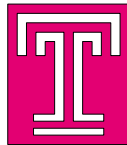


**STOPPING AN INVISIBLE EPIDEMIC: LEGAL ISSUES IN  
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# STOPPING AN INVISIBLE EPIDEMIC: LEGAL ISSUES IN THE PROVISION OF NALOXONE TO PREVENT OPIOID OVERDOSE

Scott Burris,\* Leo Beletsky,\*\* Carolyn Castagna,\*\*\* Casey Coyle,\*\*\*\* Colin Crowe\*\*\*\*\* & Jennie Maura McLaughlin\*\*\*\*\*

## I. INTRODUCTION

Early in 2008, Australian actor Heath Ledger died in his Manhattan apartment as a result of a drug overdose<sup>1</sup> caused by a cocktail of prescription drugs, including powerful prescription opioids.<sup>2</sup> Death by drug overdose is not particularly unusual among celebrities. Indeed, in the same week that Ledger died, actor Brad Renfro<sup>3</sup> also joined fallen stars like

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1. James Barron, *Medical Examiner Rules Ledger's Death Accidental*, N.Y. TIMES, Feb. 7, 2008, at B3.

2. *Id.*; see also Frank D. Roylance & Meredith Cohn, *A Prescription for Danger: Actor Heath Ledger's Death Shows that Patients are Vulnerable to Overdosing on Medications*, BALT. SUN, Feb. 7, 2008, at 1C.

3. Stephen M. Silverman & Elaine Aradillas, *Coroner: Brad Renfro Died of Heroin Overdose*,

River Phoenix,<sup>4</sup> John Belushi,<sup>5</sup> Mark Tuinei,<sup>6</sup> Janice Joplin,<sup>7</sup> and Jim Morrison<sup>8</sup> in meeting a premature end by overdosing on prescription opioids, heroin, or both.

As it turns out, celebrities are not exceptional in their vulnerability to drug overdose. As is often the case with celebrity tragedies, Ledger's death briefly put the media spotlight on a major public health problem. The deaths of Ledger and Renfro are part of an epidemic of drug overdose,<sup>9</sup> which is now seriously competing with car accidents as a leading cause of death among otherwise healthy people in their youth and prime of life.<sup>10</sup> Indeed, by 2004, unintentional overdose had overtaken even such high-profile killers such as AIDS and homicide on the overall U.S. mortality tables.<sup>11</sup> Opioids are

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PEOPLE ONLINE, Feb. 8, 2008, <http://www.people.com/people/article/0,,20177159,00.html>; see also Richard Winton, *Actor Brad Renfro Died of Heroin Overdose*, L.A. TIMES, Feb. 9, 2008, at B4.

4. Seth Mydans, *Death of River Phoenix is Linked to Use of Cocaine and Morphine*, N.Y. TIMES, Nov. 13, 1993, at A8.

5. Marcia Chambers, *Pathologist Cites Heroin in Death of Belushi*, N.Y. TIMES, Sept. 19, 1985, at A26.

6. Anthony Ramirez, *Pro Football; Autopsy Finds Tuinei Died of Drug Overdose*, N.Y. TIMES, May 12, 1999, at D2.

7. George Gent, *Death of Janis Joplin Attributed to Accidental Heroin Overdose*, N.Y. TIMES, Oct. 6, 1970, at 50.

8. Elizabeth Goodman, *Jim Morrison's Death May be Reinvestigated*, ROLLINGSTONE.COM, July 10, 2007, <http://www.rollingstone.com/rockdaily/index.php/2007/07/10/jim-morrison-death-may-be-reinvestigated/> (citing new evidence that the true cause of Morrison's death was a heroin overdose) (last visited May 21, 2009).

9. Mary Engel & Daniel Costello, *Overdose Deaths on the Rise, CDC Says*, L.A. TIMES, Jan. 26, 2008, at A15.

10. For example, in 2005, 11,345 white men between the ages of eighteen and thirty-nine were killed in auto accidents; over six thousand died of unintentional drug poisoning. See NAT'L CTR. FOR INJURY PREVENTION & CONTROL, CTRS. FOR DISEASE CONTROL & PREVENTION, WEB-BASED INJURY STATISTICS QUERY AND REPORTING SYSTEM (WISQARS), LEADING CAUSES OF DEATH REPORTS, 1999-2005 (2005), available at <http://webappa.cdc.gov/sasweb/ncipc/leadcaus10.html>.

11. In 2004, an estimated 23,144 people died of unintentional poisoning. Leonard J. Paulozzi & Yongli Xi, *Recent Changes in Drug Poisoning Mortality in the United States by Urban-Rural Status and by Drug Type*, 17 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 997, 999 tbl.2 (2008); see also CTRS. FOR DISEASE CONTROL AND PREVENTION, HIV/AIDS SURVEILLANCE REPORT: CASES OF HIV INFECTION AND AIDS IN THE UNITED STATES AND DEPENDENT AREAS, 2005 17 tbl.7 (2007), available at <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2005report/pdf/2005SurveillanceReport.pdf> (noting that in 2005, the estimated number of deaths of persons with AIDS in the United States and dependent areas was 17,011); UNITED STATES DEP'T OF JUSTICE, CRIME IN THE UNITED STATES 2005: MURDER (2006), available at [http://www.fbi.gov/ucr/05cius/offenses/violent\\_crime/murder\\_homicide.html](http://www.fbi.gov/ucr/05cius/offenses/violent_crime/murder_homicide.html) (noting that 16,692 were estimated to have been murdered in 2005).

the main fuel.<sup>12</sup> In 1999, 3543 people died from opioid overdose; by 2004, that number had climbed to 9091,<sup>13</sup> and by all accounts the death toll continues to rise.<sup>14</sup> In both rural and urban areas across the United States, opioid overdose is now being recognized as one of the most pressing of public health problems.<sup>15</sup>

The Ledger death was representative in another way. Overdose is a serious risk for heroin users, but, confounding stereotypes, the rise in opioid overdose in the United States is being driven mainly by substantial increases in deaths caused by legal drugs, particularly prescription pain medications like oxycodone (better known by its brand-name, OxyContin).<sup>16</sup> These deaths are a side-effect of a very positive development: the

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12. See Paulozzi & Xi, *supra* note 11.

13. NAT'L DRUG INTELLIGENCE CTR., METHADONE DIVERSION, ABUSE, AND MISUSE: DEATHS INCREASING AT ALARMING RATE (2006), <http://www.usdoj.gov/ndic/pubs25/25930/dlinks.htm#Figure1> [hereinafter NAT'L DRUG INTELLIGENCE CTR., ABUSE AND MISUSE].

14. See Aron J. Hall et al., *Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities*, 300 J. AM. MED. ASS'N 2613, 2614 (2008), available at <http://jama.ama-assn.org/cgi/content/full/300/22/2613> (noting the steady increase in overdose fatalities in West Virginia through 2006); Paulozzi & Xi, *supra* note 11, at 999; Editorial, *More Kids Dying*, N.Y. TIMES, July 18, 2008, at A18 ("Despite a decline in overall drug use, the rate at which young Americans between the ages of 15 and 24 have been dying from drug overdoses has jumped dramatically — more than doubling between 1999 and 2005."); Leonard J. Paulozzi, United States Dep't of Health & Human Servs., *Trends in Unintentional Drug Overdose Deaths*, Testimony Before the United States Senate Subcommittee on Crime & Drugs Committee on the Judiciary and the Caucus on International Narcotics Control (Mar. 12, 2008), available at <http://www.cdc.gov/Washington/testimony/2008/t20080312a.htm> ("[T]he mortality statistics through 2005 probably underestimate the present magnitude of the problem.").

15. See *supra* note 14; see also Peter J. Davidson et al., *Fatal Heroin-Related Overdose in San Francisco, 1997-2000: A Case for Targeted Intervention*, 80 J. URB. HEALTH 261, 261 (2003); G.L. Oxman et al., *Heroin Overdose Deaths—Multnomah County, Oregon, 1993-1999*, 49 MORBIDITY & MORTALITY WKLY. REP. 633, 633-34 (2000); Nina G. Shah et al., *Unintentional Drug Overdose Death Trends in New Mexico, USA, 1990-2005: Combinations of Heroin, Cocaine, Prescription Opioids and Alcohol*, 103 ADDICTION 126, 128 (2008); D. Solet et al., *Unintentional Opioid Overdose Deaths—King County, Washington, 1990-1999*, 49 MORBIDITY & MORTALITY WKLY. REP. 636, 636-38 (2000). Opioid overdose is a facet of an even larger overdose problem encompassing deaths from non-opioid drugs, including cocaine and amphetamines. Leonard Paulozzi et al., *Increasing Deaths from Opioid Analgesics in the United States*, 15 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 618, 621 (2006). The cost of care for overdose victims is staggering. As far back as 2000, before the steep rise, poisonings resulted in \$2.24 billion worth of direct medical costs and \$23.7 billion in lost productivity. P. Corso et al., *Incidence and Lifetime Costs of Injuries in the United States*, 12 INJ. PREVENTION 212, 215 (2006).

16. Paulozzi & Xi, *supra* note 11, at 1002; see also Paulozzi, *supra* note 15, at 624 (noting that prescription medications have surpassed illicit drugs as the most common cause of fatal drug poisoning); Leonard J. Paulozzi, *Opioid Analgesic Involvement in Drug Abuse Deaths in American Metropolitan Areas*, 96 AM. J. PUB. HEALTH 1755, 1755-56 (2006) [hereinafter Paulozzi, *Metropolitan Areas*].

greater availability of opioids for people suffering serious pain. Some of the victims are legitimate users who have accidentally used too much;<sup>17</sup> others are using illegally diverted pills.<sup>18</sup> Still, other victims are prescribed the drug, but use it non-therapeutically.<sup>19</sup> Thus, overdose cuts across the usual divide between legal and illegal drugs, posing a challenge for health care providers, public health agencies, and harm reduction organizations.<sup>20</sup>

The heart of the challenge is the possibility that things could be different: overdose is a public health problem that can be

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17. CATHERINE SANFORD, DEATHS FROM UNINTENTIONAL DRUG OVERDOSES IN NORTH CAROLINA, 1997-2001: A DHHS INVESTIGATION INTO UNINTENTIONAL POISONING-RELATED DEATHS 6 (2002), available at <http://injuryfreenc.ncdhhs.gov/About/unintentionalpoisoningsReport.pdf> (finding that of the males who died over a five-year period from unintentional drug poisoning and the source of the drug was known, eighteen percent had a prescription for the drug); see also Theodore J. Cicero et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 827, 832 (2007) (explaining that “[o]ur data indicate that there is a statistically significant correlation between legitimate, therapeutic exposure to opioid analgesics, and the magnitude of abuse,” but does not indicate how many legitimate users became abusers or how many abusers had no prescriptions to begin with).

18. Andrew Rosenblum et al., *Prescription Opioid Abuse Among Enrollees into Methadone Maintenance Treatment*, 90 DRUG & ALCOHOL DEPENDENCE 64, 67 (2007) (noting that a national survey of methadone maintenance clinic clients who primarily abuse a prescription opioid showed that eighty-six percent reported a dealer was a frequent source, fifty-four percent said friends or relatives were frequent sources, but only twenty-eight percent named a doctor’s prescription as a frequent source); see also Deni Carise et al., *Prescription OxyContin Abuse Among Patients Entering Addiction Treatment*, 164 AM. J. PSYCHIATRY 1750, 1753 (2007) (“Seventy-eight percent . . . reported that OxyContin had not been prescribed for any medical reason.”); Hall et al., *supra* note 14, at 2613 (reporting that pharmaceutical diversion was associated with approximately sixty-three percent of overdose deaths in West Virginia in 2006).

19. Theodore J. Cicero, James A. Inciardi & Alvaro Munoz, *Trends in Abuse of OxyContin and Other Opioid Analgesics in the United States: 2002-2004*, 6 J. PAIN 662, 668 (2005) (explaining that, while seventy percent of the OxyContin abusers listed a physician’s prescription as the major source of OxyContin, eighty-seven percent also had past and current histories of multiple drug abuse); see also Hall et al., *supra* note 14, at 2613 (reporting that approximately twenty-one percent of 2006 West Virginia overdose deaths exhibited evidence of doctor-shopping).

20. Ernest Drucker & Allan Clear, *Harm Reduction in the Home of the War on Drugs: Methadone and Needle Exchange in the USA*, 18 DRUG & ALCOHOL REV. 103, 104-06 (1999). Harm reduction, as it relates to drug abuse, began in the United States with the use of narcotic maintenance at the turn of the nineteenth century. Maintenance was out of vogue, though, until the 1960s when a clinical trial published in the *Journal of the American Medical Association* led to greater acceptance of methadone for the treatment of heroin addiction. In an effort to reduce HIV infection among intravenous drug users, Tacoma, New York, and San Francisco began needle exchange programs in the 1980s. *Id.*; see also C.A. McKnight et al., *Syringe Exchange Programs – United States, 2005*, 56 MORBIDITY & MORTALITY WKLY. REP. 1164, 1164 (2007) (noting that, as of November 2007, there were 185 needle exchange programs in the United States).

solved. Unlike many of the other leading causes of death, death from opioid overdose is almost entirely preventable,<sup>21</sup> and preventable at a low cost.<sup>22</sup> Opioids kill by depressing respiration, a slow mode of death that leaves plenty of time for effective medical intervention.<sup>23</sup> Overdose is rapidly reversed by the administration of a safe and inexpensive drug called naloxone. Naloxone strips clean the brain's opioid receptors and reverses the respiratory depression causing almost immediate withdrawal.<sup>24</sup> A growing number of harm reduction organizations in the United States are offering overdose prevention programs that provide injection drug users with resuscitation training and take-home doses of naloxone.<sup>25</sup> One innovative program in North Carolina is targeting users of legal opioid medications.<sup>26</sup>

This brings us to the law. Though normally preventable, opioid overdose is too often not prevented, and laws and law enforcement practices play a significant role in this failure. Part of the overdose epidemic is a side effect of the War on Drugs. Illicit drugs fluctuate in potency;<sup>27</sup> illicit drug users are often afraid to call 911 when they observe overdoses,<sup>28</sup> and drug users who have been incarcerated face an elevated risk of overdose at release,<sup>29</sup> most likely because they have lost touch

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21. See generally Tinka Markham Piper et al., *Overdose Prevention for Injection Drug Users: Lessons Learned from Naloxone Training and Distribution Programs in New York City*, HARM REDUCTION J. 4:3 (2007), available at [http://www.harmreduction.org/downloads/skoop\\_1.pdf](http://www.harmreduction.org/downloads/skoop_1.pdf).

22. Karl A. Sporer, *Strategies for Preventing Heroin Overdose*, 326 BRIT. MED. J. 442, 445 (2003) (characterizing naloxone as "inexpensive").

23. Paulozzi, *supra* note 15, at 625; see also Sporer, *supra* note 22, at 443.

24. See Sporer, *supra* note 22, at 443-44.

25. Daniel Kim, Kevin S. Irwin & Kaveh Khoshnood, *Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality*, 99 AM. J. PUB. HEALTH 402 (forthcoming Mar. 2009) (manuscript at 4), available at <http://www.ajph.org/cgi/doi/10.2105/AJPH.2008.136937>.

26. PROJECT LAZARUS: WILKES COUNTY, NORTH CAROLINA 1 (2007), available at <http://www.harmreduction.org/downloads/North%20Carolina%20Naloxone%2007.pdf>.

27. PROFESSIONAL PERSPECTIVES ON ADDICTION MEDICINE: UNDERSTANDING OPIOID ADDICTION & THE FUNCTION OF METHADONE TREATMENT 45 (Mark Stanford & Donald Avoy eds., 2006).

28. Catherine T. Baca & Kenneth J. Grant, *What Heroin Users Tell Us About Overdose*, 26 J. ADDICTIVE DISEASES 63, 65-67 (2007).

29. Ingrid A. Binswanger et al., *Release from Prison – A High Risk of Death for Former Inmates*, 356 NEW ENG. J. MED. 157, 160-63 (2007); see also Karen H. Seal et al., *Predictors and Prevention of Nonfatal Overdose Among Street-Recruited Heroin Users in the San Francisco Bay Area, 1998-1999*, 91 AM. J. PUB. HEALTH 1842, 1842 (2001).

with the potency of street drugs and their own tolerance for opioids. To complicate matters, the epidemic also reflects an important truce in the War, which has allowed the substantial (and generally beneficial) increase in the availability of opioids for pain. Better access to analgesics like oxycodone and methadone helps millions of people cope with serious pain, but it inevitably entails more legitimate patients living with a risk of overdose and more pills flowing through the supply chain that may be diverted to illicit use.<sup>30</sup> As more doctors prescribe such drugs, it is difficult to avoid an increase in unnecessary or improper prescriptions arising out of physician misjudgment about patient needs, physician-shopping by patients, and even, occasionally, what amounts to physician drug-pushing.

A more prosaic, but no less important, legal barrier to widespread naloxone access is the Food and Drug Administration's (FDA) classification of naloxone as a prescription drug. This means that public health and harm reduction agencies cannot distribute naloxone like condoms or sterile syringes. Instead, naloxone must be prescribed by a properly licensed health care provider after an individualized evaluation of the patient. Because health care providers have to be involved, naloxone programs must deal with concerns about liability, which among doctors can be powerful even when they are not well-founded in fact.<sup>31</sup> The prescription status raises the cost of naloxone distribution and makes it illegal to give naloxone to lay people willing to administer the drug to others suffering an overdose. The FDA's labeling of naloxone as an injected medicine adds a second cost. While injection drug users know how to use needles, pill users may not. Delivering naloxone

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30. See, e.g., Hall et al., *supra* note 14 (noting the relationship between increased prescribing for pain care and overdose incidence in West Virginia). See generally LOIS A. FINGERHUT, CTRS. FOR DISEASE CONTROL AND PREVENTION, INCREASES IN POISONING AND METHADONE-RELATED DEATHS: UNITED STATES, 1999-2005 (2008), available at <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/poisoning/poisoning.pdf> (data on the sources of diversion of prescription drugs to illicit use are sparse, in spite of both the policy and health importance of the issue).

31. At the bottom is the stigma of drug abuse, which has sometimes seemed to render the deaths of illegal drug users invisible to public health agencies and spread a veil of silence over the problem of accidental or deliberate misuse of opioids that have been legally prescribed. See, e.g., E.B. Ritson, *Alcohol, Drugs and Stigma*, 53 INT. J. CLINICAL PRAC. 549, 550 (1999) (observing that stigma is at least one explanation for the relative paucity of research on opioid overdose and its prevention).

via nasal spray is more user-friendly and may be a safe and effective way of increasing the availability of naloxone for pre-hospital use. Unfortunately, without clinical testing and FDA approval of an intranasal formulation, no manufacturer can produce naloxone as a nasal spray. Programs that want to use this mode must purchase generally expensive after-market kits and assemble the kits themselves or through a compounding pharmacy. The status of naloxone as a prescription drug also raises barriers to entry for new producers. Currently, only two manufacturers, Hospira<sup>32</sup> and Amphastar,<sup>33</sup> produce injectable naloxone.<sup>34</sup> The paucity of manufacturers allows those companies to raise prices substantially, which could be fatal to distribution programs relying on limiting funding.<sup>35</sup>

This Article comprehensively examines the legal barriers overdose prevention programs must surmount. Part II describes the epidemic and the current interventions. Part III addresses the legal issues that arise in public health programs that provide naloxone to opioid drug users (ODUs). Across

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32. Hospira Product Catalog, <http://www.hospira.com/Products/productcatalog.aspx> (searching "naloxone" in product name box returns listings for 0.4 mg/mL and 4 mg/mL injectable naloxone) (last visited May 21, 2009).

33. Amphastar Pharmaceuticals Products, <http://www.amphastar.com/products.htm> (listing 2 mg/mL injectable naloxone) (last visited May 21, 2009); *see also* Int'l Medication Sys., <http://www.ims-limited.com/index.htm> (last visited Jan. 15, 2009) (explaining that IMS is the manufacturing subsidiary of Amphastar and listing naloxone as one of its products) (last visited May 21, 2009).

34. AM. SOC'Y OF HEALTH-SYS. PHARMACISTS, BULLETIN: NALOXONE INJECTION (2007), *available at* <http://www.ashp.org/Import/PRACTICEANDPOLICY/PracticeResourceCenters..> As far as we can determine, both companies buy the active pharmaceutical ingredient from a third company, Mallinckrodt Chemicals.

35. There is yet another policy factor affecting entry into the market: naloxone itself is not a controlled substance. *See* 21 U.S.C. § 812 (2006) (omitting naloxone as a controlled substance). However, naloxone is manufactured from a controlled substance, noroxymorphone. *See* Controlled Substances: Proposed Revised Aggregate Production Quotas for 2008, 73 Fed. Reg. 37,496 (proposed June 6, 2008) (to be codified at 21 C.F.R. pt. 1308) (including noroxymorphone as a Schedule II controlled substance). Like other scheduled opioids, such as morphine, the production and import of noroxymorphone are subject to quotas set by the Drug Enforcement Agency (DEA). *See* 21 U.S.C. § 826 (Supp. 2008) (granting the Attorney General the authority to "determine . . . and establish production quotas for each basic class of controlled substance in . . . [Schedule] II . . . to be manufactured each calendar year to provide for the estimated medical . . . needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks"); 28 C.F.R. § 0.100 (2008) (assigning the Attorney General duties under 21 U.S.C.A. § 826 to the Administrator of the DEA); *see also* 28 C.F.R. § 0.104 (2008) (re-delegating the authority granted to the Administrator of the DEA under 28 C.F.R. § 0.100 to the Deputy Administrator of the DEA). A substantial increase in the production of naloxone would require a commensurate increase in the quota.



the United States, at least fifty-two naloxone overdose prevention programs are now operating, with many more in the planning stage.<sup>36</sup> Although models vary, programs typically operate as a part of existing harm reduction initiatives that provide sterile syringes, health services, and drug treatment referrals to injection drug users.<sup>37</sup> The programs offer training to drug users in the causes, signs, and treatment of overdose, and provide take-home doses of naloxone with instructions on its use and risks.<sup>38</sup> Because naloxone is a prescription drug, there are a variety of limitations on how it may be distributed and administered.<sup>39</sup> Programs must recruit health professionals with the authority to prescribe and dispense the drug. Medical licensure laws place limits on the extent to which programs may explicitly train and deputize drug users to use naloxone on others.<sup>40</sup> This substantially increases the financial and administrative burdens on programs. The design and operation of programs has also been influenced by liability concerns.<sup>41</sup>

In Part IV, the Article discusses legislative measures that can reduce actual and perceived barriers to the distribution of prescription naloxone, as well as the reluctance of individual drug users to seek emergency assistance when they witness an overdose. Four states have passed legislation aimed at either reducing liability of health care professionals or deputizing non-professionals,<sup>42</sup> and two have enacted legislation aimed at reducing the unwillingness of bystanders to call for help.<sup>43</sup> We critique the current laws and suggest a model. Finally, the Article briefly addresses the problem of naloxone's status as a

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36. See Kim et al., *supra* note 25 (manuscript at 4); see also Karl A. Sporer & Alex H. Kral, *Prescription Naloxone: A Novel Approach to Heroin Overdose Prevention*, 49 ANNALS EMERGENCY MED. 172, 173 (2007) (listing six locations); *Overdose Rescue Kits Save Lives* (National Public Radio broadcast Jan. 2, 2008), available at <http://www.npr.org/templates/story/story.php?storyId=17578955> ("New data compiled for NPR by researcher Alex Kral of the consulting firm RTI International show that more than 2,600 overdoses have been reversed in 16 programs operating across the nation.").

37. McKnight, *supra* note 20, at 1165.

38. Piper, *supra* note 21, at 2-3.

39. *Id.* at 5-6.

40. *Id.* at 5.

41. Sporer & Kral, *supra* note 36, at 173-75.

42. Piper, *supra* note 21, at 5 (describing New York, New Mexico, and Connecticut laws); see also CAL. CIV. CODE ANN. § 1714.22 (West Supp. 2009).

43. ALASKA STAT. § 12.55.155(d)(19) (2008); N.M. STAT. ANN. § 30-31-27.1 (West 2008).

prescription, injectable medication and calls upon the responsible federal agencies to take a stronger role in supporting the research and testing of new formulations of the medicine.

## II. NALOXONE AND ITS USES IN OVERDOSE TREATMENT

### A. *The Problem: Opioid Overdose*

The term “opioids” denotes a family of pharmaceutical agents related to opium, a substance harvested from the poppy plant.<sup>44</sup> Since ancient times, humans have used opioids for their analgesic (pain-relief), euphoric, and narcotic (sleep-inducing) properties. This family of agents includes substances naturally derived from opium (e.g., opium, morphine, codeine), semi-synthetic opiate derivatives derived through complex chemical processing (e.g., heroin), as well as substances that are artificially synthesized to mimic the effects of opioids (e.g., fentanyl, methadone).<sup>45</sup> As a function of their common pharmacological characteristics, these substances share key structural similarities. This is why naloxone, itself an opium derivative, can act as an antagonist against all these agents by blocking their chemical effects on the central nervous system.<sup>46</sup>

Opioid overdose can occur under a variety of circumstances. Time spent in prison or in treatment can lower an individual’s tolerance, making her former customary hit a lethal dose.<sup>47</sup> Users of street drugs also cannot reliably determine the potency or identity of the products they consume.<sup>48</sup> Drugs like heroin can vary widely in purity.<sup>49</sup> Increased overdose mortality is positively correlated with both spikes in purity and periods in which purity fluctuates greatly in a locality.<sup>50</sup> Addi-

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44. BEN-ERIC VAN WYK & MICHAEL WINK, *MEDICINAL PLANTS OF THE WORLD* 225 (Timber Press 2004).

45. *AVERY’S DRUG TREATMENT* 490-93 (Trevor M. Speight & Nicholas H.G. Holford eds., Wiley-Blackwell 4th ed. 1997) (1976) [hereinafter *AVERY’S*].

46. *Id.* at 497; see also Sporer, *supra* note 22, at 443.

47. Seal, *supra* note 29.

48. Robert S. Hoffman et al., *A Descriptive Study of an Outbreak of Clenbuterol-Containing Heroin*, 52 *ANNALS EMERGENCY MED.* 548, 548 (2008).

49. Shane Darke et al., *Fluctuations in Heroin Purity and the Incidence of Fatal Heroin Overdose*, 54 *DRUG & ALCOHOL DEPENDENCE* 155, 157 (1999).

50. *Id.* at 159.

tionally, unbeknownst to a buyer, a street drug may be altered through substitution, dilution, contamination, or adulteration.<sup>51</sup> Patients who are prescribed opiate medications may misuse them, mistakenly take an improper dosage, abuse them, or take them non-therapeutically.

Prescription opiates are sometimes diverted from their intended users to persons who abuse the drug.<sup>52</sup> Before reaching a prescription holder, drugs are transported from the manufacturer to distributors, pharmacies, hospitals, or clinics.<sup>53</sup> As the DEA requires careful records of each pill's journey from maker to user,<sup>54</sup> it is known that significant quantities of prescription opioids are stolen each year.<sup>55</sup> From 2000 to 2003, 12,894 theft/loss incidents were reported to the federal government, representing a loss of twenty-eight million dosage units of six opioids.<sup>56</sup> A 2006 government study found that significant amounts of methadone were lost both in transit and directly from hospitals, pharmacies, distributors, and clinics.<sup>57</sup>

In addition to wholesale theft, friends, family members, or caretakers of a patient can misappropriate the drugs for personal use or sell them for profit.<sup>58</sup> Sometimes these users legitimately suffer pain, but for one reason or another cannot access the health care system to get their own medications. Patients can also exaggerate the extent of their needs for these medications or accumulate excess supplies of opioid agents through "doctor shopping" in order to then abuse or divert

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51. Hoffman, *supra* note 48, at 548.

52. NAT'L DRUG INTELLIGENCE CTR., PHARMACEUTICALS DRUG THREAT ASSESSMENT (2004), available at <http://www.usdoj.gov/ndic/pubs11/11449/diversion.htm> [hereinafter PHARMACEUTICALS DRUG THREAT ASSESSMENT].

53. UNITED STATES DRUG ENFORCEMENT ADMIN., CONTROLLING DRUGS OR OTHER SUBSTANCES ch. 1 (2005), available at <http://www.usdoj.gov/dea/pubs/abuse/1-csa.htm#Controlling>.

54. *Id.*

55. David E. Joranson & Aaron M. Gilson, *Drug Crime Is a Source of Abused Pain Medications in the United States*, 30 J. PAIN & SYMPTOM MGMT. 299, 299 (2005) ("An important but mostly overlooked diversion source involves thefts, including armed robberies, night break-ins, and employee and customer pilferage.").

56. *Id.*

57. NAT'L DRUG INTELLIGENCE CTR., ABUSE AND MISUSE, *supra* note 13 (76,992 du of methadone lost in transit and 89,655 du stolen directly from hospitals, distributors, pharmacies, and clinics).

58. James A. Inciardi et. al., *Mechanisms of Prescription Drug Diversion Among Drug-Involved Club- and Street-Based Populations*, 8 PAIN MED. 171, 171-72 (2007).

the drugs.<sup>59</sup> Both prescription and entirely illicit opioids are readily available in black markets throughout the nation.<sup>60</sup>

The relative contribution of each diversion pathway to the overdose problem is unknown.<sup>61</sup> Available theft reports, criminal justice data, surveys of drug users, and medical examiner data provide snapshots of the problem but not a complete picture.<sup>62</sup> In a national survey of persons entering drug treatment programs, seventy-eight percent of oxycodone users reported that a doctor never prescribed them the drug for a medical reason.<sup>63</sup> Only seven percent reported obtaining the drug through an illegitimate prescription.<sup>64</sup> A survey of methadone maintenance program patients similarly found that only twenty-eight percent of patients used prescriptions as a frequent source of the drug.<sup>65</sup> More patients reported obtaining their prescription opioid of choice from a dealer (eighty-six percent) and/or a friend or family member (fifty-four percent).<sup>66</sup> Almost sixty percent stated that they regularly used two or more sources to get their drug.<sup>67</sup> However, both of these studies surveyed persons seeking treatment, and pre-

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59. PHARMACEUTICALS DRUG THREAT ASSESSMENT, *supra* note 52 (“Individuals who divert and acquire pharmaceuticals through doctor shopping do so by visiting numerous doctors in an attempt to obtain multiple prescriptions for the drugs, particularly prescription narcotics such as OxyContin, Percocet, and Percodan. Doctor shoppers often falsify or exaggerate symptoms in order to obtain prescriptions for pharmaceuticals and often visit doctors they believe to be more likely to write prescriptions for such drugs. The individuals typically have their prescriptions filled at multiple pharmacies in order to avoid detection.”); *see also* Inciardi et al., *supra* note 58, at 171-72 (predicting Internet pharmacies would be an increasingly important diversion source). *But see* Rosenblum, *supra* note 18, at 67 (finding that only three percent of persons entering treatment reported using Internet pharmacies as a primary source of prescription opioids).

60. OFFICE OF NAT’L DRUG CONTROL POLICY, HEROIN FACTS & FIGURES (2008), available at [http://www.whitehousedrugpolicy.gov/drugfact/heroin/heroin\\_ff.html](http://www.whitehousedrugpolicy.gov/drugfact/heroin/heroin_ff.html) [hereinafter HEROIN FACTS & FIGURES]; *see also* OFFICE OF NAT’L DRUG CONTROL POLICY, PRESCRIPTION DRUGS FACTS & FIGURES (2008), available at [http://www.whitehousedrugpolicy.gov/drugfact/prescriptn\\_drgs/rx\\_ff.html](http://www.whitehousedrugpolicy.gov/drugfact/prescriptn_drgs/rx_ff.html) [hereinafter PRESCRIPTION DRUGS FACTS & FIGURES].

61. *See* Joranson, *supra* note 53, at 299-301 (“National discussion about pain medication abuse and diversion should be better informed by reliable information about whether abused drugs are coming from those registered to handle controlled substances lawfully or from those who engage in criminal activities.”).

62. *See id.*

63. Carise, *supra* note 18, at 1753.

64. *Id.* at 1752-53 (finding that out of 1425 individuals who used OxyContin, only 100 reported receiving an illegitimate prescription).

65. Rosenblum, *supra* note 18, at 67.

66. *Id.*

67. *Id.*

scription opioid sources may vary widely among different drug-using populations.<sup>68</sup> According to a 2006 U.S. Department of Health and Human Services survey of the general population, out of those who admitted to abusing prescription drugs, only 3.9% reported obtaining their most recently abused pain relievers from a dealer,<sup>69</sup> while 55.7% reported getting the drug from a friend or relative for free, and 19.1 % from a doctor.<sup>70</sup>

There can be no doubt, however, that fatal opioid overdose, long a chronic health problem in the United States, is now a rapidly growing one.<sup>71</sup> National surveillance data suggest that almost 83,000 Americans died from this form of overdose between 1999 to 2005, with over 16,000 fatalities in 2005 alone.<sup>72</sup> Opioid overdose death has seen a sharp increase over the last decade, especially in the category of overdose from prescription medications.<sup>73</sup> Because of gaps in the surveillance system, the actual figure is likely to be substantially higher.<sup>74</sup>

The risks to prescription drug users are captured in the stories of unfortunate celebrities. The perils faced by street drug users were dramatized in the spring and summer of 2006, when 179 people died in Philadelphia, Pennsylvania after they

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68. See Inciardi et. al., *supra* note 58, at 174, 175 (finding that users of street drugs like heroin preferred to obtain their abused prescriptions from doctors because of a sense that dealers were inconsistent, as contrasted with club drug users who preferred dealers or "pill brokers").

69. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., DEP'T OF HEALTH & HUMAN SERVS., 2006 NAT'L SURV. ON DRUG USE & HEALTH 30 (2007), available at <http://www.oas.samhsa.gov/nsduh/2k6nsduh/2k6results.pdf>.

70. *Id.*

71. FINGERHUT, *supra* note 30; L. Paulozzi & J. Annett, *Unintentional Poisoning Deaths – United States, 1999-2004*, 56 MORBIDITY & MORTALITY WKLY. REP. 93 (2007), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5605.pdf> ("Nearly all poisoning deaths in the United States are attributed to drugs, and most drug poisonings result from the abuse of prescription and illegal drugs.").

72. FINGERHUT, *supra* note 30 (listing national figures for unintentional poisoning deaths caused by opioids and their synthetic derivatives. Deaths caused by these agents (T codes 40.1-40.4) in 2005 add up to 16,011.)

73. See *id.*; see also Xi & Paulozzi, *supra* note 11, at 1000.

74. Interview by Leonard Paulozzi with Leo Beletsky, Author (Mar. 13, 2008) (transcript on file with the author) (noting that statistical estimates of opioid overdose fatalities under-report the true extent of the problem). For a variety of logistical, administrative, and toxicological reasons, data for about one fourth of all fatal unintentional poisonings lacks specific pharmacological information about what actually caused the death. *Id.* Experience suggests that out of the thousands of these cases in the "unspecified" category, many, if not most, are caused by opioids or synthetic opioid derivatives. *Id.* Thus, the actual number of overdose deaths caused by opioid overdose is likely substantially higher than what is included in the official statistics for the specific substance categories. *Id.*

took the powerful opioid fentanyl instead of the heroin they thought they had bought.<sup>75</sup> To put that number in context, on an annualized basis, overdose was as big a killer in 2006 as homicide in a city that had declared homicide to be its number one problem.<sup>76</sup> It was also two times the number of AIDS deaths and nearly four times the number of deaths from motor vehicle accidents.<sup>77</sup> The same batch of drugs caused comparable death tolls in other cities, including Chicago and Detroit.<sup>78</sup>

Despite these shockingly high death tolls, opioid overdose has historically attracted scant attention from public health authorities, academics, and the media.<sup>79</sup> The discrepancy between the resources dedicated to alleviating this problem versus some of the other less deadly public health issues underscores the stigma related to drug abuse, especially expressed in terms of public apathy towards heroin addicts. In the context of the racial and class characteristics often associated with heroin abuse, these disparities raise ethical concerns.<sup>80</sup>

### B. Public Health Response

A range of interventions can help prevent or effectively respond to opioid overdose episodes. In the realm of criminal justice, supply and demand reduction are two of the principal

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75. See Control of a Chemical Precursor Used in the Illicit Manufacture of Fentanyl as List I Chemical, 72 Fed. Reg. 20,039 (Apr. 23, 2007) (to be codified at 21 C.F.R. pt. 1310); see also T. S. Jones et al., *Nonpharmaceutical Fentanyl-Related Deaths –Multiple States, April 2005-March 2007*, 57 MORBIDITY & MORTALITY WKLY. REP. 793, 793 (2008).

76. See Ian Urbina, *New Philadelphia Mayor's Top Task: Fight Crime*, N.Y. TIMES, Nov. 23, 2007, at A26.

77. PA. DEP'T OF HEALTH, HEALTH STATISTICS & RESEARCH: SELECTED CAUSES OF DEATH BY AGE, RACE, AND SEX BY COUNTY FOR PENNSYLVANIA RESIDENTS IN 2005 (2005), available at [http://www.dsf.health.state.pa.us/health/lib/health/VitalFiche/death/multiyr/2002-2006/d99myr5\\_3.pdf](http://www.dsf.health.state.pa.us/health/lib/health/VitalFiche/death/multiyr/2002-2006/d99myr5_3.pdf).

78. See Jones et al., *supra* note 75, at 793; see also Control of a Chemical Precursor Used in the Illicit Manufacture of Fentanyl as List I Chemical, 72 Fed. Reg. at 20,041 (“Between April 18, 2005, and November 9, 2006, the Chief Medical Examiner of Cook County, Illinois confirmed 314 fentanyl-related deaths in the city of Chicago and its suburbs. Between August 27, 2005, and December 31, 2006, the Wayne County Medical Examiner confirmed 230 fentanyl-related deaths in the city of Detroit and the surrounding county.”).

79. Shane Darke & Wayne Hall, *Heroin Overdose: Research and Evidence-Based Intervention*, 80 J. URB. HEALTH 189, 189 (2003).

80. See Kim, *supra* note 25 (manuscript at 5). See generally Sandro Galea et al., *Racial/Ethnic Disparities in Overdose Mortality Trends in New York City, 1990-1998*, 80 J. URB. HEALTH 201 (2003).

approaches.<sup>81</sup> Through production quotas,<sup>82</sup> eradication programs, stricter border controls, and intensive street-level disruption of the drug markets, supply reduction focuses on interrupting the production and distribution of the drugs to the black market.<sup>83</sup> Stiff criminal penalties, public education campaigns, and mandatory drug testing are geared towards increasing the perceived and actual costs of drug abuse.<sup>84</sup>

Despite sustained and often growing investment of financial and human resources, these strategies have not been effective in reducing drug abuse in general, and the incidence of overdose in particular.<sup>85</sup> These trends do not support much hope that the supply of or demand for these drugs will become easier to control in the coming decades. If anything, the growing role of opiates in analgesic and palliative care among the aging and ailing U.S. population,<sup>86</sup> as well as the falling price, increasing purity, and fentanyl adulteration of heroin<sup>87</sup> will likely continue to propel the incidence of overdose in the fore-

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81. See HEROIN FACTS & FIGURES, *supra* note 60; see also UNITED STATES DRUG ENFORCEMENT ADMIN., OFFICE OF DIVERSION CONTROL, ACTION PLAN TO PREVENT THE DIVERSION AND ABUSE OF METHADONE, available at [http://www.deadiversion.usdoj.gov/drugs\\_concern/methadone/methadone.htm](http://www.deadiversion.usdoj.gov/drugs_concern/methadone/methadone.htm) (2008); OFFICE OF DIVERSION CONTROL, UNITED STATES DRUG ENFORCEMENT ADMIN., ACTION PLAN TO PREVENT THE DIVERSION AND ABUSE OF OXYCONTIN (2001), available at [http://www.deadiversion.usdoj.gov/drugs\\_concern/oxy-codone/abuse\\_oxy.htm](http://www.deadiversion.usdoj.gov/drugs_concern/oxy-codone/abuse_oxy.htm) (2008).

82. See Controlled Substances: Proposed Revised Aggregate Production Quotas for 2008, 73 Fed. Reg. at 37,496 ("The proposed revised 2008 aggregate production quotas represent those quantities of controlled substances in schedules I and II that may be produced in the United States in 2008 to provide adequate supplies of each substance for the estimated medical, scientific, research and industrial needs of the United States.").

83. See, e.g., Press Release, Office of Diversion Control, U.S. Drug Enforcement Admin., Advisory: Methadone Hydrochloride Tablets USP 40 mg (Dispersible) (Jan. 1, 2008), available at [http://www.deadiversion.usdoj.gov/pubs/pressrel/methadone\\_advisory.htm](http://www.deadiversion.usdoj.gov/pubs/pressrel/methadone_advisory.htm) (reporting that manufacturers of 40 mg methadone tablets have agreed to voluntarily restrict distribution to facilities using the drug for addiction treatment).

84. *Id.*

85. HEROIN FACTS & FIGURES, *supra* note 60 (noting the increases in the resources dedicated to curbing drug trafficking and abuse, coupled with the national statistics clearly demonstrating the failure of these resources to produce the desired effect); see also Lisa D Moore & Amy Elkavich, *Who's Using and Who's Doing Time: Incarceration, the War on Drugs, and Public Health*, 98 AM. J. PUB. HEALTH 782, 782-85 (2008). See generally ROBERT J. MACCOUN & PETER REUTER, DRUG WAR HERESIES: LEARNING FROM OTHER VICES, TIMES, AND PLACES (2001).

86. See, e.g., James F. Cleary & Paul P. Carbone, *Palliative Medicine in the Elderly*, 80 CANCER 1335, 1336 (1997) (discussing the important role of opiates in cancer care for the growing number of elderly patients).

87. See HEROIN FACTS & FIGURES, *supra* note 60 (discussing the unprecedented purity and rock-bottom prices on heroin across the United States).

seeable future. Given the extremely beneficial and humane uses of opioid analgesics, a return to the days when doctors were afraid to prescribe opioids for fear of being accused of drug pushing would be an unmitigated disaster. In this context, finding ways to prevent fatalities from opioid overdose *given greater* availability becomes a clear public health priority.

Naloxone is a generically manufactured opioid that lacks any psychoactive or addictive qualities.<sup>88</sup> It blocks the effects of opiates by binding to three types of opioid receptors in the central nervous system.<sup>89</sup> It is standard practice for first responders to inject naloxone when summoned to the scene of drug overdose.<sup>90</sup> Timely administration of naloxone produces almost universal success.<sup>91</sup>

Naloxone treatment to reverse an opioid overdose has an extremely low rate of life-threatening side-effects, though the experience can be unpleasant. Upon administration, habitual opioid users typically experience symptoms of acute withdrawal, including physiological and mental cravings for the drug, confusion, and dysphoria.<sup>92</sup> The antagonistic effects of this agent typically last around forty-five minutes.<sup>93</sup> Depending on the blood levels of the opioid responsible for the overdose, re-administration could, in theory, be required to avoid a relapse under the influence of longer acting opioids, but in practice, appears rarely indicated.<sup>94</sup>

Despite the existence of this life-saving treatment, victims of opioid overdose often do not receive timely assistance.<sup>95</sup> Individuals present at an overdose may not recognize an overdose when it happens or may have incorrect information about how

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88. AVERY'S, *supra* note 45, at 497, 541.

89. *Id.* at 345-47, 541.

90. See Karl A. Sporer, *Acute Heroin Overdose*, 130 ANNALS OF INTERNAL MED. 584, 585-87 (1999).

91. See *id.*; see also AVERY'S, *supra* note 45, at 497.

92. See AVERY'S, *supra* note 45, at 497.

93. See Sporer, *supra* note 90, at 585.

94. See *id.*; see also J.J. Boyd et al., *Recurrent Opioid Toxicity After Pre-hospital Care of Presumed Heroin Overdose Patients*, 50 ACTA ANAESTHESIOLOGICA SCANDINAVICA 1266, 1270 (2006) ("[A]llowing presumed heroin overdose patients to sign out after pre-hospital care with naloxone appears to be safe. When transported to an ED, and if no adverse events related to heroin use are evident on arrival, a 1-h observation period after naloxone administration seems to be adequate."); Darke & Hall, *supra* note 79, at 195.

95. Shane Darke & Deborah Zador, *Fatal Heroin 'Overdose': A Review*, 91 ADDICTION 1765, 1766-67 (1996).



to treat it. Witnesses who were engaged in illicit drug use are often reluctant to call for help out of fear of legal repercussions.<sup>96</sup> In response, public health and harm reduction organizations in the United States and abroad have initiated overdose prevention programs. These typically consist of training drug users and other potential witnesses in first aid, in ways to spot and appropriately report signs of the most common side effects of naloxone administration, and in how to summon help treatment services.<sup>97</sup> They also train participants to administer naloxone, and provide “take-home” doses for use in the event of an overdose.<sup>98</sup> Such distribution schemes have helped save thousands of lives over just the past two or three years. In addition to the life-saving potential of these programs, their graduates may use drugs less frequently and may be more likely to seek treatment than untrained counterparts.<sup>99</sup> Despite some speculation to the contrary, there is no evidence that users equipped with naloxone will increase their risky behavior and their dosage of the drug.<sup>100</sup>

Since heroin overdose accounts for only a part of the overall problem, there is growing interest in expanding access to naloxone beyond the heroin user population. With so many deaths caused by prescription opioid pharmaceuticals, doctors arguably should make it standard practice to prescribe emergency doses of naloxone to patients receiving these drugs for pain. Patient education and training, including instruction of the patients’ families or primary caregivers, should also accompany the prescription of naloxone to ODUs. The first overdose prevention program aimed at users of prescription opioids is Project Lazarus in North Carolina.<sup>101</sup> At the urging of the program’s creators, the State medical board issued a

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96. Baca & Grant, *supra* note 28, at 63 (“Three or more persons were reported to be present during 80 of the 95 most recently witnessed overdoses. An ambulance was called in only 42 of the 95 witnessed overdoses. Seventy-five percent of the respondents who witnessed an overdose stated concern over police involvement was an important reason for delay or absence of a 911 call for help.”); *see also* Darke & Zador, *supra* note 95, at 1769.

97. Baca & Grant, *supra* note 28, at 66-67; Darke & Zador, *supra* note 95, at 1769.

98. Kerstin Dettmer, Bill Saunders & John Strang, *Take Home Naloxone and the Prevention of Deaths from Opiate Overdose: Two Pilot Schemes*, 322 BRIT. MED. J. 895, 895 (2001).

99. *Id.*

100. *Id.*

101. *See* PROJECT LAZARUS, *supra* note 26, at 8 (identifying, in Table 2, thirteen specific categories of patients for whom prescription of take-home doses of naloxone is advised); *see also* Dan Hurley, *Emergency Antidote, Direct to Addicts*, N.Y. TIMES, Dec. 11, 2007, at F5.

policy statement encouraging prescription of naloxone to patients receiving certain powerful opioid medications.<sup>102</sup> In its pilot area of Wilkes County, the Project staff will distribute naloxone administration kits, complete with the agent, syringes with special attachments for intranasal delivery, and informational pamphlets.<sup>103</sup> The Project will also provide physicians with information about instructing their patients on ways to recognize and respond to opioid overdose. Administration of naloxone will serve as the key part of a larger intervention, which will also include provision of first aid and appropriate procedures for calling for help.<sup>104</sup> The evaluation of this novel program is ongoing; if it shows promise, its experience may serve as a key model for wide implementation in other jurisdictions as a way to curb the egregious rates of overdose among ODUs.

### III. LEGAL ISSUES IN NALOXONE PRESCRIPTION PROGRAMS

In this Part, the Article considers the basic legal issues confronting a program of training and equipping drug users and others to provide naloxone as first aid at an overdose scene. Because naloxone is a prescription drug, these public health programs must be operated along formally medical lines by licensed health care providers, and important limitations exist on who may receive naloxone. Here, we address prescribing and dispensing the drug, as well as the question of professional liability.<sup>105</sup>

#### A. *Prescribing Naloxone: The Law*

Naloxone is a prescription drug but not a controlled substance,<sup>106</sup> so it is subject to the normal rules governing pre-

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102. See PROJECT LAZARUS, *supra* note 26.

103. *Id.* at 9.

104. *Id.*

105. The conclusions presented in this Part are based on a state-by-state analysis conducted in the summer of 2007 by Casey Coyle, Jennie Maura McLaughlin, and David Corbett under the direction of Professor Burriss. Detailed memos setting out laws and analysis for each state are available at Temple University, Project on Harm Reduction in the Health Care System, <http://www.temple.edu/lawschool/phrhcs/Naloxone/Naloxonepolicy.htm> (last visited May 21, 2009).

106. Some prescription drugs, like morphine, oxycodone, and Ritalin, are controlled substances. A controlled substance is any drug or substance included in the schedules I to V of

scriptions. To the extent that they are explicitly set out, these rules are found in the laws and regulations governing the practice of medicine and allied health professions in each state. Surprisingly, few states have explicit rules defining a physician's authority to prescribe or setting criteria for allowable prescriptions.<sup>107</sup> Nonetheless, a common-sense set of requirements have achieved virtually universal acceptance and can be found in disciplinary cases, controlled-substances prosecutions,<sup>108</sup> and a variety of statutes and regulations governing

the U.S. Controlled Substances Act, 21 U.S.C.A. §§ 801-904 (West 2006), and the controlled substances schedules of individual states, recognized to have a potential for abuse or lead to physical or psychological dependence. Naloxone has been excluded by the U.S. and several states from schedule II, so it is a legend drug that requires a prescription. *See, e.g.,* LA. REV. STAT. ANN. § 40:964 (2001) (explaining that naloxone is excluded from Schedule II of the Uniform Controlled Dangerous Substances Law); MO. ANN. STAT. § 195.017 (West 2004) (explaining that naloxone is excluded from the opiate derivatives included in Schedule II of the Narcotic Drug Act).

107. *See, e.g.,* 14-130-001 R.I. CODE R. § 1.93 (Weil 2007) (stating that a prescription can only be written by a "practitioner duly authorized by law in the state in which he practices to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose"). In addition, section 40-47-113 of the Code of Laws of South Carolina provides:

(A) It is unprofessional conduct for a licensee initially to prescribe drugs to an individual without first establishing a proper physician-patient relationship. A proper relationship, at a minimum, requires that the licensee make an informed medical judgment based on the circumstances of the situation and on the licensee's training and experience and that the licensee:

- (1) personally perform and document an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan;
- (2) discuss with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options; and
- (3) ensure the availability of the licensee or coverage for the patient for appropriate follow-up care.

(B) Notwithstanding subsection (A), a licensee may prescribe for a patient whom the licensee has not personally examined under certain circumstances including, but not limited to, writing admission orders for a newly hospitalized patient, prescribing for a patient of another licensee for whom the prescriber is taking call, prescribing for a patient examined by a licensed advanced practice registered nurse, a physician assistant, or other physician extender authorized by law and supervised by the physician, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.

(C) Prescribing drugs to individuals the licensee has never personally examined based solely on answers to a set of questions is unprofessional.

S.C. CODE ANN. §40-47-113 (Supp. 2008).

108. While naloxone is not a controlled substance, the case law on illegal prescription of controlled substances is an important source of guidance on what constitutes a legitimate prescription. *See* U.S. v. Moore, 423 U.S. 122, 142-43 (1975) ("The evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of 'professional practice.' . . . [H]e gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. . . . He did not regulate the dosage at all, prescribing as much

more or less specific aspects of health practice.<sup>109</sup>

For a prescription to be valid, these norms require that it be written by a properly licensed practitioner for legitimate medical purposes and in the normal course of professional practice.<sup>110</sup> The prescribing practitioner must establish a doctor-patient relationship with the recipient. This entails sufficient contact with the patient to allow an informed profes-

and as frequently as the patient demanded.”).

109. *See, e.g.*, ARIZ. REV. STAT. ANN. § 32-1401(27)(j) (2008) (“‘Unprofessional conduct’ includes. . . . [p]rescribing, dispensing or administering any controlled substance or prescription-only drug for other than accepted therapeutic purposes.”); IOWA CODE ANN. § 124.401(5) (West 2007) (“It is unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of the practitioner’s professional practice . . . .”); W. VA. CODE ANN. § 30-3-14(c)(13) (LexisNexis 2007) (“The Board may deny an application for license or other authorization to practice medicine and surgery or podiatry in this state and may discipline a physician . . . licensed or otherwise lawfully practicing in this state who, after a hearing, has been adjudged by the Board as unqualified due to. . . . [p]rescribing, dispensing, administering, mixing or otherwise preparing a prescription drug, including any controlled substance under state or federal law, 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 . . . .”).

In Nebraska, unprofessional conduct for medical practitioners includes:

(7) Prescribing drugs to an individual without first establishing a proper physician-patient relationship. A proper physician-patient relationship requires that the physician make an informed medical judgment upon examination, diagnosis, and formulation of a treatment plan and that arrangements exist to insure availability of the physician or physician coverage for follow-up patient care;

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(18) Prescribing, selling, administering, or distributing, any drug legally classified as a prescription drug other than for proper medical purposes;

....

(26) Failure to keep and maintain adequate records of treatment or service; adequate records means legible medical records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment.

172 NEB. ADMIN. CODE § 88-013 (2007).

110. *See, e.g.*, MASS. GEN. LAWS ch. 94C, § 19(a) (2007) (“A prescription for a controlled substance to be valid shall be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice.”); NEV. REV. STAT. ANN. § 453.381(1) (West 2000) (“[A practitioner] may prescribe . . . controlled substances only for a legitimate medical purpose and in the usual course of his professional practice.”); UTAH CODE ANN. § 58-17b-606(2) (West 2004) (“A practitioner may prescribe legend drugs in accordance with this chapter that, in his professional judgment and within the lawful scope of his practice, he considers appropriate for the diagnosis and treatment of his patient.”); MONT. ADMIN. R. 24.156.625(1)(p) (2007) (stating 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”).

sional evaluation of the patient's conditions and needs. This would normally involve examining of the patient as necessary to determine that the medication is indicated and safe for the patient, taking a history on matters relevant to the care, discussing the treatment plan and its alternatives with the patient, and taking steps to ensure adequate follow-up care.<sup>111</sup> Normally a doctor-patient relationship is memorialized (and evidenced by) the creation of a patient record. 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.<sup>112</sup>

Prescribing requirements as they would apply to naloxone are summarized in Table 1, at the end of this sub-part. In all states, a physician may legally participate in an overdose prevention program by prescribing naloxone to ODUs at risk of overdose. Naloxone dispensing programs typically have limited resources, however, and may wish to deploy other health care providers along with or instead of physicians. Physicians are authorized to delegate some aspects of the prescription process to other health professionals, and some professionals have independent prescribing authority.<sup>113</sup> Here, we focus on Physician Assistants (PAs) and Advanced Practice Nurses (APNs).<sup>114</sup> Both kinds of professionals have or can obtain prescribing authority in most states.<sup>115</sup> Even where they cannot

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111. 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.

112. See, e.g., *In re DiLeo*, 661 So. 2d 162, 168 (La. Ct. App. 1995) (finding that there are differing schools of thought on the appropriate dosage of medication to supply to a patient, and a physician was acting in good faith when prescribing medications in a reasonable manner to patients experiencing pain symptoms); Md. Op. Att'y Gen. No. 03-009 (2003) ("As a general rule, State law accords broad discretion to physicians to prescribe drugs for their patients, particularly drugs that are not controlled substances.").

113. See *infra* notes 115-17, 124-27 and accompanying text.

114. Most states have licensed nurses with advanced training to perform a wider range of health care functions than registered nurses. These advanced practice nurses go by a number of different titles, including registered nurse practitioners, advanced practice nurses, advanced practice registered nurses, and clinical nurse practitioners. In this Article, we will use the term Advanced Practice Nurse. See, e.g., Barbara Safriet, *Health Care Dollars and Regulatory Sense: The Role of Advanced Practice Nursing*, 9 YALE J. ON REG. 417, 423-24 (1992) (finding that advanced nurses, with titles and specific roles that differ from state to state, generally have more education and training than required for standard nurse licensure and perform various duties that are traditionally done by physicians).

115. See, e.g., D.C. CODE § 3-1201.02(2) (2007) (finding that prescribing is within scope of practice for advanced practice registered nurses); D.C. CODE § 3-1201.02(13) (2007) (stating that PAs may prescribe legend drugs under supervision of a physician); OHIO REV. CODE

independently prescribe, they are able to assist a supervising physician by examining patients, taking histories, and preparing prescriptions for the doctor to issue.

PAs are generally required to practice under the supervision of a physician, performing functions set out in a formal collaboration or supervision agreement within a roster of functions set out in state licensure law.<sup>116</sup> PAs may carry out many duties of the physician, including examining patients, making diagnoses, administering medications, and, in most states, writing prescriptions.<sup>117</sup> The form of physician supervision for the PA varies from state to state, and may include availability by telephone,<sup>118</sup> regular review of the PA's work,<sup>119</sup> limitations

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ANN. § 4723.43 (West 2004) (explaining that APNs working in collaboration with one or more physicians may apply to the Board of Nursing for a certificate authorizing the prescribing of medication); OHIO REV. CODE ANN. § 4730.09 (West 2004) (explaining that PAs may be delegated prescriptive authority by their supervising physician, if the PA is certified by the Board and prescribing authority is included in their physician supervisory plan); WIS. STAT. ANN. § 441.16 (West 2005) (stating that APNs may prescribe legend drugs as delegated by a collaborating physician or may apply for a prescribing license from the Board of Nursing); WIS. ADMIN. CODE MED. § 8.08 (2007) (finding that PAs may prescribe legend drugs under supervision of a physician).

116. *See, e.g.*, MASS. GEN. LAWS ch. 112, § 9E (2006) ("Physician assistants, depending upon their level of professional training and experience as determined by a supervising physician, may perform medical services of a general nature and may order tests and therapeutics in assisting physicians in private practice, in group practices or in health care facilities, consistent with any applicable bylaws and policies of such facilities. A physician assistant may order therapeutics and tests and issue written prescriptions for patients."); MONT. CODE ANN. § 37-20-401(3)-(5) (2007) ("'Physician assistant' means a member of a health care team, licensed by the board, who provides medical services that may include but are not limited to examination, diagnosis, prescription of medications, and treatment under the supervision of a physician licensed by the board . . . . 'Supervising physician' means a medical doctor or doctor of osteopathy licensed by the board who agrees to a supervision agreement and a duties and delegation agreement . . . . 'Supervision agreement' means a written agreement between a supervising physician and a physician assistant providing for the supervision of the physician assistant.").

117. *See, e.g.*, ALASKA ADMIN. CODE tit. 12, § 40.450(f) (2007) ("A physician assistant may prescribe, order, administer, or dispense a medication that is not a controlled substance only with the authorization of the physician assistant's primary collaborating physician. The authorization must be documented in the physician assistant's current collaborative plan on file with the division."); OKLA. ADMIN. CODE § 435:15-5-10(a) (2007) ("A physician assistant may issue written and oral prescriptions . . . as delegated by and within the established scope of practice of the supervising physician and as approved by the Board.").

118. *See, e.g.*, MICH. COMP. LAWS ANN. § 333.16109(2) (West 2001) (stating that physician must be continuously available by some form of electronic communication); OR. REV. STAT. ANN. § 677.515 (West 2008) (explaining that the physician must be available by phone or other form of direct communication); WYO. STAT. ANN. § 33-26-501 (2007) (permitting the physician to be off-site and available by telecommunications, if the Board finds the arrangement provides quality medical care); IDAHO ADMIN. CODE r. 22.01.04.020 (2007) (finding that the physician must be available by telephone).

on the sites where the PA may work,<sup>120</sup> or geographical limitations on how far away the physician may be.<sup>121</sup> States generally require supervision to be “continuous,” but with the sole exception of Missouri,<sup>122</sup> do not require the constant physical presence of the physician on-site with the PA.<sup>123</sup> Many states do not set out extensive supervision criteria, and in their absence, the degree of supervision is determined by the physician and the PA and defined in their collaborative agreement.<sup>124</sup>

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119. *See, e.g.*, ARIZ. REV. STAT. ANN. § 32-2531 (2008) (stating that the physician does not need to be on-site but must meet with the PA each week); HAW. CODE R. § 16-85-49(A) (Weil 2007) (requiring that the physician review patient records within seven working days); IDAHO ADMIN. CODE r. 22.01.04.020 (2007) (finding that the physician must make a monthly on-site visit); WIS. ADMIN. CODE MED. § 8.08 (2007) (stating that the physician must review and countersign each prescription within seventy-two hours).

120. *See, e.g.*, 49 PA. CODE § 18.155(a) (2007) (stating that a physician assistant may not practice in a location other than the primary practice location of the supervising physician unless that site has been registered with the Medical Board as a “satellite location”).

121. *See, e.g.*, DEL. CODE ANN. tit. 24, § 1770A(3) (2005) (requiring that the physician be available by electronic communication and able to be on-site within thirty minutes); D.C. MUN. REGS. tit. 17, § 4914 (2007) (permitting the physician to either be on-site or within a 15 mile radius of DC and available by telephone); ILL. ADMIN. CODE tit. 68, 1350.80 (2007) (stating that the supervising physician does not need to be on-site with the PA each day, but must be available within a reasonable travel distance to provide supervision if needed).

122. *See* MO. ANN. STAT. § 334.735(4) (West 2001) (“Physician assistants shall not prescribe nor dispense any drug . . . independent of consultation with the supervising physician.”); MO. CODE REGS. ANN. tit. 20, § 2150-7.135(3) (2007) (“A supervising physician . . . shall at all times be immediately available to the licensed physician assistant for consultation, assistance, and intervention within the same office facility unless making follow-up patient examinations in hospitals, nursing homes and correctional facilities . . . or unless practicing under federal law.”).

123. *See, e.g.*, ARK. CODE ANN. § 17-105-109(a) (West 2004) (“Supervision of physician assistants shall be continuous but shall not be construed as necessarily requiring the physical presence of the supervising physician at the time and place that the services are rendered.”); R.I. GEN. LAWS § 5-54-2 (2004) (“‘Supervision’ means overseeing the activities of, and accepting the responsibility for the medical services rendered by the physician assistants. Supervision is continuous, and under the direct control of a licensed physician expert in the field of medicine in which the physician assistants practice. The constant physical presence of the supervising physician or physician designee is not required. It is the responsibility of the supervising physician and physician assistant to assure an appropriate level of supervision depending on the services being rendered.”). Some states require that the collaborative agreement identify a back-up physician to supervise the PA in the absence of the primary supervising physician. *See, e.g.*, MD. CODE REGS. 10.32.03.02(B)(1) (2008) (“‘Alternate supervising physician’ means one or more physicians designated by the primary supervising physician to provide supervision when the primary supervising physician is not immediately available.”); 50-013-001 MISS. CODE R. § XXII(D)(1) (Weil 2007) (“Each protocol shall contain a detailed description of back-up coverage if the supervising physician is away from the primary office.”).

124. *See, e.g.*, S.C. CODE ANN. § 40-47-910(7) (2001) (stating that the physician does not need to be on-site, provided it is within the written guidelines between the PA and the supervising

APNs typically have more independence from supervision than PAs, but there are still regulations on the ability of APNs to prescribe prescription drugs. In the majority of states, APNs must have a collaboration agreement with a physician to practice (and within that practice to prescribe).<sup>125</sup> The supervision requirements are generally less detailed than for PAs, and in all states, APNs may prescribe without a physician being on-site.<sup>126</sup> Most states require that the collaboration agreement lay out methods of physician review and supervision,<sup>127</sup> or require that the physician be available for consultation by telephone or electronic means.<sup>128</sup> In ten states, APNs

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physician); ALA. ADMIN. CODE r. 540-X-7.28 (2007) (finding that the physician does not need to be on-site with the PA at all times, but the method of review must be in a written agreement between the PA and physician and be approved by the Medical Board); 18 VA. ADMIN. CODE § 85-50-101 (2007) (requiring that supervision plans must be included in written protocol).

125. See, e.g., KAN. STAT. ANN. § 65-1130(d) (2002) (“An advanced registered nurse practitioner may prescribe drugs pursuant to a written protocol as authorized by a responsible physician.”); MINN. STAT. ANN. § 148.235 (West 2005) (“A certified nurse practitioner who has a written agreement with a physician based on standards established by the Minnesota Nurses Association and the Minnesota Medical Association that defines the delegated responsibilities related to the prescription of drugs . . . may prescribe and administer drugs . . . within the scope of the written agreement and within practice as a certified nurse practitioner.”); R.I. GEN. LAWS § 5-34-39 (2004) (“A certified registered nurse practitioner . . . is permitted to prescribe in accordance with annually updated guidelines, written in collaboration with the medical director or physician consultant of their individual establishments.”).

126. In some states the statutes and regulations do not detail the collaboration requirements, but presumably the APN and physician agree to the terms of supervision in their collaborative agreement. Nothing in these statutes indicates that on-site supervision is required, so presumably provisions can be made for an APN to prescribe without the physical presence of a physician. KAN. STAT. ANN. § 65-1130(d) (2002) (explaining that APNs may prescribe in accordance with protocol established by a supervising physician); KY. REV. STAT. ANN. § 314.042(8) (West 2006) (explaining that APNs may prescribe pursuant to a written agreement with a supervising physician); MINN. STAT. ANN. § 148.235 (West 2005) (permitting APNs to prescribe drugs as authorized by collaborating physician); 1979-1980 Mich. Op. Att’y Gen. 553 (1980) (explaining that physicians may delegate the prescribing of a drug to a licensed professional nurse).

127. See, e.g., ARK. CODE ANN. § 17-87-310 (West 2004) (requiring the method of review and communication to be in collaborative agreement); N.J. ADMIN. CODE § 13:35-6.6(c) (2008) (“The content of a joint protocol . . . shall address . . . [t]he frequency and methodology to be employed to ensure periodic review of patient records . . . [i]dentification of the means by which the advanced practice nurse and collaborating physician can be in direct communication, as well as a description of arrangements which will assure that the collaborating physician or peer coverage is accessible and available.”); N.D. ADMIN. CODE 54-05-03.1-09 (2007) (stating that the method of supervision must be included in the application to the Board for a collaborative prescription agreement).

128. See, e.g., ALA. ADMIN. CODE r. 610-X-5-.08 (2007) (“The collaborating physician shall . . . [b]e readily available for direct communication or by radio, telephone or telecommunications.”); MO. CODE REGS. ANN. tit. 20, 2200-4.200(4)(A) (2007) (“In order to assure true col-



must receive approval from either the Board of Nursing or Board of Medicine to prescribe, in addition to having a collaborative practice with a physician.<sup>129</sup> In eight states, APNs can apply for certification as independent prescribers, making supervision or collaboration with a physician unnecessary.<sup>130</sup> In six states and the District of Columbia, prescribing is within the regular scope of practice for APNs.<sup>131</sup>

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laborative practice and to foster effective communication and review of services, the collaborating physician . . . shall be immediately available for consultation to the collaborating registered professional nurse or advanced practice nurse at all times, either personally or via telecommunications.”); 21 N.C. ADMIN. CODE 32M.0110 (2007) (“The primary or back-up supervising physician(s) and the nurse practitioner shall be continuously available to each other for consultation by direct communication or telecommunication.”); S.D. CODIFIED LAWS § 36-9A-17 (2004) (“Collaboration may be by direct personal contact, or by a combination of direct personal contact and indirect contact via telecommunication, as may be required by the boards.”).

129. APNs working in collaboration with a physician must also receive approval from either the Board of Nursing or Board of Medicine, as determined by state law, to prescribe in Arkansas, Colorado, Delaware, Hawaii, Indiana, Louisiana, North Dakota, Ohio, South Carolina, and West Virginia. ARK. CODE ANN. § 17-87-310 (West 2004); COLO. REV. STAT. ANN. § 12-38-111.6 (West 2003); OHIO REV. CODE ANN. § 4723.43 (West 2004); S.C. CODE ANN. § 40-33-34 (2001); 10-518-001 DEL. CODE REGS. § 8.18.1 (Weil 2007); HAW. CODE R. § 16-89C-2 (Weil 2007); 848 IND. ADMIN. CODE 5-1-1 (2007); LA. ADMIN. CODE tit. 46, § 4513(D) (2007) (as amended 33:9 La. Reg. 1870 (September 2007); N.D. ADMIN. CODE 54-05-03.1-09 (2007); W. VA. CODE R. § 19-8-3 (2007).

130. APNs may apply for independent prescribing power in Alaska, Arizona, Montana, Wisconsin, Idaho, Maine, and Oregon. OR. REV. STAT. ANN. § 678.390(1)-(2) (West 2008) (stating that if a certified nurse practitioner is certified to write prescriptions by the Board of Nursing, physician involvement is not required to prescribe legend drugs); WIS. STAT. ANN. § 441.16 (West 2005) (“The board shall grant a certificate to issue prescription orders to an advanced practice nurse who meets the education, training and examination requirements established by the board for a certificate to issue prescription orders, and who pays the fee specified.”); ALASKA ADMIN. CODE tit. 12, § 44.440 (2007) (“The board will, in its discretion, authorize an advanced nurse practitioner or ‘ANP’ to prescribe and dispense legend drugs in accordance with applicable state and federal laws.”); ARIZ. ADMIN. CODE § R4-19-511 (2007) (permitting registered nurse practitioners to apply to the Board of Nursing for prescriptive authority); IDAHO ADMIN. CODE r. 23.01.01.315 (2007) (explaining that advanced nurses may apply to the Board of Nursing for prescribing authorization); 02-380-8 ME. CODE R. § 7 (Weil 2007) (explaining that advanced nurses with authorization from the Board of Medicine may prescribe); MONT. ADMIN. R. 24.159.1461 (2007) (“An APRN granted prescriptive authority by the board may prescribe and dispense drugs pursuant to applicable state and federal laws.”).

131. Prescribing is within the scope of authority for APNs in D.C., Iowa, Nebraska, New Hampshire, New Mexico, Wyoming, and Utah. D.C. CODE § 3-1201.02(2) (2007) (defining the “practice of advanced registered nursing” to include prescription); IOWA CODE ANN. § 147.107(8) (West 2007) (“[A] registered nurse who is licensed and registered as an advanced registered nurse practitioner and who qualifies for and is registered in a recognized nursing specialty may prescribe substances . . . if the nurse is engaged in the practice of a nursing specialty regulated under rules adopted by the board of nursing in consultation with the board of medicine and the board of pharmacy.”); NEB. REV. STAT. § 38-2315(2) (2008) (stating that nurse practitioner practice includes “[p]rescribing therapeutic measures and medications relating to health conditions within the scope of practice”); N.H. REV. STAT. ANN. § 326-B:11(III) (2004)

In all states, a physician may prescribe naloxone to patients who are at risk of opiate overdose in any setting<sup>132</sup> and certainly as part of an overdose prevention intervention.<sup>133</sup> In all states, a physician could be assisted by an APN or PA. In every state, an APN may replace a physician as the prescriber in an overdose prevention program, provided the service fits within the scope of practice set out in any required collaboration with a physician. Similarly, in all but two states, a PA may act as the prescriber in an overdose prevention program, but a physician would be necessary to undertake overall supervisory responsibility for the PA.<sup>134</sup> In West Virginia, PAs are not permitted to prescribe naloxone under any circumstances,<sup>135</sup> and in Missouri, PAs may not prescribe drugs unless a supervising physician is on-site.<sup>136</sup> While a PA's supervising physician—and in many instances a physician collaborating with an APN—is required to agree to the activity and may be required to review prescriptions, with few exceptions on-site participation in the intervention is not required.<sup>137</sup>

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("An ARNP shall have plenary authority to possess, compound, prescribe, administer, and dispense and distribute to clients controlled and non-controlled drugs in accordance with the formulary established by the joint health council and within the scope of the ARNP's practice."); N.M. STAT. § 61-3-23.2 (2007) (explaining that certified nurse practitioners may prescribe drugs); UTAH CODE ANN. § 58-31b-301(3) (West 2004) ("An individual holding an advanced practice registered nurse license as of July 1, 1998, who cannot document the successful completion of advanced course work in patient assessment, diagnosis and treatment, and pharmacotherapeutics, may not prescribe and shall be issued an 'APRN – without prescriptive practice' license."); WYO. STAT. ANN. § 33-21-120(a)(i) (2007) ("Advanced practice registered nurse (APRN)' means a nurse who . . . [m]ay prescribe, administer, dispense or provide nonprescriptive and prescriptive medications including prepackaged medications, except schedule I drugs.").

132. See, e.g., N.J. ADMIN. CODE § 13:35-7.2 (2008) ("A practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient's condition, may issue a written prescription for a drug to a patient, guardian or authorized representative.").

133. According to our research, no lawsuits challenging the legality of naloxone prescription have been brought anywhere in the U.S.

134. In Florida, PAs may not prescribe parenteral medications, and so would be limited to prescribing naloxone for nasal administration. FLA. ADMIN. CODE ANN. r. 64B8-30.008(1) (2007).

135. PAs with prescriptive authority in West Virginia may only prescribe drugs that are listed on a formulary approved by the Board. W. VA. CODE R. § 11-1B-14 (2008). 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.

136. MO. ANN. STAT. § 334.735(2) (West 2001).

137. See *supra* notes 118-122 and accompanying text.

TABLE I: AUTHORITY OF APNs AND PAs TO PRESCRIBE NALOXONE

	May prescribe naloxone without on-site physician supervision	May prescribe naloxone with on-site physician supervision	Cannot prescribe naloxone
<b>Advanced Practice Nurse</b>	AL, AK*, AR*, AZ*, CA, CO*, CT, DE*, DC, FL, GA, HI*, ID*, IL, IN*, IA, KS, KY, LA*, ME*, MD, MA, MI, MN, MS, MO, MT*, NC, NE, NV, NH, NJ, NM, NY, ND*, OH*, OK, OR*, PA, RI, SC*, SD, TN*, TX, UT*, VT, VA, WA*, WV*, WI, WY		
<b>Physician Assistant</b>	AL, AK, AR, AZ, CA, CO, CT, DE, DC, FL*†, GA, HI, ID*, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MT, NE, NC, NV, NH, NJ, NM, NY, ND, OH*, OK, OR, PA, RI, SC*, SD, TN, TX, UT, VT, VA, WA*, WI, WY*	MO	WV

\* Special license or board certification required

† For nasal administration only

### B. Dispensing Naloxone: The Law

In health law terms, providing a patient with a prescription medicine is called “dispensing.”<sup>138</sup> Handing an intervention participant a written prescription for naloxone does not ensure the ODU will: (1) go to a pharmacy and (2) have it dispensed to him. Although the drug is inexpensive,<sup>139</sup> illicit drug use is

138. See, e.g., FLA. STAT. ANN. § 465.003(6) (West 2007) (“‘Dispense’ means the transfer of possession of one or more doses of a medicinal drug . . . to the ultimate consumer or her or his agent.”).

139. Some programs, like the intervention aimed at injecting drug users in New Mexico and North Carolina’s Project Lazarus, which targets both licit and illicit prescription opioid users, distribute naloxone customized for nasal delivery. This is a custom, “after-market” delivery system because the manufacturers of naloxone are not permitted by the FDA to market the drug for nasal delivery. Thus, the price is much higher than a vial of naloxone and a sy-

illegal and stigmatized, and a participant may fear that filling a naloxone prescription will mark the patient as an ODU. Drug users, whose dependence has begun to have a major impact on their behavior may not wish to spend the money to purchase even inexpensive naloxone, may lack insurance coverage, or may be too disorganized to buy their medication at a pharmacy. Generally, if an ODU presents a valid prescription to a pharmacist, the pharmacist is expected to fill it.<sup>140</sup> Laws and regulations in certain states support the duty to dispense.<sup>141</sup> However, some state regulations protect pharmacists who refuse to fill prescriptions based on personal beliefs.<sup>142</sup> Recent media attention has focused on pharmacists who refuse to dispense prescription and over-the-counter (OTC) contraceptives, but refusals of other drugs are plausible.<sup>143</sup> To avoid these complications, nearly all naloxone programs distribute the drug to the user directly following training and the medical prescription process, and provide refills after use.<sup>144</sup>

Dispensing by medical practitioners at the point of service is subject to more explicit, complicated, and varying rules than prescribing itself.<sup>145</sup> Table 2, at the end of this sub-part, sum-

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ringe. In North Carolina, the naloxone kits cost thirty dollars for two doses. Interview with Nabarun Dasgupta, MPH, Department of Epidemiology, University of North Carolina at Chapel Hill School of Public Health (Jan 15, 2008) (transcript on file with the author).

140. 25 AM. JUR. 2D *Drugs and Controlled Substances* § 253 (2008) (“[A] pharmacist owes his or her customers a duty to properly and accurately fill prescriptions.”).

141. See, e.g., MD. CODE ANN., HEALTH OCC. § 12-501 (West 2008) (stating that a refusal is only permitted “if the decision is based on professional judgment, experience, knowledge, or available reference materials”).

142. E.g., GA. COMP. R. & REGS. 480-5-.03(n) (2008) (“It shall not be considered unprofessional conduct for any pharmacist to refuse to fill any prescription based on his/her professional judgment or ethical or moral beliefs.”); see also Rob Stein, ‘Pro-Life’ Drugstores Market Beliefs; No Contraceptives for Chantilly Shop, WASH. POST, June 16, 2008, at A1 (explaining the debate over pharmacists refusing to fill contraceptive prescriptions and the lack of concrete rules in most states).

143. See Stein, *supra* note 142.

144. E.g., Sandro Galea et al., *Provision of Naloxone to Injection Drug Users as an Overdose Prevention Strategy: Early Evidence from a Pilot Study in New York City*, 31 ADDICTIVE BEHAVIORS 907, 908 (2006) (study participants at the Lower East Side Harm Reduction Center were given refills); Susan G. Sherman et al., *A Qualitative Study of Overdose Responses Among Chicago IDUs*, HARM REDUCTION J. 5:2, 4-5 (2008) (noting the importance of interacting with clients who return for refills).

145. See, e.g., FLA. STAT. ANN. § 456.001(4) (West 2007) (explaining that physicians, PAs and ARNPs are included in the definition of a “health care practitioner”); FLA. STAT. ANN. § 465.0276 (West 2007) (explaining that only practitioners authorized by law can dispense prescription drugs); TEX. OCC. CODE ANN. § 157.051(2) (Vernon 2004) (permitting physicians to delegate dispensing prescription drugs to registered nurses and PAs); FLA. ADMIN. CODE

marizes the authority of physicians, PAs and APNs to dispense naloxone at an overdose prevention site.

Most states' laws impose no significant restrictions on the authority of physicians to dispense prescription drugs they prescribe.<sup>146</sup> In the small number of states that do, the limitations were evidently crafted to prevent physicians from going into the pharmacy business without complying with pharmacy licensure laws.<sup>147</sup> The most common limitation is the requirement of an additional license from the board of medicine or pharmacy in order for a physician to dispense prescription drugs.<sup>148</sup> For example, in Florida, physicians can dispense pre-

ANN. r. 64B8-30.006 (2007) (stating PAs can only dispense samples); FLA. ADMIN. CODE ANN. r. 64B9-4.011 (2007) (noting that ARNPs must register with the Board of Nursing in order to dispense); N.H. CODE ADMIN. R. ANN. PHARM. 601.11(a) (2007) (permitting physicians, ARNPs, and PAs to dispense prescription drugs); N.H. CODE ADMIN. R. ANN. MED. 612.01 (2007) (explaining that PAs may only dispense medication within the authority delegated to them by their supervising physician); 22 TEX. ADMIN. CODE §169.4 (2007) (authorizing physicians the right to dispense prescription drugs, subject to certain restrictions).

146. *See, e.g.*, CONN. GEN. STAT. ANN. § 20-14c(3) (West 2008) (“Prescribing practitioner” means a physician . . . licensed by the state of Connecticut and authorized to prescribe medication within the scope of such person’s practice.”); CONN. GEN. STAT. ANN. § 20-14e(a) (West 2008) (“A drug dispensed by a prescribing practitioner shall be personally dispensed by the prescribing practitioner”); N.Y. EDUC. LAW § 6807(1)(b) (McKinney 2007) (“Any physician . . . legally authorized to prescribe drugs under this title who is not the owner of a pharmacy or who is not in the employ of such owner, [is not prevented] from supplying his patients with such drugs as the physician . . . deems proper in connection with his practice.”); 22 TEX. ADMIN. CODE §169.4 (2007) (“[A] physician may provide, dispense, or distribute drugs for use or consumption by the patient away from the physician’s office or after the conclusion of the physician-patient encounter only in quantities as are necessary to meet the patient’s immediate needs.”).

147. *See, e.g.*, NEB. REV. STAT. § 38-2850 (2008) (noting that physicians who regularly dispense prescriptions are required to obtain a pharmacy license); OKLA. STAT. ANN. tit. 59, § 355.1 (West 2000) (stating that only physicians licensed by the Board of Pharmacy can dispense prescription drugs); 18 VA. ADMIN. CODE 110-20-120 (2007) (explaining that the Board of Pharmacy “may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service”).

148. Arkansas, Arizona, Iowa, and Michigan require additional medical board licensing and/or approval before a physician can prescribe. ARK. CODE ANN. § 17-95-102 (West 2002) (stating that physicians are able to dispense legend drugs in injectable form, but may not dispense other drugs “without prior approval by the Arkansas State Medical Board after application to the board and on the showing of need”); IOWA CODE ANN. § 147.107(2) (West 2005 & Supp. 2008) (stating that physicians can dispense prescription drugs, but must register with the Board of Medicine); MICH. COMP. LAWS ANN. § 333.17745 (West 2001 & Supp. 2007) (finding that physicians licensed by the Board of Medicine can dispense prescription drugs); ARIZ. ADMIN. CODE § R4-16-301 (2006) (explaining that physicians must be registered by the Board of Medicine to dispense prescription drugs). Florida, Nebraska, Nevada, Oklahoma, and Virginia require pharmacy board licensing and/or approval before a physician can prescribe. FLA. STAT. ANN. § 465.0276 (West 2007) (stating that physicians licensed by the Board of

scription drugs,<sup>149</sup> but if they dispense anything other than complimentary prepackaged samples of medicinal drugs,<sup>150</sup> they must register as a dispensing practitioner with the medical licensing board.<sup>151</sup> In Virginia, physicians can dispense drugs to patients with the approval of the Board of Pharmacy or the Board of Medicine, but only when pharmacy services are not reasonably available.<sup>152</sup> Both boards require physicians to show “good cause” before allowing the authority to dispense. Moreover, the Board of Pharmacy only grants this au-

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Pharmacy as a dispensing practitioner can dispense prescription drugs); NEB. REV. STAT. § 38-2850 (2008) (explaining that physicians who “regularly” dispense prescription drugs must obtain a license from the Board of Pharmacy); NEV. REV. STAT. ANN. § 454.215 (LexisNexis 1997 & Supp. 2007) (stating that physicians can dispense prescription drugs, if authorized by the Board of Pharmacy); OKLA. STAT. ANN. tit. 59, § 355.1 (West 2000 & Supp. 2007) (finding that physicians licensed by the Board of Pharmacy can dispense prescription drugs); VA. CODE ANN. §54.1-3304 (2005) (explaining that physicians licensed by the Board of Medicine can dispense prescription drugs); 18 VA. ADMIN. CODE 110-20-120 (2007) (stating that physicians licensed by the Board of Pharmacy can dispense prescription drugs). In the majority of those states that require additional medical or pharmacy board licensing and/or approval, physicians are permitted to dispense samples without a dispensing license and/or board approval. FLA. STAT. ANN. § 465.0276(5); IOWA CODE ANN. § 147.107(2); MICH. COMP. LAWS ANN. § 333.17745; OKLA. STAT. ANN. tit. 59, § 355.1 (West 2006 & Supp. 2007); NAT’L. ASSN. BD. OF PHARM., SURVEY OF PHARMACY LAW 84 (2007) [hereinafter SURVEY OF PHARMACY LAW] (stating that except for samples Virginia physicians must be licensed by the Board of Pharmacy).

149. FLA. STAT. ANN. § 465.0276(1).

150. *Id.* § 465.0276(5).

151. *Id.* § 465.0276(2); *see also* § 465.0276(3).

152. VA. CODE ANN. § 54.1-3304 (“For good cause shown, the Board may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. This license may be renewed annually. Any physician . . . so licensed shall be governed by the regulations of the Board of Pharmacy when applicable.”). In addition, section 110-20-120 of the Virginia Administrative Code provides:

For good cause shown, the board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a *special, limited or unusual nature* as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and method of operation, hours of operation, schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing pharmacist control must accompany the application.

3. The issuance and continuation of such permits shall be subject to continuing compliance with the conditions set forth by the board.

18 VA. ADMIN. CODE § 110-20-120 (2007) (emphasis added).

thority “when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service.”<sup>153</sup> In Montana, physicians as a general rule are prohibited from dispensing drugs, but significant exceptions would cover most or all dispensing by a physician at a naloxone program.<sup>154</sup>

In most states it is customary, and legal, for physicians to dispense “samples” along with a prescription to patients at the point of service. As we discuss further below, the definition of sample varies and would not in most states encompass a vial of naloxone or a naloxone inhaler purchased by an overdose prevention program for free distribution to patients. There is only one state, Utah, in which physicians cannot dispense prescriptions and are limited to providing their patients with samples.<sup>155</sup> As defined in Utah law, however, a “sample” would encompass a dose of naloxone for a patient in an overdose prevention program.<sup>156</sup>

153. VA. CODE ANN. § 54.1-3304 (West 2007); 18 VA. ADMIN. CODE § 110-20-120.

154. Section 37-2-104 of the Montana Code Annotated states:

(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:

...

(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.

MONT. CODE ANN. § 37-7-602(3) (2000). 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.” *Id.* 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.

155. According to the Utah Division of Occupational and Professional Licensing, only a pharmacist is allowed to dispense medications in Utah. See UTAH CODE ANN. § 58-37-6 (West 2007) (omitting any discussion of the authority of physicians, PAs or ARNPs to dispense prescription drugs). Physicians, PAs, and ARNPs can only provide samples to patients. See *id.* § 58-17b-102(28) (defining protocol for providing samples).

156. As defined in Utah law, a “‘drug sample’ means a prescription drug packaged in small quantities consistent with limited dosage therapy of the particular drug, which is

An overdose prevention program staffed with APNs or PAs without on-site physician oversight would run into problems with dispensing naloxone at the point of service in a number of states. APNs can dispense prescription drugs in most states, subject to the same supervision requirements that apply to prescribing, but there are often additional restrictions that could be of relevance to a naloxone program.<sup>157</sup> Some states require APNs to be specially licensed or approved by the board of nursing or pharmacy before dispensing prescription drugs.<sup>158</sup> A few states impose geographic or other restrictions related to the availability of pharmacies. In Wisconsin, for example, APNs can dispense prescription drugs only if the treatment facility is at least thirty miles from the nearest pharmacy;<sup>159</sup> otherwise, they are limited to dispensing “complimentary samples in their original containers or packaging.”<sup>160</sup> In North Carolina, APNs can only dispense prescription drugs from a place that holds a current pharmacy permit

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marked ‘sample,’ is not intended to be sold, and is intended to be provided to practitioners for the immediate needs of patients for trial purposes or to provide the drug to the patient until a prescription can be filled by the patient.” UTAH CODE ANN. § 58-17b-102(28).

157. See, e.g., WYO. STAT. ANN. § 33-21-120(a)(i)(A) (2007) (explaining that ANPs can “dispense or provide . . . prescriptive medications including prepackaged medications”); ARIZ. ADMIN. CODE § R4-19-513(A) (2006) (“A registered nurse practitioner (RNP) granted prescribing and dispensing authority by the Board may . . . [d]ispense drugs and devices to patients . . . [and] [o]nly dispense drugs and devices obtained directly from a pharmacy, manufacturer, wholesaler, or distributor.”); OR. ADMIN. R. 855-043-0210 (2007) (“A certified nurse practitioner may submit an application to the Oregon State Board of Nursing to dispense prescription drugs.”).

158. Arizona, Delaware, New Mexico, Oregon, and Pennsylvania require nursing board approval before ANPs can dispense. N.M. STAT. ANN. § 61-3-23.2 (2008) (explaining that CNPs licensed by the Board of Nursing can dispense prescription drugs); ARIZ. ADMIN. CODE § R4-19-513 (2006) (finding that RNPs licensed by the Board of Nursing can dispense prescription drugs); 24-1900 DEL. CODE REGS. § 8.18.1 (Weil 2007) (stating that ANPs with prescriptive authority from the Board of Nursing can dispense prescription drugs). Florida and Nevada require board of pharmacy approval. NEV. REV. STAT. ANN. § 454.215(6) (West 2007) (“A dangerous drug may be dispensed by . . . [a]n advanced practitioner of nursing who holds a certificate from the State Board of Nursing and a certificate from the State Board of Pharmacy permitting him to dispense dangerous drugs.”); FLA. ADMIN. CODE ANN. r. 64B9-4.011 (2007) (finding that ARNPs licensed by the Board of Pharmacy as a dispensing practitioner can dispense prescription drugs).

159. WIS. ADMIN. CODE N § 8.09 (2007).

160. *Id.* Although “complimentary samples” are not defined in the statute, they could be interpreted to include pre-packaged doses of naloxone purchased from the manufacturer and delivered free to patients. See WIS. STAT. ANN. § 450.11(b) (West 2005) (explaining that dispensing labeling requirements do not apply to “complimentary samples of drug products or devices dispensed by a practitioner to his or her patients”).



from the Board of Pharmacy.<sup>161</sup> In Montana, APNs as a general rule are prohibited from dispensing drugs, but significant exceptions would cover most or all dispensing by an APN at a naloxone program.<sup>162</sup> Two states limit APNs to dispensing samples, unless they are dispensing from a public health clinic or nonprofit facility.<sup>163</sup> In Nebraska, APNs can only dispense samples, and not prescription drugs,<sup>164</sup> unless they are dispensing medication at a public health clinic that has a dispensing permit.<sup>165</sup> In Maryland, nurse practitioners can only dis-

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161. 21 N.C. ADMIN. CODE 46.1703(d) (2007).

162. *See supra* note 154.

163. NEB. REV. STAT. § 38-2315(2)(b) (2008); NEB. REV. STAT. § 38-2884 (2008); MD. CODE REGS. 10.27.07.08 (2007).

164. NEB. REV. STAT. § 38-2315(2)(b).

165. Section 38-2884 of the Revised Statutes of Nebraska provides:

Under a delegated dispensing permit for a public health clinic, approved formulary drugs and devices may be dispensed by a public health clinic worker or a health care professional licensed in Nebraska to practice medicine and surgery or licensed in Nebraska as a registered nurse, licensed practical nurse, or physician assistant without the onsite services of a pharmacist if:

(1) The initial dispensing of all prescriptions for approved formulary drugs and devices is conducted by a health care professional licensed in Nebraska to practice medicine and surgery or pharmacy or licensed in Nebraska as a registered nurse, licensed practical nurse, or physician assistant;

(2) The drug or device is dispensed pursuant to a prescription written on site by a practitioner;

(3) The only prescriptions to be refilled under the delegated dispensing permit are prescriptions for oral contraceptives;

(4) Prescriptions are accompanied by patient instructions and written information approved by the director;

...

(6) All drugs or devices are prepackaged by the manufacturer or at a public health clinic by a pharmacist into the quantity to be prescribed and dispensed at the public health clinic;

(7) All drugs and devices stored, received, or dispensed under the authority of public health clinics are properly labeled at all times.

...

(9) The only drugs and devices allowed to be dispensed or stored by public health clinics appear on the formulary approved pursuant to section 71- 1,147.48; and

(10) At any time that dispensing is occurring from a public health clinic, the delegating pharmacist for the public health clinic or on-call pharmacist in Nebraska is available, either in person or by telephone, to answer questions from clients, staff, public health clinic workers, or volunteers. This availability shall be confirmed and documented at the beginning of each day that dispensing will occur. The delegating pharmacist or on-call pharmacist shall inform the public health clinic if he or she will not be available during the time that his or her availability is required. If a pharmacist is unavailable, no dispensing shall occur.

pense a starter dose or sample at no cost to the patient,<sup>166</sup> but can dispense prescription drugs at a nonprofit clinic or facility.<sup>167</sup>

Several states allow APNs to dispense samples,<sup>168</sup> but the ability to dispense naloxone to an OD program depends on the

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NEB. REV. STAT. § 38-2884.

166. MD. CODE REGS. 10.27.07.08(D) (2007) (“A nurse practitioner may personally prepare and dispense a starter dosage of any drug the nurse practitioner is authorized to prescribe. The nurse practitioner shall: (1) Label the starter dosage in compliance with the labeling requirements of Health Occupations Article, §12-509, Annotated Code of Maryland; (2) Provide the starter dose free of charge; and (3) Enter the starter dose dispensed in the patient’s medical record.”).

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

168. Arkansas, Colorado, Kansas, Louisiana, Michigan, Mississippi, Missouri, Ohio, Oklahoma, South Carolina, and Virginia only allow APNs to dispense samples. ARK. CODE ANN. § 17-92-1105 (Supp. 2006) (“Nothing in this subchapter shall restrict the use of samples by a[n] . . . [APN] during the course of working at a charitable clinic whether or not the clinic has a licensed outpatient pharmacy.”); COLO. REV. STAT. ANN. § 12-38-111.6(4)(d)(IV)(D)(10) (West 2003) (finding that APNs with prescriptive authority can dispense samples); KAN. STAT. ANN. § 65-1130(d) (2002) (stating that advanced registered nurse practitioners (“ARNPs”) can dispense professional samples, in accordance with their written protocol with the supervising physician); MICH. COMP. LAWS ANN. § 333.17212(1) (West 2008) (stating that registered professional nurses (“RPNs”) can dispense complimentary starter doses, if delegated to do so by a physician); 50-015-001 MISS. CODE R. § IV(2.4)(f)(1) (Weil 2007) (explaining that nurse practitioners (“NPs”) can dispense pre-packaged samples of non-controlled substances); OHIO REV. CODE ANN. § 4723.481(D) (West 2004) (explaining that clinical nurse specialists (“CNSs”) and certified nurse-midwives (“CNMs”), who hold certificates to prescribe and who are granted physician-delegated prescriptive authority, can dispense seventy-two hour doses of sample drugs free of charge and that CNPs and CNSs can dispense greater than a seventy-two hour dose when it is the minimum quantity the sample is packaged in, within the same parameters listed previously); OKLA. STAT. ANN. tit. 59, § 567.3a(6) (West 2000) (finding that ARNPs can dispense professional samples under the supervision of a physician); S.C. CODE ANN. §40-33-34(F)(2) (2001) (stating that NPs and CNSs can “distribute professional samples to patients as listed in the approved written protocol, subject to federal and state regulations”); MO. CODE REGS. ANN. tit. 20, § 2200-4.200(1) (2007) (finding that APNs in collaborative practice agreements can only dispense “starter doses of medication to cover a period of time for seventy-two (72) hours”); LA. ADMIN. CODE tit. 46, § 4513 (2007) (explaining that APRNs, with prescriptive authority from the Board of Nursing, can dispense pre-packaged medications and samples); 18 VA. ADMIN. CODE 90-40-120 (2007) (explaining that CNPs can dispense samples as per their written protocol). According to the Utah Division of Occupational and Professional Licensing, ARNPs can only provide samples to patients. As defined in Utah law, a “‘drug sample’ means a prescription drug packaged in small quantities consistent with limited dosage therapy of the particular drug, which is marked ‘sample,’ is not intended to be sold, and is intended to be provided to practitioners for the immediate needs of patients for trial purposes or to provide the drug to the patient until a prescription can be filled by the patient.” UTAH CODE ANN. § 58-17b-102(28) (West 2007).

states' definition of "sample." Usually, the definition includes that the drug is in a pre-packaged manufacturer's package, and that it is given away free.<sup>169</sup> Definitions of this type would encompass naloxone given away at programs. Some states also specify that the dose have been supplied for free to the practitioner<sup>170</sup> and sometimes even that it be supplied by the manufacturer with the intention of stimulating sales.<sup>171</sup> Where the definition has these added elements, we have concluded that the sample route could not be used for dispensing naloxone at an OD program. In those states where dispensing samples would be helpful to operating a naloxone program, the conditions for dispensing samples vary between each state, such as the requirements for physician delegation<sup>172</sup> and supervision.<sup>173</sup> West Virginia is the only state that does not per-

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169. See, e.g., FLA. ADMIN. CODE ANN. r. 64B8-30.006 (2007) ("Dispensing of sample drugs to patients shall be permitted only when no charge is made to the patient or a third party for the service or the drugs and if the sample being dispensed could otherwise have been legally prescribed by the physician assistant.").

170. See, e.g., MICH. COMP. LAWS ANN. § 333.17745(14) (West 2007) ("'[C]omplimentary starter dose' means a prescription drug packaged, dispensed, and distributed in accordance with state and federal law that is provided to a dispensing prescriber free of charge by a manufacturer or distributor and dispensed free of charge by the dispensing prescriber to his or her patients."); OKLA. STAT. ANN. tit. 59, § 355 (West 2007) (explaining that samples must be provided to the licensed practitioner free of charge and dispensed to patients free of charge as well); KAN. ADMIN. REGS. § 100-28a-13(g)(3)-(4) (2007) (stating that PAs can only dispense prescription-only drugs when they are provided to the physician or PA at no charge and are dispensed to the patient at no charge); LA. ADMIN. CODE tit. 46 Pt XLV, § 1503 (2007) ("Bona Fide Medication Sample — a medication, other than a controlled substance, packaged by the original manufacturer thereof in such quantity as does not exceed a usual and reasonable therapeutic dosage and provided at no cost to a physician . . . for . . . dispensation at no cost to the patient."); LA. ADMIN. CODE tit. 46 Pt XLVII, § 4505 (2007) ("Distribute, Distribution or Distributed — the issuing of free samples and other gratuitous medications supplied by drug manufacturers, as defined by clinical practice guidelines contained in a collaborative practice agreement for prescriptive authority."); 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.").

171. See, e.g., 21 U.S.C.A. § 353(c) (2000) ("'[D]rug sample' means a unit of a drug, subject to subsection (b) of this section, which is not intended to be sold and is intended to promote the sale of the drug."); COLO. REV. STAT. ANN. § 12-38-111.6(10) (West 2003) (explaining that the definition of "drug sample" is the same as the Prescription Drug Marketing Act of 1987); S.C. CODE ANN. § 39-23-55(A) (1985 & Supp. 2008) ("For purposes of this section, 'sample' means a unit of a drug which is not intended by the manufacturer to be sold and which is intended to promote the sale of the drug.").

172. See, e.g., MICH. COMP. LAWS ANN. § 333.17212(1) (West 2008) (finding that RPNs can dispense complimentary starter doses, if delegated to do so by a physician).

173. See, e.g., OKLA. STAT. ANN. tit. 59, § 567.3a(6) (West 2000) (stating that ARNPs can dispense professional samples under the supervision of a physician).

mit APNs to dispense prescription drugs or samples.<sup>174</sup>

PAs are the least likely allied health professionals to be authorized to dispense drugs. Where they are authorized, their dispensing is subject to the same supervision requirements that apply to prescribing and with greater restrictions than physicians and APNs.<sup>175</sup> Two states require PAs to receive medical or pharmacy board approval before dispensing prescription drugs.<sup>176</sup> Several states impose other restrictions on PAs dispensing prescription drugs.<sup>177</sup> Several states only al-

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174. There is no provision in the statutory or administrative code that authorizes nurses to dispense prescription drugs. W. VA. CODE ANN. §§ 30-7-1 to -19 (LexisNexis 2007); W. VA. CODE R. §§ 19-8-1 to -8 (2008).

175. See, e.g., DEL. CODE ANN. tit. 24, § 1772(b) (2005) (stating that PAs may dispense legend drugs under the supervision of a physician); OHIO REV. CODE ANN. § 4730.43(A) (West 2004) (explaining that PAs, who hold certificates to prescribe and who are granted physician-delegated prescriptive authority, can dispense seventy-two hour doses of sample drugs free of charge); ILL. ADMIN. CODE tit. 68, § 1350.55 (2007) (finding that physicians may delegate through written guidelines prescriptive authority to PAs).

176. Nevada and Washington require medical or pharmacy board approval before PAs can dispense prescription drugs. NEV. REV. STAT. ANN. § 454.215(3) (LexisNexis 2007) (explaining that PAs can dispense prescription drugs, if they are authorized to dispense by the Board of Pharmacy); WASH. ADMIN. CODE § 246-918-130 (2007) (stating that PAs can dispense prescription drugs, but they must do so under the supervision of a physician and must receive medical board approval to dispense).

177. Arizona, California, D.C., Iowa, Montana, Nebraska, North Carolina, Oregon, and Wyoming impose restrictions on PAs ability to dispense, other than medical or pharmacy board approval. ARIZ. REV. STAT. ANN. § 32-2532 (2008) (explaining that when PAs dispense prescription drugs, the drugs must be “[p]repackaged in a unit-of-use package by the supervising physician or a pharmacist acting on a written order of the supervising physician and labeled to show the name of the supervising physician”); CAL. BUS. & PROF. CODE § 4170(a)(8) (West 2003 & Supp. 2008) (stating that while PAs may dispense drugs directly to a patient of the supervising physician, pursuant to the written protocol with the physician, the drugs dispensed by PAs must be packaged and labeled by a physician, by the manufacturer, or by a pharmacist); IOWA CODE ANN. § 147.107(3) (West 2005) (explaining that PAs, upon direct orders of a supervising physician, can supply prepackaged and prepared medications to a patient when pharmacist services are not available or when doing so serves the best interests of the patient); MONT. CODE ANN. § 37-2-104 (2007) (finding that PAs are typically not permitted to dispense prescription drugs, except: (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”); MONT. CODE ANN. § 37-7-602(3) (2007) (“‘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.”); D.C. MUN. REGS. tit. 17, § 4912 (2007) (explaining that PAs may dispense medication that is prepackaged by the manufacturer or by the supervising physician, and must note in the patient’s chart what medication was dispensed); IDAHO ADMIN. CODE r. 22.01.03.043 (2007) (finding that PAs can provide a patient an “emergency period” supply of medications when a pharmacist is unavailable); see MONT. CODE ANN. § 37-2-101(5) (2007) (finding that the definition of a “medical practitioner” includes “any person licensed . . . to engage in the practice of medicine”); MONT. CODE ANN. §

low PAs to dispense samples.<sup>178</sup> Four states do not permit PAs to dispense prescription drugs or samples.<sup>179</sup>

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37-3-102(8) (2007) (defining the “practice of medicine” as “the diagnosis, treatment, or correction of . . . human conditions, ailments, diseases, injuries, or infirmities, whether physical or mental, by any means, methods, devices, or instrumentalities”); MONT. CODE ANN. § 37-20-403(3) (2007) (“A physician assistant may diagnose, examine, and treat human conditions, ailments, diseases, injuries, or infirmities, either physical or mental, by any means, method, device, or instrumentality authorized by the supervising physician.”); NEB. REV. STAT. § 38-2884 (2006) (stating that PAs are authorized to dispense prescription drugs at a public health clinic that has a delegated dispensing permit, which requires supervision and training by a pharmacist); OR. REV. STAT. ANN. § 677.515(5) (West 2008) (stating that PAs can only dispense “limited emergency medications”); WYO. STAT. ANN. § 33-26-510 (2007) (stating that PAs can dispense prepackaged medications in rural clinics, but only when this authority is delegated from the supervising physician and when pharmacy services are not physically available); 21 N.C. ADMIN. CODE 46.1703 (2007) (explaining that PAs may dispense drugs at the point of service if the site is covered by a pharmacy permit).

178. PAs can only dispense samples in Florida, Idaho, Kansas, Kentucky, Mississippi, Missouri, Ohio, Oklahoma, Utah, Virginia, and West Virginia. FLA. STAT. ANN. § 459.022(7) (West 2007) (“Unless it is a drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465.”); KY. REV. STAT. ANN. § 311.858(4) (LexisNexis 2007) (finding that PAs may distribute professional samples of drugs to patients); MO. ANN. STAT. § 334.735(4) (West 2008) (PAs can dispense starter doses and professional samples, but they must consult with their supervising physician before dispensing); OHIO REV. CODE ANN. § 4730.43(A) (LexisNexis 2006) (explaining that PAs, who hold certificates to prescribe and who are granted physician-delegated prescriptive authority, can dispense seventy-two hour doses of sample drugs free of charge and that PAs can dispense greater than a seventy-two hour dose when it is the minimum quantity the sample is packaged in, within the same parameters listed previously); FLA. ADMIN. CODE ANN. r. 64B8-30.006 (2007) (“Only those physician assistants authorized by law and rule to prescribe shall be permitted to dispense sample drugs to patients.”); IDAHO ADMIN. CODE r. 22.01.03.042 (2007) (explaining that dispensation authority for PAs is typically limited to pharmaceutical samples); KAN. ADMIN. REGS. 100-28a-13(g) (2007) (stating that PAs may supply to patients, free of charge, pre-packaged and pre-labeled prescription drugs that have been supplied to the PA free of charge); 50-013-011 MISS. CODE R. § 5(502)(5) (Weil 2007) (“A physician assistant may receive and distribute prepackaged medications or samples of non-controlled substances for which the physician assistant has prescriptive authority.”); OKLA. ADMIN. CODE § 435:15-5-10 (2007) (stating that PAs are limited to dispensing professional samples under the supervision of a physician); 18 VA. ADMIN. CODE § 85-50-140 (2007) (noting that PAs can dispense drug samples that are included in their practice agreement with their supervising physician); W. VA. CODE R. § 11-5-3(3.3)(b) (2008) (stating that PAs can dispense professional samples). According to the Utah Division of Occupational and Professional Licensing, PAs can only provide samples to patients. As defined in Utah law, a “‘drug sample’ means a prescription drug packaged in small quantities consistent with limited dosage therapy of the particular drug, which is marked ‘sample,’ is not intended to be sold, and is intended to be provided to practitioners for the immediate needs of patients for trial purposes or to provide the drug to the patient until a prescription can be filled by the patient.” UTAH CODE ANN. § 58-17b-102(28) (West 2007).

179. Arkansas, Maryland, South Carolina, and Wisconsin do not permit PAs to dispense prescription drugs or samples. WIS. ADMIN. CODE MED. § 8.08(1) (2007) (“A physician assistant may not . . . dispense any drug independently.”); SURVEY OF PHARMACY LAW, *supra* note 148, at 85 (explaining that PAs cannot dispense prescription drugs in Arkansas, South Carolina or Wisconsin). We found no statutory authorization for PAs to dispense in Maryland. *Cf.*

There may also be rules governing the labeling of medications dispensed by practitioners at the point of service. Most states' laws and regulations are not clear on this point, so prudence would dictate following customary practice, noting that the drug has been dispensed and that it is clearly labeled, including the patient's name and other essential information.<sup>180</sup>

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MD. CODE ANN., HEALTH-GEN. §§ 15-101 to -145 (West 2008).

180. *See, e.g.*, OKLA. STAT. ANN. tit. 59, § 355.1 (West 2000) (explaining that when physicians dispense prescription drugs they must be dispensed in an "appropriate container to which a label has been affixed, such label to include the name and office address of the licensed practitioner, date dispensed, name of patient, directions for administration, prescription number, the trade or generic name and the quantity and strength . . . of the drug therein contained"); N.D. ADMIN. CODE 61-04-02-01 (2007) (mandating that practitioners dispensing more than an emergency seventy-two hour supply must follow the labeling and dispensation rules that are required under the pharmacy laws found in section 43-15-31.2 of the North Dakota Century Code and 61-04-06-01 of the North Dakota Administrative Code).

TABLE 2: AUTHORITY OF PRESCRIBERS TO DISPENSE NALOXONE

	No Significant Dispensing Restriction(s)	Approval Required From One or More Professional Board or Other Restriction(s)	Dispensing Authority Limited to Samples	No Dispensing Authority
<b>Physicians</b>	AL, AK, CA, CO, CT, DE, DC, GA, HI, ID, IL, IN, KS, KY, LA, ME, MA, MN, MS, MO, NH, NJ, NM, NY, NC, ND, OH, OR, PA, RI, SC, SD, TN, TX, VT, WA, WV, WI, WY (39)	AR, AZ, FL, IA, MD, MI, MT, NE, NV, OK, VA (11)	UT (1)	(0)
<b>APNs</b>	AL, AK, CT, DC, GA, HI, ID, IL, IN, KY, ME, MA, MN, NH, NJ, NY, ND, RI, TN, TX, VT, WA, WY (23)	AZ, CA, DE, FL, IA, MD, MT, NE, NV, NM, NC, OR, PA, SD, WI (15)	AR, CO <sup>†</sup> , KS <sup>†</sup> , LA <sup>†</sup> , MI <sup>†</sup> , MS, MO <sup>†</sup> , OH, OK <sup>†</sup> , SC <sup>†</sup> , UT, VA <sup>†</sup> (12)	WV (1)
<b>PAs</b>	AL, AK, CO, CT, DE, GA, HI, IL, IN, LA, ME, MA, MN, NH, NM, NJ, NY, ND, PA, RI, SD, TN, TX, VT, WA (25)	AZ, CA, DC, IA, MT, NE, NV, NC, OR, WY (10)	FL, ID, KS <sup>†</sup> , KY, MI <sup>†</sup> , MS, MO <sup>†</sup> , OH, OK <sup>†</sup> , UT, VA <sup>†</sup> , WV <sup>†</sup> (12)	AR, MD, SC, WI (4)

\* On-site supervision required

† Definition of "sample" would not generally support free distribution at a naloxone program

### *C. The Legality of Prescribing or Dispensing Naloxone for Recipients To Give or Administer to Third Parties Who Have Not Been Prescribed the Drug by a Licensed Professional*

We have so far confined our analysis to the provision of naloxone to individual ODUs at personal risk of overdose for their own use.<sup>181</sup> The several overdose prevention programs

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181. People suffering from an overdose will normally be incapacitated, and therefore will rely upon a companion to administer the naloxone. As we discuss in this section, lay people are not authorized to administer prescription medication. This technicality is commonly ignored in situations where the medicine has been prescribed to the recipient, and the recipient is unable to self-administer. Thus, parents administer medications to their children, spouses to spouses and so on. Similarly, there is no more than a technical legal problem with patient

authorized by state legislatures in recent years have included provisions for training and equipping non-licensed personnel to administer naloxone to ODUs suffering from an overdose.<sup>182</sup> This makes a great deal of sense from a public health point of view, as we discussed in Part I. States undoubtedly have the authority to authorize this practice, but, in the absence of such explicit authorization, an overdose prevention program that trained and equipped non-ODUs, or even instructed ODUs to save others, would be, technically, in breach of medical practice laws, at least under most circumstances.<sup>183</sup>

A legal prescription requires a specific patient who has been appropriately examined and found to have a medical need 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, because that person would not have a personal medical need for the medication. Nor would a recipient's commitment to give or use the naloxone on a person in need repair the problem, at least in a technical sense: Providing naloxone under those terms would amount to deputizing the lay person as a medical practitioner, which contravenes the basic idea of licensure and criminal laws that pro-

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A administering a dose of naloxone prescribed for him to patient B, who has also been prescribed naloxone. The rules may even be stretched to the point of prescribing the drug to a parent, spouse or other appropriate person with the idea that they would administer the drug to a specific ODU known to or under the prescriber's care. The problem discussed in this section arises when lay people who are not ODUs are intentionally recruited and trained to become roving life-savers for unknown third parties as part of an overdose prevention campaign.

182. For example, section 24-23-1 of West's New Mexico Statutes Annotated provides:

A. A person authorized under federal, state or local government regulations, other than a licensed health care professional permitted by law to administer an opioid antagonist, may administer an opioid antagonist to another person if:

(1) he, in good faith, believes the other person is experiencing a drug overdose; and

(2) he acts with reasonable care in administering the drug to the other person.

B. A person who administers an opioid antagonist to another person pursuant to Subsection A of this section shall not be subject to civil liability or criminal prosecution as a result of the administration of the drug.

N.M. STAT. ANN. § 24-23-1 (West 2008); *see also* N.Y. PUB. HEALTH LAW § 3309(3) (McKinney 2005) ("Use of an opioid antagonist pursuant to this section shall be considered first aid or emergency treatment for the purpose of any statute relating to liability.").

183. N.M. STAT. ANN. § 24-23-1; N.Y. PUB. HEALTH LAW § 3309(3); *supra* note 181.



hibit the unlicensed practice of medicine.<sup>184</sup> Such a prescription would be difficult to justify as arising in the usual course of medical practice, even if written in good faith for a virtuous purpose. Similar reasoning shows why it is also technically illegal to instruct legitimate ODU patients to administer their naloxone to others in the event it is needed. If the prescription is not valid, it would be a violation of pharmacy laws to dispense the medication.

Although the risks of prosecution are probably very low, a licensed professional who distributed naloxone in this way could be subject to charges of professional misconduct and be subject to fines.<sup>185</sup> 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<sup>186</sup> or possession of a prescription drug without a prescription.<sup>187</sup>

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184. Other innovative public health interventions have run into the same problem. Most notably, the use of partner-delivered therapy for sexually transmitted diseases, in which a physician provides the patient with a second dose of medication to be delivered by the patient to the sexual partner, has required regulatory changes in most states where it is being practiced. James G. Hodge, Jr. et al., *Expedited Partner Therapy for Sexually Transmitted Diseases: Assessing the Legal Environment*, 98 AM. J. PUB. HEALTH 238, 240-42 (2008).

185. See, e.g., ALASKA STAT. § 08.64.326(a)(5) (2008) (allowing the medical board to impose a sanction on a licensee that “has procured, sold, prescribed, or dispensed drugs in violation of a law regardless of whether there has been a criminal action”); KY. REV. STAT. ANN. § 311.595(9) (West 2006) (giving the board power to revoke a license for up to five years and limit a license indefinitely for engaging in unprofessional conduct); OKLA. STAT. ANN. tit. 59, § 503 (West 2000) (stating that the licensure board may suspend, revoke, or order any other appropriate sanctions against the license of any physician for unprofessional conduct); TENN. COMP. R. & REGS. 0880-2-.12(4)(b)(1) (2008) (stating that civil penalties may be imposed for a violation of the Practice Act, or regulations promulgated pursuant thereto, for an imminent and substantial threat to the health, safety and welfare of an individual client or the public in the amount of not less than \$500 or more than \$1000).

186. See, e.g., ALASKA STAT. § 08.64.360 (2008) (making the practice of medicine without a license or permit a class A misdemeanor, with each day of illegal practice treated as a separate offense; class A misdemeanors are punishable by fines up to \$10,000 under section 12.55.035(b)(5) of the Alaska Statutes and imprisonment up to one year under section 12.55.135(a) of the Alaska Statutes); ME. REV. STAT. ANN. tit. 32, § 3270 (1998) (makes practicing medicine without a license a crime); R.I. GEN. LAWS § 5-37-12 (2004) (makes the practice of medicine without a license punishable by up to three years of prison and/or a fine not exceeding \$1000); S.C. CODE ANN. § 40-1-200 (2001) (stating that a person who practices or offers to practice medicine without a license is guilty of a misdemeanor and, upon conviction, must be imprisoned for up to one year or fined up to \$50,000).

187. See, e.g., ARIZ. REV. STAT. ANN. § 13-3406(C), (E) (2001 & Supp. 2005) (stating that a person caught with a prescription drug without a prescription is subject to a \$1000 fine and/or performing not less than 240 hours of community service); FLA. STAT. ANN. § 499.005(4) (West 2006 & Supp. 2008) (stating that it is unlawful to sell, transfer, distribute, pur-

None of this should be taken as suggesting that a program cannot teach patients, friends, or family members to properly administer the drug to others. Such training is necessary to deal with the fact that patients may be unable to self-administer in an overdose situation.<sup>188</sup> We found no cases indicating that lay assistance in administering a prescription drug to the patient to whom it had been prescribed has been treated, without more, as unauthorized practice of medicine; indeed, it is a common enough act for parents and others caring for people who are unable to administer their own medications. Likewise, a physician may certainly prescribe multiple doses to a patient for whom they are indicated. But a program that explicitly encouraged distribution to, or administration upon, non-patients would be open to legal challenge.<sup>189</sup>

Whether any prosecutor would bother to bring such a case is another matter. The breach of the law is beneficial to society and the individual; at the very least, one can confidently say that law enforcement agencies have more important cases to pursue. In the absence of legislation providing an exception to the laws that require a license to practice medicine, “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 [Naloxone distribution] pilot program without fear of prosecu-

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chase, trade, hold, possess, or offer any drug not lawfully authorized by a licensed professional); S.C. CODE ANN. § 40-43-86(EE) (2001 & Supp. 2008) (stating that any person who possesses, dispenses or distributes a drug without a prescription from a licensed practitioner “is guilty of a misdemeanor and, upon conviction, must be fined not more than five hundred dollars or imprisoned not more than two years, or both”); WASH. REV. CODE ANN. § 69.41.030(1) (West 2007) (makes it unlawful for any person to “possess any legend drug except upon the order or prescription of a physician”).

188. See 88 Md. Op. Att’y Gen. 88, 98-99 (2003) (“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 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.”).

189. *Id.* at 88 (“A physician who prescribed naloxone to a participant . . . with the understanding that the participant would administer it to another individual who was not a patient of 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.”).

tion.”<sup>190</sup>

#### D. Malpractice Liability

The risk of tort liability in a naloxone prescription or dispensation context is low. Conceptually, this risk is no different from that arising in any other primary health care service, and may be lower as a consequence of the stigma of drug use and the tort doctrines related to harms caused by voluntary substance abuse. Where providers are contributing their time and expertise as a public service, state and federal volunteer protection statutes provide additional protection from tort liability.

Generally, every tort claimant must establish that he or she suffered an injury actually caused by the negligence of the defendant health-care provider. The provider's conduct is assessed by reference to the customary behavior of the relevant segment of the profession under the same or similar circumstances, to establish the “standard of care.”<sup>191</sup> Naloxone has long been the standard of care for reversing opiate overdose. It would be virtually impossible for a plaintiff to get a claim that it was not to a jury, let alone to prevail.

The advance prescription of the drug to ODU's for self (or lay) administration in the event of an overdose is, however, relatively new. A claim that this act was negligent would raise technical issues concerning the appropriate reference group, or indeed whether there could be said to be a custom at all. 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

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190. *Id.* at 89.

191. *See, e.g.,* Priest v. Lindig, 583 P.2d 173, 177 (Alaska 1978) (“[A] physician is under a duty to use that degree of care and skill which is expected of a reasonably competent practitioner in the same class to which he belongs, acting in the same or similar circumstances. Under this standard, advances in the profession, availability of facilities, specialization or general practice, proximity of specialists and special facilities, together with all other relevant considerations, are to be taken into account.”); Bahr v. Harper-Grace Hosps., 528 N.W.2d 170, 172 (Mich. 1995) (“[T]he standard of care for general practitioners is that of the local community or similar communities, and is nationwide for a specialist.”); Wickliffe v. Sunrise Hosp., Inc., 706 P.2d 1383, 1388 (Nev. 1985) (establishing that the “level of care to which hospital must conform is a nationwide standard”); Plaintiff v. City of Petersburg, 345 S.E.2d 564, 565 (W. Va. 1986) (stating that the locality rule for determining standards for medical practice is abolished); RESTATEMENT (SECOND) OF TORTS § 282 (1965).

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,<sup>192</sup> and by the endorsement of take-home naloxone programs by state legislatures and public health agencies. Naloxone prescription to prevent opiate overdose is a practice accepted by a significant number of physicians and is within the scope of practice for knowledgeable providers working with the ODU population.<sup>193</sup> It is, of course, not necessary that there be unanimity of expert opinion concerning this use of naloxone; it is enough that the provider's decision to provide take-home naloxone is medically reasonable.<sup>194</sup>

The doctrine of informed consent would also probably come into the analysis. Failure to obtain a patient's informed consent for treatment is a tort, and is particularly important where the treatment is new or novel.<sup>195</sup> At the same time, informed consent to a treatment that is new or even experimental, can, at least in theory, immunize the provider from a patient's claim that the treatment deviates from professional custom.<sup>196</sup> The prescription of naloxone as a means of preventing overdose now has a solid evidentiary base and could hardly be

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192. See, e.g., Karen H. Seal et al., *Naloxone Distribution and Cardiopulmonary Resuscitation Training for Injection Drug Users to Prevent Heroin Overdose Death: A Pilot Intervention Study*, 82 J. URB. HEALTH 303, 303-11 (2005) [Hereinafter Seal, *Naloxone Distribution*]; John Strang et al., *Heroin Overdose: The Case for Take-Home Naloxone*, 312 BRIT. MED. J. 1435, 1435 (1996); Dan Bigg, 131st Annual Meeting of the American Public Health Association, *Opiate Overdose Prevention/Intervention Using Take-Home Naloxone* (November 18, 2003) (manuscript on file with the author). See generally *supra* notes 88-100 and accompanying text (describing evidence base for take-home naloxone).

193. See, e.g., Phillip O. Coffin et al., *Preliminary Evidence of Health Care Provider Support for Naloxone Prescription as Overdose Fatality Prevention Strategy in New York City*, 80 J. URB. HEALTH 288, 288-90 (2003) ("This preliminary study suggests that a substantial number of New York City health care providers would prescribe naloxone for opiate overdose prevention."); Sarz Maxwell et al., *Prescribing Naloxone to Actively Injecting Heroin Users: A Program to Reduce Heroin Overdose Deaths*, 25 J. ADDICTIVE DISEASES 89, 90-94 (2006).

194. *Jones v. Chidester*, 610 A.2d 964, 969 (Pa. 1992) (holding that, although showing that there "exists a 'small minority' of physicians who agree with the defendant's questioned practice" is insufficient, such conduct is considered medically reasonable where "a considerable number of physicians, recognized and respected in their field," accept the decision as medically reasonable).

195. See Anna C. Mastroianni, *Liability, Regulation and Policy in Surgical Innovation: The Cutting Edge of Research and Therapy*, 16 HEALTH MATRIX: J. LAW-MEDICINE 351, 388-93 (2006); Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J. LAW & MED. 361, 364-77 (2002).

196. Gideon Parchomovsky & Alex Stein, *The Anti-Innovation Bias of Tort Law*, 107 MICH. L. REV. 285, 301-03 (2008).

considered experimental, but it is certainly important for the patient to understand that it has limitations. Indications for and methods of administration should be explained to patients, along with risks and benefits.<sup>197</sup>

Even if a jury were to determine that prescription of naloxone was unreasonable, there is no tort unless the negligent act caused the plaintiff harm. Naloxone itself is extremely safe, so the likelihood of a suit based on a side-effects injury is vanishingly small. One of two scenarios, though still speculative, would be more logical: either that the possession of naloxone actually caused the overdose by inducing the patient to take greater risks (i.e., injecting a greater amount of opioid or taking less care with drugs of unknown potency) or that having taken naloxone after an overdose, the patient did not accept emergency care and later relapsed into overdose because of the large amount of opiates still in the system, or a fresh injection. Both of these scenarios, it should be said, are based on so-far unsupported speculation about the behavioral effect of having naloxone and its use in the take-home approach.<sup>198</sup> More to the immediate point, both are rendered rather unlikely to succeed as tort claims by evidentiary considerations. If the administration of naloxone successfully reverses the overdose, it is not clear there was harm.<sup>199</sup> If the in-

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197. Because of the nature of overdose, patients may not always be able to self-administer naloxone. 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: instructions on how to spot symptoms of an overdose; basic resuscitation techniques; proper naloxone administration; and the importance of calling 911 for help.

198. Several studies of patients given naloxone by emergency medical personnel found no cases in which patients who refused further treatment died of overdose as a result. *See, e.g.,* Boyd, *supra* note 94, at 1267-70; Gary M. Vilke et al., *Assessment for Deaths in Out-of-Hospital Heroin Overdose Patients Treated with Naloxone Who Refuse Transport*, 10 ACAD. EMERGENCY MED. 893, 895-96 (2003); Gary M. Vilke et al., *Are Heroin Overdose Deaths Related to Patient Release After Pre-Hospital Treatment with Naloxone?*, 3 PREHOSPITAL EMERGENCY CARE 183, 185-86 (1999). This is analogous to the situation of a person with take-home naloxone, and indicates that a single administration will normally be enough to prevent death even if it does not counteract the full opioid dose or is followed by later re-administration of illicit opioids. Nor is there any behavioral evidence from the field to support the concern that ODUs equipped with naloxone will take greater risks in their drug use.

199. There is some evidence that even a non-fatal overdose can cause morbidity. Although

dividual dies, which certainly counts as a harm, their reliance on naloxone would have to be inferred from the circumstances or prior statements.

Even in the unlikely case in which “but for” factual causation may be established, the provider’s actions must be deemed the proximate cause of the injury—i.e., represent a major contributing factor to the injury such that liability would be fair and appropriate.<sup>200</sup> It is hardly fair to blame a prescribing professional for a harm overwhelmingly caused by a patient’s decision to inject heroin. Indeed, courts have traditionally applied the rule of “superseding” or “intervening” cause to bar people who voluntarily use dangerous drugs from blaming others for harms resulting from their own decision to use drugs.<sup>201</sup>

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there are few data, an initial study found that a third of respondents experiencing an overdose had required hospital treatment, and fourteen percent had had bad enough complications to be admitted. Indirect overdose-related harms included physical injury caused by falling down, burns and assault while unconscious. Direct overdose-related harms included peripheral neuropathy, vomiting, temporary paralysis, infections and seizures. M. Warner-Smith, S. Darke & C. Day, *Morbidity Associated with Non-Fatal Heroin Overdose*, 97 ADDICTION 963, 965-66 (2002). In theory, any of these harms would be enough to ground an action for negligence, if they could be linked in a chain of but-for causation to the prescription of naloxone. Use of naloxone itself can be unpleasant for the patient, who is pushed into instant opioid withdrawal with associated symptoms like nausea and tachycardia (rapid heartbeat). See Ingebjorg Buajordet et al., *Adverse Events After Naloxone Treatment of Episodes of Suspected Acute Opioid Overdose*, 11 EUR. J. EMERGENCY MED. 19, 21 (2004). All in all though, these sorts of injuries pale in comparison to the death that the drug prevented.

200. See, e.g., GA. CODE ANN. § 51-11-7 (West 2000) (“If the plaintiff by ordinary care could have avoided the consequences to himself caused by the defendant’s negligence, he is not entitled to recover. In other cases the defendant is not relieved, although the plaintiff may in some way have contributed to the injury sustained.”); *Robles v. Shoreside Petroleum, Inc.*, 29 P.3d 838, 841 (Alaska 2001) (stating that (1) plaintiff must show accident would not have occurred but for the defendant’s negligence and (2) the “negligent act must have been so important in bringing about the injury that a reasonable person would regard it as a cause and attach responsibility to it”); *Williams v. Manchester*, 864 N.E.2d 963, 975 (Ill. App. Ct. 2007) (stating that the plaintiff must show: (1) but for the defendant’s conduct, the accident would not have occurred; and (2) defendant’s conduct was so closely tied to the plaintiff’s injury he should be held responsible for it) (citing *McCraw v. Cegielski*, 680 N.E.2d 394, 396 (Ill. App. Ct. 1996)); *Bronson v. Hitchcock Clinic*, 677 A.2d 665, 669 (N.H. 1996) (explaining that a “plaintiff need only show with reasonable probability, not mathematical certainty, that but for the defendant’s negligence, the harm would not have occurred”).

201. See, e.g., *Walt’s Sheet Metal v. Deblar*, 826 P.2d 333, 335 (Alaska 1992) (explaining that defendant employer can escape liability if she can show that the initial injury was not a “substantial factor contributing to the later injury”); *Nolan v. Morelli*, 226 A.2d 383, 388 (Conn. 1967) (holding that a common-law action based on negligence in selling intoxicating liquor to the decedent who crashed his car must fail because the decedent voluntarily consumed the alcohol); *Hobart v. Shin*, 705 N.E.2d 907, 912 (Ill. 1998) (holding that a physician is entitled to raise patient’s contributory negligence as an affirmative defense); *Boynton v. Figueroa*, 913

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.<sup>202</sup> In the case of volunteer providers, the U.S. Volunteer Protection Act shields volunteers for acts committed within the scope of their work for a non-profit or government agency, so long as the acts are not criminal, reckless, or grossly negligent.<sup>203</sup> Many states also provide similar liability protection, so long as the agent responsible is a licensed health care provider acting voluntarily and without pay in the scope of his or her license.<sup>204</sup> Thus, volunteers

A.2d 697, 706 (N.H. 2006) (explaining that "generally, an independent intervening cause will not interfere with the connection between the original act and the injury if the intervention was probable or foreseeable").

202. *MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM 12-14* (William M. Sage & Rogan Kersh eds., Cambridge Univ. Press 2006).

203. 42 U.S.C.A. § 14503 (West 2005) ("[N]o volunteer of a nonprofit organization or governmental entity shall be liable for harm caused by an act or omission of the volunteer on behalf of the organization or entity if—(1) the volunteer was acting within the scope of the volunteer's responsibilities in the nonprofit organization or governmental entity at the time of the act or omission; (2) if appropriate or required, the volunteer was properly licensed, certified, or authorized by the appropriate authorities for the activities or practice in the State in which the harm occurred, where the activities were or practice was undertaken within the scope of the volunteer's responsibilities in the nonprofit organization or governmental entity; (3) the harm was not caused by willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer.").

204. For example, section 09.65.300 of the Alaska Statutes states:

(a) [A] health care provider who provides health care services to another person is not liable for civil damages resulting from an act or omission in providing the health care services if the health care

(1) provider is licensed in this state to provide health care services;

(2) services provided were within the scope of the health care provider's license;

(3) services were provided at a medical clinic, medical facility, nonprofit facility, temporary emergency site, or other facility owned or operated by a governmental entity or nonprofit organization and the health care provider was acting within the scope of the provider's responsibilities in the medical clinic, governmental entity, or nonprofit organization;

(4) services were provided voluntarily and without pay to the health care provider for the services, except as provided in (b)(2) and (3) of this section; and

(5) provider

(A) obtains informed consent from the person receiving the health care services as described under AS 09.55.556, except in the case of an emergency; and

(B) provides the person receiving the health care services advance written notice of the immunity provided under this section to a health care provider when providing voluntary health care services as described under this

working with naloxone distribution programs are immune from any liability, unless their actions are considered grossly negligent, wanton, or reckless.

#### IV. LEGISLATIVE AND ADMINISTRATIVE RESPONSES

The overdose epidemic has not escaped the notice of legislators. Lawmakers in several states have crafted responses aimed at removing legal barriers to implementing prevention programs and encouraging bystanders to call for emergency assistance. Four main points have been addressed in overdose legislation: (1) general legality of a take-home naloxone program, and specifically the distribution to and administration by non-professional lay savers; (2) liability of a health care provider for providing naloxone to an ODU or to a lay saver; (3) liability of a lay saver for administering naloxone in an emergency; and (4) reluctance of bystanders to call 911 for help. The several enactments are positive, but we cannot say that any of the states have arrived at a fully satisfactory legal model for responding to overdose. We will discuss the various provisions and suggest ways that legislation may be refined to better address the legal barriers to overdose prevention. We also discuss the federal role in overdose prevention: Congress has the opportunity to galvanize action through

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section.

(b) This section does not preclude

(1) liability for civil damages that are the result of gross negligence or reckless or intentional misconduct.

ALASKA STAT. § 09.65.300 (2008); *see also* FLA. STAT. ANN. § 768.1355(1) (West 2005) (making volunteers performing any service for any nonprofit organization immune from civil liability for any act or omission done in good faith by such person acting as an ordinary reasonably prudent person would, which results in personal injury or property damage as long as the injury or damage was not caused by any wanton or willful misconduct); NEB. REV. STAT. § 25-21,188.02(1) (2008) (making licensed volunteers working for free “in a free clinic or other facility operated by a not-for-profit organization” immune from “liability for any act or omission which results in damage or injury unless such damage or injury was caused by the willful or wanton act or omission of such practitioner”); WYO. STAT. ANN. § 1-1-129(b) (2007) (“[A] health care professional who is a volunteer and complies with subsection (c) of this section is not liable in damages to any person or government entity in a tort or other civil action, including an action on a medical, dental or other health-related claim for injury, death or loss to person or property that allegedly arises from an action or omission of the volunteer in the provision at a nonprofit health care facility to a low income uninsured person of medical, dental or other health-related diagnosis, care or treatment, including the provision of samples of medicine and other medical or dental products, unless the action or omission constitutes willful or wanton misconduct.”).



(modest) spending on research and demonstration projects through the Centers for Disease Control and Prevention (CDC), and if industry does not step forward to start the process, the FDA can take the unusual, but authorized, step of re-viewing naloxone's labeling on its own motion.

*A. Authorization of Naloxone Programs and Non-Professional Participation*

The first state to act was New Mexico. In 2001, Governor Gary Johnson supported a package of eight bills that brought a public health perspective to state drug policy.<sup>205</sup> As part of this effort, the legislature authorized naloxone distribution programs using lay savers and provided immunity to doctors and laypersons who administer naloxone to others.<sup>206</sup> The New Mexico Department of Health was authorized to issue regulations specifying the requirements of operating opioid antagonist administration programs.<sup>207</sup> The regulations are elaborate, stretching over eight pages of detailed requirements for the establishment and operation of a program. Every program must register with the Department of Health and routinely submit reports and records.<sup>208</sup> The regulation specifies a recommended organizational structure, including a Program Director, who oversees a Physician Medical Director, manages the records, coordinates with EMS, and selects people to participate as lay savers (called "Trained Targeted Responders"). The Physician Medical Director is responsible for ensuring responders receive proper training and that the distribution of opioid antagonists complies with state Board of Pharmacy

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205. Mark Hummels, *Johnson Launches 2001 Legislative Session*, SANTA FE NEW MEXICAN, Jan. 17, 2001, at A1; see also Common Sense for Drug Policy, *New Mexico Moves Toward Drug Policy Reform*, <http://www.csdp.org/news/news/nmupdate.htm> (listing the eight bills: 1) additional \$9.8 million for drug treatment and prevention services, 2) civil asset forfeiture reform, 3) medical marijuana, 4) syringe sales, 5) limited liability for naloxone use, 6) marijuana decriminalization, 7) habitual offender reform, and 8) reduction in incarceration penalty for hard drugs) (last visited May 21, 2009).

206. N.M. STAT. ANN. § 24-23-1(B) (West 2008); *id.* § 24-23-2 (West 2008); Steve Terrell, *Johnson Spends Another Day Signing Bills*, SANTA FE NEW MEXICAN, April 4, 2001, at A1.

207. N.M. CODE R. § 7.32.7.3 (Weil 2008) ("The statutory authority for adopting these rules is found in Section 9-7-6.E., NMSA 1978 of the Department of Health Act . . . and in Laws of 2001, Chapter 228, Section 1., which allows a person . . . to administer an opioid antagonist to another person under certain circumstances.").

208. N.M. CODE R. §§ 7.32.7.12-13 (Weil 2008).

regulations.<sup>209</sup>

The regulations recognize that licensed prescribers require no specific authorization to prescribe or administer naloxone to people at risk of opioid overdose.<sup>210</sup> The important innovation in New Mexico was the authorization for training and providing naloxone to third-party savers who have undergone an Opioid Antagonist Administration Training Program.<sup>211</sup> Responders are required to call 911 when witnessing an overdose, and prepare a detailed report of the event.<sup>212</sup> Responders are expected to report the name, address, and phone number of the overdose victim to whom they or another bystander administered naloxone.<sup>213</sup> A trained responder is even expected to record where she injected the naloxone into the victim's body.<sup>214</sup> The Program Director is then responsible for compiling all the data submitted by the responders and passing it on to the New Mexico Department of Health.<sup>215</sup>

New York followed New Mexico's lead in 2005 with legislation authorizing opioid antagonist administration programs,<sup>216</sup> and the New York Department of Health subsequently issued regulations similar in detail to New Mexico's.<sup>217</sup> Each program is required to register with the department and appoint a program director and a clinical director.<sup>218</sup> The New York regula-

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209. *Id.* § 7.32.7.10(B).

210. *Id.* § 7.32.7.8.

211. *Id.* § 7.32.7.10(A)-(C). A refresher training course is required every two years. *Id.* § 7.32.7.10(C)(2).

212. *Id.* § 7.32.7.10(C)(3), (5).

213. *Id.* § 7.32.7.13(C)-(E).

214. *Id.* § 7.32.7.13(G), (P).

215. *Id.* § 7.32.7.10(A)(8); *see also id.* § 7.32.7.13 (listing required information as "A. Name of Opioid Antagonist Administration Program; B. Name of Trained Targeted Responder submitting report; C. Name of Person to whom Opioid Antagonist was administered; D. Address of Person to whom Opioid Antagonist was administered; E. Telephone number of Person to whom Opioid Antagonist was administered; F. Amount of Opioid Antagonist administered; G. If known, list the type of overdose drugs (other than opioids) taken by the person to whom the Opioid; H. Antagonist was administered; and, I. Circumstances relating to overdose (if known); J. Date of overdose; K. Signs and symptoms indicating overdose; L. Was Emergency Medical Services called?; M. Was the person transported to a clinical facility?; N. Was rescue breathing performed on the person who overdosed?; O. Distance from nearest emergency department (in road miles); P. Location of injection site on the overdose person's body; Q. Clinical disposition of overdose incident (if known)").

216. N.Y. COMP. CODES R. & REGS. tit. 10, § 80.138 (2008).

217. *Id.*

218. *Id.* In contrast to New Mexico, the designation of these organizational officers is mandatory, not merely recommended. *See* N.M. CODE R. § 7.32.7.10 (Weil 2008) (discussing

tions also define program participants as trained responders and set out similar basic requirements, such as calling 911 during an overdose event and completing a refresher course every two years.<sup>219</sup> Program directors are responsible for issuing certificates to individuals who complete the training program.<sup>220</sup> The New York regulations authorize a range of health facilities and professionals to register as providers of overdose prevention programs, including an individual “physician, physician assistant, or nurse practitioner who is authorized to prescribe the use of an opioid antagonist.”<sup>221</sup>

California was the third state that passed legislation affirmatively authorizing an “opioid overdose prevention and treatment training program.”<sup>222</sup> Under this statute, local governments in seven counties<sup>223</sup> may operate programs directly or “register” programs operated by non-governmental agencies. Unlike New Mexico and New York, no regulations have been issued detailing exactly how programs must operate. Rather, the statute itself sets out the minimum responder-training curriculum,<sup>224</sup> and itemizes what each health jurisdiction must report about its programs.<sup>225</sup> The statute clearly allows prescription to trained third-party savers within an authorized program.<sup>226</sup>

the recommended guidelines for officers).

219. N.Y. COMP. CODES R. & REGS. tit. 10, § 80.138(c)(3)(ii), (iii) (2008); N.M. CODE R. § 7.32.7.10(C)(2), (3) (Weil 2008). However, the N.Y. scheme does not specify in detail the content of reports. Rather, each prevention program can develop their own reporting systems utilizing forms the Department provides. N.Y. COMP. CODES R. & REGS. tit. 10, § 80.138(c)(7) (2008) (“The Opioid Overdose Prevention Program will establish a procedure by which any administration of opioid antagonist to another individual by a trained overdose responder affiliated with an Opioid Overdose Prevention Program, shall be reported on forms prescribed by the department.”).

220. N.Y. COMP. CODES R. & REGS. tit. 10, § 80.138(c)(1)(v) (2008).

221. *Id.* § 80.138(a)(8)(ii).

222. CAL. CIV. CODE ANN. § 1714.22(a)(2) (West Supp. 2008).

223. Alameda, Fresno, Humboldt, Los Angeles, Mendocino, San Francisco, and Santa Cruz. *Id.* § 1714.22(d).

224. *Id.* § 1714.22(b)(2) (programs must teach: “(A) The causes of an opiate overdose; (B) Mouth to mouth resuscitation; (C) How to contact appropriate emergency medical services; and (D) How to administer an opioid antagonist”).

225. *Id.* § 1714.22(a).

226. *Id.* § 1714.22(b) (“A licensed health care provider who is permitted by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe and subsequently dispense or distribute an opioid antagonist in conjunction with an opioid overdose prevention and treatment training program, without being subject to civil liability or criminal prosecution.”). Unfortunately, the statute fails to distinguish between prescribing to non-patients and pre-

State legislation has not been the only response to qualms about the legality of overdose prevention programs. In 2007, the Boston Public Health Commission authorized a pilot program distributing a nasal-spray formulation of naloxone to ODUs.<sup>227</sup> The city-funded program in Baltimore started operation only after getting an opinion from the state attorney general (which sanctioned prescription to ODU patients, but not third-party savers).<sup>228</sup> And in North Carolina, organizers of Project Lazarus, a program aimed at licit and illicit prescription opioid users, asked the state medical board for approval. Consistent with our analysis, the program's sponsors took the position that the program was legal, but sought medical board sanction as a means to encourage physicians and others to participate in or support the program. In 2008, the Board issued a statement that did not purport to "authorize" the program, but did endorse it:

The goals of Project Lazarus are consistent with the Board's statutory mission to protect the people of North Carolina. The Board therefore encourages its licensees to abide by the protocols employed by Project Lazarus and to cooperate with the program's efforts to make naloxone available to persons at risk of suffering drug overdose.<sup>229</sup>

Given the need for action, the clear legality of prescribing naloxone to ODU patients, and the technical quality of the legal concerns about lay savers, it is not surprising that in some places programs have been started without particular attention to legal issues. Chicago Recovery Alliance, a harm reduction organization, has been distributing naloxone since 1998; physician prescription began in 2001.<sup>230</sup> Only in 2008 did a

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scribing to ODU patients. This phrasing, in conjunction with the geographic limitations in the statute, might be misread to suggest that licensed prescribers are not already authorized to prescribe naloxone to ODU patients.

227. Boston, Mass., Boston Public Health Commission Regulation Authorizing an Opioid Overdose Prevention and Reversal Pilot Program (Aug. 15, 2006), available at [http://www.bphc.org/board/pdfs/regs\\_narcan\\_8-15-06.pdf](http://www.bphc.org/board/pdfs/regs_narcan_8-15-06.pdf); see also Stephen Smith, *Addicts to Receive Overdose Antidote – Kit and Training for Heroin Users*, BOSTON GLOBE, November 2, 2007, at A1.

228. 88 Md. Op. Att'y Gen. 88, 88-89, 91-96 (2003).

229. Interview with Nab Dasgupta, University of North Carolina at Chapel Hill School of Public Health (Dec. 9, 2008) (transcript on file with the author).

230. Maxwell, *supra* note 193, at 90.

state senator introduce a bill to immunize physicians and laypersons from liability associated with naloxone administration.<sup>231</sup> Similarly, programs in Pennsylvania and Rhode Island<sup>232</sup> are operating without any formal official approval or immunity from legislators.

Programs that provide naloxone to ODUs can operate legally without legislative authorization, but states should still enact simple, flexible laws approving the programs. Legislative authorization encourages the establishment of more programs, increases the chances of government funding, reinforces the urgency of the opioid overdose problem, and eliminates legal barriers to enlisting lay savers. While the California, New Mexico, and New York laws all accomplish these goals, we recommend that laws or regulations authorizing naloxone distribution should avoid enshrining particular organizational designs, training requirements, or approaches to service delivery that may become outdated.<sup>233</sup> Care must be taken in drafting naloxone program laws to avoid reinforcing the misimpression that unauthorized programs are illegal.

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231. S.B. 2155, 95th Gen. Assem., Reg. Sess. (Ill. 2008). The bill was not passed, and a new version, which creates a relatively simple process for training and equipping lay savers, was introduced in February 2009. H.B. 00497, 96th Gen. Assem., Reg. Sess. (Ill. 2009).

232. Knox, *supra* note 36 (see chart listing overdose prevention program sites).

233. For instance, the New Mexico regulation defines an opioid antagonist as naloxone administered in "doses less than or equal to 1.0mg by subcutaneous injection or intramuscular injection, not to exceed a total overall dose of 2.0mg." N.M. CODE R. § 7.32.7.7(F) (Weil 2008). While injectable naloxone is still standard, nasal administration is gaining support as an alternative and possibly preferable method. The rigid definition of the New Mexico regulation does not allow for policy to evolve as medical knowledge and practice change. In fact, it is inconsistent with current New Mexico practice, which uses a nasal delivery device. Training requirements should also be general and competency-based, rather than prescribing curricula or other specific requirements. We do not yet have sufficient data to determine exactly how much or what sort of training is needed, and overdose programs in the U.S. are reporting that they have simplified and shortened training as their experience with the intervention has grown. See, e.g., Interview with Alice Bell, Overdose Prevention Project Coordinator, Prevention Point (Oct. 15, 2008) (describing shorter trainings in Pittsburgh); Interview with Dominick Zurlo, Biological Anthropology, Coordinator, Harm Reduction Outreach, Albuquerque Health Care for the Homeless, Inc. (Oct. 15, 2008) (describing shorter trainings in New Mexico). Laws that dictate the organizational structure of naloxone programs may also hinder progress. In North Carolina, Project Lazarus allows individual physicians to provide naloxone training to patients taking prescription opioids. See generally PROJECT LAZARUS, *supra* note 26. Without the sort of program registration requirements present in New York, New Mexico, and California, those physicians will not need to register as program directors, apoint clinical directors, or submit detailed records of each reported administration. Rather, the pilot program can develop and evolve its protocol utilizing the expertise of doctors and public health experts as well as lessons learned along the way.

The recent legislation in New Mexico, New York, and California highlights the possibility for action, but does not exhaust the range of authorization models. For example, states could deal with the lay-saver issue by defining “patient” for purposes of naloxone prescription as including a person who is not at risk of overdose but who, in the prescriber’s judgment, is capable of properly administering the drug and may be in a position to assist an overdose victim.<sup>234</sup> Supported by immunities for prescribers and savers, this would be a low-intensity way of removing legal barriers.

State epinephrine laws that permit certified third parties to treat persons having a severe allergic reaction to an insect sting offer another useful, potentially low-intensity model for authorizing distribution of naloxone to, and administration by, lay savers.<sup>235</sup> The Maryland Insect Sting Emergency Treatment Program law authorizes the state Department of Health to issue epinephrine administration certificates to people in a position to respond to severe allergic reactions.<sup>236</sup> To obtain a certificate, an applicant must be eighteen years of age, complete a training program with a physician, and submit an application to the Department.<sup>237</sup> Once certified, an individual can receive prescriptions from any Maryland physician for epinephrine, possess the necessary paraphernalia, and administer the medication to any person reacting severely to an insect sting.<sup>238</sup> The statute immunizes certificate holders as well as physicians

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234. See, e.g., H.B. 00497, 96th Gen. Assem., Reg. Sess. (Ill. 2009).

235. See, e.g., ARK. CODE ANN. §§ 20-13-401-407 (West 2005); FLA. STAT. ANN. § 381.88 (West 2007); S.C. CODE ANN. §§ 44-99-10-80 (2002). We do not regard the naloxone issue as analogous to expedited partner therapy (EPT) for sexually transmitted infections. In EPT, the physician caring for a patient provides an additional prescription to the patient to deliver to the patient’s sexual partner(s). State laws have been enacted to recognize and allow this deviation from the usual requirement that a prescription be based on an appropriate medical examination of the recipient. See Hodge, *supra* note 184, at 240. In EPT, the patient has an STI and gets a prescription based on his or her own need, which also supplies the indication for the third party. The legal barrier arises in the form of the requirement of an examination to make a prescription valid. The third party receiving the prescription from the patient will administer the drug him or herself. In naloxone programs, the main legal problem arises where a prescriber wishes to provide naloxone to a person who is not him or herself an ODU, to administer on a third party suffering an overdose. The recipient in this situation has no indication for the prescription, and is being deputized to act as a physician in some future emergency.

236. MD. CODE REGS. 10.52.16.04-06 (2008).

237. MD. CODE ANN., HEALTH-GEN. §§ 13-704-705 (West 2008).

238. *Id.* § 13-707 (West 2008) (enumerating the “abilities of certificate holders”).

from most liabilities that may stem from the injection of the medication.<sup>239</sup>

An effective naloxone certification law would allow any individual with a reasonable chance of witnessing an overdose to receive training through a range of health care providers or approved training programs. With a certificate system similar to insect sting treatment programs, a physician could train patients to use naloxone during office visits. This would increase the number of participating physicians and generally increase the accessibility of training to third parties, not least patients receiving opioid pain medicines and their families. Certified individuals would be permitted to receive naloxone prescriptions, possess related paraphernalia, and use the medication on any individual overdosing on opioids.

Policy makers could also consider fostering naloxone distribution through another link in the health care chain, pharmacies. Some states permit pharmacists to prescribe drugs when an individual needs an emergency refill.<sup>240</sup> Others allow pharmacists to make limited treatment decisions pursuant to drug therapy management plans.<sup>241</sup> In ten states, pharmacists may dispense emergency contraception on their own prescription.<sup>242</sup> Emergency contraception statutes provide a good model for naloxone. Because ODUs use pharmacies to obtain syringes and obtain prescription opioids, properly trained and motivated pharmacists would be in an excellent position to offer overdose information and to prescribe refills and dispense naloxone.

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239. *Id.* § 13-708.

240. *E.g.*, ALA. CODE § 34-23-75 (2002); FLA. STAT. ANN. § 465.0275 (West 2007).

241. *See, e.g.*, ARIZ. REV. STAT. ANN. § 32-1970(A)(2008); FLA. ADMIN. CODE ANN. r. 64B16-27.830 (2008); *see also* David B. Brushwood, *From Confrontation to Collaboration: Collegial Accountability and the Expanding Role of Pharmacists in the Management of Chronic Pain*, 29 J. L. MED. & ETHICS 69, 75-81 (2001) (explaining the benefits of collaborative relationships between physicians and pharmacists).

242. SURVEY OF PHARMACY LAW, *supra* note 148, at 100 (Table XXVIII lists each state and whether a pharmacist is permitted to dispense emergency contraception). Because the "morning after pill" (also called Plan B or RU-486) is now an OTC medication for women over eighteen, a prescription is now required only for minors.

*B. Liability of Health Care Providers Who Provide Naloxone*

Although there is little legal risk for properly licensed health care providers in prescribing naloxone to ODU patients (and probably little more in discreetly prescribing to lay savers), a few states have encouraged naloxone availability with laws that protect prescribers from legal claims based on the prescription, distribution, or administration of naloxone. Licensed health care providers who act with reasonable care in New Mexico are immune from civil or criminal charges arising from the provision of naloxone, regardless of whether the recipient is a patient, an ODU, or a trained lay saver.<sup>243</sup> The similar immunity in California, however, is limited to prescriptions issued “in conjunction with an opioid overdose prevention and treatment training program.”<sup>244</sup> And in Connecticut, the immunity does not cover prescriptions to lay savers, whether trained or not.<sup>245</sup>

All these statutes display a certain sleight of hand. It is no great thing to get “immunity” from malpractice claims with the proviso that one be acting with reasonable care. (And, of course, there is no valid reason why drug users should be afforded a lower standard of care than other patients.) On the other hand, these statutes do preclude criminal prosecution or professional discipline by a medical or nursing board, which has some real value. Provisions protecting prescribers from criminal charges and professional discipline are imperative in states that do not clearly authorize prescribing to non-ODU savers, and may be desirable as a means of encouraging pro-

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243. N.M. STAT. ANN. § 24-23-2 (West 2008) (licensed professional can prescribe naloxone “without being subject to civil liability or criminal prosecution”).

244. CAL. CIV. CODE § 1714.22(b) (West 2007).

245. CONN. GEN. STAT. ANN. § 17a-714a (West 2006) (“A licensed health care professional who is permitted by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe, dispense or administer an opioid antagonist to a drug user in need of such intervention without being liable for damages to such person in a civil action or subject to criminal prosecution.”). The proviso that the recipient be a “drug user in need of intervention” would not provide protection to a doctor who provides naloxone to a friend or family member of an ODU. The New York statute provides no direct immunity to health care providers, but does provide that “the purchase, acquisition, possession or use of an opioid antagonist pursuant to this section shall not constitute the unlawful practice of a profession,” which perhaps offers some indirect protection to professionals who issue naloxone to lay savers. N.Y. PUB. HEALTH LAW § 3309(2) (McKinney 2002 & Supp. 2008).



fessional participation even where overdose programs using lay savers are clearly authorized.

### C. *Immunity for Non-Licensed Savers*

An overdose witness without medical credentials who administers an opioid antagonist is technically practicing medicine without a license. In New Mexico, a lay saver certified as a targeted trained responder is immunized against civil or criminal liability for administering naloxone as long as she acted with reasonable care and believed the recipient was overdosing.<sup>246</sup> The New York law protects lay savers operating under the auspices of an authorized program by providing that “the purchase, acquisition, possession or use of an opioid antagonist pursuant to this section shall not constitute the unlawful practice of a profession” or other licensure offense.<sup>247</sup> It also defines naloxone administration as a “first aid or emergency treatment” for purposes of any liability statute.<sup>248</sup> The California statute provides no explicit immunity to lay savers, but its training and certification provisions suffice to insulate lay savers from legal difficulties in practice.<sup>249</sup> Connecticut’s law is silent on third party savers.<sup>250</sup>

We are aware of no instances of lay savers being prosecuted for saving a life without a license, nor have we been told of programs facing problems recruiting lay savers because of liability concerns. Nonetheless, of all the elements in a comprehensive overdose prevention scheme, lay savers are the ones who most clearly cross a legal line, and therefore the element that most clearly needs statutory authorization or protection. The issue of lay saver liability is most expeditiously dealt with by a simple, positive certification system as discussed above. Nonetheless, there is no reason *not* to give lay savers the same immunities as are provided to licensed professionals.

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246. N.M. STAT. ANN. § 24-23-1 (West 2008).

247. N.Y. PUB. HEALTH LAW § 3309(2).

248. *Id.* § 3309(3) (“Use of an opioid antagonist pursuant to this section shall be considered first aid or emergency treatment for the purpose of any statute relating to liability.”).

249. CAL. CIV. CODE § 1714.22.

250. CONN. GEN. STAT. ANN. § 17a-714a.

D. *Immunity for Those Who Provide Assistance or Call 911*

Laws that protect 911 callers from prosecution are an essential component of a comprehensive policy response to overdose. The administration of naloxone does not obviate the need to summon professional emergency assistance,<sup>251</sup> but studies report that illegal drug users are often afraid to do so for fear of police involvement.<sup>252</sup> While this fear may be exaggerated in the sense that the vast majority of 911 overdose calls do not seem to lead to prosecutions, reported cases indicate that overdose bystanders have been charged with and convicted of serious crimes after calling for help.<sup>253</sup> It is certainly better from a public health point of view to encourage people to call for emergency help than to punish them for doing so.

New Mexico is the only state to have enacted a law providing limited immunity to both the caller and the victim from drug possession charges.<sup>254</sup> Similar measures have been considered or are pending in Illinois<sup>255</sup> and Maryland.<sup>256</sup> In 2008, Alaska enacted a sentence-mitigation provision for a person convicted of a drug offense who “sought medical assistance for another person who was experiencing a drug overdose contemporaneously with the commission of the offense.”<sup>257</sup> The problem with all the bills, and New Mexico’s statute, is their narrow scope. Immunity from drug possession charges does not protect callers from drug paraphernalia arrests, for example, and individuals who jointly purchased and used

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251. Sporer & Kral, *supra* note 36, at 175.

252. See Baca & Grant, *supra* note 28 and accompanying text; see also Seal, *Naloxone Distribution*, *supra* note 192, at 309.

253. See, e.g., *Spears v. State*, 929 So. 2d 477 (Ala. Civ. App. 2005); *People v. Bez*, 802 N.E.2d 841 (Ill. App. Ct. 2003); *People v. Lewis*, No. 272531, 2007 WL 2744635 (Mich. Ct. App. Sept. 20, 2007).

254. N.M. STAT. ANN. § 30-31-27.1 (West 2008).

255. H.R. 4713, 95th Gen. Assem., Reg. Sess. (Ill. 2008).

256. H.B. 1390, Gen. Assem., Reg. Sess. (Md. 2008), available at <http://mlis.state.md.us/2008rs/bills/hb/hb1390t.pdf>. As introduced, the bill protected witnesses and victims from possession charges as well as prosecutions for an outstanding warrant. The final House version, however, only provides that seeking medical help “may be used as a mitigating factor in a criminal prosecution.” *Id.*

257. ALASKA STAT. § 12.55.155(d)(19) (2008).

drugs have been charged with offenses like homicide<sup>258</sup> and drug trafficking<sup>259</sup> after calling 911. While any immunity statute may serve the purpose of establishing a public policy in favor of leniency in the exercise of police and prosecutorial discretion, it would be more expeditious to face the issue head-on in legislation and establish a comprehensive immunity policy.<sup>260</sup>

People who seek medical help in a timely manner for an overdose victim should be immune from charges connected to causing the victim's death, as well as drug and paraphernalia charges, whether possession or distribution. Even if a caller has sold or (consensually) administered the drug to the victim, the imperative of saving the victim's life is greater than punishing the individual who seeks help. Any prosecution of 911 callers that garners media attention creates a deterrent for future callers. All such prosecutions should be eliminated in order to ensure overdose witnesses will not fear legal repercussions. Along with immunity laws, public information campaigns emphasizing the need (and safety) of calling 911 can encourage life-saving behavior by overdose bystanders.

#### *E. Congressional and FDA Action*

Most of the foregoing legal analysis is necessary only because naloxone has been classified by the FDA as a prescription drug. Were naloxone available over the counter (i.e., without a prescription), as condoms are everywhere and syringes are in most places, its distribution and use for public health purposes would be greatly simplified. Naloxone's FDA labeling as an injected medication raises the cost of distributing the drug in a nasally-administered formulation. Nasally administered naloxone is potentially more user-friendly for lay savers and for ODUs using oral opioids like oxycodone and methadone. In this section, we consider the challenges of converting naloxone from a prescription to an OTC medication, and in gaining approval of a nasally delivered formula-

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258. See *State v. Jones*, No. 05 CA 59, 2006 WL 466658, at \*5-6 (Ohio Ct. App. Feb. 24, 2006).

259. See *Lofthouse v. Commonwealth*, 13 S.W.3d 236, 242 (Ky. 2000).

260. For a detailed analysis of the New Mexico statute, see Rachel Boss, *Making a Brave New World for Drug Overdose Victims: The Challenges Facing New Mexico's 911 Good Samaritan Act and Encouraging Drug Overdose Victims and Witnesses to Call Emergency Medical Services* (2007) (unpublished paper, on file with the author, Professor Scott Burris).

tion. In reference to both changes, we discuss the unsuitability of our current drug regulatory system to dealing with low-profit medications that are needed most by poor or marginalized patients.

Currently, naloxone is produced in glass vials and ampoules and preloaded syringes and licensed for delivery through intravenous, intramuscular, or subcutaneous injection.<sup>261</sup> Doctors have the authority to use unapproved modes of delivery of approved drugs, and there has been fairly widespread use of, and some research on, the intranasal delivery of naloxone for overdose. Evidence now suggests that intranasal naloxone could be a viable alternative to injection in the pre-hospital setting.<sup>262</sup> Its use also reduces the real and perceived risk of needle stick injuries among first responders and others who are called upon to administer the drug in an emergency.<sup>263</sup> Intranasal naloxone can be used now because reasonable and informed off-label use of drugs falls within the scope of healthcare providers' professional discretion; but the lack of FDA approval precludes mass production of nasally delivered dosage units. Instead, nasal delivery kits must be made under the authority of a physician by program staff or compounding pharmacies using "after market" kits.

The ultimate goal of both advocates and regulators should be to identify and assure the availability of naloxone in formulations and doses that are safe and effective for administration by lay providers outside a hospital setting. FDA regulations

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261. LAWRENCE TRISSEL, HANDBOOK ON INJECTABLE DRUGS 1201-02 (Am. Soc'y of Health-Sys. Pharmacists 2007).

262. Erik D. Barton et al., *Efficacy of Intranasal Naloxone as a Needleless Alternative for Treatment of Opioid Overdose in the Prehospital Setting*, 29 J. EMERGENCY MED. 265 (2005); Anne-Maree Kelly et al., *Randomized Trial of Intranasal Versus Intramuscular Naloxone in Prehospital Treatment for Suspected Opioid Overdose*, 182 MED. J. AUSTL. 24 (2007); Anne-Maree Kelly et al., *Intranasal Naloxone Is a Safe First Line Treatment for Patients with Respiratory Compromise Due to Suspected Opiate Overdose*, 10 ACAD. EMERGENCY MED. 465, 466 (2006). However, the only study to measure the pharmacokinetics of naloxone under various modes of delivery found that intranasal delivery had substantially lower bioavailability compared to intramuscular and intravenous administration. See generally Jonathon Dowling et al., *Population Pharmacokinetics of Intravenous, Intramuscular, and Intranasal Naloxone in Human Volunteers*, 30 THERAPEUTIC DRUG MONITORING 490 (2008). This finding could lead the FDA to require relatively more clinical testing of an intranasal formulation than would have been the case had intranasal been shown to be bioequivalent to intramuscular.

263. See, e.g., Rob Curran, *Intranasal Medication Delivery: A Milestone Change In Practice*, 36 EMERGENCY MED. SERVICES 40, 41-45 (2007) (noting the support among EMTs for intranasal delivery route).

impose a salutary burden on proponents of new wider naloxone availability: the burden of demonstrating, by competent data, how naloxone can be properly used in the community. Meeting this burden would presumably require a series of studies to establish the pharmacokinetics of naloxone in intramuscular and intranasal forms, dose-response trials to determine the optimum dosage for intramuscular and intranasal in pre-hospital treatment of overdose and, eventually, a clinical trial of intramuscular versus intranasal in OTC use by people with opioid dependence. But the law also places a responsibility on FDA—and, indeed, other federal health agencies like the National Institute of Drug Abuse (NIDA) and the CDC—to ensure that market failure and other incidental barriers do not stand in the way of achieving the goal of optimal naloxone availability.

An intranasal delivery system is considered by the FDA to be a “new drug” requiring separate approval.<sup>264</sup> The change in mode of administration would normally require a “new drug application” (NDA). If the active ingredient and dosage are not changing and the drug is off patent, however, the change could be made through an “abbreviated new drug application” (ANDA).<sup>265</sup> The process would begin with a petition to the commissioner asking approval to seek an ANDA.<sup>266</sup> The commissioner is required to grant such a petition within ninety days unless the commissioner finds that “investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug.”<sup>267</sup> Once the ANDA is docketed, the agency will provide guidance as to the exact nature of the studies that will be required to demonstrate the “bioequivalence” of the new mode of administration. This research is normally conducted by and paid for (along with significant fees to FDA) by the applicant. The existing pharmacokinetic data on naloxone, which suggests that an intranasal formulation might require a higher

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264. See 21 C.F.R. § 330.13 (2007) (specifying that a new product containing an active ingredient that is already defined as a prescription drug is considered a new drug).

265. 21 U.S.C.A. § 355(j) (West 1999 & Supp. 2008).

266. *Id.* § 355(j)(2)(C) (West 1999).

267. *Id.* § 355(j)(2)(C)(i) (West 1999).

dose than intramuscular or intravenous,<sup>268</sup> makes it unlikely that FDA would accept an abbreviated application for intranasal naloxone. An ANDA might be suitable for a user-friendly auto-injector, of the sort used to deliver intramuscular epinephrine in cases of anaphylaxis,<sup>269</sup> because the dosing could be based on existing intramuscular data.

If the commissioner rejects the petition for an ANDA, an NDA under 21 U.S.C. § 355(b)(2), which applies to non-patented generics in a new formulation, would be necessary.<sup>270</sup> Filing a full NDA requires fresh clinical data, extensive paperwork, and substantial fees.<sup>271</sup> In the case of naloxone, however, there is already substantial data available, meaning that even an NDA would be relatively small and would have a high probability of success.

Any person with the economic wherewithal could generate the data necessary to file an NDA for naloxone. It is a generic drug whose patent has expired. Normally, as we discuss further below, a current manufacturer would be a natural proponent of the change. The fact that none have acted yet may reflect insufficient information about the potential market for a

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268. See Dowling, *supra* note 262, at 493.

269. The device is called an EpiPen®. See EpiPen, [http://www.epipen.com/epipen\\_dosing.aspx](http://www.epipen.com/epipen_dosing.aspx) (last visited May 21, 2009).

270. The 505(b)(2) application process is designed to expedite the approval of incremental changes to a drug with existing safety and efficacy data relevant to the change. CTR. FOR DRUG EVALUATION & RESEARCH, UNITED STATES FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY APPLICATIONS COVERED BY SECTION 505(B)(2) 3-4 (1999); see 21 C.F.R. § 314.3 (2007) (defining a 505(b)(2) application as an application filed under section 505(b)(1) that relies on outside literature and data to support its claims). Examples of incremental changes include alterations in dosage, the route of administration, or the prescription status. See CTR. FOR DRUG EVALUATION & RESEARCH, *supra*, at 4-5. Approval does not require the sponsor to fund new clinical studies. Rather, a sponsor can support a petition through previously published literature and FDA findings. *Id.* at 2-3. While a sponsor does not need to fund new studies, a 505(b)(2) filing for a drug modification still requires a detailed application supporting the change. See 21 C.F.R. § 314.54 (2007) (delineating what a sponsor of a modification to an approved drug must include in an application). A 505(b)(2) NDA is cheaper than a standard one; a sponsor must also pay half of the fees assessed for a full application. See 21 U.S.C.A. § 379(h)(a)(1)(A)(ii) (West Supp. 2008) (specifying that the fee is half if no additional clinical trials are required). As with an ANDA, however, the FDA will not approve an application for an incremental change if an additional study relevant to that change is necessary. 21 C.F.R. § 314.54.

271. See 21 C.F.R. § 10.25(a) (2008); 21 U.S.C.A. § 355(b)(1) (West Supp. 2008) (listing the information which must be included in a new drug application); CTR. FOR DRUG EVALUATION & RESEARCH, UNITED STATES FOOD & DRUG ADMIN., NEW DRUG APPLICATION (NDA) PROCESS (2007), available at <http://www.fda.gov/Cder/regulatory/applications/NDA.htm> (providing a stepwise, plain language explanation of the process).

formulation aimed at take-home use, or a belief that that market is too small to justify the investment. The current situation, in which there appears to be a steady hospital/emergency response market for naloxone and only one or two sellers, may be another disincentive for those currently offering the drug to invest in new, possibly less profitable markets. A new proposed label could, however, be written to focus on the OTC take-home market, by restricting the new indication for a nasal formulation to patients judged to be at risk of overdose and capable of administering or having a caregiver administer a nasal dose. A series of trials would establish the proper dose for intranasal use in this patient population, then test its safety and effectiveness in OTC use. This would be easier for proponents, who would not have to show that a nasally administered formulation could replace the injectable form in use in most emergency and hospital settings. It would also avoid any challenge to companies in that market.

A number of drug companies have produced naloxone in the past and could conceivably re-enter the market, as could an entirely new for-profit or not-for-profit company. There is a thicket of issues around the right of access to proprietary data from the original application and ongoing required monitoring of adverse events that complicate the decision, and which we will not delve into here. The FDA also accepts "citizen petitions," which can request the FDA to change a rule. A citizen petition requires a thorough explanation of the factual and legal reasoning supporting the request and an evaluation of the environmental and economic impacts of the change,<sup>272</sup> but there is no cost for filing one and on its face the required elements can be met by an individual or group without specialized FDA expertise. The petition process has the advantage of being simpler and cheaper than a new drug application, of requiring a set of formal actions and responses from the FDA, but it does not ultimately relax any of the regulatory standards in the statute and regulations. It would allow proponents of naloxone relabeling from outside industry to stake a position before the FDA, Congress and the public, but would not obviate the need to build the required evidentiary case for bioequivalence and/or safety and efficacy.

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272. 21 C.F.R. § 10.30(b) (2008).

The reclassification of naloxone in either or both the injectable and nasal delivery modes as OTC drugs would be an even more useful step in increasing access and decreasing opioid overdose deaths in America.<sup>273</sup> Drugs are limited to prescription distribution if they are habit-forming, toxic, have serious side-effects, or treat a condition laypersons cannot accurately diagnose or safely use the medication to treat without a doctor's supervision.<sup>274</sup> Evidence and experience support the prima facie case for naloxone reclassification for a take-home indication. Naloxone carries no psychoactive properties and thus has no significant abuse potential.<sup>275</sup> The drug is not toxic, as its only effect is the therapeutic effect on opioids.<sup>276</sup> The side effects are limited to transient withdrawal symptoms and a few very rare complications.<sup>277</sup> Lastly, laypersons can be trained to accurately identify an opioid overdose and administer naloxone.<sup>278</sup>

FDA regulations identify three pathways towards an OTC switch: unilateral action by the Commissioner; a new drug application; or a citizen petition.<sup>279</sup> The issue would initially be reviewed by an FDA expert advisory panel, which would make determinations as to the key issues including safety,<sup>280</sup>

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273. See Eric P. Brass, *Changing the Status of Drugs from Prescription to Over-the-Counter Availability*, 345 NEW ENG. J. MED. 810, 812 (2001) ("The need to visit a health care professional represents a substantial barrier to care for many patients because of financial, transportation, or scheduling limitations. Thus, making drugs available through direct retail sales will give patients greater access to effective therapies.").

274. 21 U.S.C. § 353(b) (West 1999 & Supp. 2008); see also United States Food & Drug Admin., *Now Available without a Prescription*, <http://www.fda.gov/fdac/special/testtube-topatient/available.html> (last visited May 21, 2009).

275. AVERY'S, *supra* note 45, at 497.

276. *Id.*

277. Sporer & Kral, *supra* note 36, at 175.

278. Traci C. Green, Robert Heimer & Laretta E. Grau, *Distinguishing Signs of Opioid Overdose and Indication for Naloxone: An Evaluation of Six Overdose Training and Naloxone Distribution Programs in the United States*, 103 ADDICTION 979, 986 (2008) ("[P]eople trained in overdose recognition and naloxone administration were comparable to medical experts in identifying situations in which an opioid overdose was occurring and when naloxone should be administered.").

279. 21 C.F.R. § 310.200(b) (2007); see also 21 U.S.C.A. § 353(b)(3) (West 1999) (codifying the secretary of the FDA also has the power to remove drugs from prescription-only status if the current status is not needed to safeguard public health); Holly M. Spencer, *The Rx-to-OTC Switch of Claritin, Allegra, and Zyrtec: An Unprecedented FDA Response to Petitioners and the Protection of Public Health*, 51 AM. U. L. REV. 999, 1016 (2002) (explaining that a citizen petition for a Commissioner's exemption is one viable mechanism).

280. 21 C.F.R. § 330.10(a)(4)(i) (2007) ("Safety means a low incidence of adverse reactions



efficacy,<sup>281</sup> and its risk-benefit ratio.<sup>282</sup> If its recommendation is positive, the committee would supply a draft “monograph” or set of requirements to the Commissioner detailing the conditions under which the drug could be marketed. For example, the monograph might specify the content and media of instructions on use to be included on the product label.<sup>283</sup> Generally, the FDA Commissioner retains the “sole discretion concerning action to be taken and policy to be expressed on any matter considered by an advisory committee.”<sup>284</sup> If the Commissioner elects to accept the recommendation, the proposed new rule (or monograph) is published in the Federal Register for comment. After the usual process of comments and steps to address opposition, a final rule may be published and take effect.<sup>285</sup>

As complicated as it is, a description of the basic regulatory scheme does not capture all the barriers to significant change in naloxone’s FDA status. The normal incentive for pharmaceutical companies to advocate a regulatory change is the

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or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability. Proof of safety shall consist of adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use. This proof shall include results of significant human experience during marketing. General recognition of safety shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.”).

281. *Id.* § 330.10(a)(4)(ii) (2007) (“Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed. Proof of effectiveness shall consist of controlled clinical investigations as defined in § 314.126(b) of this chapter, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered. General recognition of effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.”).

282. *Id.* § 330.10(a)(4)(iii) (2007).

283. *Id.* § 330.10(a)(4)(v) (2007) (“Labeling shall . . . state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.”).

284. *Id.* § 14.5 (2008).

285. *Id.* §§ 330.10(a)(5)-(7) (2007).

prospect of enhanced profit. A systematic national public health campaign to comprehensively address overdose would, as we have discussed here, include much wider use of naloxone. Naloxone distributed through programs aimed at illicit opioid users would increase, but the drug would also be introduced as a standard add-on to opioid pain prescriptions. Of course, it is too soon to tell whether such a measure for pain patients would be useful, let alone whether physicians would adopt the practice. Thus, while the potential for a wider market exists, the market has not yet been made. The lack of action by the makers of naloxone, and the lack of new entrants into the market for this non-patented medication, may reflect a lack of awareness of the potential for profit, or a more or less considered decision that the market will not be robust enough to justify action.<sup>286</sup>

Congress has provided a subsidy mechanism to overcome market failures in instances such as this. The Orphan Drug Act provides significant economic incentives and regulatory support for medications targeting a “rare disease or condition.”<sup>287</sup> “Rare disease or condition” is defined as “any disease or condition which affects less than 200,000 persons in the United States, or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.”<sup>288</sup> Once a drug is designated as an orphan, the FDA’s Office of Orphan Products can provide grants to and enter into contracts with public and private entities and individuals to help defray the costs of clinical and preclinical testing.<sup>289</sup> The designation also streamlines the

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286. There is also the question of whether, were a company inclined to increase production, the DEA would allow the necessary increase in quotas for naloxone’s raw materials. *See supra* note 35.

287. A sponsor may request orphan-drug designation of an already approved drug product for an unapproved use without regard to whether the prior marketing approval was for an orphan-drug indication. 21 C.F.R. § 316.23(b) (2007). The request can be made at any time before submission of a New Drug Application for the proposed drug or use. 21 U.S.C.A. § 360bb(a)(1) (West 1999). The orphan drug manufacturer or sponsor may request from the FDA written recommendations for clinical and nonclinical tests necessary for approval. 21 C.F.R. § 316.12(a) (2007). The Act also provides tax incentives for expenses relating to orphan drug development. 26 U.S.C.A. § 45C (West Supp. 2008).

288. 21 U.S.C.A. § 360bb(a)(2) (West 1999).

289. 21 U.S.C.A. § 360ee(a) (West 1999); *see also* United States Food & Drug Admin., Fre-

FDA's approval process, allowing the FDA to provide more intensive guidance on the research that will be required to secure approval,<sup>290</sup> and affords tax breaks<sup>291</sup> and extended market exclusivity.<sup>292</sup> The authorities have in the past treated drug addiction as a rare disease or condition because, although it affects many more than 200,000 Americans, "the pharmaceutical industry rarely profits from marketing drugs for the treatment of drug addiction and there exists little or no incentive for pharmaceutical companies to pursue research and development of new treatment medications for this population."<sup>293</sup> Suboxone, a combination of buprenorphine and naloxone used in substitution therapy, was given orphan drug status.<sup>294</sup> There is also a fee-waiver provision applicable to drugs necessary for public health.<sup>295</sup> It is not at all clear, however, whether these subsidies, even if applicable, are sufficient to motivate commercial pharmaceutical companies to act. There is a growing not-for-profit pharmaceutical sector devoted to orphan drugs,<sup>296</sup> but generally not aimed at the affluent U.S. market, and with the prevalent stigma of opioids, may see ODU as an uninspiring target population.

In practice, the FDA regulatory process is built around the well-financed entrepreneurial science of pharmaceutical companies. The FDA has a mission of serving the public interest, but the regulatory design of our pharmaceutical approval sys-

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quently Asked Questions Concerning the OOPD Grant Program, <http://www.fda.gov/orphan/grants/faq.htm> (last visited Jan, 15 2009). The orphan drug manufacturer or sponsor may request from the FDA written recommendations for clinical and nonclinical tests necessary for approval. 21 C.F.R. § 316.12(a) (2007).

290. 21 U.S.C.A. § 360aa(a) (West 1999).

291. 26 U.S.C.A. § 45C.

292. 21 U.S.C.A. § 360cc (West 1999 & Supp. 2002) (granting orphan drug applicant seven years of exclusivity as long as the applicant provides sufficient quantities of the drug to the target population during that period).

293. OFFICE OF RARE DISEASES, BIENNIAL & ANNUAL REPORT ON THE RARE DISEASES RESEARCH ACTIVITIES AT THE NATIONAL INSTITUTE OF HEALTH FOR 2004 (2004), *available at* [http://rarediseases.info.nih.gov/Wrapper.aspx?src=asp/html/reports/fy2004/FY2004\\_index.html](http://rarediseases.info.nih.gov/Wrapper.aspx?src=asp/html/reports/fy2004/FY2004_index.html).

294. UNITED STATES FOOD & DRUG ADMIN., CUMULATIVE LIST OF DESIGNATED ORPHAN DRUG PRODUCTS 11 (2008), *available at* <http://www.fda.gov/orphan/designat/list.htm>.

295. 21 U.S.C.A. §379h(d) (West 1999 & Supp. 2008) ("The Secretary shall grant to a person who is named as the applicant in a human drug application a waiver . . . [if] such waiver or reduction is necessary to protect the public health.").

296. See BIO Ventures for Global Health, <http://www.bvgh.org/default.asp> (last visited May 21, 2009).

tem casts the agency in the role of passive responder to applications built on research largely designed, conducted, and funded by industry. In theory, the agency can act affirmatively within the drug approval process on its own view of the public interest, but in practice this is a rare event.

The citizen petition process might work as a way of highlighting the need for the drug and implicitly condemning the inaction of public agencies and drug companies that are in the market now or could enter or re-enter the market as proponents for liberalized access. Although an assessment is outside the competence of the lawyers writing this Article, it is possible that a group of committed volunteer scientists could assemble enough evidence (including published studies and the publicly available clinical data from naloxone's original FDA approval) from existing sources to ground a convincing citizen petition. A petition's scientific validity, gravity—and political punch—could all be enhanced if state or local governments, and specifically health departments, could be convinced to join as petitioners. A citizen petition is, however, certainly the hardest way to get through the FDA process.

The naloxone situation highlights one way that public health can lose under our current pharmaceutical regulation paradigm. Waiting for industry to act on its own is not producing timely results. Affirmative action is required by public bodies if naloxone is to be expeditiously evaluated and deployed for public health purposes. This means not just action by the FDA, but also by the National Institutes of Health. Research could and should be funded by NIDA and other relevant institutes on the safety and efficacy of naloxone in nasal form and as a non-prescription drug.<sup>297</sup> If NIDA were to agree to conduct any necessary clinical studies for prehospital use of naloxone, this could significantly encourage pharmaceutical firms to develop naloxone products intended for outpatient use. Congress could move the process forward in several ways. In legislation introduced in the last Congress, Senator Dick Durbin of Illinois proposed funding for local research and demonstration projects, and directed the CDC to compile

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297. As an example, NIDA vigorously supported research on buprenorphine as a mode of treatment for opioid dependency. Nat'l Inst. on Drug Abuse, *Buprenorphine: What Buprenorphine Is and Why It's Important*, available at <http://www.drugabuse.gov/drugpages/buprenorphine.html>.

data and develop a plan to reduce overdose deaths.<sup>298</sup> Both steps would cost little and help much, not least in helping to make the case for FDA action. Congress could go further, directing the Commissioner of FDA to undertake a review of naloxone's status, or establishing an interagency or independent expert commission to review the overdose problem.<sup>299</sup>

## V. CONCLUSION

This country needs a comprehensive public health approach to drug overdose prevention. The immediate agenda includes wider implementation of overdose prevention programs, certification programs to allow lay people to possess and administer naloxone, and immunity provisions to remove barriers to providing naloxone or calling 911 in an emergency. Only a few states have taken legislative or administrative action to support naloxone programs, and even in some of those states the response has only been partial. The National Institutes of Health have done far too little to support research on overdose prevention, particularly of naloxone programs, and we need companies that produce naloxone—or that produce drugs like oxycodone and methadone and do not now produce naloxone—to begin the process of getting FDA approval for easier-to-use formulations or even an OTC version of naloxone. And if the drug companies won't act, we need the FDA to shake off its passivity and take affirmative action in the public interest. Finally, we need the physicians who prescribe pain medication, and their professional organizations, to wake up to this problem and get involved in finding solutions. If deaths keep rising, the political pressure to "do something" will become irresistible. Unless a solid public health approach is in place, we could well see the return of regulatory barriers to good pain care.

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298. Drug Overdose Reduction Act, S. 3557, 109th Cong. (2006).

299. Congress used the independent panel approach in, to take a recent example, the Advisory Committee on Gulf War Veterans' Illnesses.