DATE: January 20, 2007

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

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.**

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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 IDU Patient?

A. Professional Licensure Law

The practice of medicine in Montana is governed by the Board of Medical Examiners (the "Board"), with regulations in the Montana Administrative Code. 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. The statutory and administrative codes of Montana do not explicitly define the basis or scope of the physician's general authority to prescribe. However, the Board is authorized 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.

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. In the absence of

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5 Admin. R. Mont. 24.156.101 (2007), et seq.
11 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the US.
specific provisions, we presume a prescription for naloxone would be governed by the same broad principles that govern prescriptions for controlled substances. It is unlawful and constitutes unprofessional conduct for a physician to prescribe "a controlled substance … otherwise than in the course of legitimate or reputable professional practice."\textsuperscript{12}

In determining whether a prescription arises within the course of legitimate professional practice, courts may consider such factors 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 and efforts to provide other harm reducing services.\textsuperscript{13} The medical board is authorized to punish physicians whose prescription practices constitute unprofessional conduct.\textsuperscript{14}

B. Analysis

While not explicitly required by Montana law, it is prudent for physicians to adhere to the standards applicable to the prescription of controlled substances. These common-sense rules require providing a physical examination as appropriate, 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.

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

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

A. Professional Licensure Law

Allied health professionals in this state are authorized to replace physicians in some or all aspects of a prescription program. Advanced practice registered nurses (APRNs) can prescribe medication,\textsuperscript{15} if authorized by the Board.

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{12} Admin. R. Mont. 24.156.625(1)(p) (2007).
\item \textsuperscript{13} United States v. Moore, 423 U.S. 122 (U.S. 1975).
\item \textsuperscript{14} Supra fn 12.
\item \textsuperscript{15} Admin. R. Mont. 24.159.1464 (2007);
\end{itemize}
\end{footnotesize}
Physician assistants (PAs) can prescribe prescription drugs, if authorized by their supervising physician.

B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I and II, is valid under Montana 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: APRNs and PAs 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) Prescriptions will comply with all applicable state and federal laws.
(2) All prescriptions will include the following information:
   (a) name, title, address, and phone number of the advanced practice registered nurse who is prescribing;
   (b) name of client;
   (c) date of prescription;
   (d) the full name of the drug, dosage, route, amount to be dispensed, and directions for its use;
   (e) number of refills;
   (f) signature of prescriber on written prescription; and
   (g) DEA number of the prescriber on all scheduled drugs.
(3) Records of all prescriptions will be documented in client records.
   …
(8) An advanced practice registered nurse with prescriptive authority will not delegate the prescribing or dispensing of drugs to any other person.
   …
(10) An APRN with prescriptive authority from the board will comply with the requirements of 37-2-104, MCA.

Admin. R. Mont. 24.159.1461 (2007):
(1) An APRN granted prescriptive authority by the board may prescribe … drugs pursuant to applicable state and federal laws. If the APRN has prescriptive authority, the peer shall also have prescriptive authority.
   (a) NPs, CRNAs, and CNMs with unencumbered licenses may hold prescriptive authority.
   …
(2) Prescriptive authority permits the APRN to receive pharmaceutical samples and to prescribe … prescription drugs in the prevention of illness, the restoration of health, and/or the maintenance of health in accordance with 37-2-104, MCA.
(3) The Board of Pharmacy will be notified in a timely manner by the board when the status of an APRN's prescriptive authority changes.

(1) A physician assistant may prescribe … drugs to the extent authorized by the supervising physician.
   …
(e) A prescription written by a physician assistant must comply with regulations relating to prescription requirements adopted by the board of pharmacy.
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 Montana 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 Montana is governed by the Montana Pharmacy Practice Act, with regulations found in the administrative code. Pharmacists are expected to fill a prescription that meets regulatory guidelines.

In Montana, "medical practitioners," which include physicians, PAs and APRNs, are typically not permitted to dispense prescription drugs. There are, however, three notable exceptions: 1) "dispensing a drug to a patient by a medical practitioner whenever there is no community pharmacy available to the patient," 2) "the dispensing of drugs occasionally, but not as a usual course of doing business, by a medical practitioner" and 3) "a medical practitioner…dispensing drug samples." A "drug sample" “means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.” While we found are no further regulations for healthcare providers dispensing prescription

20 Mont. Code Ann. § 37-2-101(5) (2007) (“Medical practitioner” means any person licensed by the state of Montana to engage in the practice of medicine … or a nursing specialty as described in 37-8-202 and in the licensed practice to administer or prescribe drugs”).
(1) Except as otherwise provided by this section, it is unlawful for a medical practitioner to engage, directly or indirectly, in the dispensing of drugs.
(2) This section does not prohibit:
(a) a medical practitioner from furnishing a patient any drug in an emergency;
(b) the administration of a unit dose of a drug to a patient by or under the supervision of a medical practitioner;
(c) dispensing a drug to a patient by a medical practitioner whenever there is no community pharmacy available to the patient;
(d) the dispensing of drugs occasionally, but not as a usual course of doing business, by a medical practitioner;
(e) a medical practitioner from dispensing drug samples.
Admin. R. Mont. 24.159.1461 (2007):
(1) An APRN granted prescriptive authority by the board may … dispense drugs pursuant to applicable state and federal laws. If the APRN has prescriptive authority, the peer shall also have prescriptive authority.
(a) NPs, CRNAs, and CNMs with unencumbered licenses may hold prescriptive authority.
…
(2) Prescriptive authority permits the APRN to receive pharmaceutical samples and to … dispense … prescription drugs in the prevention of illness, the restoration of health, and/or the maintenance of health in accordance with 37-2-104. (Emphasis added).
Mont. Code Ann. § 37-20-404 (2007): (“A physician assistant may … dispense … drugs to the extent authorized by the supervising physician. … All dispensing activities allowed by this section must comply with 37-2-104 and with packaging and labeling guidelines developed by the board of pharmacy under Title 37, chapter 7”). (Emphasis added).
22 Id.
drugs from the provider’s office, we recommend that they follow basic standards for record-keeping that must normally accompany such practice by pharmacists.  

B. Analysis

Pharmacists should and ordinarily will fill a valid prescription for naloxone. Health care providers licensed to dispense drugs may do so at a naloxone prescription program if doing so falls within any of the three relevant exceptions to the state’s rule against prescribers dispensing. In some areas, there may not be a community pharmacy “available,” either for geographic reasons or because the ODU patient would be unwilling to purchase naloxone because of stigma or other concerns. Likewise, if the prescriber ordinarily does not dispense medications in the course of practice, the occasional provision of naloxone at an overdose prevention site would presumably meet the standard of not being “a usual course of doing business.” We found no cases, regulations or statutes that further specified the meaning of key terms such as “occasionally” or what it means for a community pharmacy to be available. The provision of a sample dose along with a prescription would also seem to be consistent with the letter and spirit of state law.

Conclusion: Dispensing naloxone by a valid prescription by a non-pharmacist would not violate Montana law and may be done on premises of the 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


(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist or pharmacy technician under a board-approved utilization plan, shall make a reasonable effort to obtain, record, and maintain the following information:
(a) full name of the patient for whom the drug is intended;
(b) address and telephone number of the patient;
(c) patient's age or date of birth;
(d) patient's gender;
(e) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.
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 license sanctions. The patient or volunteer who dispensed naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license. We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. We found no law that made it a crime to possess a prescription without a prescription.


(1) In addition to those forms of unprofessional conduct defined in 37-1-316, MCA, the following is unprofessional conduct for a licensee or license applicant under Title 37, chapter 3, MCA:

…
(c) conduct likely to deceive, defraud or harm the public;
…
(h) willful disobedience of a rule adopted by the board, or an order of the board regarding evaluation or enforcement of discipline of a licensee;
…
(v) any other act, whether specifically enumerated or not, that in fact constitutes unprofessional conduct;
(w) failing to comply with an agreement the licensee has entered into with the program established by the board under 37-3-203(4), MCA;


The following is unprofessional conduct for a licensee or license applicant governed by this chapter:

…
(2) permitting, aiding, abetting, or conspiring with a person to violate or circumvent a law relating to licensure or certification;
…
(16) assisting in the unlicensed practice of a profession or occupation or allowing another person or organization to practice or offer to practice by use of the licensee’s license;
…
(18) conduct that does not meet the generally accepted standards of practice. A certified copy of a malpractice judgment against the licensee or license applicant or of a tort judgment in an action involving an act or omission occurring during the scope and course of the practice is conclusive evidence of but is not needed to prove conduct that does not meet generally accepted standards.

26 Mont. Code Ann. § 37-3-102 (2007) (“If a person who does not possess a license to practice medicine in this state under this chapter and who is not exempt from the licensing requirements of this chapter performs acts constituting the practice of medicine, the person is practicing medicine in violation of this chapter”).
None of this should be taken as suggesting that a program cannot teach patients to properly administer the drug on others. Such training is necessary, as discussed above, to deal with the fact that patients may be unable to self-administer in an overdose situation, or may be called upon to assist another patient. But a program in this state that explicitly encouraged distribution to or administration upon non-patients would be open to legal challenge. Legislatures in a few states have taken action to eliminate legal barriers to emergency use of naloxone among non-patients. These are discussed in the Conclusion, below.

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

Non-compliance with prescription and other professional practice rules may carry license sanctions and/or fines.\(^{27}\) There is no risk of professional censure 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.\(^{28}\) Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.\(^{29}\)

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

\(^{27}\) Mont. Code Ann. § 37-3-323 (2007) (Board can revoke license, suspend license for up to one year or impose a fine, not in excess of $500, for each offense of unprofessional conduct).

\(^{28}\) *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).

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 IDU 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

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30 Pierce v. ALSC Architects, P.S., 270 Mont. 97 (Mont. 1995); see Plaintiff v. City of Petersburg, 345 S.E.2d 564 (W. Va. 1986); Restatement (Second) of Torts §282 (1993).
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.32

“Loss of chance” doctrine in tort law establishes liability when negligent
or otherwise harmful behavior substantially contributes to an injury, even if the
injury may have also occurred from other causes. A plaintiff could also allege
that the provision of naloxone led to delay or failure to summon medical help,
leading to the “loss of a chance” to receive medical care.33 However, the
imposition of liability under this doctrine would be highly problematic if
programs explicitly instruct patients not to rely wholly on the effects of naloxone,
but rather to use it as a stop-loss measure before medical help can be summoned.

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.34 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.35

33 Aasheim v. Humberger, 215 Mont. 127 (Mont. 1985); see Martin v. E. Jefferson Gen. Hosp.,
582 So.2d 1272 (La. 1991).
34 Faulconbridge v. State, 333 Mont. 186 (Mont. 2006).
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 Montana 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

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.\textsuperscript{36}

\textbf{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.

\textsuperscript{36} N.Y. Pub. Health Law §3309 (McKinney 2006):

[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.