DATE: January 20, 2007

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

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 (ODUs). 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 the 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 ODUs in this state is fully consistent with state and federal laws regulating drug prescribing.

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 ODUs 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 ODUs 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; 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; and the recipient of a vial of naloxone for which she has no prescription could be found guilty of illegal possession of a prescription drug. (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

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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.
lay persons, and to protect medical professionals from tort and other liability. 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 ODU Patient?

A. Professional Licensure Law

The practice of medicine in Utah is governed by the Utah Medical Practice Act, with regulations in the Utah Medical Practice Act Rules. The Physicians Licensing Board (the “Board”) has the authority to license physicians and to punish licensed physicians who behave in ways that violate the law or fall beneath the standards of good faith and regular practice of medicine. Utah case law authorizes the Board to set limits on allowable prescription practices, either by enacting specific regulations banning certain prescription practices, or through the disciplinary process.

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. Therefore, a prescription for naloxone must meet the same standards as a prescription for any other drug: “[a] practitioner may prescribe legend drugs in accordance with this chapter that, in his professional judgment and within the lawful scope of his practice, he considers appropriate for the diagnosis and treatment of his patient.”

Using standard research techniques, we identified no case-law discussing physicians’ general authority to prescribe drugs and devices in the state, nor is

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8 State v. Hoffman, 733 P.2d 502 (Utah 1987); see also Utah Code Ann. §58-12-31 (West 1953).
10 Utah Code Ann. §58-37-2(1)(f)(i) (West 1953) (“Controlled substance’ means a drug or substance included in Schedules I, II, III, IV, or V of Section 58-37-4, and also includes a drug or substance included in Schedules I, II, III, IV, or V of the federal Controlled Substances Act, Title II, P.L. 91-513, or any controlled substance analog”); Utah Code Ann. §58-37-4(b)(i)(A) (West 1953) (Naxolone is excluded from Schedule II of the Controlled Substances Act, so it is a prescription or legend drug).
there case-law challenging the legality of prescription of naloxone specifically.\textsuperscript{12} This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US. The Board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.\textsuperscript{13}

\section*{B. Analysis}

While not explicitly required by Utah statutes, it is prudent for physicians as a general matter to follow certain procedures when issuing prescriptions to all prescription drugs, including providing a physical examination when 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.

\textbf{Conclusion:} A prescription for naloxone to an ODU patient is consistent with the standard for a valid prescription under Utah laws governing the physician’s authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone. Some of the prescription tasks can be delegated to allied health professionals.

\section*{II. May Anyone Other Than Physician Issue A Prescription For Naloxone?}

\subsection*{A. Professional Licensure Law}

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Advanced practice registered nurse practitioners (ARNPs) can write prescriptions if they have completed a course in patient assessment, diagnosis and treatment, and pharmacotherapeutics.\textsuperscript{14} Physician assistants (PAs) can prescribe prescription drugs under the supervision of a physician.\textsuperscript{15} PAs can prescribe without the

\textsuperscript{12} According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
\textsuperscript{13} Utah Code Ann. §58-1-501(2) (West 1953).
\textsuperscript{14} Utah Code Ann. § 58-31b-301(3) (West 1953):
\quad An individual holding an advanced practice registered nurse license as of July 1, 1998, who cannot document the successful completion of advanced course work in patient assessment, diagnosis and treatment, and pharmacotherapeutics, may not prescribe and shall be issued an ‘APRN--without prescriptive practice’ license.
\textsuperscript{15} Utah Code Ann. §58-70a-501 (West 1953):
supervising physician immediately present, so long as there is a method of immediate consultation by electronic means.\textsuperscript{16}

**B. Analysis**

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Utah law. In the same way, a prescription issued by an allied health professional in accordance with the relevant regulations is valid. A consultation with a non-physician healthcare provider may eliminate the need for the patient to actually meet a physician before a naloxone prescription is issued.

**Conclusion:** Allied health professionals may replace a physician in specific functions during the prescription process. The same rules that govern the prescription and/or dispensation of any other prescription drug apply to naloxone.

(1) A physician assistant may provide any medical services that are not specifically prohibited under this chapter or rules adopted under this chapter, and that are:
(a) within the physician assistant's skills and scope of competence;
(b) within the usual scope of practice of the physician assistant's supervising physician; and
(c) provided under the supervision of a supervising physician and in accordance with a delegation of services agreement.

Utah Admin. Code r. 156-70a (2007):

In accordance with Section 58-70a-501, the working relationship and delegation of duties between the supervising physician and the physician assistant are specified as follows:
(1) The supervising physician shall provide supervision to the physician assistant to adequately serve the health care needs of the practice population and ensure that the patient's health, safety and welfare will not be adversely compromised. The degree of on-site supervision shall be outlined in the Delegation of Services Agreement maintained at the site of practice. Physician assistants may authenticate with their signature any form that may be authenticated by a physician's signature.
(2) There shall be a method of immediate consultation by electronic means whenever the physician assistant is not under the direct supervision of the supervising physician.
(3) The supervising physician shall review and co-sign sufficient numbers of patient charts and medical records to ensure that the patient's health, safety, and welfare will not be adversely compromised. The Delegation of Services Agreement, maintained at the site of practice, shall outline specific parameters for review that are appropriate for the working relationship.
(4) A supervising physician shall not supervise more than two full time equivalent (FTE) physician assistants without the prior approval of the division and the board, and if patient health, safety, and welfare will not be adversely compromised.

\textit{See also} NATL. ASSN. BD. OF PHARM., SURVEY OF PHARMACY LAW (2007) (PAs authorized to prescribe prescription drugs).

\textsuperscript{16} Id.
III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

As noted in the licensure law described in sections I and II, 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.

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 Utah 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 Utah is governed by the Pharmacy Practice Act with regulations found in the Pharmacy Act Practice Rules. Pharmacists are expected to fill a prescription that meets regulatory guidelines.

Physicians, ARNPs and PAs cannot dispense prescription drugs; however, each of these occupational groups can provide patients with drug samples. As defined in Utah law, a “sample means a prescription drug packaged in small quantities consistent with limited dosage therapy of the particular drug, which is marked ‘sample,’ is not intended to be sold, and is intended to be provided to practitioners for the immediate needs of patients for trial purposes or to provide the drug to the patient until a prescription can be filled by the patient.”

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 (see part II) can dispense samples of the drug directly to clients as a means of assuring access to the medication until such time as the individual can fill a prescription in a pharmacy.

Conclusion: Dispensing naloxone by valid prescription would violate Utah law and may not be done on premises of the distribution program. However, health care providers may provide sample doses in reasonable amounts to participants in a naloxone program.

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

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19 NATL. ASSN. BD. OF PHARM., SURVEY OF PHARMACY LAW (2007). According to the Utah Division of Occupational and Professional Licensing, only a pharmacist is allowed to dispense medications in Utah. Physicians, PA’s and ARNPs can only provide samples to patients. Utah Code Ann. §58-17b-102(28) (West 1953).
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) and be subject to heavy fines. The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with illegally distributing a prescription drug or 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. We found no provision that made it a crime to possess a legend drug without a prescription.

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

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20 Utah Code Ann. §58-67-402(1) (West 1953): After proceeding pursuant to Title 63, Chapter 46b, Administrative Procedures Act, and Title 58, Chapter 1, Division of Occupational and Professional Licensing Act, the division may impose administrative penalties of up to $10,000 for acts of unprofessional conduct under this chapter.

21 Utah Admin. Code r. 156-17b-402(11) (2007) ("Dispensing a prescription drug to anyone who does not have a prescription from a practitioner … initial offense: $500--$2,000 … subsequent offense(s): $2,500--$10,000").

22 Utah Code Ann. §58-67-301(1) (West 1953) ("A license is required to engage in the practice of medicine, on or for any person in Utah, as a physician and surgeon, except as specifically provided in Section 58-1-307 or 58-67-305"); Utah Code Ann. §58-67-102(8) (West 1953):

'Practice of medicine' means:
(a) to … treat, correct, … or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, … by any means or instrumentality, … except that conduct described in this Subsection (8)(a) that is performed by a person legally and in accordance with a license issued under another chapter of this title does not constitute the practice of medicine.
Naloxone Prescription Or Distribution, And How Can The Risk Of Liability Be Minimized?

Non-compliance with prescription and other professional practice rules may carry license sanctions and fines. There is no risk of professional censure.

23 Utah Code Ann. 58-67-502 (West 1953) ("Unprofessional conduct' includes, in addition to the definition in Section 58-1-501, using or employing the services of any individual to assist a licensee in any manner not in accordance with the generally recognized practices, standards, or ethics of the profession, state law, or division rule"); Utah Code Ann. §58-1-501 (West 1953):
(1) "Unlawful conduct” means conduct, by any person, that is defined as unlawful under this title and includes:

(c) knowingly employing any other person to practice or engage in or attempt to practice or engage in any occupation or profession licensed under this title if the employee is not licensed to do so under this title;

(f)(i) unless Subsection (2)(m) or (4) applies, issuing, or aiding and abetting in the issuance of, an order or prescription for a drug or device to a person located in this state:
(A) without prescriptive authority conferred by a license issued under this title, or by an exemption to licensure under this title;
(B) with prescriptive authority conferred by an exception issued under this title or a multistate practice privilege recognized under this title, if the prescription was issued:
(I) without first obtaining information, in the usual course of professional practice, that is sufficient to establish a diagnosis, to identify conditions, and to identify contraindications to the proposed treatment; or
(II) based on a questionnaire completed by the patient on the internet, or toll-free telephone number, when there exists no other bona fide patient-practitioner relationship; or

(2) "Unprofessional conduct" means conduct, by a licensee or applicant, that is defined as unprofessional conduct under this title or under any rule adopted under this title and includes:
(a) violating, or aiding or abetting any other person to violate, any statute, rule, or order regulating an occupation or profession under this title;
(b) violating, or aiding or abetting any other person to violate, any generally accepted professional or ethical standard applicable to an occupation or profession regulated under this title;

(m) unless Subsection (4) applies, issuing, or aiding and abetting in the issuance of, an order or prescription for a drug or device:
(i) without first obtaining information in the usual course of professional practice, that is sufficient to establish a diagnosis, to identify conditions, and to identify contraindications to the proposed treatment; or
(ii) based on a questionnaire completed by the patient on the internet, or toll free telephone number when there exists no other bona fide patient-practitioner relationship or bona fide referral by a practitioner involved in an existing patient-practitioner relationship.

(4) Notwithstanding Subsections (1)(f) and (2)(m), the division may permit a person licensed to prescribe under this title to prescribe a legend drug to a
for participating in a naloxone prescription program. 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.25 Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.26

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

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

person located in this state if the division in collaboration with the appropriate professional board has permitted the specific prescriptive practice of the legend drug by rule.


(1) After proceeding pursuant to Title 63, Chapter 46b, Administrative Procedures Act, and Title 58, Chapter 1, Division of Occupational and Professional Licensing Act, the division may impose administrative penalties of up to $10,000 for acts of unprofessional conduct under this chapter.

(2) Assessment of a penalty under this section does not affect any other action the division is authorized to take regarding a license issued under this chapter.

25 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).

behavior of the relevant segment of the profession under the same or similar circumstances, which is said to establish the ‘‘standard of care.’’\textsuperscript{27} The essence of 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,\textsuperscript{28} 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

\textsuperscript{27} Swan v. Lamb, 584 P.2d 814 (Utah 1978); see Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).

applied the rule of “superseding cause” to hold that people who voluntarily use dangerous drugs cannot blame others for the harm the drugs cause.  

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 and unless a state expressly rejects the protection offered by the VPA. Utah law provides similar liability protections from damages caused by employees working within their official functions for non-profit or charitable organizations, so long as the "damage or injury was not caused by an intentional or knowing act by the volunteer which constitutes illegal, willful, or wanton misconduct." For volunteer healthcare professionals the law provides immunity as long as the healthcare professional is acting within the scope of their license, the healthcare professional does not receive any compensation and so long as acts or omissions did not result from grossly negligent or willful and wanton conduct. It appears that volunteers working

33 Utah Code Ann. §58-13-3(3) (West 1953):

A health care professional who provides health care treatment at or on behalf of a health care facility is not liable in a medical malpractice action if:
(a) the treatment was within the scope of the health care professional's license under this title;
(b) neither the health care professional nor the health care facility received compensation or remuneration for the treatment;
(c) the acts or omissions of the health care professional were not grossly negligent or willful and wanton; and
with naloxone distribution programs would be immune from any liability, except for in cases involving gross negligence and wanton, and reckless conduct.

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 Utah law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician or licensed medical provider working in collaboration with 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

(d) prior to rendering services, the health care professional disclosed in writing to the patient, or if a minor, to the patient's parent or legal guardian, that the health care professional is providing the services without receiving remuneration or compensation and that in exchange for receiving uncompensated health care, the patient consents to waive any right to sue for professional negligence except for acts or omissions which are grossly negligent or are willful and wanton.
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 ODUs 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.  

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 ODUs.


[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.