

**Opioid overdose prevention programs  
with take-home naloxone in West  
Virginia and other Central  
Appalachian states**

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## Opioid overdose prevention programs with take-home naloxone (OOPPs/THN) in West Virginia and other Central Appalachian<sup>1</sup> states

### Executive Summary

Prescription painkiller overdose (OD) deaths have been on a steep rise in the US for more than a decade, and show no signs of abating. From 2001 to 2010, unintentional poisonings in West Virginia (WV) more than tripled, largely due to this epidemic of fatal painkiller ODs. In 2010, WV had the highest unintentional poisoning death rate in the US—26.5 deaths per 100,000 people. Other states in Central Appalachia also have high and increasing unintentional poisoning rates, including Kentucky (2<sup>nd</sup> highest) and Tennessee (7<sup>th</sup> highest).

In the 1990s, many US cities faced a similar epidemic of heroin overdoses. To address increasing OD deaths, harm reduction programs in Chicago, New York, San Francisco, and other cities, initiated prevention programs in the early 2000s that featured the distribution of the prescription drug naloxone (NARCAN<sup>®</sup>), a highly effective OD antidote, directly to drug users. These programs were instrumental in reversing fatal overdose trends, and as a result have been replicated in other cities, states, and counties across the US. However, despite the identification of nearly 200 programs by CDC in 2010, none were identified in West Virginia, Kentucky, Ohio, Tennessee, or Virginia (in Central Appalachia), nor in other states facing high-risk of prescription painkiller overdose. One such program has since been initiated in Scioto County, OH.

Although there are differences between inner city heroin addicts at risk for overdose, and prescription painkiller users in largely rural Appalachia, it is likely that similar OD prevention programs, that include naloxone distribution, can effectively prevent OD deaths among rural prescription drug users. Ongoing research is examining the feasibility and acceptability of such programs in several rural WV communities.

**Several legislative actions** could facilitate the initiation of opioid overdose prevention programs with take-home naloxone in West Virginia and in other states in Central Appalachia, including:

#### 1. Law Legalizing Opioid Overdose Prevention Programs with Take-Home Naloxone

To date, 8 states (NM, NY, IL, WA, CA, RI, CT and MA) have passed laws that remove liability and legality issues for OOPPs/THN. As this report was being prepared, legislatures in Colorado, Kentucky, and New Jersey were considering similar legislation.

#### 2. Law Providing Immunity for Good Samaritan 911 Callers

To encourage OD witnesses to call 911, 10 states (CA, CO, CT, FL, IL, MA, NY, RI, and WA) as well as the District of Columbia, have passed 911 “Good Samaritan” laws that offer immunity to callers (and victims) from arrest and prosecution for possession and use (though not for more serious offenses, such as drug trafficking). As this report was being prepared, the Missouri legislature was considering similar legislation.

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<sup>1</sup> Central Appalachia, in this report, refers to the north central, central, and south central sub-regions of Appalachia, as mapped by the Appalachian Regional Council, including parts of WV (all but the northern panhandle), OH, KY, TN, VA, and NC. See map at: [http://www.arc.gov/research/MapsofAppalachia.asp?MAP\\_ID=31](http://www.arc.gov/research/MapsofAppalachia.asp?MAP_ID=31).

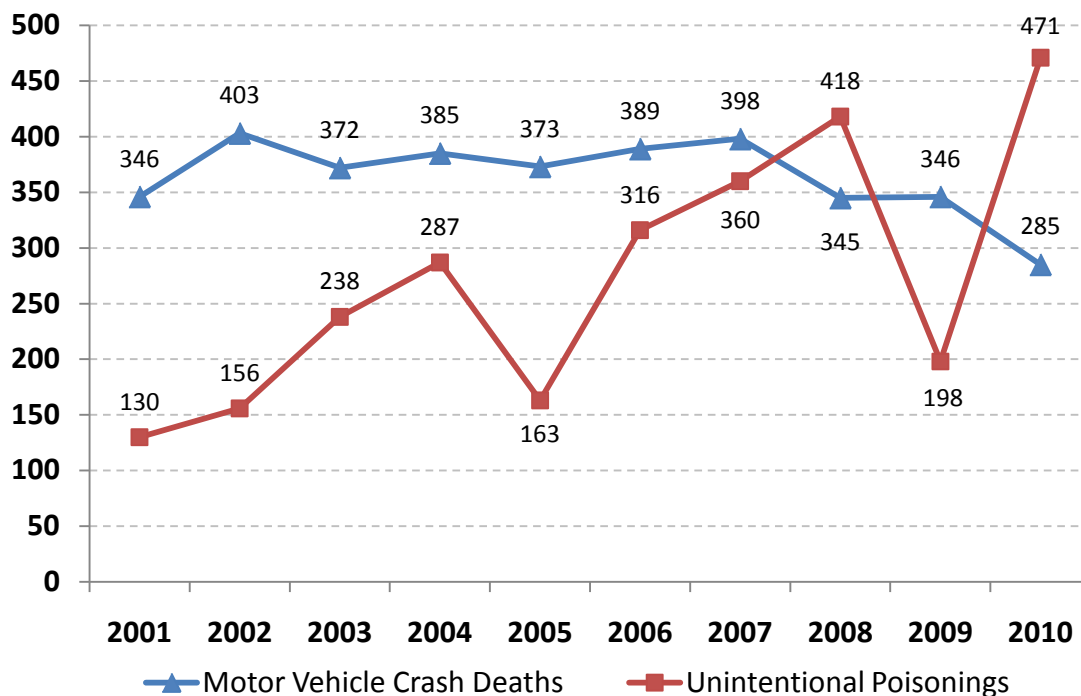


## Opioid overdose prevention programs with take-home naloxone (OOPPs/THN) in West Virginia and Central Appalachia

### I. Introduction

Prescription opioid pain relief medication is associated with benefits and risks to contemporary society. Opioid painkillers are often the only or most effective analgesics for relief of severe pain among patients. On the other hand, prescription opioid overdose deaths have risen steeply for more than a decade, have reached epidemic proportions across the US,<sup>1</sup> and show no signs of abating.<sup>2</sup>

In 2008, unintentional poisoning became the leading cause of unintentional injury death in West Virginia, exceeding motor-vehicle traffic deaths.<sup>3</sup> Over the 10-year period 2001 through 2010, unintentional poisonings in West Virginia more than tripled, from 130 in 2001 to 471 in 2010 (Figure 1).<sup>3</sup> **The increase in unintentional poisoning deaths in West Virginia, and in the US as a whole, has been driven by the increase in prescription opioid-related deaths.**<sup>4</sup> National Center for Health Statistics (NCHS) data for 2010 show West Virginia now leading the nation in unintentional poisonings (age-adjusted rate of 26.5 deaths per 100,000 persons).<sup>5</sup> Other Central Appalachian states (Kentucky—2<sup>nd</sup>, 22.3; Tennessee—7<sup>th</sup>, 15.2) are in the top ten.<sup>5</sup>



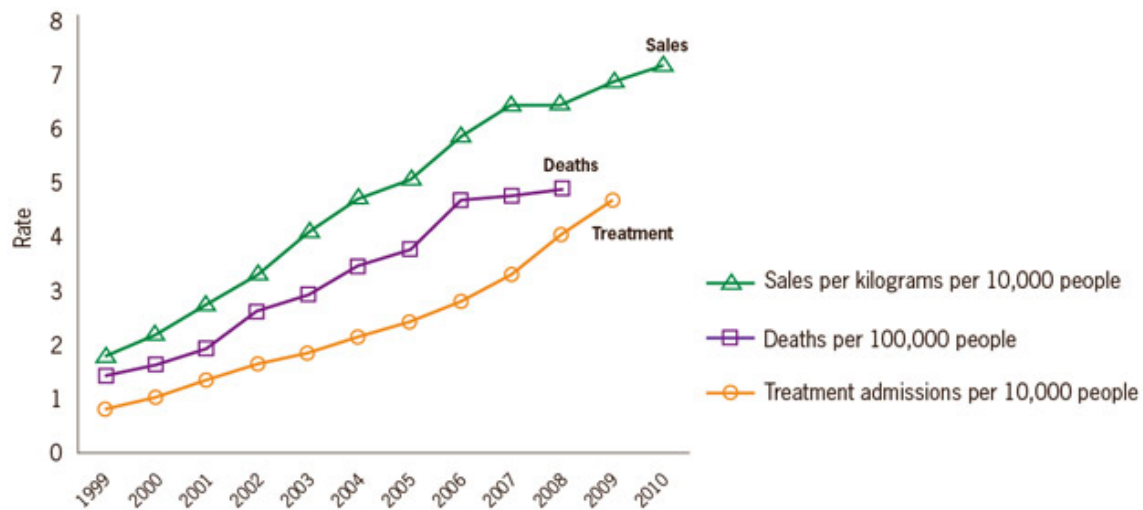
**Figure 1.** Number of deaths by motor vehicle crashes and unintentional poisonings, West Virginia, 2001-2010. (Source: CDC WISQARS)

The aims of this report are: 1) to report on the characteristics and effectiveness of an innovative overdose prevention intervention that could potentially stop and even reverse the trend of opioid (and heroin) overdoses in West Virginia and Central Appalachia, and 2) to outline legislative actions that could positively facilitate the development and administration of such programs in West Virginia and in other states in Central Appalachia.

## II. The Intervention: Opioid Overdose Prevention Programs with Take-home Naloxone

### Background

In the mid-1990s, changes were made to guidelines for the use of opioid analgesics in the treatment of pain.<sup>6,7</sup> Increased use of opioid analgesics for chronic non-cancer pain was supported by the belief that pain was undertreated in the US, and that health care professionals had “an ethical obligation to manage pain and relieve the patient’s suffering.”<sup>6</sup> Coupled with aggressive marketing by pharmaceutical manufacturers,<sup>8</sup> these guidelines contributed to increased prescriptions for opioid analgesics. Subsequent trends in the numbers of prescriptions, the number of opioid overdose deaths, and the number of substance abuse treatment admissions have followed comparable trajectories (see Figure 2).<sup>1</sup>



**Figure 2.** Rates of prescription painkiller sales, deaths and substance abuse treatment admissions (1999-2010)<sup>1</sup>

SOURCES: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009.

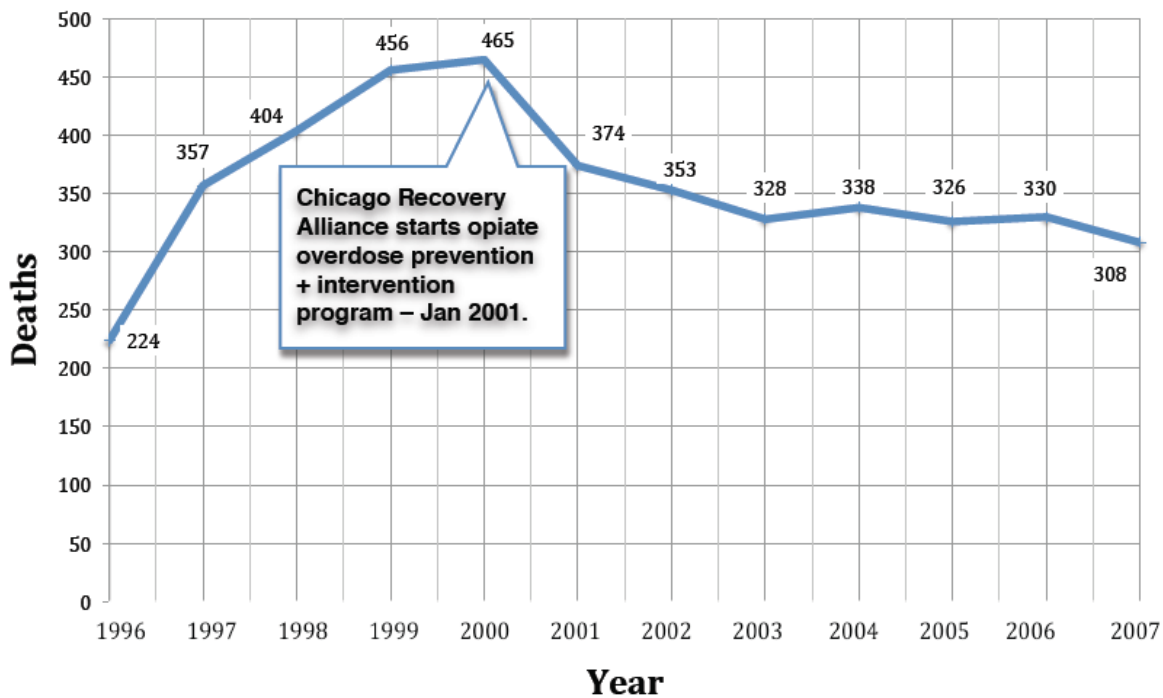
Also in the 1990s, cities in the United States and abroad were facing increasing heroin overdose deaths.<sup>9</sup> Harm reduction organizations in some of these urban centers began to address the heroin overdose problem through programs that featured education in overdose recognition and response, and the distribution of naloxone to heroin users. Naloxone (NARCAN<sup>®</sup>), an antidote for opioid overdose that was first synthesized in 1960, has been effectively and safely administered to opioid overdose victims by physicians, emergency medical system (EMS) responders, and other healthcare providers since its approval by the Food and Drug Administration in 1971.<sup>10</sup> However, many opioid overdose victims die because no one will call 911. Individuals who witness an overdose are often drug users themselves, and in many cases, will not call 911 for fear of being arrested if law enforcement officers respond.<sup>11</sup> If an overdose is witnessed, proper and timely response can lead to an overdose reversal, and a life saved. In the majority of cases, a 1- to 3-hour window of time exists (from the onset of an overdose until death occurs) during which there is opportunity to intervene.<sup>9</sup>

Opioid overdose prevention programs that feature take-home naloxone (OOPPs/THN) distribute the antidote directly to drug users, their peers, their family members, and other nonmedical laypersons. Implicit in these programs is the assumption that naloxone will be administered to drug overdose victims, including persons for whom the drug was not prescribed. Participants in these urban programs were largely recruited from among populations of injection drug users (IDUs) who frequented syringe exchange sites, HIV clinics, and other inner city, harm reduction outreach facilities.

Early results of these programs, in particular the very high percentages of self-reported overdose reversals resulting from the administration of Naloxone, were encouraging. As a result of early program successes, these programs, which were first piloted in Germany,<sup>12</sup> the United Kingdom,<sup>12</sup> and the United States in the late 1990's,<sup>13</sup> continued into the 2000's, and influenced the development of scores of similar programs in cities, counties, and states across the United States,<sup>14-24</sup> and in other countries, including Canada,<sup>25</sup> China,<sup>26</sup> Scotland,<sup>27</sup> and Wales.<sup>28</sup>

*An Example of a Naloxone Distribution Program in the U.S.—the Chicago Recovery Alliance*

In 1991, the Chicago Recovery Alliance (CRA)—a program addressing prevention of HIV and other adverse drug-related outcomes—was founded to serve injection drug users (IDUs).<sup>13</sup> The CRA began conducting overdose recognition and response training to selected CRA participants in 1996 in response to a rapid increase in heroin overdose deaths. In 2001, the program was expanded to include the distribution of naloxone to users, combined with more comprehensive overdose prevention and response training. The trend in heroin overdose deaths reversed in 2001, with a 20% reduction in deaths (see Figure 3).<sup>29</sup> Similar impacts have been noted from other OOPPs/THN in other U.S. cities.



**Figure 3.** Heroin-related overdose deaths in Cook County, Illinois, 1996-2007. Source: Cook County Medical Examiner's Office.

CRA program officials reported that between 2001 and 2006, over 3,500 10-ml vials of naloxone were prescribed and distributed, and 319 opiate overdoses were reversed.<sup>13</sup> Overdose prevention programs with prescribed take-home naloxone appeared in other urban centers in the U.S. in the late 1990s and early 2000s, including Baltimore,<sup>17</sup> Boston,<sup>20</sup> New York,<sup>15,16</sup> Los Angeles,<sup>18</sup> Pittsburgh,<sup>19</sup> and San Francisco.<sup>14</sup> Some states (New Mexico,<sup>24</sup> Massachusetts,<sup>22</sup> and Rhode Island<sup>21</sup>) and a few counties (Wilkes County in North Carolina<sup>23</sup> and, more recently, Scioto County in Ohio<sup>30</sup>) have also initiated such programs. In its most recent Annual Report, the Chicago Recovery Alliance reported 2,972 OD reversals through its take-home naloxone distribution program through 2011.<sup>31</sup> (<http://www.anypositivechange.org/CRAar11.pdf>)

#### *Features of OOPPs w/THN*

Most of the OOPPs/THN—also known as Overdose Education and Naloxone Distribution (OEND), or simply Take-home Naloxone (THN) programs—cited in this report,<sup>12-28</sup> had similar core program elements, including:

- participant identification and recruitment
- training in overdose recognition and response
- physician (prescriber) consultation/issuance of a prescription
- provision of a Naloxone kit
- periodic follow up—e.g., annual.

The training component itself usually addressed overdose recognition; improper overdose response; proper overdose response (including basic life-support techniques, such as placing the victim in the rescue position and administering rescue breathing); and revival strategies (such as rubbing the sternum; naloxone administration, usually either intramuscular injection or intranasal spray; calling 911; staying with and observing the victim until medical help arrived; and administration of follow-up naloxone doses if required). Follow up doses could be necessary if, for example, the first dose failed to reverse the overdose, or if the victim became re-intoxicated with opioids because the initial dose of naloxone wore off.

Through these programs, naloxone has usually been provided in kits that include two doses of the drug; a breathing mask to facilitate rescue breathing; a short instruction card or sheet which supplements the initial training; and documentation of the prescription. Early programs provided pre-filled syringes, or vials and syringes for participant filling, and administration was by intramuscular (IM) injection. More recently, intranasal administration (spraying naloxone into the victims' nostrils) has been increasingly used.

OOPPs w/THN initially drew criticism, including the major objection that distributing a highly effective antidote to users themselves could prompt greater risk-taking—i.e., increased use and higher doses per use—by users.<sup>16,23,32,33</sup> Other criticisms included:

- Distributing naloxone seems to implicitly condone illicit drug use,<sup>32</sup>
- Non-medical persons, particularly drug users, could not effectively recognize and appropriately respond to (including naloxone administration) overdoses,<sup>10</sup>
- Misuse of naloxone in non-overdose situations would, at the very least, translate to wasted resources,<sup>10</sup>

- Program participants could assume liability or face prosecution in the event of an adverse event, or in the event law enforcement responded to a 911 call,<sup>10</sup>
- Legality issues surrounding naloxone administration to overdose victims for whom it was not prescribed,<sup>32</sup> and
- The potential for the return of respiratory depression after Naloxone wears off.<sup>23</sup>

Contrary to some of the widely held assumptions underlying such criticism, overdose prevention programs featuring take-home naloxone have shown that:

- The availability of the overdose antidote naloxone does not apparently encourage increased use of opioids nor result in increased overdoses (In fact, there is some evidence that use decreased among program participants, and that users who have survived overdose by means of the administration of Naloxone may be more inclined to seek treatment for their dependency),<sup>13,15,16,26,33</sup>
- Laypersons with training, including drug users and their peers, are comparable to medical experts in recognizing overdoses, and knowing when naloxone should be administered,<sup>10</sup> and
- Naloxone has been administered in emergency situations by laypersons with little or no adverse effects.<sup>13,14</sup>

Research has suggested that drug user communities favor these programs and are overwhelmingly agreeable to participation,<sup>16,34-37</sup> but that some of the other necessary partners (e.g., physicians,<sup>38,39</sup> pharmacists, EMS personnel,<sup>40</sup> etc.) have reservations and doubts initially, usually due to potential liability or other concerns such as listed above.

A report issued in January 2012 by the Centers for Disease Control and Prevention (CDC) presented the results of a survey of 48 organizations across the U.S. that represented 188 local OOPPs/THN.<sup>41</sup> These organizations reported over 10,000 overdose reversals, since the first such program began distributing naloxone over 15 years ago. However, a disconcerting finding emerged from the CDC report: in the US states with the highest age-adjusted rates of drug overdose deaths (excepting New Mexico), only a handful of OOPPs/THN currently exist.<sup>41</sup> For example, in the Central Appalachian states with very high rates of drug overdose death—including West Virginia, which had the highest rate of all states in 2010, along with Tennessee, Kentucky and Ohio—there were no known OOPPs/THN at all. (See Figure 4.)<sup>41</sup>

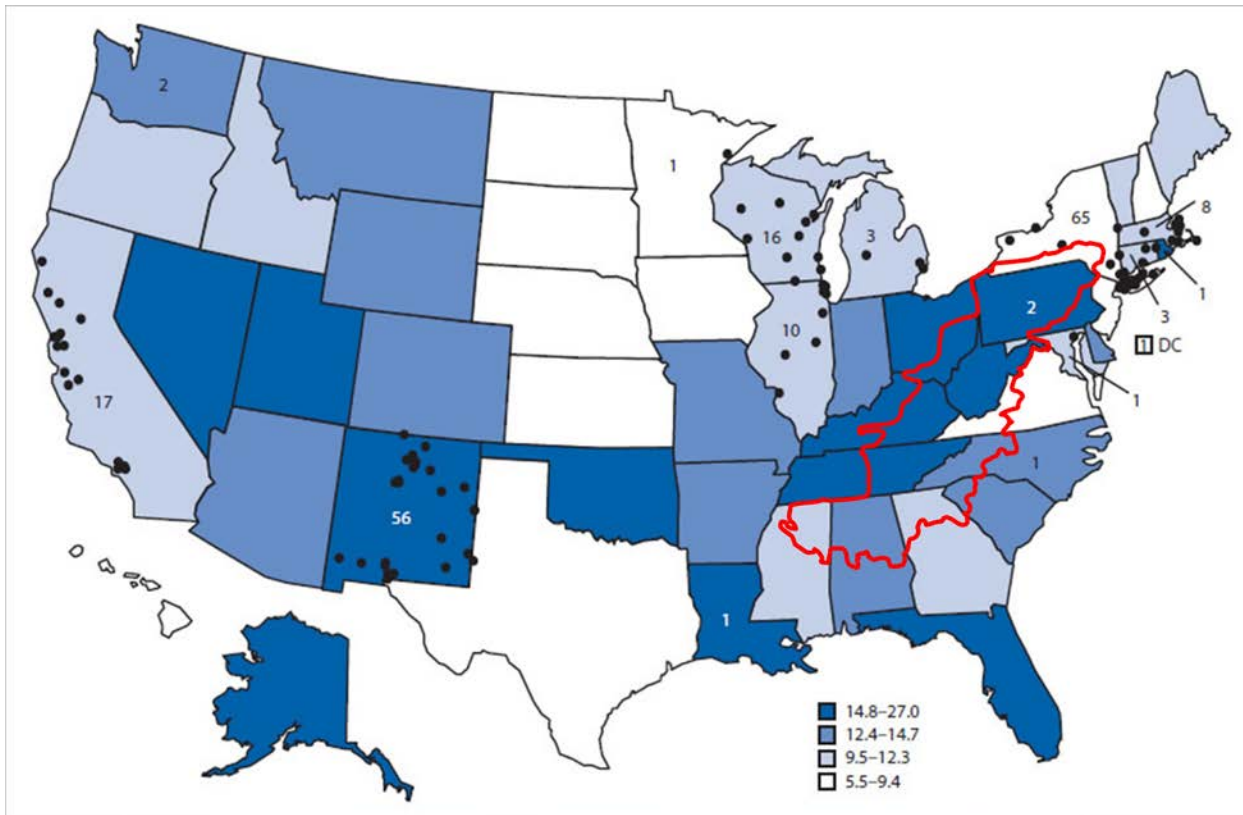
Other states among those with the highest rates—including Alaska, Florida, Nevada, Oklahoma, and Utah—likewise had no known OOPPs/THN. Of those states with the highest overdose death rates known to have such programs, New Mexico had 56 (second only to New York's 65), but Pennsylvania had only 2, and Louisiana had only 1.<sup>41</sup> Evidence from the scientific literature suggests that OOPPs/THN result in overdose reversals, and represent an effective intervention in the prevention of opioid overdose deaths.

### ***III. Translating OOPPs/THN to WV and other high-risk Central Appalachian states and facilitating such programs with legislation***

Most of the current OOPPs/THN emerged to address inner city heroin users. However, prescription opioid users/abusers live in urban and rural settings, represent all demographic and socio-economic groups, represent different modes of use initiation and continuation, migrate from prescription to illicit drug abuse



and vice versa, employ different abuse mechanisms and routes of entry—in short, they do not fit a common profile, and are not easy to identify nor engage, at least until they seek treatment, engage with law enforcement, or overdose. As a result, identifying locale-specific, demographic, and use characteristics, and gauging the acceptability and feasibility of such programs through pilot research efforts will be necessary in most cases.



**Figure 4.** Number ( $n=188$ ) and location of local OOPPs/THN in 2010, and age-adjusted rates of drug overdose deaths, United States, 2008.<sup>41</sup>

[Note: This figure has been enhanced with an outline of the Appalachian Region to show the scarcity of OOPPs/THN in the high-risk Central Appalachian region, which includes all of West Virginia except the northern panhandle, southeastern Ohio, eastern Kentucky, and eastern Tennessee.]

Project Lazarus, an overdose prevention program in Wilkes County North Carolina, is one program focusing upon preventing and reversing prescription opioid overdoses in a rural setting.<sup>23</sup> Another program—Deaths Avoided With Naloxone (DAWN)— the first overdose prevention program featuring training in overdose recognition and reversal and take-home naloxone in the state of Ohio, has been initiated in Portsmouth to serve all of Scioto County.<sup>30</sup>

#### *West Virginia Feasibility Study*

Currently, a study of the feasibility of initiating an OOPP/THN in southern West Virginia is underway. The research team is comprised of representatives from a large, non-profit addiction treatment organization based in Cabell County, WV; two county substance abuse prevention coalitions (Logan and Mingo Counties); a faith-

based addiction recovery program (Boone County); and the West Virginia University Injury Control Research Center. The project team designed and obtained funding for the study, and will conduct structured interviews with West Virginians who misuse and abuse opioids, and therefore are at high-risk for overdose in these three high-risk southern WV counties. The intent is to identify demographic and drug use characteristics, as well as attitudes toward overdose prevention and the use of naloxone among nonmedical users of prescription painkillers. Select prescribers and pharmacists within these counties will also be interviewed to determine their knowledge of, and attitudes toward, such programs. Study findings will reveal acceptability of such programs to key participants, identify potential barriers to implementation, and determine what specific components of an OOPP/THN may be adaptable to southern West Virginia.

If this approach is found to be feasible and acceptable, the project team will seek additional funding to tailor and evaluate a pilot program for communities in these three high-risk counties. The long-term research goal is to develop, evaluate, and disseminate effective OOPPs/THN throughout southern West Virginia and Central Appalachia, where risk of overdose is high, but potentially effective, lifesaving OOPPs/THN have not been introduced.

### *Policy and Legislative Issues*

The success of OOPPs/THN in many different settings across the U.S., and in other countries, has led to increasing support among medical and public health leaders in the U.S. Both the American Medical Association<sup>42</sup> and the American Public Health Association<sup>43</sup> have issued policy statements supporting the wider distribution of naloxone. The Directors of the White House Office of National Drug Control Policy (ONDCP),<sup>44</sup> and the National Institute on Drug Abuse (NIDA)<sup>45</sup> have also recently commented publicly on the need to make naloxone more widely available. A recent article co-written by officials of NIDA and the U.S. Food and Drug Administration (FDA) highlights this issue very succinctly: “Despite its potential to safely, rapidly, and completely reverse an opioid overdose, the public health impact of this medication has not yet reached its full potential.”<sup>46</sup>

An economic analysis of take-home naloxone programs for heroin users, found them to be cost-effective across a variety of scenarios, including a worst case scenario.<sup>47</sup>

In 2008, the Beasley School of Law at Temple University was commissioned by the Drug Policy Alliance to analyze the laws in each of the 50 US states, and prepare a report on the legislative issues regarding naloxone relevant to each state.<sup>48</sup> Those state-specific findings remain useful today to legislatures contemplating the passage of laws intended to facilitate the development and implementation of OOPPs/THN in their states. In the findings related to West Virginia, three potential legal barriers were noted: “A professional distributing naloxone in this way could be found to be violating professional licensure laws; the patient or program participant distributing or administering the drug could be found to be guilty of the crime of practicing medicine without a license; and the recipient of a vial of naloxone for which she has no prescription could be found guilty of illegal possession of a prescription drug.”<sup>48</sup>

To facilitate the development and initiation of OOPPs/THN in West Virginia (and, by extension, in other Central Appalachian states), legislatures could consider passing laws that specifically remove the legal and liability

issues for prescribers, and other program participants that constitute barriers to the development and implementation of such programs.

### *1. The legality of OOPPs/THN*

In most states, the administration of naloxone by nonmedical laypersons, to overdose victims for whom naloxone is not prescribed, is *technically* illegal.

There are exceptions in states that have passed laws that specifically allow OOPPs/THN. Currently there are 8 states with such laws (NM, NY, IL, WA, CA, RI, CT and MA).<sup>48</sup> At the time this report was finalized, at least three additional states—Colorado, Kentucky, and New Jersey—were deliberating such bills in their legislatures.<sup>49-51</sup> Some of these state laws, including those in California and Massachusetts, address the three distinct legal barriers noted for West Virginia. The California law is available online here:

[http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab\\_2101-2150/ab\\_2145\\_bill\\_20100929\\_chaptered.html](http://www.leginfo.ca.gov/pub/09-10/bill/asm/ab_2101-2150/ab_2145_bill_20100929_chaptered.html)

### *2. Protection for “Good Samaritans” that call 911 to report overdose emergencies*

Although many states, including West Virginia, have “Good Samaritan” laws, which are intended to protect bystanders who provide good-faith assistance to victims during medical emergencies, only a few (10 states—not including West Virginia—and the District of Columbia) have laws that specifically protect overdose victims and individuals who call 911 for medical assistance in the event of drug overdose requiring emergency medical response.<sup>48</sup> At the time this report was finalized, at least one additional state—Missouri—was deliberating a 911 Good Samaritan bill in its legislature.<sup>52</sup> The provision of immunity to victims and callers for residual drug possession and use, should not be extended for perpetrators of more serious crimes, such as trafficking. The Florida 911 Good Samaritan law can be viewed by following this link: [http://laws.flrules.org/files/Ch\\_2012-036.pdf](http://laws.flrules.org/files/Ch_2012-036.pdf).

## **IV. Conclusions**

OOPPs/THN represent one of many approaches for preventing prescription opioid nonmedical use, dependence, addiction, and overdose. Although overdose prevention programs with take-home naloxone (OOPPs/THN) have been shown to be effective in reversing overdoses among inner-city heroin users, such programs need to be assessed for feasibility and piloted among nonmedical users of prescription opioids in rural, high-risk counties in West Virginia and elsewhere in the Central Appalachian region (e.g., eastern KY and eastern TN) by researcher-community teams. A positive finding and data from the study currently underway in southern WV could serve as basis for a proposal for additional funding to launch a pilot program. Based upon the success of such programs in other locales, an effective program in WV could likely expand to other counties in Southern WV, other high-risk counties in WV, and high-risk regions in KY, TN, OH and VA in the Central Appalachian Region. To facilitate the projected development and implementation of OOPPs/THN in this region, however, existing legislative barriers may need to be addressed and removed.

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