DATE: September 25, 2007

RE: Legality of Prescribing Take-Home Naloxone to Treat Opiate Overdose in Georgia

INTRODUCTION

Naloxone, the standard treatment for heroin overdose, is a safe and effective prescription drug typically administered by emergency room personnel or first responders acting under standing orders of physicians. High numbers of overdose deaths and evidence that witnesses to heroin overdose are often unwilling or unable to call for help has motivated some public health professionals to institute programs that distribute naloxone directly to opiate drug users (ODU). In such programs, drug users, their partners, or others are instructed in resuscitation techniques and provided a “take-home” dose of naloxone for administration in cases when medical help is not immediately available.

Evidence from US and abroad indicates that naloxone distribution helps reduce opiate overdose deaths and results in cost-savings to society.1 Despite the high and rising incidence of overdose events in many US locales, however, both the number and the scope of overdose programs remain inadequate. Legal concerns about provider and program liability act as one of the most important limiting factors, often complicating or derailing authorization, expansion, funding and implementation of these programs.

We were funded by the Drug Policy Alliance to analyze the legal issues for naloxone distribution programs in the fifty United States. Our analysis finds that:

1. **Naloxone is not a controlled substance as defined by federal or state law, but is a prescription drug subject to the general laws and regulations that govern all prescriptions in regular medical practice.**
2. **Prescribing naloxone to ODU in this state is fully consistent with state and federal laws regulating drug prescribing.**

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3. Teaching overdose response techniques, including the administration of naloxone, to naloxone recipients and others who might be in a position to administer it to an ODU to whom it has been prescribed is legal and appropriate.

4. Naloxone may not be given to patients or participants in an overdose prevention program with the explicit purpose of encouraging them to distribute or administer the drug to other ODU who are not patients.

5. Any legal risks in distributing naloxone in this state are not substantial and can be mitigated by informed program design; the risks of malpractice liability are consistent with those generally associated with providing healthcare, and can be further minimized by following the guidelines we describe.

This Memorandum addresses the following specific questions:

1. May a physician legally prescribe naloxone to an ODU patient?
2. May an allied health professional other than physician prescribe naloxone to an ODU patient?
3. What instructions should accompany naloxone prescription/dispensation?
4. How may naloxone be dispensed?
5. Is it legal to prescribe or dispense naloxone for recipients to give or administer to third parties who have not been prescribed the drug by a licensed professional?
6. What is the risk of disciplinary action by a professional board arising from naloxone prescription or distribution, and how can the risk be minimized?
7. What kind of malpractice liability may arise from naloxone prescription or distribution, and how can the risk of liability be minimized?
Executive Summary

From a legal standpoint, naloxone is no different than any other prescription drug. Authorized medical professionals can prescribe and dispense naloxone in the same way they would any other drug. Naloxone is indicated for patients who, upon examination, are at risk of opiate overdose and who are judged by the professional to be capable of benefiting from naloxone administration. The amount of naloxone prescribed or dispensed depends upon the prescriber’s assessment of need. (See Parts I & II describing who may prescribe naloxone.)

As part of the process of prescribing, the patient should be given information about when and how to use the drug, as well as other steps that are advisable in responding to an overdose. Because a person suffering an overdose may not be able to administer the drug him or herself, it is also appropriate to (1) teach groups of patients how to administer the drug so that they can assist each other in an overdose emergency; and (2) instruct—in person, or through written materials—friends, family members and others who may witness an overdose how to administer the drug to a patient. It is not uncommon for third parties to assist patients in administering their drugs, for all sorts of reasons. The key legal requirement is that the recipient have a valid prescription for the drug. (See Parts III & IV.)

Because a legal prescription requires some examination and a specific medical indication, naloxone may not be prescribed or dispensed to patients or program participants to hand out or administer to other ODU who are not patients of the prescriber. A program based on this model would be legally vulnerable in this state. A professional distributing naloxone in this way could be found to be violating professional licensure laws and the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license. (See Part V.)

Assuming the provider does not violate regulations that generally apply to drug prescription in this state, acts competently, and follows the additional guidelines we set out, criminal or civil liability is very unlikely to arise out of naloxone prescription activities. (See Parts VI and VII.) Presumably, few prosecutors would be hard-hearted enough to punish a person for saving a life, but an ODU who uses his or her own naloxone to save the life of a person who has not been prescribed the drug does, technically, break the law. A few states have taken positive action to clearly legalize emergency administration of naloxone by lay persons, and to protect medical professionals from tort and other liability.

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2 We will refer to a person who has received a legal prescription for naloxone as a “patient.”
3 We will define examination, generally, as an interaction sufficient to allow the physician to determine the patient's diagnosis and treatment needs in the context of the service being sought or medical issues being raised.
Such legislation can help lower legal barriers and increase access to naloxone here. (See “Conclusion.”)

The Legal Analysis in Detail

I. May a Physician Legally Prescribe Naloxone to an IDU Patient?

A. Professional Licensure Law

The practice of medicine in Georgia is governed by the Medical Practices Act, with regulations found in title 360 of the Georgia Administrative Code. The State Board of Medical Examiners is vested with the authority to promulgate and enforce regulations for medical practice.

Naloxone is labeled for administration to reverse opiate overdose in clinical settings, such as hospitals, but is often administered by first responders acting on standing orders of physicians in the field. Federal and state law affords physicians broad discretion to prescribe drugs for off-label uses, and such prescriptions are a routine part of medical practice. Naloxone is not a controlled substance under state or federal law.

Using standard research techniques, we identified no case-law discussing physicians’ general authority to prescribe drugs and devices in the state, nor is there case-law challenging the legality of prescription of naloxone specifically. This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US. State law offers no explicit standards for prescribing a prescription drug, but presumably the generic standards applicable to controlled substances provide a basic framework: a physician may prescribe a drug if he or she is “acting in the usual course of his professional practice; and for a legitimate medical purpose.”

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5 Ga. Code Ann. § 43-34-21(d) (West 2007); see generally Bentley v. State Bd. of Med. Exmrs., 111 S.E. 379 (Ga. 1922) (Board has such implied powers only as are reasonably necessary to execute express powers conferred); see also Geiger v. Jenkins, 401 U.S. 985 (1971) (The state may regulate and control practice of medicine and those who engage therein, subject only to limitation that measures adopted must be reasonable, necessary, and appropriate to accomplish legislature’s valid objective of protecting health and welfare of its inhabitants).
7 “Controlled substance” means a drug classified in any of the schedules (I through V) of the Controlled Substances Act, Ga. Code Ann., § 16-13-21 (West 2007), recognized to have a potential for abuse or to lead to physical or psychological dependence. Naloxone is excluded as a controlled substance and is thus a legend drug requiring a prescription. Ga. Code Ann., § 16-13-26 (West 2007).
8 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
In determining whether a prescription arises within the usual course of professional practice, courts may consider such matters as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the patient’s risk factors, efforts to provide other harm reducing services, follow up and so on.\textsuperscript{10}

Controlled substances case law also generally requires that the prescription serve a "legitimate medical purpose." In Georgia, it is the burden of the State to prove the prescription was not for legitimate medical purpose.\textsuperscript{11} According to the cases, "a legitimate medical purpose is the alleviation of pain in the human body or the control or correction of physical problems in the human body."\textsuperscript{12}

B. Analysis

While not explicitly required by Georgia law, it is prudent for physicians to adhere to the standards applicable to the prescription of controlled substances. These common-sense rules require providing a physical examination if necessary, documenting a history, discussing the treatment plan and its alternatives with the patient, and ensuring adequate follow-up care. Physicians have broad discretion about dosage of non-controlled drugs, and may decide to prescribe whatever amount of the agent they reasonably deem necessary to meet the patient’s needs. Physicians who have an on-going relationship with the patient do not have to conduct a physical examination every time they issue or renew a prescription. By law, physicians are also authorized to delegate some aspects of the prescription process to other health professionals (see Part II below).

Conclusion: A prescription for naloxone to an ODU patient is consistent with the standard for a valid prescription under Georgia laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone.

II. May Anyone Other Than Physician Issue A Prescription For Naloxone?

A. Professional Licensure Law

\textsuperscript{10} See generally United States v. Moore, 423 U.S. 122, 142-43 ("[R]espondent's conduct exceeded the bounds of "professional practice."... [H]e gave inadequate physical examinations or none at all. He ignored the results of the tests he did make.... He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded.").

\textsuperscript{11} Strong v. State, 272 S.E.2d 281 (Ga. 1980).

\textsuperscript{12} White v. State, 247 S.E.2d 536 (Ga. 1978).
Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Generally, the regulations allow licensed allied health professionals perform medical functions set out in a formal job description or collaboration agreement between the physician and the allied health professional. Georgia law features an unusual terminology in which only a physician may independently “prescribe” medication. Physician assistants are, however, authorized to independently “carry out” prescriptions under the general supervision of a physician to the extent set out in their job descriptions, which amounts to the same thing as prescribing.

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(5.1) "Job description" means a document signed by a licensed physician and describing the duties which may be performed by a physician's assistant, by which document the physician delegates to that physician's assistant the authority to perform certain medical acts pursuant to subsection (b) of this Code section and which acts shall include, without being limited to, the administering and ordering of any drug. …
(7) "Nurse protocol" means a written document mutually agreed upon and signed by a nurse and a licensed physician, by which document the physician delegates to that nurse the authority to perform certain medical acts … which acts shall include, without being limited to, the administering and ordering of any drug.

(8) "Order" means to select a drug, medical treatment, or diagnostic study through physician delegation in accordance with a nurse protocol or a physician's assistant's job description. Ordering under such delegation shall not be construed to be prescribing, which act can only be performed by the physician, nor shall ordering of a drug be construed to authorize the issuance of a written prescription.


[A] physician's assistant shall be allowed to carry out a prescription drug order … pursuant to the authority delegated by the supervising physician of that physician's assistant. Delegation of such authority shall be contained in the job description required by this Code section. The delegating physician shall remain responsible for the medical acts of the physician's assistant performing such delegated acts and shall adequately supervise the physician's assistant. …
(5) … The physician's assistant may authorize refills up to six months from the date of the original prescription drug or device order; provided, however, that refills may be authorized up to 12 months from the date of the original prescription drug or device order for oral contraceptives or other drugs or devices approved by the board. …


Requirements of … Dangerous Drug Prescription Drug Orders as Carried Out by a Physician’s Assistant (PA) Licensed to Practice in the State of Georgia.
(1) Under O.C.G.A. § 43-34-103(e.1), a physician's assistant (PA) licensed by the Georgia Composite Board of Medical Examiners is permitted to issue a prescription drug order or orders for any dangerous drugs, as defined in O.C.G.A. § 16-13-71 without the co-signature of a supervising physician pursuant to the authority delegated by the PA's supervising physician and contained in the PA's job description.
(b) Delegation of such authority shall be contained in the job description required by O.C.G.A. § 43-34-103(e.1). The delegating physician shall remain responsible for the medical acts of the PA.
Advance practice registered nurses (APRNs) may “order” medications, which means “to prescribe pursuant to a nurse protocol agreement [with a physician] which drug … is appropriate for a patient and to communicate the same in writing, orally, via facsimile, or electronically.”¹⁶

(3) The PA shall only be authorized to exercise the rights granted by O.C.G.A. § 43-34-103(e.1) using a prescription drug order which includes the following:
(a) The name, address, and telephone number of the prescribing physician;
(b) The patient's name and address;
(c) The drug name, strength and quantity prescribed;
(d) The directions to the patient with regard to taking the drug;
(e) The number of authorized refills, if any;
(f) The DEA permit number of the supervising physician or, if applicable, the DEA number of the PA; and
(g) Such prescription drug order form shall be valid only if signed by the physician's assistant and the following terminology appears on the prescription drug order:
“This prescription authorized through (pre-printed name of the prescribing supervising physician, M.D. or D.O.) by (pre-printed name of the PA printed below the signature line, with such line bearing the signature of the PA), PHYSICIAN'S ASSISTANT” (Physician's Assistant must be spelled out, not abbreviated as PA).

1. An example, which satisfies the requirements for both Controlled Substance and Dangerous Drug prescription drug order, is as follows:
“This prescription authorized through O.C. Cornwallis, M.D. by ___________________________, Physician's Assistant Jane Doe (pre-printed).

(4) Any prescription drug order form containing less information than that described in this subsection shall not be offered to or accepted by any pharmacist.

See National Association of Boards of Pharmacy, Survey of Pharmacy Law 2007 (physician assistant can dependently prescribe).


(10) "Nurse protocol agreement" means a written document mutually agreed upon and signed by an advanced practice registered nurse and a physician, by which document the physician delegates to that advanced practice registered nurse the authority to perform certain medical acts pursuant to this Code section, and which acts may include, without being limited to, the ordering of drugs, medical devices, medical treatments, diagnostic studies, or in life-threatening situations radiographic imaging tests. Such agreements shall conform to the provisions set forth in subsection (c) of this Code section.

Id.

c) A nurse protocol agreement between a physician and an advanced practice registered nurse pursuant to this Code section shall:
(1) Be between an advanced practice registered nurse who is in a comparable specialty area or field as that of the delegating physician;
(2) Contain a provision for immediate consultation between the advanced practice registered nurse and the delegating physician; if the delegating physician is not available, the delegating physician for purposes of consultation may designate another physician who concurs with the terms of the nurse protocol agreement;
(3) Identify the parameters under which delegated acts may be performed by the advanced practice registered nurse, including without limitation the number of refills which may be ordered, the kinds of diagnostic studies which may be
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Georgia law. With the appropriate supervision agreements in place, allied health professionals may staff a naloxone prescription program without the presence of a physician on-site.

Conclusion: A non-physician healthcare provider may staff a naloxone prescription program under the general supervision of a physician.

III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

ordered, the extent to which radiographic image tests may be ordered, and the circumstances under which a prescription drug order may be executed. In the event the delegating physician authorizes the advanced practice registered nurse to order an X-ray, ultrasound, or radiographic imaging test, the nurse protocol agreement shall contain provisions whereby such X-ray, ultrasound, or radiographic imaging test shall be read and interpreted by a physician who is trained in the reading and interpretation of such tests; a report of such X-ray, ultrasound, or radiographic imaging test may be reviewed by the advanced practice registered nurse; and a copy of such report shall be forwarded to the delegating physician, except that such provision for an ultrasound shall not be required for an advanced practice registered nurse acting within his or her scope of practice as authorized by Code Sections 43-26-3 and 43-26-5;

(4) Require documentation either in writing or by electronic means or other medium by the advanced practice registered nurse of those acts performed by the advanced practice registered nurse which are specific to the medical acts authorized by the delegating physician;

(5) Include a schedule for periodic review by the delegating physician of patient records. Such patient records review may be achieved with a sampling of such records as determined by the delegating physician;

(6) Provide for patient evaluation or follow-up examination by the delegating physician or other physician designated by the delegating physician pursuant to paragraph (2) of this subsection, with the frequency of such evaluation or follow-up examination based on the nature, extent, and scope of the delegated act or acts as determined by the delegating physician in accordance with paragraph (3) of this subsection and accepted standards of medical practice as determined by the board;

(7) Be reviewed, revised, or updated annually by the delegating physician and the advanced practice registered nurse;

(8) Be available for review upon written request to the advanced practice registered nurse by the Georgia Board of Nursing or to the physician by the board; and

(9) Provide that a patient who receives a prescription drug order for any controlled substance pursuant to a nurse protocol agreement shall be evaluated or examined by the delegating physician or other physician designated by the delegating physician pursuant to paragraph (2) of this subsection on at least a quarterly basis or at a more frequent interval as determined by the board.
While there is no explicit regulatory scheme, as noted in the licensure law described in sections I, in general it is recommended that a healthcare provider formulate a therapeutic plan for their patient and discuss such plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient before issuing a prescription.¹⁷

B. Analysis

The intended use of naloxone is to prevent opiate overdose. Indications for and methods of administration should be explained to patients, along with risks and benefits. Because of the nature of overdose, patients may not always be able to self-administer the necessary dose. Some overdose prevention programs properly instruct pairs or groups of patients in naloxone administration and other emergency measures so that patients can assist each other. Prescribing staff may also provide written and oral instructions that patients can relay to their friends, family, or others who can help administer the drug in an event of an overdose. Such instructions parallel information given to patients who may need emergency injections of insulin or epinephrine and are entirely consistent with the legal prescription of the drug. These instructions should include:

1. information on how to spot symptoms of an overdose;
2. instruction in basic resuscitation techniques;
3. instruction on proper naloxone administration, and
4. the importance of calling 911 for help.

Naloxone distribution programs in Georgia should not instruct clients to administer naloxone to persons who do not have a prescription for the drug (see Part V below).

Conclusion: Program participants receiving a take-home dose of naloxone should receive verbal and written instructions on how and when to use this drug. Program staff should not instruct patients to administer naloxone to persons who do not have a valid prescription for the drug.

IV. How May Naloxone be Dispensed?

A. The Regulatory Scheme

Naloxone is subject to the general rules covering dispensing of prescription drugs under state law. The practice of pharmacy in Georgia is governed by the Pharmacy Act,¹⁸ with regulations found in title 480 of the Georgia Code. Pharmacists are expected to fill a prescription that meets

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regulatory guidelines, barring personal objections.¹⁹ A physician, registered nurse
in accordance with a nurse protocol and a physician assistant in accordance with a
job description may dispense prescription drugs.²⁰ A physician must delegate in a
written order the authority for a physician assistant or registered nurse to dispense
the agent at the point of service.²¹ A physician assistant and advanced practice
registered nurse may dispense samples provided by a manufacturer.²² Finally,

¹⁹ GA ADC 480-5-.03 (West 2007) (“It shall not be considered unprofessional conduct for any
pharmacist to refuse to fill any prescription based on his/her professional judgment or ethical or
moral beliefs”).
(9) "Dispense" means to deliver a controlled substance to an ultimate user or
research subject by or pursuant to the lawful order of a practitioner, including
the prescribing, administering, packaging, labeling, or compounding necessary
to prepare the substance for that delivery, or the delivery of a controlled
substance by a practitioner, acting in the normal course of his professional
practice and in accordance with this article, or to a relative or representative of
the person for whom the controlled substance is prescribed.
(10) "Dispenser" means a practitioner who dispenses.
(23) "Practitioner" means:
(A) A physician …
(B) A pharmacy, hospital, or other institution licensed, registered, or otherwise
authorized by law to distribute, dispense, conduct research with respect to, or to
administer a controlled substance in the course of professional practice or
research in this state;
(C) An advanced practice registered nurse acting pursuant to the authority of
Code Section 43-34-26.3. For purposes of this chapter and Code Section 43-34-
26.3, an advanced practice registered nurse is authorized to register with the
federal Drug Enforcement Administration and appropriate state authorities; or
(D) A physician's assistant acting pursuant to the authority of subsection (e.1) of
Code Section 43-34-103. For purposes of this chapter and subsection (e.1) of
Code Section 43-34-103, a physician's assistant is authorized to register with the
federal Drug Enforcement Administration and appropriate state authorities.
(25) "Registered" or "register" means registration as required by this article.
(26) "Registrant" means a person who is registered under this article.
²² GA ADC 480-30-.01 (West 2007):
‘Dispensing procedure’ means a written document signed by a licensed
pharmacist and a licensed practitioner which document establishes the
appropriate manner under which drugs may be dispensed under authority of a
nurse protocol or job description. …
(c) "Job description" means a document signed by a licensed practitioner that
describes the duties which may be performed by a physician's assistant, by
which document the physician delegates to that physician's assistant the
authority to perform certain medical acts. …
(d) "Nurse protocol" means a document mutually agreed upon and signed by a
nurse and licensed physician by which document the physician delegates to that
nurse the authority to perform certain medical acts.
A physician's assistant shall be allowed to request, receive, and sign for
professional samples and may distribute professional samples to patients,
pursuant to authority delegated by the supervising physician of that physician's
assistant.
there are regulations governing the dispensation of drugs directly from the provider’s office, regulating storage\textsuperscript{23} and labeling.\textsuperscript{24}

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Provided that the healthcare provider has followed the prescription guidelines, she or another licensed professional so authorized by a written delegation agreement can dispense the drug directly to the clients. If a program decides to dispense naloxone on premises, it must follow the dispensation rules required in the Georgia Administrative Code.

Conclusion: Dispensing naloxone by valid prescription does not violate Georgia law and may be done on premises of the distribution program.

An advanced practice registered nurse may be authorized under a nurse protocol agreement to request, receive, and sign for professional samples and may distribute professional samples to patients.

Ga. Code Ann., § 43-34-26.3 (West 2007) ("Professional sample means a complimentary dose of a drug, medication, medication voucher, or medical device provided by the manufacturer for use in patient care.").

\textsuperscript{23} GA ADC 480-30-.05 (West 2007):

(1) Any person dispensing drugs in accordance with a dispensing procedure and under authority of a job description or nurse protocol shall exercise diligent care in protecting drugs and records possessed from loss or theft. Agents of the Georgia Drugs and Narcotics Agency (GDNA) shall have the responsibility of offering to such persons written recommendations concerning the satisfactory storage, keeping, handling, and security of such drugs and records. When not in actual use, all drugs shall be stored in a place which is secured.

(2) All drugs which bear or are required to bear, upon the package, the words, "Caution, Federal Law Prohibits Dispensing Without a Prescription" or words of like import, shall be stored in a secured area. All drugs shall be stored beyond the normal reach of small children.

(3) No person dispensing drugs in accordance with a dispensing procedure and under authority of a job description or nurse protocol shall operate in any manner or dispense any drugs under unclean, unsanitary, overcrowded, or unhealthy conditions, or under any condition which endangers the health, safety, or welfare of the public.

(4) All outdated and deteriorated drugs shall be removed from stock at regular intervals of not more than six months duration, and under no circumstances will any drug be dispensed which bears a date of expiration which has been reached, or is in a deteriorated condition.

\textsuperscript{24} GA ADC 480-30-.03 (West 2007):

All drugs dispensed in accordance with a dispensing procedure and under authority of a job description or nurse protocol must be labeled with the following information: (a) Date and identifying serial number; (b) Name of patient; (c) Name of practitioner prescribing; (d) The name, address and telephone number of the facility where the drugs are dispensed in accordance with a dispensing procedure and under the authority of a job description or nurse protocol; (e) Name of drug and strength; (f) Directions for use to the patient; (g) The expiration date of the drug; and (h) Any information required by the Drug Enforcement Administration or the Food and Drug Administration.
V. Is It Legal To Prescribe Or Dispense Naloxone For Recipients To Give Or Administer To Third Parties Who Have Not Been Prescribed The Drug By A Licensed Professional?

A legal prescription requires a specific patient who has been examined and found to have a medical indication for the drug. Before the drug can properly be dispensed, the patient must be given information about the indications for the drug, its proper use, and its risks and benefits. Naloxone could not properly be prescribed to a person who was not an ODU at risk of overdose, even if that person promised to give it to or use it on a person in need. Although a physician may prescribe multiple doses to a patient for whom they are indicated, the physician may not prescribe “extra” naloxone to a patient with explicit instructions to give it to or use it on a person in need.

A licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct (see section VI). The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license. We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. Additionally, the recipient of naloxone without a prescription could be charged with possession of a dangerous drug.

None of this should be taken as suggesting that a program cannot teach patients to properly administer the drug on others. Such training is necessary, as discussed above, to deal with the fact that patients may be unable to self-administer in an overdose situation, or may be called upon to assist another patient. But a program in this state that explicitly encouraged distribution to or administration upon non-patients would be open to legal challenge. Legislatures in a few states have taken action to eliminate legal barriers to emergency use of naloxone among non-patients. These are discussed in the Conclusion, below.

VI. What Is The Risk Of Disciplinary Action By A Professional Board Arising Kind Of Medical Discipline Or Criminal Liability May Arise From Naloxone Prescription Or Distribution, And How Can The Risk Of Liability Be Minimized?

25 Ga. Code Ann. § 43-34-37 (West 2007) (refusal, revocation or suspension of licenses to practice medicine; grounds; investigation of fitness to practice).
26 Ga. Code Ann. § 43-34-26 (West 2007); Ga. Code Ann., § 43-34-46 (West 2007) (“fine of not less than $ 500.00 nor more than $ 1,000.00 or by imprisonment from two to five years, or both”).
Non-compliance with prescription and other professional practice rules may carry license sanctions and fines.\textsuperscript{28} There is no risk of professional censure for participating in a naloxone prescription program run as described here. Our analysis above makes clear that prescribing naloxone to ODU patients is well within the normal parameters of medical practice.

Of course, naloxone prescribing might give rise to political controversy in a particular place, exposing the professionals and the program to closer scrutiny by potentially hostile regulators. Program managers and staff have to be prepared to produce clear and detailed documentation of proper physician involvement, specific and detailed protocols, and licensure information. Case law confirms the general notion that courts defer to the judgment of licensed medical professionals, so long as they produce clear factual evidence of reasonable efforts to comply with the rules and regulations of professional conduct.\textsuperscript{29} Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\textsuperscript{30}

\section*{VII. What Kind of Tort or Civil Liability May Arise from Naloxone Prescription or Distribution; What Remedies Exist to Minimize Such Risk?}

\textbf{A. The Legal Scheme}

Any practice of medicine implies a risk that something may go wrong. In the context of a naloxone prescription/dispensing program, a patient may suffer one of the rare side effects from the drug. An error in administration by a patient’s companion, a failure to seek timely medical help after the administration of naloxone, or re-injection of opiates after naloxone might all lead to death or serious injury.

Generally, every tort claimant must establish that he or she suffered an injury that was actually caused by the defendant healthcare provider. A healthcare provider is required to practice his or her profession in a reasonably competent manner. Particular conduct is assessed by reference to the customary behavior of the relevant segment of the profession under the same or similar circumstances, which is said to establish the “‘standard of care.’”\textsuperscript{31} The essence of

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\textsuperscript{28} Ga. Code Ann., § 43-34-46 (West 2007) (non-compliance with this article or … any provision of this article shall be guilty of a felony … [but] shall be punished by a fine of not less than $500.00 nor more than $1,000.00 or by imprisonment from two to five years, or both).
\textsuperscript{29} Williams v Ohio Bd. of Nursing, 1993 WL 69465 (Ohio App. 10 Dist. Mar. 9, 1993); Sermchief v. Gonzales, 660 S.W.2d 683 (Mo. banc 1983).
\textsuperscript{31} Ketchup v. Howard, 543 S.E.2d 371 (Ga.App. 2000) (Legal duty a medical professional owes to his or her patient is to exercise that degree of skill and care ordinarily employed by members of same medical profession under same or substantially similar circumstances); Restatement (Second) of Torts, §282, 1993 Washington, DC: American Law Institute Publishers.
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the inquiry is whether the provider’s treatment decisions were reasonable and consistent with accepted medical principles, considering all the circumstances.

In order to prove negligence, the plaintiff must prove that (1) the provider’s failure to meet the professional standard of care (2) caused an injury, and that the defendant provider (3) had a duty to avoid harming the plaintiff. Tort doctrine requires the plaintiff to prove that the injury would not have occurred ‘‘but for’’ the healthcare provider’s unreasonable behavior.

B. Analysis

Naloxone is the drug of choice for overdose. Assuming that the patient is an ODU at risk of a fatal overdose, and is properly instructed in the administration and risks of the drug, a simple risk–benefit analysis would suggest that the provider’s decision to prescribe was reasonable and not negligent. The reasonableness of the decision would be supported by the public health and clinical literature discussing take-home naloxone, and, in an actual case, by expert testimony from clinicians and public health experts. If the prescription of naloxone is reasonable, there can be no tort liability even if the other elements of the case are established.

“But for” causation will be extremely difficult to establish where the injury results from overdose because at the moment naloxone was administered serious injury was already likely to happen. Where the injury is caused by the rare occurrence of side effects of naloxone, the causal connection is still tenuous: the behavior of the injured party, in overdosing on heroin, is the key causal factor that necessitated treatment with the agent. Injury was likely to be as severe, if not more so, had naloxone not been administered. It is not considered malpractice to prescribe a drug that carries a low risk of side effects to avert death or severe impairment, particularly if the patient is adequately informed of the risks. Even in the unlikely cases in which ‘‘but for’’ factual causation may be established, the provider’s actions must represent a major contributing factor to the injury for liability to arise. It is hardly fair to blame a prescribing professional for a harm primarily caused by a patient’s decision to inject heroin; courts have usually applied the rule of ‘‘superseding cause’’ to hold that people who voluntarily use dangerous drugs cannot blame others for the harm the drugs cause.

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Programs and providers cannot be found liable for actions of clients who administer naloxone to third parties who were not prescribed the drug, unless the program or provider have expressly instructed clients to administer naloxone in this manner. Program and providers should not issue such instructions. The actions by third parties are superseding cause of injury, not connected directly to the actions of providers or the program. Under doctrine, the court would likely ask if such an outcome was reasonably foreseeable. A death or injury resulting from an unauthorized administration of a low risk medication prescribed to a non-patient is arguably too unforeseeable a result to establish liability. Informing clients of the need to contact first responders and administer the necessary resuscitation procedures to overdose victims can further mitigate the risk of any liability under these circumstances.

Any practice within the scope of the practitioner’s usual duties is covered by malpractice insurance, which will pay for any litigation arising out of that practice according to the terms of the insurance contract. Naloxone prescription to prevent opiate overdose is a practice accepted by a significant number of physicians and is within the scope of practice for providers working with the general population.

In the case of volunteer providers, the US Volunteer Protection Act shields volunteers for acts committed within the scope for their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent.\footnote{42 U.S.C.A. § 14503 (West 2000).} Georgia state law provides similar liability protections from damages caused by health care providers:

No health care provider … who voluntarily and without the expectation or receipt of compensation provides professional services ... shall be liable for damages or injuries alleged to have been sustained by the person nor for damages for the injury or death of the person when the injuries or death are alleged to have occurred by reason of an act or omission in the rendering of such services.\footnote{Wells v. Rogers, 636 S.E.2d 171 (Ga.App. 2006).}

This is effective so long as the agent responsible is a licensed health care provider acting voluntarily and without pay in the scope of his or her license. This would seem to shield from immunity both institutions for which the volunteer is serving as well as individual health provider volunteers. Thus, it appears that under Georgia law, volunteers working with naloxone distribution programs would be immune from any liability, except for in cases involving gross negligence and wanton, and reckless conduct.

\textbf{Conclusion: The risk of tort liability in a naloxone program is low. Conceptually, this risk is no different from any other healthcare context.} By
following state rules and general standards of practice, providers can protect themselves from the imposition of tort liability. Malpractice insurance and laws that apply specifically to volunteer providers may provide additional protection.

CONCLUSION

A. Guidelines

Naloxone prescription is legal in this state. However, as with any healthcare practice, institutions and professionals providing this service should follow the relevant rules and regulations that govern their practice to avoid professional, civil, and criminal liability.

The following is a summary of the program guidelines dictated by Georgia law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician.
2. In order to receive a prescription, each patient must undergo an examination that is reasonable in light of professional standards to produce a proper diagnosis and treatment plan.
3. The prescription must be made out to the specific patient and must contain all the information required by law.
4. Each prescription should be accompanied by oral and/or written information on the following:
   • information on how to spot symptoms of an overdose;
   • instruction in basic resuscitation techniques;
   • instruction on proper naloxone administration, and
   • the importance of calling 911 for help.

B. Changes in State Law

Under the current law of this state, dispensing or administering naloxone to third parties who have not been prescribed the drug is illegal. Passing legislation to allow these practices would help reduce overdose deaths and ease the concerns of providers and clients about possible legal penalties. New York’s legislature recently passed a law to provide clear authorization of medical providers to “prescribe” or “dispense” naloxone to unknown ODU via trained patients or volunteers (“Trained Overdose Responders” under NYS law); establish immunity for providers participating in such programs; and establish
immunity for patients and volunteers using naloxone in providing first aid to victims of heroin overdose.\textsuperscript{37}

\section*{C. Cooperation with First Responders}

Programs should also work with police and EMTs to inform them about program goals and practices. Alerting first responders to the presence of take-home naloxone can help inform their work and alleviate resistance or roadblocks to program implementation. By building their programs according to the regulatory schemes we have referenced above, programs can successfully navigate the legal questions around dispensation of this life-saving agent to ODU.

\textsuperscript{37} \textit{N.Y. Pub. Health Law} §3309 (McKinney 2006): 
\begin{quote}
\text{[T]he purchase, acquisition, possession or use of an opioid antagonist by an Opioid Overdose Prevention Program or a Trained Overdose Responder in accordance with this section and the training provided by an authorized Opioid Overdose Prevention Program shall not constitute the unlawful practice of a professional or other violation under title eight of the education law or article 33 of the public health law.}
\end{quote}