DATE: August 8, 2007

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

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 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/dispensal?
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, 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; 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 Hawaii is governed by the Medical Practice Act, with regulations found in the Hawaii Administrative Code. The Board of Medical Examiners has the authority to license physicians, and to punish licensed physicians who behave in ways that violate the law or fall below the standards of good faith and regular practice of medicine. No provision of the medical practice act explicitly defines the basis or scope of the physician's general authority to prescribe, but the law has been interpreted to authorize the Hawaii Board of Medical Examiners to set limits on allowable practices, either by enacting specific regulations banning certain 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.

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.

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5 Haw. Admin. R. § 16-85 (Lexis 2007), et seq.
10 While naloxone is not specifically excluded from the schedules in the Hawaii Controlled Substances Act, we have not found any state that considers naloxone a controlled substance. We were unable to contact the Board of Pharmacy, but we assume naloxone is not intended to be a controlled substance in Hawaii.
11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
The only articulated standard of any kind for a prescription under Hawaii law is the standard used in the Uniform Controlled Substances Act, holding that a prescription is only valid if it is written (1) with a valid medical purpose, and (2) in the course of professional practice. We assume that this standard, similar to the standards used throughout the nation, would be applied to assess the validity of a prescription for naloxone. Hawaii courts have not extensively interpreted "medical purpose," but case law in other states suggests looking to whether or not other physicians would regard the practice as legitimate medical treatment. There are also no Hawaii cases which have defined the "usual course of practice" prong of the test. 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. The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct. 

B. Analysis

While not explicitly required by Hawaii statutes, it is prudent for physicians to adhere to the standards applicable to the prescription of controlled substances. These common-sense rules require providing an appropriate physical examination, 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 Hawaii laws governing the physician's authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone.

15 See generally State v. Adams, 645 P.2d 308 (Haw. 1982).
II. May Anyone Other Than Physician Issue A Prescription For Naloxone?

A. Professional Licensure Law

Allied health professionals in this state are authorized to replace physicians in some or all aspects of prescribing. For advanced practice registered nurses (APRNs) to prescribe, they must have a collegial working relationship with a licensed physician and be authorized by the board to prescribe. 

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16 Haw. Admin. R. § 16-89C-10 (Lexis 2007):
(a) Each relationship between a recognized APRN with prescriptive authority and a licensed physician shall be documented in an agreement, the form of which is provided by the department, which attests that:
1) The physician shall be actively engaged in the same or related specialty practice and affiliated with the same institution in which the recognized APRN is to practice;
2) The physician and the recognized APRN jointly acknowledge and accept the responsibility that the collegial working relationship is based upon written policies for the delivery of health care services that will have the interest and welfare of the patient foremost in mind;
3) The recognized APRN and the physician acknowledge and accept the responsibility that the recognized APRN's prescriptive authority is governed by the exclusionary formulary and that there shall be strict adherence to the exclusionary formulary; and
4) Details of the collegial working relationship between the recognized APRN with prescriptive authority and the physician shall, at minimum, include:
   (A) Name and area of practice specialty of the recognized APRN;
   (B) Name and area of practice of the physician or physicians;
   (C) Any limitation, agreed to by the parties, such as drugs not to be prescribed (although permitted by the exclusionary formulary) or the party to prevail when there is disagreement on the prescription for a patient;
   (D) Method of communication between the recognized APRN and the physician or physicians;
   (E) Name of the institution or institutions which employ or is affiliated with the recognized APRN and the physician; and
   (F) Name of interim physician or physicians who will act in place of the primary physician in the event unforeseen circumstances preclude the relationship with the primary physician. The interim physician shall comply with all conditions of the agreement.
(b) The collegial working relationship agreement shall be signed by the recognized APRN with prescriptive authority, the physician, and the interim physician, dated, notarized, and filed with the department for approval at least five weeks prior to the intended implementation of the relationship. Approval by the director of the department or designee is required, and in the case of disapproval of any relationship, the recognized APRN shall be provided the reason for disapproval and the right to a hearing pursuant to chapter 91, HRS.

17 Haw. Admin. R. § 16-89C-2 (Lexis 2007):
Only an advanced practice registered nurse granted prescriptive authority by the department shall be able to practice as an advanced practice registered nurse with prescriptive authority or use any sign, card, or device to indicate that the person has received recognition as an advanced practice registered nurse with prescriptive authority.

assistants (PAs) must work with a supervising physician who may delegate prescriptive authority to the PA. In neither case is immediate, on-site supervision of the allied health professional required.

(a) To be eligible to be granted prescriptive authority, an APRN shall submit a completed application prescribed by the department and shall submit evidence of satisfying the following requirements:
(1) Current and unencumbered recognition as an APRN by the board of nursing in accordance with chapter 457, HRS, and chapter 16-89;
(2) An official transcript of a master's degree in clinical nursing or nursing science sent directly from the school to the department;
(3) Current certification in the nursing practice specialty sent directly to the department from a recognized national certifying body, or if currently licensed by the state department of health, in accordance with chapter 321, HRS, and chapter 11-141, evidence of a valid unencumbered license;
(4) Successful completion of one of the following within the three-year time period immediately preceding the date of application for prescriptive authority:
   (A) At least thirty contact hours, as part of a master's degree program from an accredited college or university, of advanced pharmacology education, including advanced pharmacotherapeutics that is integrated into the curriculum; or
   (B) At least thirty contact hours of advanced pharmacology, including advanced pharmacotherapeutics, from an accredited college or university; or
   (C) At least thirty contact hours of continuing education approved by board-recognized national certifying bodies in advanced pharmacology, including advanced pharmacotherapeutics related to the applicant's scope of nursing practice specialty;
(5) Verification of one thousand hours of clinical experience in an institution as a recognized APRN practitioner in the applicant's nursing practice specialty, within a three-year time period immediately preceding the date of application;
(6) A collegial working relationship agreement in compliance with section 16-89C-10, between a physician, who is currently licensed in this State where such license is unencumbered and where such license excludes a limited or temporary license, and a recognized APRN to be granted prescriptive authority; and
(7) Payment of a non-refundable application fee.
(b) Upon satisfying all requirements in subsection (a) and payment of required fees, the department shall grant prescriptive authority to the recognized APRN. A pocket identification card with the designation "APRN-Rx" and a number as assigned by the department shall be issued to the recognized APRN granted authority to prescribe.
(c) Nothing in this section shall preclude a registered nurse or an APRN from carrying out the prescribed medical orders of a licensed...physician...licensed in accordance with chapters...453...HRS, or the orders of a recognized APRN granted prescriptive authority in accordance with this chapter.

18 Haw. Admin. R. § 16-85-49(a) (Lexis 2007):
The supervising physician shall:
(1) Possess a current unrestricted Hawaii license to practice medicine and surgery that is in good standing with the board;
(2) Submit a statement that the supervising physician will direct and exercise supervision over any subordinate physician assistant in accordance with this subchapter and recognizes that the supervising physician retains full professional and legal responsibility for the performance of the physician assistant and the care and treatment of the patient;
(3) Permit the physician assistant to be utilized in any setting authorized by the supervising physician including, but not limited to, clinics, hospitals, ambulatory
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Hawaii 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. APRN’s can be authorized in Hawaii by the board to prescribe medicine, if they are working in collaboration with a physician. PAs may be delegated prescriptive authority by their supervising physician. Appropriately authorized PAs or APRNs may operate a naloxone prescription program without the immediate, on-site supervision of a physician.

Conclusion: APRNs and PAs can issue prescriptions for naloxone with a collaborating physician’s authorization. The same rules that govern the prescription and/or dispensation of any other prescription drug apply to naloxone.
III. What Instructions Should Accompany Naloxone Prescription or Dispensing?

A. The Regulatory Scheme

While there is no explicit regulatory scheme for prescribing, 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 Hawaii 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. Under the Pharmacy Act, with regulations found in the Hawaii Administrative Code, pharmacists are expected to fill a prescription that meets regulatory guidelines. The prescribing physician or APRN may also dispense the agent at the point of service. PAs may be delegated dispensing authority by their supervising physician. Finally, regulations governing the dispensation of drugs directly from the provider’s office set basic standards for storage and record-keeping that have to accompany such practice.

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20 Haw. Admin. R. § 16-95 (Lexis 2007), et seq.
22 Supra fn. 18.
(a) A prescription drug shall be dispensed only if its label bears the following:
(1) The name, business address, and telephone number of the seller. The business address shall be the physical location of the pharmacy or the dispensing practitioner’s office;
(2) The name of the person for whom the drug was prescribed…;
(3) The serial number of the prescription;
(4) The date the prescription was prepared;
(5) The name of the practitioner if the seller is not the practitioner;
(6) The name, strength, and quantity of the drug;
(7) The ‘use by’ date for the drug, which shall be:
(A) The expiration date on the manufacturer’s container; or
(B) One year from the date the drug is dispensed, whichever is earlier;
(8) The number of refills available, if any;
(9) In the case of the dispensing of an equivalent generic drug product, the statement ‘same as (brand name of the drug product prescribed or the referenced listed drug name)’, or words of similar meaning; and
(10) Specific directions for the drug’s use; provided that if the specific directions for use are too lengthy for inclusion on the label, the notation ‘take according to written instructions’ may be used if separate written instructions for use are actually issued with the drug by the practitioner or the pharmacist, but in no event shall the notation ‘take as directed’, referring to oral instructions, be considered acceptable.
If any prescription for a drug does not indicate the number of times it may be refilled, if any, the pharmacist shall not refill that prescription unless subsequently authorized to do so by the practitioner. The act of dispensing a prescription drug other than a professional sample or medical oxygen contrary to this subsection shall be deemed to be an act that results in a drug being misbranded while held for sale.
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 the drug directly to the clients. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules.

Conclusion: Physicians, ARPNs and PAs may dispense properly prescribed naloxone on the premises of a naloxone distribution 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 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 fines. The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing

(b) In addition to the requirements enumerated in subsection (a), a prescription drug shall be dispensed only:

…

(3) By a practitioner to an ultimate user; provided that:

(A) The practitioner shall inform the patient, prior to dispensing any drug other than a professional sample, that the patient may have a written, orally ordered, or electronically transmitted or conveyed prescription directed to a pharmacy…of the patient's own choice;

(B) The practitioner shall promptly record in the practitioner's records:

(i) The prescription in full;

(ii) The name, strength, and quantity of the drug, and specific directions for the drug's use;

(iii) The date the drug was dispensed; and

(iv) The name and address of the person for whom the drug was prescribed…

medicine without a license.\textsuperscript{25} 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 did not locate any Hawaii law making it a crime to unlawfully possess or distribute a prescription 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.

\section*{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?}

Non-compliance with prescription and other professional practice rules may carry license sanctions and fines.\textsuperscript{26} There 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

\textsuperscript{25} Haw. Rev. Stat. Ann. § 453-2(a) (2006) ("Except as otherwise provided by law, no person shall practice medicine...in the State...without having a valid unrevoked license...obtained from the board of medical examiners").  


(a) In addition to any other actions authorized by law, any license to practice medicine and surgery may be revoked, limited, or suspended by the board at any time in a proceeding before the board, or may be denied, for any cause authorized by law, including but not limited to the following:

\begin{itemize}
  \item (7) Professional misconduct, hazardous negligence causing bodily injury to another, or manifest incapacity in the practice of medicine or surgery;
  \item (8) Incompetence or multiple instances of negligence, including but not limited to the consistent use of medical service which is inappropriate or unnecessary;
  \item (9) Conduct or practice contrary to recognized standards of ethics of the medical profession as adopted by the Hawaii Medical Association or the American Medical Association;
\end{itemize}

(13) Violation of chapter 329, the uniform controlled substances act, or any rule adopted thereunder except as provided in section 329-122…
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{27} Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\textsuperscript{28}

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 behavior of the relevant segment of the profession under the same or similar circumstances, which is said to establish the “standard of care.”\textsuperscript{29} 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

\textsuperscript{27} 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).


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.

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

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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. 33 Hawaii state law provides similar liability protections from damages caused by volunteers at a “nonprofit organization, a nonprofit corporation, a hospital, or a governmental entity” for an “act or omission…resulting in damage or injury” if “[t]he volunteer was acting in good faith and within the scope of the volunteer's official functions and duties.” 34 It appears that under Hawaii 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.

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

(a) A volunteer shall be immune from civil liability in any action on the basis of any act or omission of a volunteer resulting in damage or injury if:
(1) The volunteer was acting in good faith and within the scope of the volunteer's official functions and duties for a nonprofit organization, a nonprofit corporation, a hospital, or a governmental entity;
(2) The damage or injury was caused by the volunteer's negligent conduct; and
(3) With respect to a nonprofit organization, nonprofit corporation, or hospital, the entity for which the volunteer was acting either:
(A) Has a general liability policy in force, both at the time of injury and at the time the claim is made against the entity, and the minimum coverage is in an amount of not less than: $200,000 per occurrence and $500,000 aggregate; or
(B) Has total assets, exclusive of grants and allocations, of less than $50,000.
(b) In any suit against a nonprofit organization, a nonprofit corporation, a hospital, or a governmental entity for civil damages based upon the negligent act or omission of a volunteer, proof of the act or omission shall be sufficient to establish the responsibility of the entity therefor under the doctrine of respondeat superior, notwithstanding the immunity granted to the volunteer with respect to any act or omission included under subsection (a).
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 Hawaii law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician, an advanced nurse practitioner, or a 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

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.35

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.

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[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.
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.