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Medicaid Reimbursement for Take-home Naloxone: A Toolkit for Advocates

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INTRODUCTION

Naloxone is an opioid antagonist drug used to counter the effects of an opiate overdose. It can be administered in medical settings, such as an emergency room, or prescribed as a take-home medication to be used in case of an emergency. Currently, most types of insurance will cover and reimburse for naloxone administered directly in a medical setting. However, coverage of prescription take-home naloxone is limited.

The Medicaid program provides health insurance for a large and growing number of Americans. Therefore, securing coverage for take-home naloxone—including costs of counseling/training and for the medicine itself—within Medicaid should be a critical priority for advocates. This toolkit is designed to facilitate advocacy for that goal. It provides background information on naloxone, the Medicaid program, and Medicaid drug coverage policies. It then outlines an action plan for advocating that state Medicaid programs cover take-home naloxone. The toolkit concludes with success stories from Washington State, North Carolina, California and New York, highlighting important lessons for advocates.

BACKGROUND

Naloxone

Each year, about 17,000 people die as a result of an opioid overdose.ⁱ Naloxone, also known under the trade name Narcan, is an inexpensive drug that reverses the effects of respiratory depression following heavy opioid use, resulting in a significantly decreased likelihood of death following an overdose. Administration of naloxone in a medical setting is standard practice for hospital medical staff and first responders caring for a patient who has overdosed on opioids. Research has demonstrated naloxone to be safe, successful, non-addictive, and cost-effective.ⁱⁱ

Naloxone can also be prescribed directly to patients at risk of overdose. As a take-home drug, naloxone can be administered in two ways: as an intramuscular injection, or intranasally with the use of a device called an atomizer (which generally uses the higher concentration of naloxone available; see “Take-Home Naloxone Formulations” below).ⁱⁱⁱ Anyone in the presence of someone who has overdosed on opioids can administer the drug. This approach broadens and expedites the availability of naloxone to individuals who might otherwise die of overdose. Providers can prescribe take-home naloxone to individuals who are taking prescription opioid painkillers, as well as to other individuals who providers believe may be at risk for opioid overdose, such as heroin users.

Take-Home Naloxone Formulations

Naloxone:

- ✓ 0.4/mL naloxone for IM injection is available in two forms from **Hospira** (NDC 0409-1219-01 for 10mL multidose vial and NDC 00409-1215-01 for 1mL single dose vial). Mylan announced in March 2014 that it has also launched a 0.4 mg/mL formulation in 1mL single dose vials.¹
- ✓ 2mg/2mL naloxone is available from **IMS/Amphastar** (NDC 76329-3369-1). This is the concentration that is used for intranasal administration. While the FDA does not approve naloxone for intranasal administration, it is the standard of care in many areas because it is a needleless alternative.²

Delivery materials:

- ✓ For injectable naloxone, there are numerous manufacturers for intramuscular (IM) syringes, 23 G, 3cc, 1 inch.
- ✓ For nasally administered naloxone, the mucosal atomization device (MAD-Nasal) from LMA North America fits onto the luer-lock of the IMS/Amphastar naloxone.²

Note that on April 3, 2014, the FDA announced its approval of a new hand-held auto-injector naloxone device.³ Pricing and availability information for this device is not yet available.⁴

1 marketwatch.com/story/mylan-launches-naloxone-hydrochloride-injection-2014-03-11

2 lmana.com

3 fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391465.htm

4 All information, other than 2014 updates, is from PrescribetoPrevent.org.

Medicaid

Medicaid is a joint federal-state program that provides health insurance for low-income individuals and families. Currently, all states provide some coverage for low-income children, pregnant women, and parents of dependent children; some states also cover childless adults. States have significant flexibility in terms of who they cover and the income levels for eligibility.^{iv}

This document will refer to different types of Medicaid coverage. Medicaid as it existed before the passage of the Affordable Care Act (ACA)—sometimes referred to as “traditional” Medicaid—consists of fee-for-service coverage provided by a state agency, as well as managed care coverage generally provided through Medicaid managed care organizations. Post-ACA, in states that elect to expand Medicaid under the Affordable Care Act, additional people will be covered in Medicaid expansion plans, also known as “Alternative Benefit Plans.”

“Fee-for-Service” Medicaid

In fee-for-service Medicaid, the physician or other provider is paid for each service provided. Each state determines its own fee-for-service payment procedures, in compliance with federal law.^v

Medicaid Managed Care

The majority of Medicaid beneficiaries nationwide are enrolled in Medicaid managed care plans. Generally, states contract with managed care organizations, or MCOs, to provide all or most Medicaid services to individuals; the MCOs receive monthly payments from the state. For purposes of this toolkit, it is important to note that in any given state, Medicaid MCOs may have coverage policies that differ somewhat from the state’s fee-for-service program; this will be discussed in further detail below.

Medicaid Expansion Plans (Alternative Benefit Plans)

Under the Affordable Care Act, states have the option of expanding Medicaid to cover all nonelderly adults with incomes under 138% of the federal poverty level, currently \$15,856 for an individual or \$32,499 for a household of four.^{vi} The Federal government pays 100% of Medicaid costs for the newly eligible population for 2014 through 2016, and 90% thereafter. As of December 2013, 26 states plus the District of Columbia had announced that they would pursue the Medicaid expansion in 2014, and two additional states are seeking to move forward with expansion post-2014.^{vii} Therefore, Medicaid is becoming an even more important source of care for low-income populations, particularly childless adults.

Medicaid expansion plans are also termed “Alternative Benefit Plans”; this toolkit will use the term “Medicaid expansion plans.”^{viii} Coverage in a Medicaid expansion plan in a given state may differ from the state’s fee-for-service Medicaid program or from existing Medicaid MCOs in the state. Medicaid expansion plans must cover certain categories of “Essential Health Benefits,” including prescription drugs.

Note that some states also cover people in Medicaid through small- or large-scale programs called “Medicaid waivers.” Because they involve wide variability in coverage, eligibility and benefits, specific discussion of waivers is beyond the scope of this toolkit.

Medicaid Coverage of Prescription Drugs

Currently, all states provide prescription drug coverage to their existing Medicaid enrollees. States that expand their Medicaid programs under the Affordable Care Act must provide drug coverage to the Medicaid expansion population.

For all types of Medicaid, it is very important to note that coverage of naloxone does not necessarily equate to coverage of take-home naloxone: a program may “cover” naloxone, but only for direct administration in a medical setting. In addition, a state may cover the drug, but not the provider’s time in training and educating patients, or the device needed to administer the drug. These issues are discussed in detail later in the toolkit.

States are allowed to apply a range of pharmaceutical management techniques to their existing and expansion Medicaid drug benefit. (The terms below may be used differently by different states).^{ix} Be sure to confirm with your state Medicaid agency precisely what each term means in your state’s program.

- **Formulary:** A list of all the drugs that a state’s Medicaid program covers. Most, but not all, states maintain a formulary. States must have a process for making available a drug that is not on the formulary on a case-by-case basis if the prescriber can demonstrate that it is medically necessary. Medicaid managed care plans may maintain their own formularies, which may differ from the state’s Medicaid fee-for-service prescription drug formulary.
- **Preferred Drug List:** Usually a subset of the formulary, a preferred drug list (PDL), includes drugs that are available without specific restrictions, with lower rates of cost-sharing, or both.
- **Prior Authorization:** A common “management” technique for certain prescription drugs is to require that either the prescriber or the dispenser (pharmacist) seek prior authorization from the insurer before giving a drug to a Medicaid beneficiary. Under federal law, Medicaid prior authorization decisions must be made within 24 hours, and patients must be given a 72-hour supply of the drug in an emergency. Even with these protections, however, prior authorization can result in delays or present barriers to access to prescription drugs.

Within a state, drug coverage may vary among the Medicaid fee-for-service program, existing Medicaid MCOs, and new Medicaid expansion coverage established under the Affordable Care Act. Any of these types of coverage may apply some or all of the “pharmaceutical” management techniques described above (formularies, prior authorization, etc.).

Individual states have discretion about whether to provide naloxone coverage under their fee-for-service program and MCO plans. If a state covers naloxone under its fee-for-service program, any Medicaid MCOs in the state are supposed to cover it as well. However, this may not translate into coverage for take-home naloxone.

Under the Affordable Care Act, Medicaid expansion plans are subject to a specific formulary requirement for prescription drug coverage: they must cover at least as many drugs per United States Pharmacopeia (USP) class as the plan selected as a “benchmark” for coverage in their state, and must cover a minimum of one drug per class even if their state’s benchmark plan covers none.^x Naloxone is in the Opioid Antagonist USP class.

ADVOCACY FOR PRESCRIPTION TAKE-HOME NALOXONE COVERAGE IN STATE MEDICAID PROGRAMS

If you decide to advocate for greater Medicaid coverage of prescription take-home naloxone in your state, consider the action steps detailed below.

Gather information to determine the current status of naloxone coverage in your state’s Medicaid program

Fee-for-Service Medicaid:

To determine what take-home naloxone policies are in effect in your state, first check your state’s Medicaid website for publicly available information, specifically your state’s Medicaid formulary and/or preferred drug list (PDL) (see page 6 for a discussion of formularies and PDLs). State Medicaid websites can be found through the clickable map at medicaiddirectors.org/about/state-directors. Some states may not have a downloadable PDL, but instead may have a drug database that is searchable by drug name or drug code (see text box on page 4 for national drug code (NDC) numbers for the relevant naloxone formulations).

Naloxone may be listed as “naloxone” or under the trade name “Narcan.” Also, naloxone may appear as one component of a drug combination; for example, Suboxone, prescribed for opioid addiction, contains both buprenorphine and naloxone. However, the formulation for reversing overdose is just naloxone.

It is likely that not all of the information you would like to know about naloxone coverage will be easily accessible; for example, a PDL may include naloxone but not say whether prescription take-home naloxone is included. After collecting all available information, contact your state Medicaid agency directly to ask specific questions; contact information can be found on each of the state’s websites through medicaiddirectors.org/about/state-directors.

You may need to ask the following:

- What formulations/dosages of naloxone does fee-for-service Medicaid cover? (see page 4 for all available formulations).
- Is coverage restricted to certain settings (such as emergency rooms or other hospital settings), or is prescription take-home naloxone covered?

If your Medicaid program does cover prescription take-home naloxone, ask:

- Does Medicaid require prior authorization or apply any other restrictions?
- Does Medicaid reimburse providers for counseling related to the use of prescription take-home naloxone?
- Does Medicaid reimburse for the cost of the syringe or atomizer needed to administer naloxone?
Note: For reasons discussed on page 10, it is unlikely that a state's program covers the nasal atomizer.
- What costs (such as copayments) are patients responsible for?

When you speak with your state's Medicaid agency, you should also ask some questions about how drug coverage works in your state's Medicaid MCOs and, if applicable, expansion plans. These questions are detailed in the following two sections.

Medicaid Managed Care Organizations (MCOs):

As noted above, if any given state chooses to cover naloxone, the state's Medicaid MCOs must also cover it. However, this does not necessarily mean that the MCOs will reimburse for take-home prescriptions. And, the MCOs might apply utilization management techniques (such as prior authorization) that differ from what the state's fee-for-service program applies.

Conversely, even if your state's fee-for-service program doesn't cover take-home naloxone, Medicaid MCOs in the state might. And, some states may have contractual requirements that limit the MCOs' flexibility.

1. To clarify the applicable situation in your state, when you speak with your state agency about fee-for-service drug coverage, ask how drug coverage is determined in Medicaid MCOs.
2. Next, determine if your state Medicaid website includes information about any MCO insurers operating in your state. If the website does not list MCOs operating in your state, ask the state Medicaid agency. For each Medicaid MCO (states may have one or several), search the website for its PDL and determine to what extent prescription take-home naloxone is covered and whether it requires prior authorization.
3. If additional information is still required, contact each MCO directly to ask the same questions noted above for the fee-for-service program:
 - What formulations/dosages of naloxone does the MCO's plan cover? (see text box on page 4 for all available formulations)
 - Is coverage restricted to certain settings (such as emergency rooms or other hospital settings), or is prescription take-home naloxone covered?

4. If the Medicaid MCO does cover prescription take-home naloxone, consider asking:

- Does the MCO's plan require prior authorization or apply any other restrictions?
- Does the MCO plan reimburse providers for counseling related to the use of prescription naloxone?
- Does Medicaid reimburse for the cost of the syringe or atomizer needed to administer naloxone? Note: For reasons discussed on page 10, it is unlikely that a state's program covers the nasal atomizer.
- What costs are patients responsible for?

Medicaid Expansion Plans:

First, determine if your state is expanding Medicaid to all adults under 138% of the federal poverty level under the Affordable Care Act. As of March 2014, 26 states plus the District of Columbia had announced that they would pursue the Medicaid expansion in 2014, and two additional states are seeking to move forward with expansion post-2014.^{xi}

If your state is expanding Medicaid, you should ask your state Medicaid agency for clarification of how drug coverage determinations are being made for expansion plans in your state, and to ask questions specifically about coverage of naloxone for the expansion population. You can use the list of questions under “Medicaid managed care organizations” above.

If your state is not expanding Medicaid, you don't need to do this assessment now. However, you may want to join in broader advocacy efforts to encourage your state's policymakers to expand Medicaid.

Beyond Reimbursement: Understanding the broader context of barriers to take-home naloxone access

It is important to have a thorough understanding of the various barriers, large and small, to comprehensive distribution of take-home naloxone in your state. Though this toolkit focuses on reimbursement, understanding these other barriers is crucial for context and for undertaking a broad campaign to promote access. For example, if general lack of awareness of opioid overdose poses a barrier to your goals, then your group may want to focus a considerable amount of effort on educating the general public and major stakeholders about this issue.

Other common barriers may be the stigma surrounding drug overdose and drug users, misconceptions about those who may suffer an opioid overdose, and reluctance to equip those at risk with harm reduction tools. A recent survey identified several additional concerns among providers, such as that naloxone might offer a “safety net” that encourages riskier behavior.^{xii} To address some of these concerns, see the website for the Harm Reduction Coalition and other sites listed in the Resources section on page 20 for relevant materials.

The following are some specific challenges to broader access to prescription take-home naloxone that are common across multiple states:

- **Atomizer:** As described above, prescription take-home naloxone can be administered in two ways: as an intramuscular injection, or intranasally (generally at the higher available concentration) with the use of a device called an atomizer. The atomizer needed to administer intranasal naloxone at home presents a special challenge for insurance coverage. Currently, this atomizer does not have a national drug code (NDC), an identifier that is generally required for insurers, including Medicaid, to process reimbursement. Therefore, even where a state Medicaid program covers take-home naloxone, it may not cover the associated atomizer. In these states, patients prescribed intranasal naloxone would be responsible for purchasing this equipment on their own, which may present a barrier for some patients. States that have implemented Medicaid coverage for take-home naloxone have attempted to address the atomizer issue in a number of different ways (see case studies on page 13).

State laws that address liability concerns related to naloxone

A number of states have passed laws that address both bystander and physician concerns regarding distribution and administration of take-home naloxone. These laws generally provide forms of legal protection for physicians prescribing, or bystanders for possessing or administering, take-home naloxone. For example, state laws may: (i) provide immunity from civil or criminal liability for physicians and/or laypeople who administer naloxone; (ii) authorize prescriptions to third parties other than those at risk of overdose; and (iii) waive criminal liability for possession of naloxone without a prescription. Currently, seventeen states (NY, IL, WA, CA, RI, CT, MA, NC, OR, CO, VA, KY, MD, VT, NJ and OK) plus the District of Columbia have passed laws with one or more of these provisions. The Network for Public Health Law has a full database of these state laws.^{xiii}

- **Liability concerns:** Both prescribers of naloxone and bystanders who could administer naloxone during an opioid overdose may fear legal liability for their actions. Bystanders may have concerns about administering the drug incorrectly or about criminal liability if they were using drugs illegally with someone who has overdosed. Though prescribing naloxone for take-home use is “fully consistent with state and federal laws regulating drug prescribing,”^{xiii} physicians prescribing naloxone may feel uneasy about providing a drug that a layperson may administer, or may be concerned about 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. See text box for information on how some states have passed laws to alleviate these concerns.

Make a list of opportunities

Helpful factors in your state could include current Medicaid managed care organizations that already reimburse for take-home naloxone, or recent media coverage focusing on the overdose epidemic in your state. Determine how each opportunity might be used to promote your goal of expanded access through Medicaid reimbursement.

Identify key decision and policy makers

Decisions about drug coverage in state Medicaid programs are generally made by a “Pharmacy and Therapeutics” Committee, a “Drug Utilization Review Board,” or both.^{xiv} These entities make recommendations about whether specific drug products should be available in a state’s Medicaid program, and whether they should be “preferred” drugs that are available without prior authorization. If information about your state’s decision-making body is not readily available, contact your state Medicaid agency for information.

You will also need to identify the decision makers for Medicaid MCOs and the expansion plans. As noted above, Medicaid MCOs are required to cover the same drugs as their respective states’ fee-for-service plans. However, even if a state covers take-home naloxone under its fee-for-service coverage, a Medicaid MCO in that state might only cover naloxone administered in a hospital setting. Some states may have contractual requirements that limit the MCOs’ flexibility. When you speak with your state agency about fee-for-service drug coverage, ask for clarification of how drug coverage is determined in MCOs and, if relevant in your state, in expansion plans.

It is possible that engaging directly with Medicaid decision makers or with Medicaid MCOs in your state will not yield the coverage changes you seek. In this case, you may need to consider a broader advocacy campaign to persuade other key policymakers in your state, such as the Governor and his or her staff, state legislators, or state, county, and local health departments. Depending on your state’s politics and the structure of its Medicaid program, these allies may be able to either encourage the Medicaid program to change, or directly expand reimbursement through, for example, a change in state law. The following steps can help you build support for an advocacy campaign, whether directed solely at the Medicaid agency, or at a larger audience.

Identify key stakeholders and potential allies

A stakeholder could be any of the people or entities that would have some form of vested interest in Medicaid coverage of take-home naloxone. Many of these stakeholders could serve as allies in expanding access to naloxone and specifically in advocating for Medicaid coverage of prescription take-home naloxone.

Healthcare providers and allied health professionals have a unique role to play in fighting the opioid overdose epidemic and promoting overdose reversal using naloxone. Providers can reduce the risk of overdose by increasing patient screening and education, particularly for those patients at risk such as those who receive opioid prescriptions. Increased prescribing of take-home naloxone is another important step in overdose prevention.

Other allies could include groups that work on substance use disorder and mental health issues generally, as well as overdose survivors and families of overdose victims or survivors.

In addition, determine if any officials in state government have taken stances related to overdose. These officials may serve as effective supporters in your advocacy. Along with their staff, these government decision makers can serve as a source of information about what types of strategies may be successful.

Draw support by raising awareness

In some states, politics surrounding drug overdose or Medicaid policy may dictate a more low-key advocacy approach. You may choose to focus your advocacy narrowly on Medicaid officials and their staff, without engaging in a broader public campaign for support.

However, you may determine that garnering public support in your state will be an important element of your advocacy campaign. In most circumstances, generating public support will involve a multi-layered public awareness plan that employs advocacy materials for varied audiences (e.g. policymakers, agency staff, or the public).

SUCCESS STORIES

In some states, advocacy has already led to Medicaid reimbursement for take-home naloxone. The following case studies of Washington State, California, North Carolina and New York State offer some key lessons learned for advocates in other states.

Washington State

In Washington State, the rate of drug overdose deaths (involving any drug category) increased by 41% from 1999 to 2010.^{xv}

Washington's Medicaid program, Apple Health, serves children, low-income elderly receiving Medicare benefits, and elderly, as well as non-disabled adults at 70% or less of the Federal Poverty Level. As of June 2013, there were over 1.1 million people enrolled in Medicaid in the state.^{xvi} Under the Affordable Care Act, Washington will be expanding Medicaid to all adults under 138% of the federal poverty level.^{xvii}

Washington's Medicaid program now covers take-home naloxone in intramuscular and intranasal forms, in both in the fee-for-service and managed care programs. The program does not cover the cost of the nasal atomizer.

Lessons from the Washington experience:

1. **Build on existing state policies related to naloxone and overdose prevention.**

In 2010, Washington was the second state to pass a “Good Samaritan” naloxone law.^{xviii} In addition to waiving criminal liability for drug charges for people who seek medical assistance for someone experiencing overdose, the law allows people acting “in good faith” to “receive a naloxone prescription, possess naloxone, and administer naloxone to an individual suffering from an apparent opiate-related overdose.” This allows prescription of take-home naloxone not only to someone at risk of overdose, but to someone who might need to administer it to a friend or family member. (Note: even if a Good Samaritan Law allows prescriptions to be issued to third parties, Medicaid and other insurers will not necessarily cover it in these cases. Washington State Medicaid does not currently cover take-home naloxone if it is prescribed to a patient who is not at risk to him or herself).

The Network for Public Health Law has a database of relevant state Good Samaritan laws, including both general ones and those that are specific to naloxone use.^{xix} Identify if your state has one of these laws, which should reassure physicians, patients, and payers.

2. Consider a “collaborative practice” model to expand access to naloxone.

Washington State allows a “collaborative practice” model or “collaborative drug therapy agreement,” and it has been used for naloxone, allowing pharmacists to dispense take-home naloxone directly to customers. Pharmacists must enter into an agreement with a prescriber, and submit a copy for review by the Washington Board of Pharmacy. This protocol allows people to get naloxone without a visit to a prescriber, since a visit could pose a logistical hurdle even with insurance reimbursement for the drug itself.

Sharing information for pharmacists and prescribers including examples that adhere to state regulations, rules and procedures is essential to promote implementation. One good resource can be found at stopoverdose.org/pharmacy.htm.

If your state permits similar agreements, Medicaid and other insurers could reimburse for take-home naloxone whether it is prescribed by a medical provider or dispensed by a pharmacist under an approved agreement. Talk to pharmacists or your state board of pharmacy to see if this option exists and be prepared to discuss the model with Medicaid or other payers.

3. Be aware of potential limitations on access to take-home naloxone even if an insurer claims or agrees to cover it.

As discussed above, Medicaid programs are permitted to put a number of limitations on access to prescription drugs. One such limit is requiring “prior authorization,” which means the prescriber has to get approval from Medicaid before it will reimburse for a drug. This step can limit providers’ willingness to prescribe a drug and delay or block access for patients.

In Washington State, advocates discouraged any potential prior authorization requirement on take-home naloxone, arguing that the drug’s use is safe and well-supported by evidence and did not require special oversight or approval by the insurer. Naloxone is also fairly cheap per dose, and therefore, prior authorization would not serve an effective cost-control purpose. Naloxone does not present a “moral hazard” risk in that access is not likely to lead to overutilization, and it is not a diversion risk because it cannot be abused. The state did not implement a prior authorization requirement.

Another issue that may arise in discussions with Medicaid is the number of refills available without seeing a physician or pharmacist again. Washington State ultimately decided to permit one refill, which advocates considered acceptable.

Prior authorization and number of refills available may also be concerns when discussing coverage with private insurance plans.

4. Explore options for overdose education as part of what insurers reimburse.

Though take-home naloxone is simple and safe to use, it still requires some patient education to understand the indications and contraindications, specifically how to recognize a likely opioid overdose, and awareness of how Washington’s recent new laws encourage calling 911.

Different models—such as brief counseling by a prescriber, or online education—might be effective for different clients. Online education that includes information about Washington State’s Good Samaritan Overdose law, which includes a legal immunity provision, is available at stopoverdose.org. In advocating for coverage of take-home naloxone in Medicaid and by other payers, it is important to consider overdose education as part of the reimbursement. For example, prescribers can potentially bill insurers under SBIRT—Screening, Brief Intervention, and Referral to Treatment—for counseling related to overdose and naloxone. See SAMHSA’s recent overdose prevention toolkit for more information on SBIRT and billing for overdose counseling.^{xx}

5. **Frame your advocacy message effectively.**

Advocacy efforts may be particularly effective if they put naloxone coverage into the broader context of opioid safety and overdose prevention education. For example, researchers advocating for the use of take-home naloxone in Washington wrote an op-ed on rising rates of fatal overdose involving prescription opioids and heroin.^{xxi} The op-ed included information about opioid overdose and described the value of naloxone, explaining how take-home naloxone had successfully reversed more than 10,000 overdoses nationwide at the time of the publication. It called for awareness among patients and prescribers and coverage by insurers.^{xxii}

California

In California, the rate of drug overdose deaths (involving any drug category) increased 31% from 1999 to 2010.^{xxiii}

California’s Medicaid program, Medi-Cal, serves children under 21 years old, their parents, pregnant women, seniors, nonelderly adults that are blind or disabled, those individuals in a skilled nursing or intermediate care home, and those that have been screened for breast and/or cervical cancer. As of June 2013, there were close to 8 million people enrolled in Medicaid in the state.^{xxiv} Under the Affordable Care Act, California will be expanding Medicaid to all adults under 138% of the federal poverty level.^{xxv}

Advocates, supported by substance use and pharmacy expertise, successfully achieved coverage for take-home naloxone under Medi-Cal.

Lessons from the California experience:

1. **Identify the board or committee that makes pharmacy decisions for Medicaid in your state.**

As discussed on page 10, each state has one or more entities that make determinations about drug coverage within the Medicaid program. In California, this body is known as the Pharmacy Review Board. Those advocating for coverage of take-home naloxone met directly with the Board to make their case. Contact your state Medicaid program to determine what body exists in your state and how to contact them.

You should also identify if your state or city has other programs that provide health coverage for low-income populations. In California, Healthy SF, a safety net program for those ineligible for

Medi-Cal based on income, covers take-home naloxone with city dollars. If your state has similar local health plans, you may decide to extend coverage advocacy efforts to them as well.

2. Assemble key data on the effectiveness and cost-effectiveness of take-home naloxone.

In their meetings with Medi-Cal decision makers, advocates came prepared with data regarding naloxone's track record of safety and effectiveness.^{xxvi} In addition, they were asked to provide information about the cost-effectiveness of naloxone. See the resources section of this document for existing articles and factsheets that you can use to make your case.

3. Pharmacists may be powerful allies.

Achieving coverage status for the take-home version of naloxone came about after a substance use expert teamed up with a pharmacist in a local health department. They met jointly with the Medi-Cal Drug Use Review. Pharmacists often have detailed knowledge of and experience with the process by which medications go from manufacturers to patients, making them crucial allies in advocating for changes in pharmaceutical coverage.

4. Be aware that health insurance may not reimburse for the atomizer needed for intranasal administration.

As is the case in other states, including those profiled here, difficulty securing reimbursement for the atomizer needed for intranasal use remains a problem. As described earlier, the problem stems from the atomizer lacking a National Drug Code or UPN, which are universal product identifiers typically used in insurance billing systems. In California, the atomizer is not currently covered by Healthy SF. The atomizer can be reimbursed under Medi-Cal, but this requires pharmacists to complete a Treatment Authorization Request form (TAR), then wait up to 24 hours to obtain approval by the Medi-Cal program. Given the relatively low cost of atomizers and razor thin margin from Medi-Cal, this process is unlikely to be worth the time for many pharmacists, though the cost may still be a deterrent to patients. In addition, pharmacies cannot easily access the atomizers because they are carried by device distributors with which few pharmacies have pre-existing relationships.

Advocates across the country hope to find a way to address the atomizer problem, such as facilitating the assignment of a National Drug Code or UPN so that the atomizer can be more easily reimbursed. In the meantime, however, advocates and providers can consider different ways to work around this problem. In San Francisco, the city finances the distribution of atomizers to patients via clinics, dividing the naloxone kit into two parts: the clinic distributes atomizers and educational brochures, and baggies, and the pharmacy dispenses the medication.

In general, the syringe required for intramuscular administration of naloxone is reimbursable. Some providers, however, are more comfortable prescribing the intranasal formulation or believe that some patients would be more comfortable administering it.

It is not known if Medi-Cal will cover the recently-approved naloxone auto-injector in the future, but the anticipated high cost of the device is likely to be a major barrier to access.

North Carolina

In North Carolina, the rate of drug overdose deaths (involving any drug category) doubled from 1999 to 2010.^{xxvii}

North Carolina's Medicaid program serves low-income parents, children, seniors, and people with disabilities. As of June 2013, there were 1.5 million people enrolled in Medicaid in the state.^{xxviii} To date, North Carolina has opted not to expand Medicaid to all adults under 138% of the federal poverty level under the Affordable Care Act.^{xxix}

North Carolina Medicaid's coverage of naloxone began with the creation of Project Lazarus' efforts to curb drug overdoses in the state. Project Lazarus is a nonprofit organization that created a pilot program in 2008 in response to high drug overdose death rates in Wilkes County, North Carolina.^{xxx} The goal of the Wilkes Co. project was to prevent drug overdose deaths while meeting the needs of people experiencing chronic pain. Project Lazarus has now expanded statewide as part of a Kate B. Reynolds Trust and Office of Rural Health grant directly under the auspices of Community Care North Carolina (CCNC), the state's nonprofit Medicaid managed care plan. This CCNC grant program focuses on opioid safety initiatives and building community coalitions including the expansion of access to take-home naloxone.^{xxxi}

Lessons from the North Carolina experience:

1. **Consider starting with a targeted program to create an evidence base for statewide coverage.**

Project Lazarus started as a pilot program in Wilkes County, North Carolina, an area that was experiencing overdose rates four times as high as the state average. From 2009-2011, Project Lazarus contributed to a 69% decline in unintentional overdose deaths in the county.^{xxxii}

Based on this track record, Project Lazarus through the grant described above and under the auspices of CCNC was able to expand anti-overdose efforts statewide.^{xxxiii} The initiative includes training for communities, care managers, primary care providers and emergency room physicians. CCNC also distributes take-home naloxone rescue kits.

If there are currently any city or county anti-overdose programs in your state that distribute naloxone, determine if there is evidence available on their effectiveness. Ideally, this would be data published in a scientific journal, but more informal data may also be helpful. Demonstrating success within your state could help persuade the state Medicaid agency or specific Medicaid managed care plans to work with you to cover take-home naloxone or otherwise support anti-overdose efforts.

2. **Incorporate education for providers and pharmacists.**

Project Lazarus, a community program of CCNC, promotes access to take-home naloxone, including reimbursement, within a broader context of education and training for physicians and pharmacists. As discussed above Project Lazarus through CCNC is providing training for care managers, primary care providers, and emergency room physicians. Topics include identifying patients at risk of problems with opioid use; working with patients through pain treatment agreements; and clinical tools for assessing chronic v. acute pain.^{xxxiv}

If you plan to advocate for reimbursement of take-home naloxone by Medicaid or other payers in your state, consider developing broader training programs that put naloxone in the context of comprehensive anti-overdose and pain management efforts.

3. **Explore the possibility of standing orders for naloxone.**

In North Carolina, physicians can write a “standing order” for naloxone. This allows the non-physicians who conduct trainings statewide to actually distribute naloxone rescue kits without requiring a separate visit to the doctor.^{xxxv}

While standing orders do not in themselves address the reimbursement issue, they may, in combination with Medicaid coverage, help expand access to take-home kits.

4. **Identify pharmacies willing to distribute take-home naloxone.**

Not all pharmacies in North Carolina have take-home naloxone readily available. Therefore, physicians who prescribe naloxone need to direct patients to specific pharmacies that they know typically stock the drug.

New York State

In New York State, the rate of drug overdose deaths (involving any drug category) increased by 56% from 1999 to 2010.^{xxxvi}

New York’s Medicaid program serves low-income parents, children, seniors, and childless adults. As of June 2013, there were over 5.1 million people enrolled in Medicaid in the state.^{xxxvii} New York has opted to expand Medicaid to all adults under 138% of the federal poverty level under the Affordable Care Act.^{xxxviii}

For over ten years, harm reduction groups in New York have been distributing naloxone kits and conducting trainings, supported by grant funding. As of January 1, 2014, the state’s Medicaid program began to cover the intramuscular formulation of take-home naloxone. Pharmacies can bill for up to two single-use vials or pre-filled syringes, and each prescription can be refilled up to five times.^{xxxix}

Lessons from the New York experience:

I. **Don’t be daunted.**

Most people have very little, if any, experience with Medicaid coverage policy, but you do not have to be a Medicaid expert to engage in advocacy for reimbursement of take-home naloxone. Matt Curtis of VOCAL-NY notes that once advocates in the state identified the appropriate decision makers, they could ask questions about process along the way. The whole process, from early discussions with the state to the coverage determination, took about a year.

2. **Build on prior policy advances.**

In New York State, the 2005 Opioid Overdose Prevention Act created a legal framework for the prescription of take-home naloxone, including standard setting and liability protection for administration by laypeople. Subsequent to passage of the law, the state and city departments of health were able to start to provide funding for community-based naloxone distribution by harm reduction groups, who ultimately were able to advocate for Medicaid reimbursement.

If your state does have liability and other protections related to naloxone,^{xi} incorporate that information into your advocacy to reassure decision makers.

3. **Look for allies within the government.**

New York State has an AIDS Institute that is part of the Department of Health. In addition to HIV and hepatitis, the Institute addresses drug user health, and administers the state's Opioid Overdose Prevention Program.^{xii} The AIDS Institute was not only supportive of advocates' efforts to achieve Medicaid reimbursement, but were strong advocates themselves, leading the way for the policy change from within government.

In your state, identify offices or individuals who may be able to support your advocacy efforts, either publicly or behind the scenes.

4. **Pay attention to Medicaid changes in the state.**

The change in reimbursement in New York took place against the backdrop of a major statewide overhaul of the Medicaid system, which has included initiatives to support harm reduction services through Medicaid for the first time. Medicaid is constantly changing in many states, from benefit and payment changes to large-scale redesigns under waivers from the federal government that permit new flexibilities. As you implement a strategy to advocate for Medicaid reimbursement of naloxone—and even after you achieve success—keep track of changes to the Medicaid program both to identify opportunities and to detect any potential threats to access.

KEY RESOURCES FOR ADVOCATES

National Association of State Medicaid Directors, “Directory of State Medicaid Directors”: medicaiddirectors.org/about/state-directors

American Public Health Association (APHA), “APHA Policy Statement on Preventing Overdose Through Education and Naloxone Distribution”: <http://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/16/13/08/reducing-opioid-overdose-through-education-and-naloxone-distribution>

Center for Health Law, Policy and Practice, “Closing Death’s Door: Actions Steps to Facilitate Emergency Opioid Drug Overdose Reversal in the United States”: med.wright.edu/sites/default/files/citar/od/Naloxonewhitepaper09.pdf

NaloxoneInfo.org: naloxoneinfo.org/advocacy

Therapeutic Intranasal Drug Delivery, “Intranasal Naloxone for Acute Opiate Overdose: Reducing Needle Stick Risk, Improving Time to Medication Delivery”: intranasal.net/OpiateOverdose/

OSF, “Intranasal Naloxone and Opioid Overdose”: opensocietyfoundations.org/sites/default/files/intranasal-naloxone-04112012_I.pdf

OSF, “Stopping Overdose: Peer-Based Distribution of Naloxone”: opensocietyfoundations.org/sites/default/files/stopping-overdose-eng-20130807.pdf

Prescribe to Prevent, “Stocking/Paying for Naloxone & Billing”: prescribetoprevent.org/stockingpaying-for-naloxone-billing/

Harm Reduction Coalition, “DOPE Project, Case Study”: harmreduction.org/issues/overdose-prevention/tools-best-practices/naloxone-program-case-studies/dope-project/

Harm Reduction Coalition, “Massachusetts OEND, Case Study”: harmreduction.org/issues/overdose-prevention/tools-best-practices/naloxone-program-case-studies/massachusetts-oend/

Harm Reduction Coalition, “Guide to Developing and Managing Overdose Prevention and Take-home Naloxone Projects”: harmreduction.org/wp-content/uploads/2012/11/od-manual-final-links.pdf

Project Lazarus: projectlazarus.org/

Overdose Prevention Alliance: overdosepreventionalliance.org/

Harm Reduction International: ihra.net/sub-categories-overdose

Drug Policy Alliance: drugpolicy.org/drug-overdose

Reach for Me Campaign: reach4me.org/index.php/resources

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- v Medicaid Fee-For-Service. Medicaid.gov website. Available at: [medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Fee-for-Service.html](https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Fee-for-Service.html)
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