



USING LAW TO SUPPORT PHARMACY NALOXONE DISTRIBUTION

## Issue Brief

# Using Law to Support Pharmacy Naloxone Distribution

On a Sunday in October 2013, one Minnesota Sheriff's Deputy responded to two separate lethal overdoses.<sup>1</sup> In both cases, opioids were the prime suspect.<sup>2</sup> Prescription opioids and heroin are causing similar fatalities all across the nation. More drastic action is required to save lives.

Prescription drug overdose has reached epidemic proportions.<sup>3</sup> Unintentional drug poisoning deaths in the United States increased six-fold from 1980 to 2010.<sup>4</sup> Pharmaceutical opioid overdose claimed the lives of 16,651 people in the United States in 2010.<sup>5</sup> While the epidemic is national, some jurisdictions have experienced especially high numbers of fatalities associated with overdose. During a four month period in Massachusetts, November 2013 to February 2014, 185 people died from suspected heroin overdoses.<sup>6</sup> In New York City, "overdose deaths related to prescription painkillers increased 233 percent between 2000 and 2012."<sup>7</sup> Heroin-related overdose deaths in the City increased 84 percent between 2010 and 2012.<sup>8</sup> These statistics are particularly troubling because, overdose death is preventable through the timely provision of a cheap, safe, and effective drug: naloxone.<sup>9</sup>

Public health professionals are seeking new ways to make the overdose antidote more available. Because opioid prescription medications are often the cause of overdose, pharmacy practice is a logical avenue for increased naloxone access.<sup>10</sup> On October 20, 2014, the National Association of Boards of Pharmacy recognized the need "to support programs that involve an active role for pharmacists in expanding access to the opioid overdose reversal drug, naloxone."<sup>11</sup> Some jurisdictions have already created new programs with pharmacies, increasing access to the overdose antidote without the traditional requirements of a physician consult and prescription.

This brief aims to explore the legal mechanisms enabling enhanced pharmacy naloxone distribution, and help public health professionals — including prescribers and pharmacy managers, as well as state, local, and territorial health departments — understand key legal issues. First, this brief will introduce the overdose antidote and provide some basic background. Second, collaborative pharmacy practice will be described, including details about how the model is being used in several jurisdictions. Then, the pharmacist-as-prescriber model for naloxone distribution will be explored. Next, this brief will explain standing order legislation, like that recently passed in New York. Then, challenges to consider in relation to naloxone distribution in a retail pharmacy will be described. Lastly, this brief will look to the future and discuss next steps.



## Background

Naloxone, known by the brand name Narcan, is an opioid antagonist. The “lifesaving antidote”<sup>12</sup> reverses opioid overdose by blocking the opiate receptors in the nervous system and reversing depression of the respiratory system. Naloxone was first approved by the US Food and Drug Administration in 1971.<sup>13</sup> Used in hospitals and ambulances for decades, the medication has no abuse potential.<sup>14</sup> It is easy to administer; research and pilot programs suggest that even untrained laypeople can use it successfully.<sup>15</sup> Although not a controlled substance, naloxone may not be dispensed without a prescription.<sup>16</sup> Because most overdoses are witnessed by another person and there is normally sufficient time to act, it is important to get the drug into the hands of the people who can act immediately.<sup>17</sup>

The first efforts to institute take-home naloxone started in Chicago in the 1990’s.<sup>18</sup> Since 2001, dozens of new laws and regulations have enabled doctors and other medical professionals to prescribe and dispense naloxone more easily.<sup>19</sup> The new legal frameworks have encouraged the creation of hundreds of programs to train lay people to administer naloxone outside of a health care setting.<sup>20</sup> Overdose education and naloxone distribution programs provide an effective and cost-sensitive intervention.<sup>21</sup> Between 1996 and 2010, programs providing naloxone received reports of 10,171 overdose reversals.<sup>22</sup> Since the establishment of the New York State Opioid Overdose Prevention Program in 2006, over 650 overdose reversals have been reported statewide.<sup>23</sup> By June 2012, San Francisco’s Drug Overdose Prevention and Education (DOPE) counted 782 reversals.<sup>24</sup> In light of this evidence, advocates are working to get naloxone in the hands of more people who can help save lives.<sup>25</sup>

Two concepts that come up in the opioid overdose prevention context are standing orders (also referred to as non-patient-specific orders) and third party prescription. Standing orders are generally used to allow one prescriber to write an order covering administration of medication by others to a patient who may be unknown to the prescriber at the time of the order. When the patient meets certain criteria, a nurse or other medical staff member acting under the order can administer the medication without the physician personally examining the patient. For example, medications like acetaminophen are often prescribed by a standing order to patients in a nursing home, so that a doctor call is not required each time a patient requests a pain reliever. Standing orders are also widely used in ambulances and for vaccinations, like influenza shots administered by school nurses.

A third-party prescription is an order written for medication dispensed to one person with the intention that it will be administered to another person. In the context of naloxone, it could be the family member of a person at risk for overdose getting a prescription filled in their own name, with the intent that they would use the naloxone in the event the loved-one overdosed. State practice laws are generally ambiguous regarding the reach of standing orders and generally discourage or prohibit third-party prescriptions.<sup>26</sup> In the past few years, a large number of states have passed laws that explicitly permit third party prescription and standing orders for naloxone.<sup>27</sup>

## Collaborative Practice Agreements

Collaborative practice agreements (CPA), whereby a practitioner delegates medication management authority to a pharmacist, are one way that providers have increased naloxone access through pharmacies. Historically, “pharmacists prepared and dispensed remedies while offering front-line medical advice to their customers.”<sup>28</sup> After the 1951 Durham-Humphrey amendment to the Food, Drug, and Cosmetic Act, prescribing could only be done by practitioners licensed by law.<sup>29</sup> The collaborative practice approach was developed to utilize pharmacists as drug therapy experts, thus improving the efficiency and quality of care.<sup>30</sup> The Pharmacist Practitioner Program of the Indian Health Service was an early pioneer in the approach.<sup>31</sup>

By 1997, sixteen states had enacted legislation to allow pharmacists to participate in drug/medication therapy management (MTM) through collaborative arrangements with physicians and other health care providers.<sup>32</sup> Using MTM, the pharmacist works with the primary care provider to “holistically care for patients, take responsibility for their drug-



related needs, classify drug therapy problems, and document them.”<sup>33</sup> The pharmacist is delegated drug therapy management authority by a physician, which can include “initiating, modifying and monitoring drug therapy,” among other things.<sup>34</sup> MTM collaborative practice is legal in a majority of states for an array of health conditions.<sup>35</sup> Collaborative practice authority exists in 48 states and the District of Columbia, as of May, 2014.<sup>36</sup> There is wide variation between states regarding the authority that can be delegated using these agreements.

## Washington

In King County, Washington, some pharmacists distribute naloxone to high-risk people through a CPA.<sup>37</sup> Washington law explicitly includes “initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs” in the practice of pharmacy.<sup>38</sup> Kelley-Ross Pharmacy partnered with the public health agency of Seattle and King County and the University of Washington Alcohol and Drug Abuse Institute.<sup>39</sup> Relying on Washington laws and regulations,<sup>40</sup> the first naloxone Collaborative Drug Therapy Agreement<sup>41</sup> was signed August 9, 2012.<sup>42</sup> The agreement was renewed in March, 2014.<sup>43</sup> The Medical Director of the public health agency is the signatory prescriber.<sup>44</sup>

Kelley-Ross pharmacists provide training and dispense naloxone in the form of a nasal spray.<sup>45</sup> The pharmacists are required to document all patient interactions that result in a “prescribing and dispensing” event in the pharmacy management system.<sup>46</sup> A training checklist is initialed by the patient and attached to the prescription as part of the permanent record.<sup>47</sup> Additionally, the authorizing prescriber and the pharmacists perform regular quality assurance reviews.<sup>48</sup>

## Rhode Island

About ten years ago in Providence, Rhode Island, two researchers started the Preventing Overdose and Naloxone Intervention (PONI) pilot program with the intent to train people at needle-exchange sites, drug-abuse treatment centers, and homeless shelters in the use of naloxone.<sup>49</sup> To further the aim of wider naloxone distribution, Dr. Josiah Rich at the Miriam Hospital has “essentially written a prescription for anyone who requests the drug, and Walgreens has agreed to dispense it, along with some training.”<sup>50</sup> Building on the Washington model and relying on the Rhode Island collaborative practice statute, Dr. Rich entered into a formal CPA with Walgreens in early 2013.<sup>51</sup> The statute and related rules in Rhode Island have a broad definition of collaborative pharmacy practice, which allows “work in collaboration” for “the purpose of drug therapy management of patients.”<sup>52</sup> The statute does not explicitly permit initiating a new treatment.<sup>53</sup> Cooperation with the State of Rhode Island Board of Pharmacy (the “Board”) helped to implement the program.<sup>54</sup> For example, the statute requires a pharmacist to have “advanced training” and the Board approved a Continuing Education module as the required training for the naloxone CPA.<sup>55</sup>

The procedure in the Rhode Island allows pharmacists to identify patients who meet eligibility criteria and initiate naloxone drug therapy according to a protocol. The protocol requires the pharmacist to fax written notification to the prescriber if there is patient participation or naloxone dispensation.<sup>56</sup> Also, the recipient must sign a consent form (in which they may limit the timeframe) so that the prescriber can access their medical records.<sup>57</sup>

Subsequently, on March 3, 2014, the Rhode Island Department of Health released Rules and Regulations Pertaining to Opioid Overdose Prevention, promulgated according to an administrative procedure allowing emergency regulations.<sup>58</sup> Under the Regulations, one prescriber is now able to issue a non-patient-specific order to numerous organizations, such as police departments, allowing for increased access to naloxone.

## Pharmacist-as-Prescriber

Some states have enacted legislation to allow pharmacists to furnish medication to a patient without the involvement of a licensed physician or other medical professional. In most states that allow the practice, prescribing has very defined



limits.<sup>59</sup> For example in 2006, eight states allowed pharmacists to prescribe emergency contraception without a physician prescription.<sup>60</sup> On a national scale, the Indian Health Service Clinical Pharmacy Specialists program grants pharmacists broad prescriptive authority, with the scope of practice determined by the medical staff at each facility.<sup>61</sup>

## New Mexico

New Mexico has always been on the forefront of naloxone legislation.<sup>62</sup> Recently, the state became the first in the country to permit all pharmacists to prescribe naloxone directly to patients without any physician involvement.<sup>63</sup> To obtain prescriptive authority, pharmacists complete a Board of Pharmacy-approved training and maintain this certification by completing two hours of live continuing education in this area every two years.<sup>64</sup> The “Pharmacist Protocol for Prescribing Naloxone” was approved by the New Mexico Medical Board, the Nursing Board, and the Board of Pharmacy.<sup>65</sup> Under the Protocol, informed consent must be documented and the pharmacist must notify the patient's designated physician or primary care provider within 15 days of dispensing naloxone.<sup>66</sup>

## Standing Order Legislation

As of November 2014, twelve states have enacted legislation or regulations to explicitly allow for the dispensing of naloxone under standing orders.<sup>67</sup> Illinois added the Drug Overdose Prevention Program to its Alcoholism and Other Drug Abuse and Dependency Act effective January 1, 2010.<sup>68</sup> California,<sup>69</sup> Delaware,<sup>70</sup> Kentucky,<sup>71</sup> Minnesota,<sup>72</sup> New Jersey,<sup>73</sup> North Carolina,<sup>74</sup> Pennsylvania,<sup>75</sup> Rhode Island,<sup>76</sup> Tennessee,<sup>77</sup> Vermont,<sup>78</sup> and Wisconsin<sup>79</sup> all put legislation in place very recently.

Many of these laws are very similar. For example, Kentucky, New Jersey, North Carolina, and Tennessee include the “standing order” language in near identical provisions. Prescribers are given the authority to prescribe the medication via such an order, and are granted limited immunity with regard to such prescriptions so long as they act in good faith.<sup>80</sup> Some states also include an obligation to act with reasonable care. Similar to the California law detailed below, Vermont only authorizes prescribing to a person who “has been educated about opioid-related overdose prevention and treatment in a manner approved by the Department.”

## Illinois

The Illinois standing order statute has been in place the longest, but a naloxone distribution program began operating even before explicit authorizing legislation. In the fall of 1996, naloxone training and distribution started informally by several doctors at Chicago Recovery Alliance.<sup>81</sup> The program formalized overdose training that incorporated naloxone in 2001.<sup>82</sup> As mentioned above, in 2010, the legislature passed a law clarifying that health care professionals can prescribe naloxone without fear of legal repercussion, and expanded the universe of people to whom they can prescribe.<sup>83</sup>

## California

The Drug Overdose Prevention and Education (DOPE) program in San Francisco began distributing naloxone in 2003 under the Medical Director of the San Francisco Department of Public Health.<sup>84</sup> Nurse practitioners were present while naloxone trainings happened, and signed off on prescriptions while DOPE staff did the trainings.<sup>85</sup>

Currently, San Francisco Department of Public Health pharmacies dispense kits that are funded through a city program.<sup>86</sup> Under a collaborative practice agreement, the pharmacists initiate and dispense the naloxone prescription.<sup>87</sup>

Opioid overdose prevention and treatment training programs have been authorized under California law since 2008. California law authorized standing orders with training provided by an opioid overdose prevention and treatment training program effective January 1, 2014.<sup>88</sup> Any physician may issue a standing order, including one for third party distribution.<sup>89</sup> Each training program must provide training on the causes of opiate overdose, mouth to mouth resuscitation, how to contact appropriate emergency medical services, and how to administer an opioid antagonist.<sup>90</sup> Just recently on



September 15, 2014, a bill was signed into law authorizing pharmacists to furnish naloxone pursuant to procedures and protocols of the State Board of Pharmacy and the Medical Board.<sup>91</sup> The law includes provisions to ensure training of pharmacists and education for the person to whom the drug is furnished.<sup>92</sup>

## New York

Since 2007, New York law has authorized Opioid Overdose Prevention Programs to dispense naloxone and has limited liability for those administering an opioid antagonist. On June 24, 2014, Governor Andrew M. Cuomo signed “An act to amend the public health law, in relation to use of opioid antagonists.”<sup>93</sup> Under the Act, a healthcare professional may prescribe “by a patient-specific or non-patient specific prescription, dispense or distribute, directly or indirectly, an opioid antagonist to an opioid antagonist recipient.” The definition of recipient is very inclusive: “A person at risk of experiencing an opioid-related overdose, or a family member, friend or other person in a position to assist a person experiencing or at risk of experiencing an opioid-related overdose.” The Act permits individuals to pass along naloxone to others.<sup>94</sup> The Governor’s press release notes that “[p]harmacists, using their professional expertise, will . . . be able to dispense naloxone to anyone who needs it.”<sup>95</sup> The new law explicitly permits both standing order<sup>96</sup> and third-party prescriptions. Local advocates are enthusiastic about the potential of naloxone distribution under the proposed law.<sup>97</sup>

## Challenges

There are several potential challenges to the distribution of naloxone through pharmacies. This section will help public health professionals understand issues that could arise with attitudes, insurance billing and information privacy.

One barrier to broad naloxone distribution is stigma. Providers may feel that naloxone might offer a “safety net” that encourages riskier behavior, although this concern is not backed by evidence.<sup>98</sup> There may also be uneasiness about “providing a drug that a layperson may administer or . . . the liabilities if there is an adverse outcome or if the drug is administered to a third party rather than to the person for whom it was prescribed.”<sup>99</sup>

Another problem may be billing insurance for third party naloxone prescriptions. There is some evidence that insurers support the distribution of naloxone,<sup>100</sup> but at least one claim, in New Mexico, has been denied.<sup>101</sup> There are a variety of ways that a drug may be covered by a plan. Coverage may only be for direct administration in a medical setting and not take-home naloxone from a pharmacy.<sup>102</sup> Even if a plan covers the drug dispensed at the pharmacy, it may not cover the provider’s time in training patients, or the nasal atomizer or syringe needed to administer the drug.<sup>103</sup> Some plans may limit third-party prescriptions. Insurance is a contractual relationship between the insurer and the insured, which may limit coverage to only prescriptions that are intended to be used on the insured. Medicaid programs can have several types of plans -“traditional fee-for-service” coverage, coverage offered through a Managed Care Organization, and that under Alternative Benefit Plans.<sup>104</sup> The formulary (which drugs are covered) can be managed differently for each plan type. Some states are working to ensure that Medicaid policy allows for naloxone third party prescriptions.<sup>105</sup> Of course, if a program were to supply the naloxone or if the patient paid out-of-pocket, insurance billing would not be an issue. Legislative action could also mandate coverage.

Some patients may be concerned with the release of information (ROI), like that happening in Rhode Island’s collaborative practice model. Patients in Washington, where a ROI is not required, value the fact that the program is somewhat discreet.<sup>106</sup> On the other hand, with access to medical records, the prescriber and the stakeholder agency may have more oversight of the program as it is administered at the pharmacy.

## Next Steps

If unfettered access to naloxone is the goal, over-the-counter (OTC) status would tear down many barriers. There is a movement to eliminate the need for prescriptions for naloxone.<sup>107</sup> The Food and Drug Administration (FDA) has considered the issue, but the OTC transition process is cumbersome and requires a financial commitment.<sup>108</sup> In the New Drug Application process, the applicant must provide the FDA with data and pay a user fee.<sup>109</sup> Some new studies would be required. For example, consumer studies would be required to “assess whether the individual administering the drug

could properly diagnose the opioid overdose and determine that it is appropriate to give naloxone based upon the information in the drug facts label."<sup>110</sup>

There may be some drawbacks to OTC. There may be new additional costs that disproportionately affect the disadvantaged members of our society. Many Medicaid and Medicare recipients get prescription medications for a very low cost, and it can be expected that OTC naloxone will be priced with a profit motivation. For the time being, state and local action provide the best course for pharmacy naloxone distribution.

As more jurisdictions enact enabling legislation, a state, local, or territorial health department Medical Director, or other prescriber, may initiate a standing order with a retail pharmacy chain. To ensure efficient collaboration, a Cooperative Agreement could form the basis of the contractual relationship and incorporate similar elements to agreements and protocols already in use. An effective arrangement would require that all prescribing and dispensing events be documented, preferably in an electronic records system. A training checklist should be completed and retained for each prescription. Having each prescription faxed back to the prescriber may be beneficial, but stakeholders would need to examine administrative and privacy concerns. Quality assurance reviews like those used in Washington would help ensure compliance with protocol and facilitate ongoing communication if issues arise.

Pharmacy distribution models demonstrate that there is more than one appropriate channel to get naloxone to those who need it most. Because research demonstrates that even untrained individuals can administer naloxone appropriately, lawmakers should move away from models that require specific programs for training and distribution. Broader legislation provides for creative solutions.

As a viable and efficient option to increase naloxone access, pharmacy distribution should be considered by more jurisdictions. Hopefully, by enabling jurisdictions to select appropriate legal models, naloxone can get into the hands of those who are poised to save lives.

## SUPPORTERS



Robert Wood Johnson Foundation

**The Network for Public Health Law is a national initiative of the Robert Wood Johnson Foundation with direction and technical assistance by the Public Health Law Center at William Mitchell College of Law.**

**This document was developed by Jada Fehn, Public Health Law Fellow, Visiting Attorney Program of the Robert Wood Johnson Foundation. The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.**

<sup>1</sup> Shannon Prather, *Families, recovering addicts, police tell the horrors of heroin*, STAR TRIB., February 4, 2014, <http://www.startribune.com/local/north/243271811.html>; Amy Forliti et al., "We're All Paying:" Heroin Spreads Misery in US, A.P., April 5, 2014, <http://bigstory.ap.org/article/were-all-paying-heroin-spreads-misery-us-2>.

<sup>2</sup> *Id.*

<sup>3</sup> Leonard Paulozzi et al., *CDC Grand Rounds: Prescription Drug Overdoses - a U.S. Epidemic*, 61 (01) MORBIDITY AND MORTALITY WEEKLY REPORT 10 (January 13, 2012); Cristina Menses, *Spotlight on Heroin Epidemic Leaves Many Victims in the Dark*, NETWORK FOR PUBLIC HEALTH LAW (Apr. 17, 2014), [https://www.networkforphl.org/the\\_network\\_blog/2014/04/17/436/spotlight\\_on\\_heroin\\_epidemic\\_leaves\\_many\\_victims\\_in\\_the\\_dark](https://www.networkforphl.org/the_network_blog/2014/04/17/436/spotlight_on_heroin_epidemic_leaves_many_victims_in_the_dark) (noting the "epidemic" designation was too late for many people who experience disparate treatment in this country).

- 
- <sup>4</sup> AMERICAN PUBLIC HEALTH ASS'N, POLICY STATEMENT LB-12-02 – PREVENTING OVERDOSE THROUGH EDUCATION AND NALOXONE DISTRIBUTION 1, (November 5, 2013)(citing Christopher Jones et al., *Pharmaceutical Overdose Deaths, United States 2010*, 309(7) J. AM. MED. ASS'N 657 (Feb. 20, 2013)).
- <sup>5</sup> Christopher Jones et al., *Pharmaceutical Overdose Deaths, United States 2010*, 309(7) J. AM. MED. ASS'N 657 (Feb. 20, 2013).
- <sup>6</sup> *Massachusetts: 4 months and 185 heroin deaths*, A.P., April 5, 2014, [http://hosted2.ap.org/MANOR/4e06196a1f11442a96197ec8174afd24/Article\\_2014-04-05-Heroin-Massachusetts/id-f171dde314a14c01b4b2486edaed6831](http://hosted2.ap.org/MANOR/4e06196a1f11442a96197ec8174afd24/Article_2014-04-05-Heroin-Massachusetts/id-f171dde314a14c01b4b2486edaed6831).
- <sup>7</sup> Press Release, N.Y.C. Dep't Health & Mental Hygiene, Prescription Painkiller and Heroin Overdose Deaths Continue to Rise in New York City (February 6, 2014), available at <http://www.nyc.gov/html/doh/html/pr2014/pr003-14.shtml>
- <sup>8</sup> *Id.*
- <sup>9</sup> Corey Davis, *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws*, Network for Public Health Law 2, <http://www.networkforphl.org/asset/qz5pvn/network-naloxone-10-4.pdf> (last visited May 1, 2014).
- <sup>10</sup> Eliza Wheeler et al., *Take-Home Naloxone for Opioid Overdose: Exploring the Legal, Policy and Practice Landscapes*, NETWORK FOR PUBLIC HEALTH LAW (October 18, 2012), <https://www.networkforphl.org/asset/lhscnj/October-Webinar.pdf>
- <sup>11</sup> Press Release, the National Association of Boards of Pharmacy, NABP Issues Policy Statement Supporting the Pharmacist's Role in Increasing Access to Opioid Overdose Reversal Drug (Oct. 20, 2014), available at <http://www.nabp.net/news/nabp-issues-policy-statement-supporting-the-pharmacist-s-role-in-increasing-access-to-opioid-overdose-reversal-drug>.
- <sup>12</sup> *Why Naloxone?*, <http://www.naloxoneinfo.org/>, (last visited May 1, 2014).
- <sup>13</sup> NDA 016636, Drugs@FDA Database, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=SearchDrugDetails> (last visited May 1, 2014).
- <sup>14</sup> *Why Naloxone?*, *supra* note 12.
- <sup>15</sup> Maya Doe-Simkins et al., *Overdose rescues by trained and untrained participants and change in opioid use among substance-using participants in overdose education and naloxone distribution programs: a retrospective cohort study*, 14(297) BMC PUBLIC HEALTH 2014 (April 1, 2014), <http://www.biomedcentral.com/1471-2458/14/297/>.
- <sup>16</sup> 21 U.S.C. §§ 353(b)(1).
- <sup>17</sup> Leo Beletsky et al., *Prevention of Fatal Opioid Overdose*, 308 J. AM. MED. ASS'N, November 14, 2012, at 1863-1864, available at <http://ssrn.com/abstract=2176279> (“During the time it typically takes some overdoses to turn fatal, it is possible to reverse the respiratory depression and other effects of opioids with the antagonist naloxone.”)
- <sup>18</sup> Eliza Wheeler et al., *supra* note 10, (“Earliest take-home naloxone efforts in Chicago, 1996.”)
- <sup>19</sup> See Davis, *supra* note 9.
- <sup>20</sup> Eliza Wheeler et al., *Community-Based Opioid Overdose Prevention Programs Providing Naloxone - United States, 2010*, 61 (06) MORBIDITY AND MORTALITY WEEKLY REPORT 101 (February 17, 2012).
- <sup>21</sup> See AMERICAN PUBLIC HEALTH ASS'N, *supra* note 4.
- <sup>22</sup> Wheeler, *supra* note 10.
- <sup>23</sup> Press Release, *supra* note 7.
- <sup>24</sup> Wheeler, *supra* note 10, at slide 13.
- <sup>25</sup> Alexander Y Walley, *Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis*, 346 BRIT. MED. J. 174 (January 31, 2013), available at <http://www.bmj.com/content/346/bmj.f174>.
- <sup>26</sup> Davis, *supra* note 9.
- <sup>27</sup> See Wheeler et al., *supra* note 10.
- <sup>28</sup> St. Louis College of Pharmacy, A Brief History of Pharmacy, <https://www.stlscop.edu/practice/history/>
- <sup>29</sup> Raymond Hammond et al., *Collaborative Drug Therapy Management by Pharmacists*, 23(9), PHARMACOTHERAPY 1210, 1213 (2003), available at <https://www.accp.com/docs/positions/positionStatements/pos2309.pdf>.
- <sup>30</sup> *Id.*
- <sup>31</sup> *Id.*
- <sup>32</sup> *Id.*, citing Jannet Carmichael et al., *Collaborative Drug Therapy Management by Pharmacists*, 17(5) PHARMACOTHERAPY 1050 (1997).

<sup>33</sup> Beth Farnstrom, MTM Profile: Clinical collaboration, PHARMACY TODAY 32, 32 (March 2009), available at [http://www.fairview.org/fv/groups/public/documents/web\\_content/s\\_029088.pdf](http://www.fairview.org/fv/groups/public/documents/web_content/s_029088.pdf).

<sup>34</sup> Hammond, *supra* note 29, at 1221.

<sup>35</sup> *Id.*, at 1213 and See CDC, STATE LAW FACT SHEET SELECT FEATURES OF STATE PHARMACIST COLLABORATIVE PRACTICE LAWS (Dec., 2013), available at [http://www.cdc.gov/dhbsp/pubs/docs/Pharmacist\\_State\\_Law.PDF](http://www.cdc.gov/dhbsp/pubs/docs/Pharmacist_State_Law.PDF).

<sup>36</sup> Kansas collaborative practice law becomes effective July 1, <http://www.pharmacist.com/kansas-collaborative-practice-law-becomes-effective-july-1-1>

<sup>37</sup> *Make Narcan available to reverse heroin overdose*, THE OLYMPIAN, April 17, 2014, available at

<http://www.theolympian.com/2014/04/17/3090318/make-narcan-available-to-reverse.html?sp=/99/109/#storylink=cpyhttp://www.theolympian.com/2014/04/17/3090318/make-narcan-available-to-reverse.html?sp=/99/109/>

<sup>38</sup> WASH REV COD ANN. § 18.64.011(23) (Lexis Nexis 2014) (“Practice of pharmacy’ includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices. Pharmacist prescriptive authority--Prior board notification of written guideline or protocol required.”)

<sup>39</sup> Ryan Oftebro, *Kelley-Ross Pharmacy Provides Take-Home Naloxone to Prevent Opioid Overdose*, August 20, 2013, available at

<https://www.krrph.com/kelley-ross-pharmacy-provides-take-home-naloxone-to-prevent-opioid-overdose/>.

<sup>40</sup> WASH REV COD ANN., *supra* note 38; WASH. ADMIN. CODE § 246-863-100 (1)(2014) (“A pharmacist planning to exercise prescriptive authority in his or her practice (see RCW 18.64.011(11)) by initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs must have on file at his/her place of practice a properly prepared written guideline or protocol indicating approval has been granted by a practitioner authorized to prescribe. A copy of the written guideline or protocol must also be on file with the board of pharmacy. (2) For purposes of pharmacist prescriptive authority under RCW 18.64.011(11), a written guideline or protocol is defined as an agreement in which any practitioner authorized to prescribe legend drugs delegates to a pharmacist or group of pharmacists authority to conduct specified prescribing functions. Any modification of the written guideline or protocol shall be treated as a new protocol. It shall include: (a) A statement identifying the practitioner authorized to prescribe and the pharmacist(s) who are party to the agreement. The practitioner authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners’ current practice. (b) A time period not to exceed 2 years during which the written guideline or protocol will be in effect. (c) A statement of the type of prescriptive authority decisions which the pharmacist(s) is (are) authorized to make, which includes: (i) A statement of the types of diseases, drugs, or drug categories involved, and the type of prescriptive authority activity (e.g., modification or initiation of drug therapy) authorized in each case. (ii) A general statement of the procedures, decision criteria, or plan the pharmacist(s) is (are) to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved. (d) A statement of the activities pharmacist(s) is (are) to follow in the course of exercising prescriptive authority, including documentation of decisions made, and a plan for communication or feedback to the authorizing practitioner concerning specific decisions made. Documentation may occur on the prescription record, patient drug profile, patient medical chart, or in a separate log book.”)

<sup>41</sup> Collaborative Drug Therapy Agreement for Naloxone Medication in Opioid Overdose Reversal, Washington State Hospital Association, available at [http://www.wsha.org/files/257/Blank\\_Naloxone\\_CDTA\\_08092012\\_1.pdf](http://www.wsha.org/files/257/Blank_Naloxone_CDTA_08092012_1.pdf), (last visited May 12, 2014)[hereinafter C.D.T.A.].

<sup>42</sup> Telephone Interview with Ryan Oftebro, President, and Joshua Akers, Community Operations Manager, Kelley-Ross Prescription Pharmacy (April 25, 2014).

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> Oftebro, *supra* note 39.

<sup>46</sup> C.D.T.A. Appendix 1, *supra* note 41.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*, at Part II, Procedure.

<sup>49</sup> Felice J. Freyer, *Rhode Island makes lifesaving overdose drug easily available*, PROVIDENCE JOURNAL (February 15, 2014), available at <http://www.providencejournal.com/breaking-news/content/20140215-rhode-island-makes-lifesaving-overdose-drug-easily-available.ec>; see also Michael Yokell et al., Opioid Overdose Prevention and Naloxone Distribution in Rhode Island, 94(8) MED. & HEALTH R.I. (AUG. 2011).

<sup>50</sup> Freyer, *supra* note 49.

<sup>51</sup> Telephone Interview with Jeffrey Bratberg, Clinical Associate Professor, University of Rhode Island College of Pharmacy (April 16, 2014).

<sup>52</sup> R.I. GEN. LAWS §5-19.2-2 (2014); see also 14-130 R.I. Code R. § 001 (LexisNexis 2014) (“Collaborative pharmacy practice’ is that practice of pharmacy whereby a pharmacist with advanced training and experience relevant to the scope of collaborative practice agrees to work in collaboration with one or more physicians for the purpose of drug therapy management of patients, such management to be pursuant to a protocol or protocols

authorized by the physician(s) and subject to conditions and/or limitations as set forth by the Department. A health care professional who has prescribing privileges and is employed by a collaborating physician may be in such an agreement.”) In contrast, New York law is clear that management of drug therapy is for a patient “who is being treated by a physician for a specific disease or disease state.” In fact, the term is “collaborative drug therapy management” and not just collaborative pharmacy practice. See N.Y. EDUC. LAW § 6801-a (Gould 2014).

<sup>53</sup> R.I. GEN. LAWS, *supra* note 52.

<sup>54</sup> Freyer, *supra* note 49.

<sup>55</sup> Bratberg, *supra* note 51.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> Rules and Regulations Pertaining to Opioid Overdose Prevention, R23-1-OPOID (State of Rhode Island and Providence Plantations Department of Health (March 2014), available at <http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/7687.pdf>; See also R.I. GEN. LAWS §42-35-3(b) (2014)(“If an agency finds that an imminent peril to the public health, safety, or welfare requires adoption of a rule upon less than thirty (30) days’ notice, and states in writing its reasons for that finding, it may proceed without prior notice or hearing or upon any abbreviated notice and hearing that it finds practicable, to adopt an emergency rule. The rule so adopted may be effective for a period of not longer than one hundred twenty (120) days renewable once for a period not exceeding ninety (90) days, but the adoption of an identical rule under subdivisions (a)(1) and (a)(2) is not precluded.”)

<sup>59</sup> *Pharmacist Prescribing: Is Collaborative Practice a Path of the Future?*, 41(6) NATIONAL ASSOCIATION OF BOARDS OF PHARMACY NEWSLETTER 121, 134 (June-July 2012), available at [http://www.nabp.net/publications/assets/June-July12.pdf?utm\\_source=BenchmarkEmail&utm\\_campaign=e\\_News\\_07\\_18\\_12&utm\\_medium=email](http://www.nabp.net/publications/assets/June-July12.pdf?utm_source=BenchmarkEmail&utm_campaign=e_News_07_18_12&utm_medium=email).

<sup>60</sup> Diana Greene Foster et al., *Pharmacy Access to Emergency Contraception in California*, 38(1) PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH (MARCH 2006), available at <https://www.guttmacher.org/pubs/journals/3804606.html>.

<sup>61</sup> Scott Giberson and Tamara Cox, *Indian Health Service: Leader in Pharmaceutical Care*, 25(11) US PHARMACIST (Nov. 2000), available at [http://legacy.uspharmacist.com/oldformat.asp?url=newlook/files/Feat/indianhealth.cfm&pub\\_id=8&article\\_id=622](http://legacy.uspharmacist.com/oldformat.asp?url=newlook/files/Feat/indianhealth.cfm&pub_id=8&article_id=622).

<sup>62</sup> Davis, *supra* note 9 at 2, (“In 2001, New Mexico became the first state to amend its laws to make it easier for medical professionals to prescribe and dispense naloxone, and for lay administrators to use it without fear of legal repercussions.”)

<sup>63</sup> Bruce Krasnow, *New Mexico pharmacists to prescribe anti-overdose drug*, SANTA FE NEW MEXICAN (March 26, 2014), available at [http://www.santafenewmexican.com/news/health\\_and\\_science/new-mexico-pharmacists-to-begin-prescribing-anti-overdose-drug/article\\_1399d567-d665-5017-b20a-9ff071dde447.html](http://www.santafenewmexican.com/news/health_and_science/new-mexico-pharmacists-to-begin-prescribing-anti-overdose-drug/article_1399d567-d665-5017-b20a-9ff071dde447.html).

<sup>64</sup> N.M. ADMIN. CODE § 16.19.26.13 (LexisNexis 2014).

<sup>65</sup> Dale Tinker, *Naloxone Rescue Kits and Medicaid Payment*, RX NEWS- NEW MEXICO PHARMACISTS ASSOCIATION (Sept. 30, 2013), <http://www.nm-pharmacy.com/RxNews/9-30-13b.pdf>.

<sup>66</sup> N.M. ADMIN CODE, *supra* note 64.

<sup>67</sup> NAT’L ASS’N OF STATE ALCOHOL AND DRUG ABUSE DIRECTORS, OVERVIEW OF STATE LEGISLATION TO INCREASE ACCESS TO TREATMENT FOR OPIOID OVERDOSE 5 (Colleen Haller ed., Dec. 2013)[ hereinafter NASADAD].

<sup>68</sup> 2014-20 ILL. COMP. STAT. ANN. 301/5-23 (d) (LexisNexis) (“A health care professional who, acting in good faith, directly or by standing order, prescribes or dispenses an opioid antidote to a patient who, in the judgment of the health care professional, is capable of administering the drug in an emergency, shall not, as a result of his or her acts or omissions, be subject to disciplinary or other adverse action. . . .”)

<sup>69</sup> See discussion *infra California*.

<sup>70</sup> Del. Code. Tit.16 § 3001D

<sup>71</sup> KY. REV. STAT. ANN. § 217-186 (LexisNexis 2014)(“A licensed health-care provider who, acting in good faith, directly or by standing order, prescribes or dispenses the drug naloxone to a patient who, in the judgment of the health-care provider, is capable of administering the drug for an emergency opioid overdose, shall not, as a result of his or her acts or omissions, be subject to disciplinary or other adverse action under KRS Chapter 311, 311A, 314, or 315 or any other professional licensing statute. A prescription for naloxone may include authorization for administration of the drug to the person for whom it is prescribed by a third party if the prescribing instructions indicate the need for the third party upon administering the drug to immediately notify a local public safety answering point of the situation necessitating the administration. A person acting in good faith who administers naloxone as the third party under this section shall be immune from criminal and civil liability for the administration, unless personal injury results from the gross negligence or willful or wanton misconduct of the person administering the drug.”)

<sup>72</sup> Minn. Stat. § 604A.04 Good Samaritan Overdose Prevention.

<sup>73</sup> N.J. STAT. ANN. § 24:6J-4 (2014) (“A health care professional or pharmacist who, acting in good faith, directly or through a standing order, prescribes or dispenses an opioid antidote to a patient capable, in the judgment of the health care professional, of administering the opioid antidote in an

emergency, shall not, as a result of the professional's acts or omissions, be subject to any criminal or civil liability, or any professional disciplinary action under Title 45 of the Revised Statutes for prescribing or dispensing an opioid antidote in accordance with this act.”)

<sup>74</sup> N.C. GEN. STAT. § 90-106.2 (a)(2014)(“As used in this section, ‘opioid antagonist’ means naloxone hydrochloride that is approved by the federal Food and Drug Administration for the treatment of a drug overdose.(b) A practitioner acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose. As an indicator of good faith, the practitioner, prior to prescribing an opioid under this subsection, may require receipt of a written communication that provides a factual basis for a reasonable conclusion as to either of the following: (1) The person seeking the opioid antagonist is at risk of experiencing an opiate-related overdose. (2) The person other than the person who is at risk of experiencing an opiate-related overdose, and who is seeking the opioid antagonist, is in relation to the person at risk of experiencing an opiate-related overdose: a. A family member, friend, or other person. b. In the position to assist a person at risk of experiencing an opiate-related overdose. (c) A person who receives an opioid antagonist that was prescribed pursuant to subsection (b) of this section may administer an opioid antagonist to another person if (i) the person has a good faith belief that the other person is experiencing a drug-related overdose and (ii) the person exercises reasonable care in administering the drug to the other person. Evidence of the use of reasonable care in administering the drug shall include the receipt of basic instruction and information on how to administer the opioid antagonist. (d) All of the following individuals are immune from any civil or criminal liability for actions authorized by this section: (1) Any practitioner who prescribes an opioid antagonist pursuant to subsection (b) of this section. (2) Any person who administers an opioid antagonist pursuant to subsection (c) of this section.”)

<sup>75</sup> P.A. SB 1164 Section 13.8

<sup>76</sup> R23-1-OPIOID R.I. Code R. § 3

<sup>77</sup> TENN. PUB. ACTS CH. 623, H.B. 1427, 108th Leg., Reg. Sess. (Tenn. 2014) (“A licensed healthcare practitioner otherwise authorized to prescribe an opioid antagonist acting in good faith and exercising reasonable care may, directly or by standing order, prescribe an opioid antagonist to the following persons: (1) A person at risk of experiencing an opiate-related overdose, or (2) A family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.”)

<sup>78</sup> VT. STAT. ANN. tit. 18 § 4240(c)(2014)(“A health care professional acting in good faith may directly or by standing order prescribe, dispense, and distribute an opioid antagonist to the following persons, provided the person has been educated about opioid-related overdose prevention and treatment in a manner approved by the Department: (A) a person at risk of experiencing an opioid-related overdose; or (B) a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose.”)

<sup>79</sup> 2013-2014 Wis. Sess. Laws Act 200 (2013 A.B. 446).

<sup>80</sup> N.J. STAT., *supra* note 73.

<sup>81</sup> Dan Bigg, *Case Study Chicago Recovery Alliance*, <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/naloxone-program-case-studies/chicago-recovery-alliance/> (last visited May 13, 2014).

<sup>82</sup> Traci Green et al., *Distinguishing signs of opioid overdose and indication for naloxone: an evaluation of six naloxone training and distribution programs in the United States*, 103(6) ADDICTION 979, app. (2011).

<sup>83</sup> ILL. COMP. STAT. ANN., *supra* at 68.

<sup>84</sup> Wheeler, *supra* note 10, at slide 13.

<sup>85</sup> *Id.*

<sup>86</sup> Email from Phillip Coffin, Director of Substance Use Research, San Francisco Department of Public Health, to author (May 7, 2014)(on file with author).

<sup>87</sup> Email from Phillip Coffin, Director of Substance Use Research, San Francisco Department of Public Health, to author (May 8, 2014)(on file with author).

<sup>88</sup> CAL. CIV. CODE § 1714.22 (Deering 2014)(“(c)(1) A licensed health care provider who is authorized by law to prescribe an opioid antagonist may issue standing orders for the distribution of an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose.(2) A licensed health care provider who is authorized by law to prescribe an opioid antagonist may issue standing orders for the administration of an opioid antagonist to a person at risk of an opioid-related overdose by a family member, friend, or other person in a position to assist a person experiencing or reasonably suspected of experiencing an opioid overdose. (d)(1) A person who is prescribed or possesses an opioid antagonist pursuant to a standing order shall receive the training provided by an opioid overdose prevention and treatment training program.”)

<sup>89</sup> *Id.* (“For purposes of this section, the following definitions shall apply: . . . (2) “Opioid overdose prevention and treatment training program” means any program operated by a local health jurisdiction or that is registered by a local health jurisdiction to train individuals to prevent, recognize, and respond to an opiate overdose, and that provides, at a minimum, training in all of the following:(A) The causes of an opiate overdose.(B) Mouth to mouth resuscitation.(C) How to contact appropriate emergency medical services.(D) How to administer an opioid antagonist.”)

<sup>90</sup> *Id.*

<sup>91</sup> AB-1535, 2013-2014 Leg., Reg. Sess. (Ca. 2014).

<sup>92</sup> *Id.*

<sup>93</sup> Press Release, Governor Andrew M. Cuomo, Governor Cuomo Signs Legislation to Combat Heroin, Opioid and Prescription Drug Abuse Epidemic (June 24, 2014), available at <https://www.governor.ny.gov/press/06242012-drug-abuse-legislation>; S6477B, 2014 Leg. Sess. (NY 2014); A8637B, 2014 Leg. Sess. (NY 2014).

<sup>94</sup> *Id.* at 3(B)(III) (“An opioid antagonist recipient may possess an opioid antagonist obtained pursuant to this paragraph” and “may distribute such opioid antagonist to a recipient.” )

<sup>95</sup> Press Release at note 96.

<sup>96</sup> New York law has permitted non-patient specific orders between a pharmacist and a physician in the context of immunizations since 2008 so there is a foundation for collaboration. N.Y. Education Law §6527

<sup>97</sup> Press Release, *supra* note 7.

<sup>98</sup> Green, Barriers to medical provider support for prescription naloxone as overdose antidote for lay responders

<sup>99</sup> Naomi Seiler et al., Medicaid Reimbursement for Take-home Naloxone: A Toolkit for Advocates, 10 (Oct., 2014), available at [http://publichealth.gwu.edu/pdf/hp/naloxone\\_medicaid\\_report\\_gwu.pdf](http://publichealth.gwu.edu/pdf/hp/naloxone_medicaid_report_gwu.pdf) .

<sup>100</sup> Insurers are interested in mitigating opioid related costs. See Bingham et al., *10 Strategies to Combat the Rx Abuse Epidemic – An Insurer’s Perspective*, CLAIMS MAGAZINE (January 2014).

<sup>101</sup> Krasnow, *supra* note 63 (“One pharmacist already has said that a private insurance company denied a reimbursement for a Narcan prescription.”)

<sup>102</sup> Seiler, *supra* note 99 at 6.

<sup>103</sup> *Id.*

<sup>104</sup> [http://publichealth.gwu.edu/pdf/hp/naloxone\\_medicaid\\_report\\_gwu.pdf](http://publichealth.gwu.edu/pdf/hp/naloxone_medicaid_report_gwu.pdf)

<sup>105</sup> Letter of Direction from Anne Foster, Chief Medical officer New Mexico Medical Assistance Division, (September 27, 2013)(directing Medicaid Managed Care Organizations to cover naloxone rescue kits.)

<sup>106</sup> Oftebro & Akers, *supra* note 42.

<sup>107</sup> Wheeler, *supra* note 10, at slide 31.

<sup>108</sup> Andrea Leonard-Segal, Naloxone Expanded Access: OTC Status, Considerations for a Nonprescription Drug Development Program, available at <http://www.fda.gov/downloads/drugs/newsevents/ucm300875.pdf>.

<sup>109</sup> *Id.*

<sup>110</sup> Kathryn Foxhall, *OTC Naloxone? It’s Possible*, DRUG TOPICS (May 15, 2012), <http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-news/otc-naloxone-its-possible?page=full>