

HEALTH**LOCAL HEALTH OFFICERS AND DEPARTMENTS – EMERGENCY
MEDICAL SERVICES – PHYSICIANS – DRUGS – LEGAL
RESTRICTIONS RELATING TO PROPOSED NALOXONE
DISTRIBUTION PROGRAM**

April 30, 2003

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Commissioner
Baltimore City Health Department*

You have requested our opinion concerning a proposed program of the Baltimore City Health Department to prevent deaths from heroin overdoses. The program, called “Staying Alive,” would teach illicit drug users how to reduce the risk of overdose and would distribute naloxone, a drug used to treat overdoses, to heroin users. An individual receiving naloxone would be instructed how to administer the drug to other illicit drug users. You pose two questions:

1. Would a physician who prescribes naloxone as part of the Staying Alive program be subject to criminal prosecution or professional censure?
2. Would an individual to whom naloxone is prescribed be vulnerable to criminal prosecution if that individual administered the drug to someone experiencing a heroin overdose?

For the reasons set forth in this opinion, the answers to your questions are as follows:

1. A physician who prescribed naloxone to a participant in the Staying Alive program for treatment of *that participant* would not be liable for criminal prosecution or professional censure. However, if the physician prescribed the drug to a participant with the understanding that the participant would administer it to another individual who was not a patient of the physician, the physician might be subject to criminal prosecution and disciplinary action for aiding the unauthorized practice of medicine and for violation of State laws relating to prescription drugs.

2. Similarly, a participant in the Staying Alive program would not be liable to criminal prosecution if the participant were prescribed naloxone for the participant's own use. However, if the participant were prescribed the drug on the understanding that he or she would administer it to another person, the participant might be subject to criminal prosecution for the unauthorized practice of medicine, for the unlicensed provision of emergency medical services, and for violation of State laws pertaining to prescription drugs.

These legal impediments may be eliminated if legislation were enacted to provide exceptions to the laws relating to prescription drugs and the practice of medicine. In the meantime, the Health Department could appeal to the appropriate prosecuting and regulatory agencies to exercise their prosecutorial discretion to permit the Health Department to operate a pilot program without fear of prosecution.

I

Background

A. *Naloxone*

Death from a heroin overdose is usually the result of respiratory failure. Naloxone hydrochloride ("naloxone") is an injectable "opiate antagonist" – *i.e.*, it reverses the depressive effects of drugs like heroin on the respiratory system. Treatment with naloxone can reverse respiratory failure in a few minutes.¹ Burris, et al., *Legal Aspects of Providing Naloxone to Heroin Users in the United States*, 12 Int'l. J. Drug Policy 237, 238 (2001). The drug has been used in medical settings for 30 years and is considered the standard of care for treating heroin overdoses. As a result, naloxone is routinely used by emergency medical personnel to offset the effects of heroin. *See id.* at pp. 237-39.

Naloxone has a low risk of side effects and no potential for abuse. Burris, *supra*, at pp.238-39. It is not a controlled dangerous

¹ Heroin binds to certain receptors in the brain stem, making the brain insensitive to the build-up of carbon dioxide in the blood, and thereby impedes a person's normal impulse to breathe. Naloxone is believed to displace heroin at those receptors and thus to trigger the individual's breathing mechanisms. Burris, *supra*, at p.238.

substance. *See* 21 C.F.R. §1308.12(b)(1) (excluding naloxone from Schedule II); Annotated Code of Maryland, Criminal Law Article (“CR”), §5-403(b)(2) (same). However, the Food and Drug Administration has not licensed it for “over-the-counter” distribution. Instead, under federal and State law, it is only available pursuant to a prescription. *See* USP DI, Approved Drug Products and Legal Requirements (23rd ed. 2003) (including naloxone on list of prescription drugs); *see also* 21 U.S.C. §353(b)(1); Annotated Code of Maryland, Health-General Article (“HG”), §21-220(a).

B. “Staying Alive”

You advise that there are 40,000 injection drug users in Baltimore City. During the past year approximately 340 drug users in the City died from overdoses. Nine out of ten of those deaths were attributed to heroin overdoses. Approximately 50 percent of heroin addicts experience at least one non-fatal overdose, and 70 percent of users witness an overdose by another addict. Most heroin overdoses occur in the presence of another person, often an “injection partner” of the overdose victim. Burris, *supra*, at pp.237, 239.

In response, the Baltimore City Health Department has designed the Staying Alive program with the goal of reducing drug overdose deaths in Baltimore City. The program will educate illicit drug users in overdose prevention and management. Health educators will train participants in various first aid skills, including rescue breathing. In addition, the program will provide detailed instruction on naloxone and its effects on a heroin overdose. Program staff will teach participants how to administer the drug by intramuscular injection.

An illicit drug user who completes the education course will receive a certificate from the Health Commissioner, together with an overdose response kit. Each overdose response kit will include a vial of naloxone, ten single-use intramuscular needles and syringes, a packet of alcohol swabs, and a packet of protective mouth barriers for rescue breathing.

The Health Department hopes to reach a total of 2,500 injection drug users and to distribute 800 overdose response kits in the highest risk areas of the City during the first two years of the program. Researchers at Johns Hopkins University and the University of Maryland will help evaluate the effect of the program.

You state that public health agencies in several other jurisdictions have implemented naloxone distribution programs in order to reduce the number of deaths from heroin overdose and have reported positive results.

You ask whether physicians involved in such a program in Maryland could be vulnerable to professional discipline, and whether physicians and participating drug addicts could be subject to criminal prosecution.

II

Analysis

As a general rule, State law accords broad discretion to physicians to prescribe drugs for their patients, particularly drugs that are not controlled substances. However, the Staying Alive program, as it is currently envisioned, would provide for the dispensing and distribution of naloxone beyond the physician-patient relationship. As we understand it, a physician would prescribe and dispense naloxone to a heroin addict who participates in the program with the understanding that the participant would later administer the drug to another drug user, perhaps an “injection partner” of the participant, if the participant believed that the other individual was suffering a heroin overdose. The physician would not necessarily have a physician-patient relationship with the individual to whom the drug would be administered – indeed, that person might well be unknown to either the physician or the program. In essence, the participating addict would be enlisted as a specialized emergency medical technician for heroin overdoses.

The distribution of a prescription drug to a program participant, for administration to another individual unknown to the prescribing physician, raises issues under State laws governing the practice of medicine, the provision of emergency medical services, and the dispensing and distribution of prescription drugs.

A. Potential Liability of Physician

1. Possible Violations of Medical Practice Act

Prescribing medication is part of the practice of medicine as defined by the Maryland Medical Practice Act. *See* Annotated Code of Maryland, Health Occupations Article (“HO”), §14-101(k)(2)(i) (“practice medicine” includes “diagnosing ... treating ... [and]...

prescribing for ... any physical, mental, or emotional ailment or supposed ailment of an individual ... by ... drug...”). A physician’s authority to dispense prescription medications is recognized in the Maryland Pharmacy Act. *See* HO §12-102(c)-(d), (f)-(g). However, a physician may dispense prescription drugs only to a patient of the physician. COMAR 10.13.01.04C.²

The Medical Practice Act allows a physician to delegate medical duties in accordance with “rules, regulations, and orders” of the Board of Physician Quality Assurance (“BPQA”).³ HO §14-306(a). For example, a physician may delegate medical acts to other health care professionals, including licensed emergency medical technicians. HO §14-306(b); Annotated Code of Maryland, Education Article (“ED”), §13-516(f).

The BPQA has adopted regulations governing the delegation of medical acts to individuals who are not otherwise regulated by a State licensing board. Those regulations require the delegating physician to:

- (1) Evaluate the risk to the patient and the outcome of the delegated acts;
- (2) Delegate only those technical acts that are customary to the practice of the supervising physician;
- (3) Delegate only those technical acts for which the assistant has been trained;
- (4) Be responsible for the acts of the assistant; and
- (5) Supervise the assistant.

COMAR 10.32.12.03A.

² The law also requires the physician to provide a written prescription and to maintain certain records concerning the drugs dispensed. COMAR 10.13.01.04D-E, H, K.

³ During its recently concluded session, the General Assembly passed legislation under which the BPQA will be renamed the “State Board of Physicians” effective July 1, 2003. Senate Bill 500 (2003).

These regulations pose a hurdle for the Staying Alive program, especially in that they require the physician to assess the outcome and risk to the patient (*i.e.*, the overdosing addict) and to “supervise” the delegated act (*i.e.*, the administration of naloxone). First, under the Staying Alive program as it is currently envisioned, the delegating physician would not necessarily have an opportunity to make an individualized assessment of outcome and risk with respect to the person to whom the drug is administered.

Second, it appears unlikely that the physician could provide the required supervision. The regulations elaborate on the degree of supervision required when a physician delegates various types of “technical acts” to an unlicensed individual. *See* COMAR 10.32.12.04. The regulations permit a physician to delegate, without on-site supervision, “technical acts which include but are not limited to” a number of activities, including the provision of medication in certain circumstances. In particular, a physician may allow an unlicensed person to:

provid[e] sample packets of medication, selected by a physician who is physically present at the time of selection, to patients as directed by the delegating physician and in conformance with [§12-102(a), (d), (f) of the Maryland Pharmacy Act]⁴;

COMAR 10.32.12.04(D)(1)(h). A physician also may delegate “preparing and administering oral drugs” without on-site supervision. COMAR 10.32.12.04D(1)(i). However, the administration of a naloxone injection does not fall within either of these specifically authorized delegations. The inclusion of the phrase “but not limited to” in the introductory clause of Regulation .04D suggests that other unlisted medical acts may be delegated without on-site supervision, although it does not provide any criteria for determining what those acts might be.

Another portion of the BPQA regulations specifically allows a physician to delegate “preparing and administering injections limited to intradermal, subcutaneous, and intramuscular” This would apparently encompass a naloxone injection. However, the

⁴ The cross-reference to the Maryland Pharmacy Act refers to dispensing free drug samples or starter dosages to a patient of the physician with appropriate recordkeeping. HO §12-102(a), (d), (f).

regulation authorizes such a delegation “with on-site supervision.” COMAR 10.32.12.04D(2)(a).⁵ “On-site supervision” is defined as “oversight exercised by a delegating physician *who is present at the site and able to be immediately available in person* during the course of” the injection. *See* COMAR 10.32.12.02B(6) (emphasis added). The specific authorization to delegate intramuscular injections “with on-site supervision” suggests that the BPQA did not intend to authorize the delegation of intramuscular injections to an unlicensed person without on-site supervision.

Thus, while the regulations appear to allow a physician to delegate a medical act such as an intramuscular injection to a trained lay person, they contemplate that the injection will be performed in the vicinity, and with the availability, of the delegating physician at the time of treatment.

The regulations also specifically provide that a physician may not delegate the act of dispensing medication or “initiating independently any form of treatment, exclusive of cardiopulmonary resuscitation.” COMAR 10.32.12.04E. *See also* 80 *Opinions of the Attorney General* 173, 178 (1995). Based on your description of the Staying Alive program, it appears that a participant who observed an overdose and injected the overdose victim would be initiating treatment as well as administering the medication.

In summary, if a physician provided naloxone to a participant in the program with the understanding that the drug would be administered to another unidentified individual, the physician would essentially be prescribing and dispensing a prescription drug to treat an individual that the physician had never met and knew little about. In that situation, the responsibility for diagnosing the overdose and administering the medication would have been delegated to the participant. However, there is no specific provision in the BPQA regulations that allows for the delegation to a lay person of the medical act of diagnosing and administering medication by intramuscular injection without supervision.

⁵ The regulations permit the delegation of intravenous injections only with the “direct supervision” of the physician. COMAR 10.32.12.04D(2)(b). “Direct supervision” is defined as “oversight by a delegating physician who is: (a) *personally treating* the patient; and (b) *in the presence* of the assistant and the patient.” COMAR 10.32.12.02B(5) (emphasis added).

Under the BPQA regulations, a person assisting a physician who acts beyond the permissible scope of delegation by a physician is considered to be practicing medicine without a license. COMAR 10.32.12.05A. Thus, the physician could be found to be “practic[ing] medicine with an unauthorized person or aid[ing] an unauthorized person in the practice of medicine,” which is a basis for disciplinary action by the BPQA against the physician. HO §14-404(a)(18). Such discipline could include a reprimand of the physician, placement of the physician on probation, a fine, or suspension or revocation of the physician’s license to practice medicine. HO §§14-404, 14-405.1, 14-407; COMAR 10.32.12.05B. For the same reasons, the BPQA could also deny or refuse to renew a license. HO §14-205(a)(1)(iii).

2. Possible Violations of State Drug Laws

The Maryland Food, Drug, and Cosmetic Act (“the Act”) sets forth various requirements related to prescription drugs. *See* HG §21-201 *et. seq.* While the Act sets a number of requirements for dispensing prescription drugs,⁶ fundamental to the concept of a prescription drug is that it is to be used under professional supervision. That is, a prescription is required because the drug must be used under the “supervision of a health practitioner authorized by law to administer such a drug.” HG §21-220(a)(2); *see also* 21 U.S.C. §353(b)(1) (using similar language in stating federal prescription requirement). Because the Staying Alive program contemplates the administration of naloxone to a person who may be unknown to the physician, it raises a question as to whether a prescription drug is being administered under the supervision of a “health practitioner.”

Under the Act, an improperly dispensed drug is considered a “misbranded drug.” A physician who dispenses a misbranded drug could be convicted for a violation of the Act. HG §§21-220(d), 21-256(1), (5). Such a violation is a criminal misdemeanor that carries

⁶ For example, the Act requires that a drug dispensed under a prescription have a label that states: (1) the name and address of the dispenser; (2) the serial number of the prescription; (3) the date of the prescription or the date that the prescription was filled; and (4) the name of the prescriber. HG §21-221(a)(1)-(4). The label is also to contain certain additional information to the extent that information appears in the prescription, in particular: (1) the name of the patient; (2) directions for use; and (3) any cautionary statements. HG §21-221(a)(5).

a potential sentence of up to one year imprisonment and a fine of up to \$10,000. HG §21-1215(a)(1). Subsequent violations carry the possibility of an enhanced sentence of up to three years incarceration and a fine of up to \$25,000. HG §21-1215(a)(2). In addition, the statute provides for injunctive relief and civil penalties of up to \$5,000 for each day that a violation continues. HG §21-1215(b).

B. Potential Liability of Participant Who Administers Naloxone to Another Person

1. Possible Violations of Medical Practice Act

A participant in the Staying Alive program who received naloxone to administer to others might be vulnerable to criminal prosecution for the unauthorized practice of medicine. As noted above, the definition of “practice medicine” in the Maryland Medical Practice Act includes prescribing and treating with medication. HO §14-101(k)(2)(i). An individual may not practice medicine in Maryland without a license. HO §§14-301, 14-601.⁷ There is no provision that explicitly permits a physician to delegate to an unlicensed person the authority to perform a future medical act on an unidentified individual or to administer a naloxone injection in the absence of the physician. Thus, a participant in the program who was provided naloxone and later administered the drug to another drug user, might be considered to be practicing medicine without a license.

An individual who practices medicine without a license is subject to criminal prosecution. Such an offense is a misdemeanor punishable by imprisonment for up to 5 years and a fine of up to \$50,000. HO §14-607(a)(1), (4). In addition, the BPQA could issue a cease and desist order or seek injunctive relief against the participant. HO §14-206(e).

2. Possible Violations of Emergency Medical Services Law

The administration of naloxone to a drug user experiencing an overdose is a form of emergency medical assistance that is separately regulated by State law. The Emergency Medical Services

⁷ Individuals who are licensed emergency services providers may provide emergency medical services without being licensed as a physician. HO §14-301; ED §13-516.

Law defines “emergency medical services” to include “medical services provided prehospital to prevent imminent death or aggravation of illness or injury ...” Annotated Code of Maryland, Education Article (“ED”)§13-516(a)(5). This definition appears to encompass the activities for which participants will be trained in the Staying Alive program.

The Emergency Medical Services Law generally prohibits a lay person from providing emergency medical services without a license or certificate from the State Emergency Medical Services Board (“EMS Board”). ED §13-516(b). Violation of the licensing requirement is a misdemeanor that could result in a fine of up to \$1,000 and imprisonment of up to one year. ED §13-516(b)(4).

However, there are a number of exceptions to the licensing requirement. For example, the licensing requirement does not apply to “an individual who is not engaged in providing emergency medical services on a regular basis who provides emergency medical services at the scene of a medical emergency in rare instances.” ED §13-516(b)(2)(iii). The sporadic provision of first aid and naloxone by a program participant to another heroin addict in the midst of an overdose may well fall within this exception. On the other hand, it might be argued that the exception was not designed to cover specially trained individuals who are expected to respond to specifically anticipated emergencies.

3. Possible Violations of State Drug Laws

The participant could also face the same criminal liability under the Maryland Food, Drug, and Cosmetic Act as outlined above with respect to the physician. In addition, the unauthorized distribution of a prescription drug could violate the State criminal code. In particular, a person may dispense a prescription drug only pursuant to a prescription by an “authorized provider.” Annotated Code of Maryland, Criminal Law Article (“CR”), §5-701(b). An “authorized provider” is defined as a person “licensed, registered, or otherwise allowed to administer, distribute, dispense, or conduct research on” drugs “in the course of professional practice or research.” CR §5-101(d)(1). In addition, a person may not distribute, or possess with intent to distribute, a prescription drug, unless otherwise authorized by law. CR §5-701(d)(1). An individual who violates either of these proscriptions is guilty of a misdemeanor that carries a potential sentence of up to two years imprisonment and a fine of up to \$1,000. CR §5-701(e).

As currently designed, a participant in the Staying Alive program would administer naloxone to an injection partner without a prescription specific to the person receiving the injection. Thus, it could be argued that the participant would be distributing the drug without legal authorization. In those circumstances, the participant may be subject to criminal prosecution under CR §5-701.

4. Immunity from Civil Liability

A participant who administered naloxone to an addict experiencing an overdose would likely be immune from *civil* liability to the addict. *See* Annotated Code of Maryland, Courts & Judicial Proceedings Article, §5-603(c). That statute provides that an individual is not civilly liable for providing medical aid to a victim during an emergency if the aid is provided without compensation in a “reasonably prudent” manner and if care of the victim is relinquished when licensed medical personnel become available.

C. Resolution of Legal Impediments to Program

These legal impediments to the Staying Alive program may be eliminated through modification of the program, or the enactment of legislation specifically designed to permit such a program.

1. Modification of Program

A physician and a program participant should not be at risk of criminal liability if, as part of the program, the physician establishes a patient-physician relationship with a drug user participant and prescribes naloxone for *that participant*.⁸ In our opinion, it is also permissible for the physician, in the course of prescribing the drug, to instruct another person, such as a family member or friend, how

⁸ A physician is subject to professional discipline if the physician “sells, prescribes, gives away, or administers drugs for illegal or illegitimate medical purposes.” HO §14-404(a)(27). The prescription of naloxone to an injection drug user at risk of an overdose for the addict’s own use would not be an “illegal or illegitimate” medical purpose. *See* Burris, *supra*, at p. 242.

There is some debate about the wisdom of providing naloxone to a heroin addict in advance of an overdose. *See Distributing “miracle drug” for heroin questioned; City’s plan to let addicts give Narcon called unwise*, Baltimore Sun, p.1B (March 10, 2003). We express no opinion on the merits of such a policy.

to assist the participant in administering the drug. For example, it would be permissible for a physician to provide naloxone to “injection partners” and to instruct each of them how to assist the other. In that case, neither of the participants would be engaging in the unauthorized practice of medicine. However, as a practical matter, it may be unlikely that an overdosing addict would be capable of initiating his or her own treatment, including administration of the drug.

2. Legislation

Appropriate legislation enacted by the General Assembly could resolve issues of potential criminal liability and professional discipline under State law.

A possible model for legislation authorizing a naloxone distribution program is the Insect Emergency Treatment Program enacted by the General Assembly in 1995. *See* HG §13-701 *et seq.* That program authorizes a lay person to administer a subcutaneous injection of epinephrine in an emergency situation to a person suffering an adverse reaction to an insect sting. An individual who satisfies training and other requirements set forth in the statute may obtain a prescription for pre-measured doses of epinephrine and the necessary paraphernalia for the administration of subcutaneous injections. HG §13-707. Because the prescription, dispensing, and administration of the drug are authorized by statute, there would be no criminal liability arising from participation in the Insect Sting Emergency Treatment Program. In addition, the statute also explicitly provides immunity from civil liability for the participant and the prescribing physician. HG §13-708.

In another analogous context, the General Assembly enacted legislation to remove legal clouds over sterile needle exchange programs targeted at injection drug users to inhibit the spread of HIV infection. *See* HG §24-801 *et seq.* (Baltimore City needle exchange program); HG §24-901 *et seq.* (Prince George’s County needle exchange program). That legislation provides limited immunity for participants and staff of the needle exchange programs from the State criminal laws prohibiting possession of drug paraphernalia. HG §§24-808, 24-908.

Finally, another state has enacted legislation that expressly authorizes naloxone distribution programs. To ensure that a program like Staying Alive would be lawful, the New Mexico Legislature amended its state laws to permit administration of naloxone by

unlicensed persons in specific circumstances. That legislation allows an individual other than a licensed health care professional to administer an opioid antagonist, such as naloxone, as authorized by federal, state, or local regulations. Chapter 228, §1, Laws of New Mexico 2001, *codified at* N.M. Stat. Ann. §§24-23-1, 24-23-2. Under that legislation, an unlicensed person who administers naloxone to another individual is immune from civil liability *or criminal prosecution* if the unlicensed person (1) believes in good faith that the other person is experiencing a drug overdose, and (2) acts with reasonable care in administering the antidote. §24-23-1. The legislation also immunizes from civil or criminal liability a physician or other health care professional who prescribes, dispenses, distributes, or administers an opioid antagonist with reasonable care. §24-23-2.

The New Mexico Department of Health implemented that state’s legislation by adopting regulations. The regulations permit a person other than a licensed health care professional to administer naloxone to another person and create an Opioid Antagonist Administration Program similar in some respects to Staying Alive. *See* New Mexico Administrative Code 7.32.7. The regulations strongly recommend that administration of the drug be coupled with a call for emergency medical services. *Id.* 7.32.7.8.

3. Exercise of Prosecutorial Discretion

In anticipation of proposing legislation, the City Health Department might appeal to the relevant enforcement agencies to exercise their prosecutorial discretion to permit a pilot program to be undertaken on a temporary basis. In particular, the Health Department could seek assurances from the relevant agencies that they would not institute criminal prosecution or professional disciplinary proceedings under narrowly defined circumstances tailored to the program.

Criminal prosecutors and administrative regulatory agencies enjoy a measure of prosecutorial discretion. For example, “it is well settled that the [State’s Attorney’s] determination of which criminal charges, *if any*, to bring is a matter of prosecutorial discretion....As a general rule, whether the State’s Attorney does or does not institute a particular prosecution is a matter which rests in his discretion.” *Beverly v. State*, 349 Md. 106, 707 A.2d 91 (1998) (emphasis added). Criminal prosecutors commonly agree to forgo criminal prosecution of violations of the criminal law as part of plea

agreements or as part of an agreement to confer immunity in return for a witness' testimony.

Administrative agencies exercised similar discretion in setting enforcement priorities. It is not uncommon for administrative regulatory agencies to provide "no action" or "business review" letters that articulate the agency's enforcement intentions under specified factual circumstances. *See, e.g.*, COMAR 02.02.01.05 (procedures for obtaining "no action position" from Securities Division); COMAR 02.04.02 ("business review" procedure for inquiring as to Attorney General's antitrust enforcement intentions in specific circumstances); 17 CFR §140.99 (procedures for obtaining "no action letter" from Commodities Futures Trading Commission).

In the context of a proposed public health program involving naloxone distribution, a criminal prosecutor or administrative agency could determine that it would not be in the public interest to prosecute possible violations that arose out of a program designed to provide life-saving assistance to a population otherwise difficult to reach. Such an approach may be particularly appropriate when the program is designed as a temporary pilot project to assess its efficacy, and when the results of the pilot program would be available to the Legislature to evaluate the merits of creating statutory authorization for such a program on a more permanent basis. Such determinations could be embodied in a memorandum of understanding among the relevant agencies that carefully defined the circumstances under which the agencies would forgo prosecution. Of course, whether an agency would enter into such a memorandum of understanding or otherwise provide an assurance that it would not prosecute would be a matter within the purview of that agency.

III

Conclusion

In summary, our opinion is as follows:

(1) A physician who prescribed naloxone to a participant in the proposed Staying Alive program, for treatment of *that participant*, would not be liable to criminal prosecution or professional censure. However, if the physician prescribed the drug to a participant with the understanding that the participant would administer the drug to another individual who is not a patient of the physician, the physician may be subject to criminal prosecution and

disciplinary action for aiding the unauthorized practice of medicine and for violation of State laws relating to prescription drugs.

(2) Similarly, a participant in the program would not be liable to criminal prosecution if the participant were prescribed naloxone through the program for the participant’s own use. However, if the participant were prescribed the drug, on the understanding that he or she would administer it to another unidentified person, the participant may be subject to criminal prosecution for the unauthorized practice of medicine, for the unlicensed provision of emergency medical services, and for violation of State laws pertaining to prescription drugs.

These legal impediments may be eliminated if the proposal is modified to provide for administration of naloxone only in the context of a physician-patient relationship. Alternatively, legislative action could eliminate the possibility of criminal liability by tailoring exceptions pertinent to prescription drug requirements and to restrictions on the unauthorized practice of medicine and performance of emergency medical services. Pending enactment of such legislation, the City Health Department could seek assurances from the relevant prosecuting and regulatory agencies concerning their enforcement intentions.

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