DATE: January 20, 2008

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

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 U.S. and abroad indicates that naloxone distribution helps reduce opiate overdose deaths and results in cost-savings to society. Despite the high and rising incidence of overdose events in many U.S. 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/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; 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 West Virginia is governed by the West Virginia Medical Practice Act, with regulations in the administrative code. The Board of Medicine (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 Board sets limits on allowable prescription practices through the disciplinary process.

Naloxone is labeled for administration to reverse opiate overdose in clinical settings, such as hospitals, but is often administered by first responders acting on standing orders of physicians in the field. Federal and state law affords physicians broad discretion to prescribe drugs for off-label uses, and such prescriptions are a routine part of medical practice. Naloxone is not a controlled substance under state or federal law. Therefore, a prescription for naloxone must meet the same standards as a prescription for any other drug. A prescription must be made in good faith and "in a therapeutic manner in accordance with accepted medical standards and in the course of the physician's … professional practice."

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 U.S.

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4 W. VA. CODE ANN. §30-3-3 (West 2007), et seq.
5 W. VA. CODE R. § 11-1A-1 (2007), et seq.
6 W. VA. CODE ANN. §30-3-7 (West 2007)
7 W. VA. CODE ANN. § 30-3-14 (West 2007).
8 W. VA. CODE ANN. § 30-3-14(c)(13).
10 W. VA. CODE ANN. § 60A-1-101(d) (West 2007) ("Controlled substance' means a drug, substance or immediate precursor in Schedules I through V of article two’); W. VA. CODE ANN. § 60A-2-206(b)(1) (West 2007) (Naxolone is excluded from Schedule II of the Uniform Controlled Substances Act; therefore, naxolone is treated as a prescription or legend drug).
11 W. VA. CODE ANN. § 30-3-14(c)(13).
12 According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the U.S.
The Board is authorized to punish practitioners whose prescription practices constitute unprofessional conduct. Disciplinary actions of this sort most commonly arise in the case of prescription of controlled substances. These cases apply the familiar standard under which a prescription is valid if it is written for a legitimate medical purpose, in the normal course of professional practice.\(^\text{13}\)

**B. Analysis**

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

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

**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 nurse practitioners (ANPs) can independently write prescriptions, but they must have approval from the West Virginia Board of Examiners for Registered Professional Nurses and do so within the limits of the collaborative agreement established with their supervising physician.\(^\text{14}\) Physician assistants (PAs) can prescribe

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\(^{14}\) W. VA. CODE R. 19-8-3 (2007):

3.1. The advanced nurse practitioner … shall submit a notarized application for prescriptive authority on forms provided by the Board along with a fee of one hundred twenty-five dollars ($125.00).

a. A voided sample of the prescription form shall be submitted with the application.

b. The advanced nurse practitioner … shall submit written verification of an agreement to a collaborative relationship with a licensed physician for prescriptive practice on forms provided by the Board. The applicant shall certify
on this form that the collaborative agreement includes the following:
A. Mutually agreed upon written guidelines or protocols for prescriptive authority as it applies to the advanced nurse practitioner's or certified nurse-midwife's clinical practice;
B. Statements describing the individual and shared responsibilities of the advanced nurse practitioner ... and the physician pursuant to the collaborative agreement between them;
C. Provision for the periodic and joint evaluation of the prescriptive practice;
D. Provision for the periodic and joint review and updating of the written guidelines or protocols.
c. The advanced nurse practitioner ... with prescriptive authority shall submit additional documentation of the regulations of Section 3.1.b of this rule at the request of the Board.

3.3. The advanced nurse practitioner applicant for prescriptive authority shall meet all eligibility requirements as specified in W. Va. Code § 30-7-15b.
a. If any evidence exists that all eligibility requirements have not been met, the Board shall not grant prescriptive authority.

3.6. Upon satisfactory evidence that the applicant has met all requirements for prescriptive authority as set forth in W. Va. Code §§ 30-7-15a, 15b, 15c, § 30-15-1 through 7c, and this rule, the Board may grant authority to prescribe drugs as set forth in this rule and shall assign an identification number.
a. The Board shall notify the Board of Medicine ... and the Board of Pharmacy of those advanced nurse practitioners ... who have been granted prescriptive authority, and shall also provide the prescriber's identification number and effective date of prescriptive authority.
A. The advanced nurse practitioner ... shall file with the Board any restrictions on prescriptive authority that are not imposed by W. Va. Code § 60A-3, or this rule, but which are agreed to within the written collaborative agreement and the name of the collaborating physician(s) for each advanced nurse practitioner ... on the approved list.

W. VA. CODE ANN. § 30-7-15a (West 2007):
(a) The board may, in its discretion, authorize an advanced nurse practitioner to prescribe prescription drugs in a collaborative relationship with a physician licensed to practice in West Virginia and in accordance with applicable state and federal laws. An authorized advanced nurse practitioner may write or sign prescriptions or transmit prescriptions verbally or by other means of communication.
(b) For purposes of this section an agreement to a collaborative relationship for prescriptive practice between a physician and an advanced nurse practitioner shall be set forth in writing. Verification of such agreement shall be filed with the board by the advanced nurse practitioner. The board shall forward a copy of such verification to the board of medicine. Collaborative agreements shall include, but not be limited to, the following:
(1) Mutually agreed upon written guidelines or protocols for prescriptive authority as it applies to the advanced nurse practitioner's clinical practice;
(2) Statements describing the individual and shared responsibilities of the advanced nurse practitioner and the physician pursuant to the collaborative agreement between them;
(3) Periodic and joint evaluation of prescriptive practice; and
(4) Periodic and joint review and updating of the written guidelines or protocols.
(c) The board shall promulgate legislative rules in accordance with the provisions of chapter twenty-nine-a of this code governing the eligibility and extent to which an advanced nurse practitioner may prescribe drugs.
prescription drugs, although not independently. PAs can prescribe under the authority and supervision of a physician, in a place where the physician routinely practices and with the authorization of the Board of Medicine. On-

15 NATL. ASSN. BD. OF PHARM., SURVEY OF PHARMACY LAW.
16 W. VA. CODE R. 11-1B-14.11 (“Nothing in this rule shall be construed to permit any physician assistant to independently prescribe or dispense drugs”).
17 W. VA. CODE R. 11-1B-6.1 (2007):
The physician assistant, whether employed by a health care facility or the supervising physician, shall perform only under the supervision and control of the supervising physician. Supervision and control of a physician assistant certified by the NCCPA requires the availability of a physician for consultation and direction of the actions of the physician assistant. It does not necessarily require the personal presence of the supervising physician at the place or places where services are rendered, if the physician assistant certified by the NCCPA is performing (specified) duties at the direction of the supervising physician. In the case of a physician assistant who has not been certified by the NCCPA, the presence of the supervising physician or alternate supervising physician on the premises where the noncertified assistant performs delegated medical tasks is required.
18 W. VA. CODE R. 11-1B-6.1 (2007) (“The physician assistant may function in any setting within which the supervising physician routinely practices, but in no instance shall a separate place of work for the physician assistant be established”).
19 W. VA. CODE R. 11-1B-14 (2007):
14.1. A physician assistant may be authorized by the Board to issue written or oral prescriptions for certain medicinal drugs at the direction of his or her supervising physician if all of the following conditions are met:
a. The physician assistant has performed patient care services for a minimum of two (2) years immediately preceding the submission to the Board of the job description requesting limited prescriptive privileges: Provided, That to meet this condition, the first year of patient care services may be as a student in an approved physician assistant program;
b. The physician assistant has successfully completed an accredited course of instruction in clinical pharmacology approved by the Board of not less than four (4) semester hours. The course of instruction may be completed within an approved undergraduate or graduate program for physician assistants. Physician assistants who have not met this requirement shall complete an additional course of study approved by the Board in which fifteen (15) contact hours equals one (1) semester hour. The Board may, at its discretion, grant up to fifteen (15) contact hours for two or more years of prescribing experience in other jurisdictions;
c. The physician assistant obtains Board approval of his or her job description which includes the categories of drugs the physician assistant proposes to prescribe at the direction of his or her supervising physician; and
d. The physician assistant continues to maintain national certification as a physician assistant, and in meeting the national certification requirements, completes a minimum of ten (10) hours of continuing education in rational drug therapy in each certification period.
14.2. Evidence of completion of all conditions for the granting of limited prescriptive privileges shall be included with the physician assistant’s biennial renewal application and report to the Board.
14.3. The Board is responsible for approving a formulary classifying pharmacologic categories of all drugs which may be prescribed by a physician assistant authorized by the Board to prescribe drugs. The formulary shall exclude Schedules I and II of the Uniform Controlled Substances Act,
site supervision by a supervising physician is not required in every instance for a PA to prescribe, as long as the prescribed drug is listed within the approved formulary by the Board. However, naloxone is not listed on the Board-approved formulary.

anticoagulants, antineoplastics, radio-pharmaceuticals, general anesthetics and radiographic contrast materials. The formulary may be revised annually, and shall include the following designated sections:

a. Section a. -- A choice of drugs commonly used in primary care outpatient settings to be prescribable by physician assistants who have completed an accredited course of study in clinical pharmacology approved by the Board.
b. Section b. -- Additional drugs used less commonly in primary care outpatient settings to be prescribable by physician assistants who have satisfied the requirements to prescribe Section a. drugs set forth under paragraph 14.3.a., of this rule. In addition, Section b. drugs may be prescribed by physician assistants only in the following limited situations:

1. On a direct order from the supervising physician to the physician assistant during consultation at the time of the patient's examination by the physician assistant, which is specifically noted in the patient's chart; or
2. On a refill prescription for a previously diagnosed and stable patient whose prescription was initiated by the supervising physician.

14.4. A prescription drug not included in the approved formulary shall not be contained in the job description of any physician assistant.

14.5. Prescriptions issued by a physician assistant shall be issued consistent with the supervising physician's directions or treatment protocol provided to his or her physician assistant. The maximum dosage shall be indicated in the protocol and in no case may the dosage exceed the manufacturer's recommended average therapeutic dose for that drug.

14.6. Each prescription and subsequent refills given by the physician assistant shall be entered on the patient's chart.

14.7. The prescription form utilized by a physician assistant approved for limited prescriptive privileges shall be imprinted with the name of the supervising physician, the name of the approved physician assistant, the address of the health care facility, the telephone number of the health care facility, the categories of drugs or drugs within a category which the assistant may prescribe and the statement, "Physician Assistant Prescription - it is a violation of state law to dispense drugs not imprinted on this prescription." The physician assistant shall write the name of the patient, the patient's address and the date on each prescription form. The physician assistant shall sign his or her name to each prescription followed by the letters "PA-C." The supervising physician shall provide the Board with a copy of the prescription form used by his or her physician assistant prior to its use. A copy of this prescription form shall be provided by the physician assistant to area pharmacies where the physician assistant may issue a prescription by word of mouth, telephone or other means of communication in his or her name at the direction of the supervising physician.

14.9. Prescriptions for other legend drugs shall not be prescribed or refillable for a period exceeding six (6) months.

14.10. The Board of Medicine shall provide the Board of Pharmacy with a list of physician assistants with limited prescriptive privileges and shall update the list within ten (10) days after additions or deletions are made.

W. VA. CODE R. 11-1B-2 (2007):

f. 'Supervision' means the opportunity or ability of the physician to provide or exercise control and direction over the services of physician assistants. Constant
B. Analysis

We have concluded above that a physician's prescription for naloxone, issued under the procedures outlined in Part I, is valid under West Virginia law. In the same way, a prescription issued by an ANP in accordance with the relevant regulations is valid. A PA cannot prescribe naloxone in West Virginia, but could examine patients and otherwise assist a physician in other aspects of a naloxone prescribing program.

Conclusion: ANPs who have been authorized by their respective boards and in their physician agreements to prescribe may prescribe naloxone to participants in an overdose prevention program without the on-site supervision of a physician. 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 sections I and II, a healthcare provider must formulate a therapeutic plan for their patient and discuss the plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient before issuing a prescription.22

21 We contacted the West Virginia Board of Medicine and naloxone is not listed in the Board-approved formulary for prescription drugs that can be prescribed by PAs.
22 W. VA. CODE ANN. § 30-3-14(c)(13).
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 West Virginia 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 West Virginia is governed by the statutory code,\textsuperscript{23} with regulations found in the administrative code.\textsuperscript{24} Pharmacists are expected to fill prescriptions that meet regulatory guidelines.

The prescribing healthcare provider may also dispense the agent at the point of service. Generally, physicians can dispense drugs, as long as they register with the Board as a dispensing physician, pay the annual fee and maintain

\textsuperscript{23} W. VA. CODE ANN. § 30-5-1 (West 2007), \textit{et seq.}\n\textsuperscript{24} W. VA. CODE R. § 15-1-1 (2007), \textit{et seq.}
and adhere to storage requirements. However, physicians that dispense professional samples or "[l]egend drugs which are not controlled substances provided by free clinics" are exempt from those requirements. ANPs cannot


3.1. Each physician … who wishes to dispense legend drugs to patients shall register with the Board as a dispensing physician, on the form provided by the Board. The annual fee for registration as a dispensing physician shall be fifteen dollars ($15.00).

3.2. Physicians … who are registered with the Board as dispensing physicians may dispense drugs to their own patients but not fill prescriptions written by other physicians or podiatrists, nor sell at retail such legend drugs. They may make reasonable charges for their services, including any legend drugs they may dispense, and may dispense amounts of drugs as they deem sufficient to a patient's course of treatment.

3.3. Physicians … who are not registered with the Board as dispensing physicians may not dispense legend drugs. However, the following activities by a physician … shall be exempt from the requirements of section 3 through 8 applicable to dispensing physicians:

(a) Legend drugs administered to the patient, which are not controlled substances when an appropriate record is made in the patient's chart.
(b) Professional samples distributed free of charge by a physician or podiatrist or certified physician assistant under his or her supervision to the patient when an appropriate record is made in the patient's chart; or
(c) Legend drugs which are not controlled substances provided by free clinics or under West Virginia state authorized programs, including the medicaid, family planning, maternal and child health, and early and periodic screening and diagnosis and treatment programs: Provided, however, That all labeling provisions of section 8 shall be applicable except the requirements of section 8.3(a).


4.3. A dispensing physician must have access to reference books relating to the dispensing of medication, including the most recent edition of USP DI.
4.4. A dispensing physician must have immediate access to the package insert, or its equivalent, for every legend drug dispensed to patients.
4.5. A dispensing physician must maintain equipment necessary for the dispensing of legend drugs, including a typewriter or computer …
4.6. A dispensing physician must maintain a dispensing area, where all stock quantities of legend drugs maintained for dispensing to patients must be stored under conditions that meet USP criteria as published in USP DI, to prevent deterioration. Legend drugs must be stored in a locked or otherwise secure area to prevent access when the dispensing physician is not present in the office.


26 W. Va. Code R. 11-5-2.10 (2007) ("Professional samples' means complimentary drugs packaged and distributed in accordance with federal and state statutes and regulations and provided to a physician … free of charge by manufacturers or distributors and distributed free of charge by the physician … to his or her patients").


dispense prescription drugs. PAs can dispense prescription drugs, if permitted to do so 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 must accompany such practice.

B. Analysis

There is no provision in the statutory or administrative code that authorizes nurses to dispense prescription drugs. "State pharmacy law and Board regulations do not apply to" ANPs. NATL. ASSN. BD. OF PHARM., SURVEY OF PHARMACY LAW.

W. VA, CODE R. 11-5-4:

4.1. A dispensing physician may not delegate the dispensing function to another physician … nor to other office personnel. However, a dispensing physician may delegate nonjudgmental functions to supportive personnel, subject to the requirement that the dispensing physician must personally perform the following duties:
(a) Discuss with patients matters pertaining to the drug, its reasons for usage, and contraindications or answer questions regarding the dispensing physician’s intent.
(b) Perform any other functions of any kind which require the knowledge, judgment, ability or skill of a dispensing physician.

4.2. A dispensing physician who is the supervising physician for a "Type A" Physician Assistant may delegate the dispensing function to that "Type A" Physician Assistant. A "Type A" Physician Assistant must follow all rules applicable to the dispensing physician. A "Type A" Physician Assistant may dispense only those legend drugs that he or she is authorized to prescribe. A "Type A" Physician Assistant may dispense legend drugs to those patients for whom the "Type A" Physician Assistant has prescribed the legend drugs at the direction of the supervising physician, but may not dispense legend drugs to patients for whom the supervising physician has prescribed legend drugs.

There is actually no reference to "Type A" in the code or rules. However, according to the West Virginia Board of Medicine, "Type A" is a PA as we know them today, which is NCCPA certified. "Type B" PAs, as referred to in the code, W. VA. CODE ANN. § 30-3-16(e)(2), are those PAs who are not NCCPA certified and were grandfathered in prior to first day of July, 1983. There are approximately 11 of those in our system. Everyone who is licensed after that date is NCCPA certified or Type A.


9.1. A dispensing physician must maintain records that are available for inspection.
9.2. Patient records must facilitate an audit trail for each patient to whom legend drugs are dispensed. They may be maintained either in a patient's chart or in an equivalent but separate patient medication record.
9.3. Daily records must facilitate an audit trail for each day on which scheduled controlled substances are dispensed. They may be maintained in a daily log or in a file of prescriptions.

9.4. For each legend drug dispensed, both patient records and daily records shall include:
(a) Patient's name,
(b) Drug name and strength,
(c) Quantity dispensed,
(d) Directions for use.
Pharmacists should and ordinarily will fill a valid prescription for naloxone. Physicians can dispense naloxone if they have registered as dispensing physicians, or if the overdose program qualifies as a “free clinic” and the naloxone is provided at no charge to the patient. Type A” PAs can dispense naloxone, if permitted to do so by their supervising physician. Advanced practice nurses are not authorized to dispense naloxone. If a program decides to dispense naloxone on premises, it must follow standard dispensation rules, which include the requirements for record keeping, packaging and proper labeling of the agent, including the patient’s name and other essential information.

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8.1. Each legend drug dispensed by a dispensing physician must be packaged in its own separate container and labeled with its own specific directions.
8.2. Labels must be machine-made or printed legibly.
8.3. Legend drugs that are not classified as controlled substances must be packaged in a container labeled with the following information:
   (a) Dispensing physician's name, address and telephone number.
   (b) Patient's name
   (c) Date dispensed
   (d) Name of drug
   (e) Full directions for use
   (f) Appropriate ancillary label(s), such as "Keep Refrigerated" or "This drug may cause drowsiness."

   …

8.5. The directions "Take as directed" are permitted only as an exception to the general rule requiring full directions for use, because they are not specific and can lead to patient confusion and error.


7.1. Dispensing physicians shall package legend drugs in appropriate containers. The Board recognizes the United States Pharmacopeia standards as expressed in USP DI as the standard reference for determining legend drug packaging requirements.
   (a) If a legend drug is susceptible to light, it must be packaged in a light-resistant container, as specified in USP DI.
   (b) If a legend drug is susceptible to moisture, it must be packaged either in a well-closed container or in a tight container, as specified in USP DI.
   (c) Paper or plastic bags, boxes or envelopes do not meet packaging requirements for legend drugs and should not be used.
7.2. All legend drugs must be dispensed in containers that comply with the child-resistant packaging standards mandated by the Federal Poison Prevention Packaging Act of 1970 (PPPA).
   (a) The Board recognizes that under the PPPA child-resistant packaging is to be the rule and not the exception.
   (b) The Board further recognizes that under the PPPA there are specific exceptions to the requirement of child-resistant packaging.
      (1) If the patient receiving the legend drug requests, or if the prescriber determines that it is appropriate, a legend drug may be dispensed in a noncomplying container that is not child-resistant.
Conclusion: Dispensing naloxone by valid prescription does not violate West Virginia law and may be done on premises of the distribution program by a physician or PA.

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 license sanctions. The patient or volunteer who distributed or administered naloxone to recipients who were not prescribed this agent could be charged with practicing medicine without a license. We cannot say that a person who saved a life in this way would actually be charged with a crime or harshly punished if convicted, but the act would be technically illegal. We found no provision that made it a crime to possess a legend drug without a prescription.

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

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

35 W. VA. CODE ANN. § 30-3-14(j).
36 W. VA. CODE ANN. § 30-3-13 (West 2007).
Non-compliance with prescription and other professional practice rules may carry license sanctions or fines. 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. Blatant non-compliance, cutting corners, cover-ups, and sloppy record-keeping have resulted in the imposition of professional censure and criminal charges.

37 W. VA. CODE ANN. § 30-3-14(c):
The Board may deny an application for license or other authorization to practice medicine and surgery … in this state and may discipline a physician … or otherwise lawfully practicing in this state who, after a hearing, has been adjudged by the Board as unqualified due to any of the following reasons: …(13) Prescribing, dispensing, administering, mixing or otherwise preparing a prescription drug … other than in good faith and in a therapeutic manner in accordance with accepted medical standards and in the course of the physician’s … professional practice.

38 W. VA. CODE ANN. § 30-3-14(j):
Whenever it finds any person unqualified because of any of the grounds set forth in subsection (c) of this section, the Board may enter an order imposing one or more of the following:
(1) Deny his or her application for a license or other authorization to practice medicine and surgery or podiatry;
(2) Administer a public reprimand;
(3) Suspend, limit or restrict his or her license or other authorization to practice medicine and surgery … for not more than five years, including limiting the practice of that person to, or by the exclusion of, one or more areas of practice, including limitations on practice privileges;
(4) Revoke his or her license or other authorization to practice medicine and surgery … or to prescribe or dispense controlled substances for a period not to exceed ten years;
…
(7) Require him or her to practice under the direction of a physician … designated by the Board for a specified period of time; and
(8) Assess a civil fine of not less than one thousand dollars nor more than ten thousand dollars.

39 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).
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.

41 Plaintiff v. City of Parkersburg, 176 W.Va. 469 (1986); Restatement (Second) of Torts §282 (1993).
“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.43

“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.44 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.45 A death or injury resulting from an unauthorized administration of a low risk medication prescribed to a non-patient is arguably too unforeseeable a result to establish liability. Informing clients of the need to contact first responders and administer the necessary resuscitation procedures to overdose victims can further mitigate the risk of any liability under these circumstances.

Any practice within the scope of the practitioner’s usual duties is covered by malpractice insurance, which will pay for any litigation arising out of that practice according to the terms of the insurance contract. Naloxone prescription

to prevent opiate overdose is a practice accepted by a significant number of physicians and is within the scope of practice for providers working with the general population. In the case of volunteer providers, the US Volunteer Protection Act shields volunteers for acts committed within the scope for their work for a non-profit or government agency, so long as the acts are not criminal, reckless or grossly negligent and unless a state expressly rejects the protection offered by the VPA.\(^{46}\)

**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 West Virginia 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.  

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.

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47 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.