DATE: September 30, 2007

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

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.**

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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 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. (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.”)\(^4\)

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 Maryland is governed by the Medical Practice Act, Md. Code Ann., Health Occ. §§ 14-101 to 14-702, with regulations found in subtitle 32 of title 10 of the Code of Maryland Regulations. The State Board of Physician Quality Assurance (the "Board") has the authority to license physicians,\(^5\) and to punish licensed physicians who behave in ways that violate the law or are beneath the standards of good faith and regular practice of medicine.\(^6\) The Board, after consulting with the State Board of Pharmacy, may adopt rules and regulations regarding the dispensing of prescription drugs by a licensed physician.\(^7\) Leaving aside any limitations imposed by other laws, a physician is free to prescribe any drug or device she believes will benefit the patient and the prescription of which is consistent with proper professional conduct. Professional conduct is evaluated and enforced by the Board.

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.\(^8\) Naloxone is not a controlled substance under state or federal law.\(^9\)

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

\(^{4}\) The legality of a naloxone program was analyzed by the state Attorney General in response to a question from the Baltimore Department of Health. The conclusions of the Attorney General are consistent with the analysis and conclusions of this memo. See Office of the Attorney General State of Maryland, Opinion No. 03-009, 2003 WL 21003267 (Md.A.G.).

\(^{5}\) MD Code, Health Occupations, § 14-301 (West 2007), et seq.

\(^{6}\) MD Code, Health Occupations, § 14-404 (West 2007).

\(^{7}\) MD Code, Health Occupations, § 14-205 (West 2007).


\(^{9}\) “Controlled substance” means a drug classified in any of the schedules (I through V) of the Controlled Substances Act, MD Code, Criminal Law, § 5-101 (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. MD Code, Criminal Law, § 5-403 (West 2007).
there case-law challenging the legality of prescription of naloxone specifically.\textsuperscript{10} This reflects physicians’ broad discretion in prescribing and dispensing medical agents such as naloxone in this state and elsewhere in the US.\textsuperscript{11} 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] prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner’s professional practice."\textsuperscript{12}

The Board is authorized to punish physicians whose prescription practices constitute unprofessional conduct. Although we found no cases in Maryland, in other states disciplinary actions of this sort most commonly arise in the case of prescription of controlled substances, and apply the standard set out above. \textsuperscript{13}

B. Analysis

While not explicitly required by Maryland statutes, 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 Maryland laws governing the physician’s authority to prescribe. The same rules that apply to any prescription drug in this state apply to naloxone.

\textsuperscript{10} According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.

\textsuperscript{11} See Office of the Attorney General, State of Maryland, Opinion No. 03-009, 2003 WL 21003267 (Md.A.G.) (“As a general rule, State law accords broad discretion to physicians to prescribe drugs for their patients, particularly drugs that are not controlled substances.”).

\textsuperscript{12} MD ADC 10.19.03.07 (West 2007).


Medical purpose means an intention to utilize a controlled dangerous substance for physical or mental treatment, for diagnosis, or for the prevention of a disease condition not in violation of any state or federal law and not for the purpose of satisfying physiological or psychological dependence or other abuse.
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 a prescription program. The regulations allow licensed allied health professionals to step in to collect routine sections of a medical history and conduct some medical examinations in collaboration with a physician.\(^\text{14}\) Physician assistants can conduct physical examinations, perform diagnostic tests and issue prescriptions under the supervision of a physician.\(^\text{15}\) Supervision need not be on-site, but a physician must be immediately available by electronic means to provide instructions or guidance. Subject to a written practice agreement with a physician, nurse practitioners may independently conduct physical assessments of patients; order, perform and interpret laboratory tests; and prescribe drugs.\(^\text{16}\) There is no requirement of immediate physician supervision.

\(^{14}\) MD ADC 10.27.07.01 (West 2007):
“Written agreement” means the development and implementation of a written agreement between a nurse practitioner and a licensed physician concerning the performance by the nurse practitioner of the functions authorized by these regulations.

MD ADC 10.32.03.08 (West 2007) (“In order for a supervising physician to delegate prescriptive authority [to a physician’s assistant], the supervising physician shall ensure that the delegation agreement includes … [a] statement describing whether the physician intends to delegate … [p]rescribing of … [p]rescription drugs”).

\(^{15}\) MD Code, Health Occupations, § 15-301(c) (West 2007):
Patient services that may be provided by a physician assistant include: (1)(i) Taking complete, detailed, and accurate patient histories; and (ii) Reviewing patient records to develop comprehensive medical status reports; (2) Performing physical examinations and recording all pertinent patient data; (3) Interpreting and evaluating patient data as authorized by the supervising physician for the purpose of determining management and treatment of patients; (4) Initiating requests for or performing diagnostic procedures as indicated by pertinent data and as authorized by the supervising physician; (5) Providing instructions and guidance regarding medical care matters to patients; (6) Assisting the supervising physician in the delivery of services to patients who require medical care in the home and in health care institutions, including: (i) Recording patient progress notes; (ii) Issuing diagnostic orders; and (iii) Transcribing or executing specific orders at the direction of the supervising physician… (7) Exercising prescriptive authority under an approved delegation agreement.

The administrative code defines supervision:
(a) "Supervision" means the responsibility of the physician to exercise on-site supervision or provide immediately available direction for physician assistants performing delegated medical acts.
(b) "Supervision" includes:
(i) Oversight of the physician assistant and acceptance of direct responsibility for the patient services and care rendered by the physician assistant;
(ii) Continuous availability to the physician assistant either in person, through written instructions, or by electronic means; and
(iii) Designation of one or more alternate supervising physicians.

MD ADC 10.32.03.02.

\(^{16}\) MD ADC 10.27.07.02 (West 2007):
A nurse practitioner may perform independently the following functions under
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under Maryland law. With the appropriate supervision or collaboration agreements in place, both PAs and NPs may prescribe naloxone at an overdose prevention program without the presence of a physician on site.

Conclusion: Allied health professionals may replace a physician in the day to day operation of a naloxone program. 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

According to the licensure law described in section I, for a healthcare provider to prescribe medication, he or she must evaluate a patient sufficiently to support a diagnosis for a need for the treatment plan and monitor the patient’s condition.\textsuperscript{17}

\textsuperscript{17} MD ADC 10.27.07.02 (West 2007).

According to the administrative code, a nurse practitioner must

\begin{itemize}
\item[(1)] Obtain certification under these regulations;
\item[(2)] Enter into a written agreement with a physician whereby the physician on a regularly-scheduled basis shall:
\begin{itemize}
\item[(a)] Accept referrals,
\item[(b)] Establish and review drug and other medical guidelines with the nurse practitioner,
\item[(c)] Participate with the nurse practitioner in periodically reviewing and discussing medical diagnoses and the therapeutic or corrective measures employed in the practice setting,
\item[(d)] Jointly sign records if needed to document accountability of both the physician and nurse practitioner,
\item[(e)] Be available for consultation in person, by telephone, or by some other form of telecommunication, and
\item[(f)] Designate an alternate physician if the physician identified in the written agreement temporarily becomes unavailable(3) Obtain approval of the written agreement as set forth in Regulation .06.
\end{itemize}
\end{itemize}

\textsuperscript{17} MD ADC 10.19.03.07 (West 2007).
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 Maryland 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 Maryland is governed by the Pharmacy Act, Md. Code Ann., Health Occ. §§ 12-101 to 12-802, with regulations found in the administrative code, subtitle 34 of title 10. The State Board of Pharmacy has the power to adopt rules and regulations necessary to protect the public health, safety, and welfare, which includes regulations governing standards for prescriptions.18 In Maryland, drugs are ordinarily to be dispensed only by pharmacists, but certain medical practitioners (including physicians but not NPs or PAs) may dispense when “a pharmacy is not conveniently available to the patient.”19 Practitioners must obtain a written permit

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19 MD ADC 10.13.01.02 (West 2007).
from the appropriate board to dispense, except that no permit is required to dispense a “starter dose” or sample at no cost to the patient. NPs are authorized to dispense to patients, but only in certain health care facilities. NPs may, however, dispense free starter doses or samples of any drug they are authorized to prescribe, without any location limit. We found no authority in Maryland law or regulations for dispensing of prescription medications by PAs.

**B. Analysis**

Pharmacists should and ordinarily will fill a valid prescription for naloxone. It may be reasonably argued that a pharmacy is “not reasonably available” to an ODU patient, allowing a physician with a dispensing permit to dispense naloxone on-site at an overdose prevention program. Provided that naloxone is provided without cost, both physicians and NPs may provide naloxone to patients at a naloxone program. Physicians dispensing medication directly are required to follow the general labeling rules set out in the Pharmacy Code. If a program decides to dispense naloxone on premises, it must follow

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20 MD ADC 10.13.01.04 (West 2007).
21 MD ADC 10.27.07.08 (West 2007):
   A nurse practitioner may … dispense any drug that a nurse practitioner is authorized to prescribe in the course of treating a patient at … [a] medical facility or clinic that is operated on a nonprofit basis; … A public health facility, a medical facility under contract with a State or local health department, or a facility funded with public funds; or … [a] nonprofit hospital or a nonprofit hospital out-patient facility as authorized under the policies established by the hospital.

22 MD ADC 10.27.07.08:
   A nurse practitioner may personally prepare and dispense a starter dosage of any drug the nurse practitioner is authorized to prescribe. The nurse practitioner shall:
   (1) Label the starter dosage in compliance with the labeling requirements of Health Occupations Article, §12-509, Annotated Code of Maryland;
   (2) Provide the starter dose free of charge; and
   (3) Enter the starter dose dispensed in the patient's medical record.

23 The administrative code sets out the documentation requirements for dispensing on this basis:
   A licensee shall maintain a single form in each patient's chart for each patient to whom prescription drugs are dispensed. At a minimum, the form shall:
   (1) Indicate that a pharmacy is not conveniently available to the patient;
   (2) State that the determination that a pharmacy is not conveniently available was made solely by the patient; and
   (3) Be signed and dated by the patient before dispensing prescription drugs to the patient for the first time.

MD ADC 10.13.01.04.

24 See MD Code, Health Occupations, § 12-505:
   In addition to any other information required by law, the label shall include:
   (1) The date the prescription is filled; and
standard dispensation rules, which include the requirement to maintain a dispensation record, and proper labeling of the agent, including the patient’s name and other essential information.  

**Conclusion:** Dispensing naloxone by valid prescription does not violate Maryland law. A physician with a permit to dispense may provide naloxone to patients on-site, provided a pharmacy is not reasonably accessible in the view of the physician or patient. Both physicians and nurse practitioners may dispense starter doses or samples at no cost to patients.

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

(2) Unless otherwise required by the prescriber:
(i) An expiration date of the drugs or devices which shall be the lesser of:
1. 1 year from the date of dispensing;
2. The month and year when the drugs or devices expire;
3. The appropriate expiration date for repackaged drugs or devices; or
4. A shorter period as determined by the pharmacist;
(ii) Any appropriate special handling instructions regarding proper storage of the drugs or devices; and
(iii) Subject to the provisions of subsection (c) of this section, the name and strength of the drugs or devices.

25 MD ADC 10.34.03.09 (West 2007): Drug Dispensing-Record Keeping.
A. The director or the director's pharmacist designee shall establish and maintain a master log for all drugs that are repackaged from bulk packages before the receipt of a medication order for internal, external, or injectable use within the institutional facility which lists the following information: (1) Name of drug; (2) Strength; (3) Manufacturer; (4) Lot number; (5) Quantity repackaged; (6) Expiration date of repackaged drugs; (7) Manufacturer’s expiration date; (8) Date of repackaging; (9) Name of repacker; and (10) Name of verifying pharmacist.
B. The director or the director's pharmacist designee shall determine whether generic products are properly labeled, including the name of the manufacturer of these generic products.
C. Section A of this regulation does not apply to any injectables dispensed within 72 hours of repackaging.
physician may not prescribe “extra” naloxone to a patient with explicit instructions to give it to or use it on a person in need.\textsuperscript{26}

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.\textsuperscript{27} 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\textsuperscript{28} or illegally dispensing a prescription drug.\textsuperscript{29} 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.\textsuperscript{30}

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.\textsuperscript{31} 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.

\textsuperscript{26}This was the conclusion of the Attorney General. See Office of the Attorney General, State of Maryland, Opinion No. 03-009, 2003 WL 21003267 (Md.A.G.).

\textsuperscript{27}MD Code, Health Occupations, § 14-404 (West 2007) (license denial, suspension, or revocation for unprofessional conduct in the practice of medicine); MD Code, Health Occupations, § 14-405.1 (West 2007) (“[i]f … the Board finds that there are … grounds to suspend or revoke a license … or to reprimand a licensed physician … the Board may impose a fine … (1) Instead of suspending the license; or (2) In addition to suspending or revoking the license or reprimanding the licensee”).

\textsuperscript{28}MD Code, Health Occupations, § 14-301 (West 2007); Office of the Attorney General, State of Maryland, Opinion No. 03-009, 2003 WL 21003267 (Md.A.G.) (April 30, 2003) (“A patient who is prescribed naloxone with the understanding that he or she would administer it to another unidentified person may be subject to criminal prosecution for the unauthorized practice of medicine.”).

\textsuperscript{29}MD Code, Criminal Law, § 5-701 (West 2007).

\textsuperscript{30}The Attorney General identifies additional provisions that might be violated by third-party prescribing or distribution. See Office of the Attorney General, State of Maryland, Opinion No. 03-009, 2003 WL 21003267 (Md.A.G.).

\textsuperscript{31}The Attorney General reached the same conclusion. See Office of the Attorney General, State of Maryland, Opinion No. 03-009, 2003 WL 21003267 (Md.A.G.).
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.32 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 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.33 Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.34

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.”

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, 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 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. Maryland state law provides similar liability protections from damages caused by health care providers at a “medical facility, nonprofit facility, temporary emergency site, or other facility owned or operated by a governmental entity or nonprofit organization” for an “act or omission in providing the health care services.” 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. Thus, it appears that under Maryland 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

40 Abramson v. Reiss, 638 A.2d 743 (Md. 1994).
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 Maryland law we have outlined above:

1. Each patient receiving naloxone must be issued a prescription for the drug by a physician, a 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 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 OUDs 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.41

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.