. Att’y Gen. Op.* No. 2015-01 at 5.

¹⁶ Ind. Code § 16-18-2-30.5 (defining “auto-injector” as “a spring loaded needle and syringe (1) containing a single dose of medication and (2) that automatically releases and injects the medication.”)

¹⁷ Drs. Brice Mohundro and Michael Mohundro, *Important Considerations When Dispensing Epinephrine Auto-Injector Devices*, *Pharmacy Times* (Sept. 23, 2010), <http://www.pharmacytimes.com/p2p/p2pepinephrine-0910>.

¹⁸ Ind. Code § 20-34-4.5-3(a).

¹⁹ Ind. Code § 21-44.5-2-5(c); *see also* Ind. Code § 21-44.5-1-3 (defining “member of the campus community” as a “student, faculty member, or staff member of a postsecondary educational institution.”)

²⁰ Ind. Code §§ 16-41-43-2 (defining “entity”), 16-41-43-5(a) (establishing the conditions for prescribing auto-injectable epinephrine for an entity).

administered, and authorize an individual to administer the drug on the physician's authority without ever examining the patient that requires treatment.

In recognition of the potential risks of inappropriate use of epinephrine, the civil liability protection provided to certain individuals who administer or attempt to administer epinephrine is limited to situations where their actions do not constitute gross negligence. With respect to prescribers, however, the only limitation on the civil liability protection applies in P.L. 45-2014 (HEA 1323-2014) with respect to prescriptions and standing protocols given to post-secondary educational institutions. So long as the prescriber was not grossly negligent in his or her prescribing activities, the civil liability protections would apply, as described in more detail below.

1. Schools

Once prescribed to a school or school district, auto-injectable epinephrine must be stored in a safe location²¹ and may be administered only by a school nurse or trained employee.²² A school nurse may administer auto-injectable epinephrine to students, school personnel, or visitors of the school if the person is demonstrating signs of life-threatening anaphylaxis and the person's own epinephrine is unavailable.²³

A school employee may also administer the auto-injectable epinephrine but only if the employee has voluntarily received training in anaphylaxis and the proper administration of auto-injectable epinephrine by a health care provider who in turn meets the following requirements: is licensed or certified in Indiana, the administration of auto-injectable epinephrine is within the health care provider's scope of practice, has received training in the administration of auto-injectable epinephrine, and is knowledgeable in recognizing the symptoms of anaphylaxis and the administration of auto-injectable epinephrine.²⁴

The nurse or trained employee is not liable for civil damages resulting from the administration of epinephrine, unless the act or omission constitutes gross negligence or willful or wanton misconduct.²⁵ Furthermore, a licensed health care provider who (1) writes a prescription, drug order, or protocol for auto-injectable epinephrine, or (2) provides training to the school personnel, is not liable for civil damages resulting from administration of the auto-injectable epinephrine, without qualification.²⁶

2. Universities

The "auto-injectable epinephrine laws" authorize a post-secondary educational institution to develop a policy for the emergency administration of auto-injectable epinephrine in situations where medical professionals are unavailable.²⁷ The policy must contain the following:

²¹ Ind. Code § 20-34-4.5-1(b).

²² Ind. Code § 20-34-4.5-2 *et seq.*

²³ Ind. Code § 20-34-4.5-2(a).

²⁴ Ind. Code § 20-34-4.5-2(b)(1)(A), (B).

²⁵ Ind. Code § 20-34-4.5-4(a).

²⁶ Ind. Code § 20-34-4.5-4(b)(1), (2).

²⁷ Ind. Code §§ 21-44.5-2-1, to -2.

1. It must grant permission for a “trained designee”²⁸ to: (A) administer auto-injectable epinephrine to a member of the campus community to treat anaphylaxis when a “licensed campus medical professional” is unavailable, and (B) require a trained designee, who is responsible for at least one member of the campus community, to carry a supply of auto-injectable epinephrine.²⁹
2. Next the policy must designate a “licensed campus medical professional,” who must be a licensed physician, physician assistant, or advanced practice nurse or registered nurse employed or contracted by the institution.³⁰ The policy must provide that the licensed campus medical professional has responsibility for training designees in the administration of auto-injectable epinephrine, identification of an anaphylactic reaction, and indications for when to use epinephrine.³¹
3. Finally, the policy must specify that the “licensed campus medical professional” may do the following: (1) establish and administer a standardized training protocol for emergency administration of epinephrine by trained designees; (2) ensure trained designees have satisfactorily completed the training protocol; (3) obtain a supply of auto-injectable epinephrine under a standing protocol from a licensed physician; and (4) control distribution of auto-injectable epinephrine to trained designees.³²

A “licensed campus medical professional,” acting pursuant to statute, is not liable for civil damages for “any act or omission” committed in accordance with the chapter unless the act or omission constitutes gross negligence or willful or wanton misconduct.³³ A “trained designee,” acting pursuant to statute, is not liable for civil damages resulting from “the administration of auto-injectable epinephrine,” unless the act or omission constitutes gross negligence or willful or wanton misconduct.³⁴

Furthermore, a licensed health care provider who writes a prescription, drug order, or protocol “is not liable for civil damages resulting from the administration of auto-injectable epinephrine . . .

²⁸ A trained designee is defined by statute as a student, faculty member, or staff member of the institution who has been trained by a licensed campus medical professional in the emergency administration of auto-injectable epinephrine. Ind. Code §§ 21-44.5-1-4 (defining “trained designee”), 21-44.5-1-3 (defining “[m]ember of the campus community”).

²⁹ Ind. Code § 21-44.5-2-2(a)(1).

³⁰ Ind. Code §§ 21-44.5-2-2(b), 21-44.5-1-2 (defining “Licensed campus medical professional”).

³¹ Ind. Code § 21-44.5-2-2(a)(2)(A), (B).

³² Ind. Code § 21-44.5-2-2(c).

³³ Ind. Code § 21-44.5-2-6(a).

³⁴ Ind. Code §§ 21-44.5-2-6(b).

unless the act or omission^{35]} constitutes gross negligence or willful or wanton misconduct” (emphasis added).³⁶

3. Other “entities”

Finally, once prescribed to a qualifying “entity”—a business, association, or governmental entity—auto-injectable epinephrine may be administered by a nurse or trained employee. An entity’s nurse may administer auto-injectable epinephrine to employees, agents, or visitors of the entity if the person is demonstrating signs of life-threatening anaphylaxis and the individual’s own epinephrine is unavailable.³⁷

An employee or agent of the entity may also administer the auto-injectable epinephrine but only if the employee or agent has voluntarily received training in recognizing anaphylaxis and the proper administration of auto-injectable epinephrine by a health care provider who in turn meets the following requirements: is licensed or certified in Indiana, the administration of auto-injectable epinephrine is within the health care provider’s scope of practice, has received training in the administration of auto-injectable epinephrine, and is knowledgeable in recognizing the symptoms of anaphylaxis and the administration of auto-injectable epinephrine.³⁸

The nurse, employee, or agent is not liable for civil damages resulting from the administration of epinephrine, unless the act or omission constitutes gross negligence or willful or wanton

³⁵ Whether the operative phrase “act or omission” refers to the act of prescribing auto-injectable epinephrine or the act of administering the drug is somewhat unclear. On the one hand, it seems odd or perhaps unfair to predicate a prescriber’s liability upon how a drug is later administered or not administered (*i.e.*, omitted) by a third party, as the case may be. On the other hand, if the statute were referring to the physician’s act of *prescribing*—inclusion of the word “omission” seems out of context. We note that within the same statutory section the language “gross negligence or willful or wanton misconduct” refers to the acts or omissions by licensed campus medical professionals and trained designees in relation to whether they are covered by the civil liability protection. Use of the same terminology with respect to licensed health care providers, considered in light of the purpose of the legislation, would indicate that the prescriber would be covered by the civil liability protection so long as *his or her* actions in prescribing did not amount to gross negligence or willful misconduct. This could include, for example, prescribing for use on persons who the physician knows has a heart condition and to recipients who the physician knows has not and will not obtain training on how to recognize actual instances of anaphylaxis. Conditioning the civil liability protection on third party actions beyond the control of the physician would discourage prescribing of epinephrine by physicians and thwart the purposes of the statute. See *Indiana State Highway Comm’n v. White*, 291 N.E.2d 550, 553 (1973) (“[W]hen we are called upon to construe words and phrases in a single section of a statute, we must construe them together with the other parts of the same section and with the statute as a whole. They must be construed in harmony with the intent the Legislature had in mind, in order that the spirit and purpose of the statute be carried out.”). In the interest of greater clarity, the legislature may wish to more explicitly indicate that the limitation of the civil liability protection for physicians and other prescribers applies “unless the act or omission by the licensed healthcare provider constitutes gross negligence or willful or wanton misconduct” (emphasis added), similar to the naloxone statute, Ind. Code § 16-42-27-3(a) (“Except for an act of gross negligence or willful misconduct, a prescriber who *dispenses or prescribes* an overdose intervention drug in compliance with this chapter is immune from civil liability *arising from those actions.*”) (Emphasis added.) On the other hand, if, contrary to the conclusions reached in this opinion, the legislature’s intent is to limit the scope of the liability protection to exclude protection in situations where there is gross negligence connected to the acts of third parties, it would be appropriate to indicate that clearly in the statute.

³⁶ Ind. Code § 21-44.5-2-6(c).

³⁷ Ind. Code § 16-41-43-4(a)(1), (2).

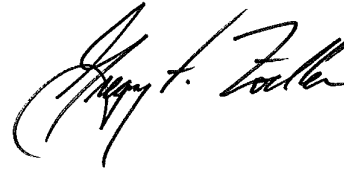
³⁸ Ind. Code § 16-41-43-4(b)(1)(A), (B).

misconduct.³⁹ A licensed health care provider who (1) writes a prescription, drug order, or protocol or (2) provides training to an entity's personnel is not liable for civil damages resulting from the administration of auto-injectable epinephrine without qualification for whether the act or omission by the third party constitutes gross negligence or willful or wanton misconduct.⁴⁰

CONCLUSION

It is my opinion that under the "auto-injectable epinephrine laws" prescribers who (1) write a prescription, drug order, or protocol or (2) provide training to school or entity personnel, are not liable for civil damages resulting from the administration of auto-injectable epinephrine at schools, businesses, associations, and governmental entities. It is my further opinion that prescribers are not liable for civil damages resulting from the administration of auto-injectable epinephrine at postsecondary educational institutions, unless the act or omission by the physician constitutes gross negligence or willful or wanton misconduct.

Sincerely,

A handwritten signature in black ink, appearing to read "Gregory F. Zoeller". The signature is fluid and cursive, with the first name "Gregory" being particularly prominent.

Gregory F. Zoeller
Indiana Attorney General

³⁹ Ind. Code § 16-41-43-6(a).

⁴⁰ Ind. Code § 16-41-43-6(b)(1), (2).