Washington State Health Care Authority

Report to the Legislature

Opioid overdose reversal medication bulk purchasing and distribution program

Second preliminary progress report

Second Substitute Senate Bill 5195; Section 7(6); Chapter 273; Laws of 2021

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Executive summary

The Washington State Health Care Authority (HCA) is evaluating options for creating and maintaining a bulk purchasing and distribution program for opioid reversal medications as directed by Second Substitute Senate Bill (2SSB) 5195 (2021), and submitting this report as required in Section 7(6):

> "(6) By January 1, 2022, the health care authority shall submit a report to the legislature on the progress towards establishing the bulk purchasing and distribution program. The health care authority shall submit an updated report on the progress towards establishing the bulk purchasing and distribution program by January 1, 2023."

Given the state of the opioid epidemic, Washington State needs new strategies to address increasing drug-caused deaths involving opioids. HCA worked closely with the Center for Evidence-based Policy (the Center) at Oregon Health and Science University (OHSU) and with patients and providers across the state to evaluate different policy options that may improve access and affordability of naloxone in Washington. HCA also received considerable feedback on some challenges and concerns that providers and other health care entities have about avoiding unintended consequences of the options being considered.

With this in mind, HCA has five policy options that may provide viable solutions for the state. Each option can be implemented independent of the others, and they may be developed in tandem should multiple policy options prove to be the viable solution for Washington.The five policy options are:

1. Increasing annual funding for the current Opioid Education and Naloxone Distribution (OEND) program at the Washington State Department of Health (DOH) to allow for expansion that can meet demand for naloxone. This strategy is used by agencies and organizations that do not bill insurance coverage, particularly for organizational partners that serve uninsured, underinsured, and/or partners that cannot access reimbursement for naloxone purchasing.
2. Negotiating a discounted rate of naloxone by leveraging state purchasing power and make that price available to all providers purchasing naloxone and for Washington's uninsured who use the Prescription Drug Card.
3. Expanding availability of naloxone to social programs by allowing these organizations to bill Apple Health (Medicaid) and commercial payers for reimbursement for the cost of naloxone that they purchase and distribute to individuals with health care coverage.
4. Expanding access to naloxone through managing claims denied by private insurance for those agencies and organization not being reimbursed by payers for naloxone.
5. Establishing a statewide bulk purchasing and distribution program for agencies without access to affordable naloxone supply or where this would be a more competitive price to what they are currently paying their wholesaler.

Given the different options available to HCA, the agency is working to better understand how these different solutions may impact patients, providers, and health systems and ultimately lead to greater access of naloxone.

Background

Washington State is in the midst of an opioid epidemic. Despite progress over the last decade in addressing overutilization of prescription opioids, increasing awareness of opioid use disorder, and other public health strategies to address this crisis, drug-caused deaths involving opioids rose statewide from 988 in 2019 to a then record 1,428 in 2020 and another record of 2,004 in 2021.

To address this emergency, 2SSB 5195 was signed into law in 2021 to increase access to opioid overdose reversal medications. Section 7 of this legislation tasks HCA with creating and maintaining a system for purchasing and distributing naloxone as a means to increase access and use of this medication to reduce the number of opioid overdose fatalities in Washington.

Naloxone is a Food and Drug Administration (FDA)-approved medication used to reverse the effects of opioids by blocking the receptor which opioids act on. Naloxone is available for purchase and use in Washington under a standing order. The task assigned to HCA is to increase the efficiency in which health systems and community organizations are able to purchase and distribute naloxone and evaluate the potential to reduce costs through bulk purchasing strategies.

Naloxone is available through traditional drug purchasing and distribution channels. Naloxone is produced by several different drug manufacturers in several dosage forms, and these products are made available to purchase by health systems, pharmacies, and other organizations through drug wholesalers. These entities distribute naloxone to end-users, either patients themselves or caretakers, and some may seek reimbursement for this cost or distribute it at no charge. DOH also has a naloxone purchasing and distribution program. HCA is seeking to evaluate this and other options for entities to purchase naloxone.

However, there are challenges with creating a new purchasing system when existing channels for purchasing and distributing exist for prescription drugs. These systems operate with known efficiencies, and a new purchasing system must address both pricing and incentives in order to be successful in addressing the growing opioid crisis.

This legislative report provides a summary as to the progress of HCA in establishing this new naloxone purchasing and distribution program as described in section 7(6) of 2SSB 5195 (2021).

Progress toward establishing a bulk purchasing and distribution program

HCA implemented a process to reimburse providers for naloxone dispensed to uninsured residents, in accordance with section 5(2) of 2SSB 5195 (2021) in August 2022 with an effective date retroactive to January 1, 2022.

HCA created a project plan for identifying and evaluating different purchasing strategies to determine viable options for creating a bulk purchasing and distribution program in Washington. HCA contracted with the Center for Evidence-based Policy (the Center) at Oregon Health and Science University (OHSU) to explore policy and program considerations in the context of existing naloxone purchasing and distribution. HCA worked closely with the Center to evaluate how these different options may positively impact the state.

HCA and the Center identified impacted parties to provide input and feedback to better understand the different options for a bulk purchasing and distribution program at HCA. In 2021, HCA and the Center contacted stakeholders, including payers, providers, distributors and others about how they could participate in an evaluation process. Additionally, HCA broadcasted information to the public about how they could participate, too. Through various surveys and webinars, HCA and the Center received commentary about the various designs and proposals for potential bulk purchasing and distribution programs.

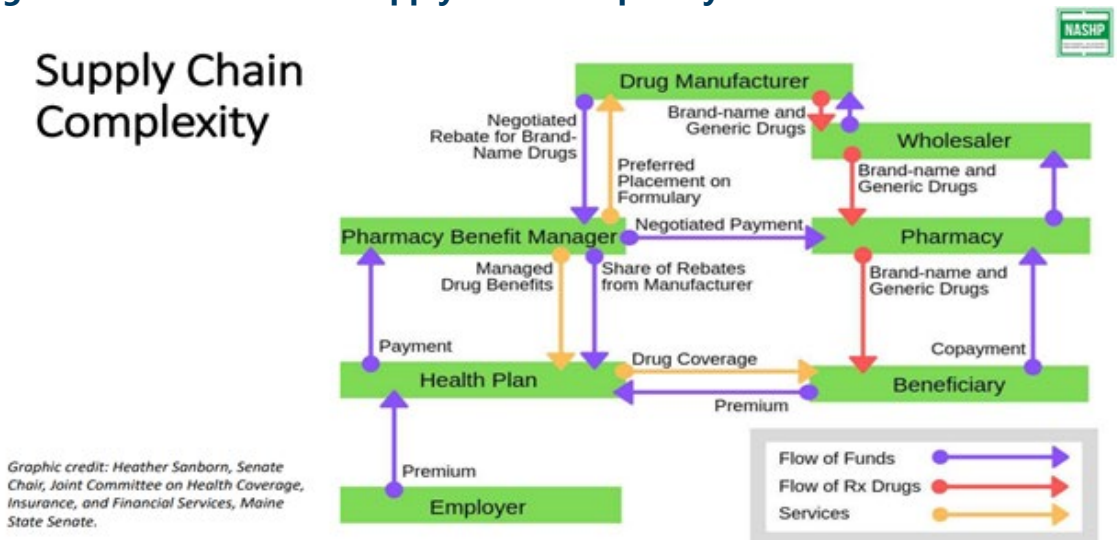
Among the most important aspects of this public feedback were around the creation of guiding principles. HCA and the Center sent a survey to stakeholders in February 2022, asking for responses to open-ended questions about how the program should impact Washington. After gathering answers and identifying key themes among stakeholders, HCA established the five guiding principles for this work as:

1. Improve health equity.
2. Maximize access and affordability to Washingtonians.
3. Ensure simplicity.
4. Create a flexible, scalable, and sustainable model or models.
5. Build on and advance Washington's health reform efforts.

With these guiding principles in place, HCA was able to evaluate policy and program considerations through these lenses to better understand how a successful naloxone purchasing and distribution program could positively impact Washington.

HCA and the Center reviewed the existing structure of purchasing and distribution of naloxone to identify areas where the agency may be able to participate in facilitating improved access and availability of naloxone in Washington. Figure 1 shows a simplified model of the existing pharmacy distribution system, which is a primary method for how Washington residents obtain naloxone.

Figure 1. Pharmaceutical supply chain complexity



Credit: The National Academy for State Health Policy

Within this existing pharmacy distribution system, HCA and the Center evaluated how HCA may be able to partner or act as the drug manufacturer, wholesaler, pharmacy, or pharmacy benefit manager (PBM) as roles where a bulk purchasing and distribution program could exist. HCA also interviewed staff at the Washington State Department of Health (DOH) about the Overdose Education and Naloxone Distribution (OEND) program that was established in 2019. The OEND program helps improve access to naloxone statewide by using grant dollars to purchase naloxone through a wholesaler and distribute it to community organizations who then provide the opioid overdose reversal medication directly to patients.

After compiling research on potential strategies and engaging with stakeholders, HCA and the Center identified five considerations for how HCA could create and maintain a bulk purchasing and distribution program:

1. Increasing annual funding for the current Opioid Education and Naloxone Distribution (OEND) program at the Washington State Department of Health (DOH) to allow for expansion that can meet demand for naloxone. This strategy is used by agencies and organization that do not bill insurance coverage, particularly for organizational partners that serve uninsured, underinsured, and/or partners that cannot access reimbursement for naloxone purchasing
2. Negotiating a discounted rate of naloxone by leveraging state purchasing power and make that price available to all providers purchasing naloxone and for Washington's uninsured who use the Prescription Drug Card.
3. Expanding availability of naloxone to social programs by allowing these organizations to bill Apple Health and commercial payers for reimbursement for the cost of naloxone that they purchase and distribute to individuals with health care coverage.
4. Expanding access to naloxone through managing claims denied by private insurance for those agencies and organization not being reimbursed by payers for naloxone.
5. Establishing a statewide bulk purchasing and distribution program for agencies without access to affordable naloxone supply or where this would be a more competitive price to what they are currently paying their wholesaler.

It is important to note that these policy options are not mutually exclusive, and these policies can be combined, in part or in whole, to create the optimal bulk purchasing and distribution program for achieving the state's goals.

However, before considering each individual option, HCA and the Center identified a few significant challenges that will be present in the option considered. Although these challenges do create barriers or uncertainty in our planning and execution, we have included potential mitigation strategies on how these challenges may be addressed.

Common challenges identified

HCA and the Center identified two key challenges that limit the ability for HCA to purchase naloxone at a significant discount relative to others. The first is the ability for HCA to negotiate meaningful discounts for bulk purchasing in Washington, and the second is the cost-effectiveness of creating new infrastructure or systems, which require significant investment.

Although many different organizations and purchasers are paying for naloxone at different prices, HCA understands that with a limited number of manufacturers and generic competition, securing a discount through bulk purchasing that reduces the cost of naloxone statewide may not be possible. Generic manufacturers often operate their revenue close to the margins to obtain market-share of their drugs, so they may not be interested in a bulk purchasing model. Similarly, brand manufacturers may consider offering discounts for bulk purchasing arrangements, but the discount offered may not be lower than what the generic manufacturer offers, therefore not making that arrangement the most viable option.

One mitigation strategy for this is addressed in Option 2 (negotiate with state purchasing power), which depends on the size of the population, and therefore potential market share, that HCA can negotiate with to drive potential discounts. More on this mitigation strategy will be discussed in Option 2. Another strategy for mitigating the challenges in negotiating a discount are to wait until more generic manufacturers enter the market. With more manufacturers, market competition increases as each company attempts to create profits based on their price and market share. As more manufacturers enter the market, prices will drop as these new manufacturers attempt to gain market share, which could effectively lower the price beyond what HCA could negotiate for discounts. Additionally, some manufacturers may be more willing to give discounts to HCA if they want to regain market share, they recently lost. However, it is unknown how or when this strategy may apply to HCA in its pursuit of establishing a bulk purchasing and distribution program.

The challenge with creating new infrastructure or systems is that these options require significant investment which instead could be used to procure more naloxone to improve access. Although a bulk purchasing program could be established that has its own system of warehouses, delivery vans, and surveillance for ordering, tracking, and monitoring, this system would not meet the guiding principles of maximizing access and affordability, ensuring simplicity, or creating a sustainable model.

One mitigation strategy for addressing this challenge is how HCA could contract with these entities to provide these services. This mitigation strategy focuses on guiding principles 3 and 4, by ensuring simplicity and creating a flexible, scalable, and sustainable program because these entities already exist within the pharmacy supply chain and do business with other entities. The benefits of contracting with existing companies significantly outweigh those of creating new infrastructure for the purposes of a bulk purchasing and distribution program.

Five strategies for a bulk purchasing and distribution program

As a result of these challenges, potential options for bulk purchasing and distribution programs should leverage existing models and frameworks where HCA can use its role to improve access and affordability to naloxone.

1. Continue and enhance the support to the current OEND program and purchasing for uninsured Washington residents

The first policy option for consideration would be to continue HCA's current activities of exploring how ArrayRx, the state's prescription drug purchasing consortium, may help the OEND program at DOH access naloxone at a discounted rate and with HCA handling reimbursement of naloxone for uninsured people.

DOH's OEND program provides naloxone without charge to agencies that are unable to bill payers and that often serve the uninsured. As a result of SB 5195, HCA has met with the OEND program at DOH to discuss how ArrayRx may help the program purchase naloxone at discounted rates as compared to what they may be purchasing through their current contract. By reviewing the price of naloxone between these options, OEND can purchase naloxone at the lowest cost, thereby maximizing the amount of naloxone distributed to communities across the state.

2. Negotiate with state purchasing power

The second policy option would attempt to leverage the state's existing purchasing power to contract with a manufacturer or manufacturers for discounted naloxone. Under this strategy, ArrayRx would solicit bids from manufacturers of naloxone to create a new state-negotiated price that would be available to purchasers who elect to purchase naloxone through an approved wholesaler or group purchasing organization (GPO).

This program would be optional for purchasers in the state as some entities already receive additional discounts through federal or other purchasing options. However, this option would certainly reduce costs for some purchasers, which could be used to support purchasing more naloxone or providing other services related to opioid use disorder. In addition, this option would support more affordable Naloxone for those using the Washington Prescription Drug Card.

There may also be a need for providers who are able to bill to be funded for their initial supply of naloxone prior to the revenue stream from payers being established, A grants program could also be explored if needed. An analysis of legal and operational impacts would be needed to understand the implications of establishing such a grants program.

This option is viable to consider given that it affects a large population in Washington and should not create significant administrative burden for patients or providers. By leveraging the existing pharmacy distribution system, providers should be able to order from a wholesaler or GPO with an existing distribution infrastructure.

This strategy can be combined with any of the other strategies listed in this report, but it depends on the willingness of manufacturers to accept this state-negotiated rate for purchasers. HCA is considering it as a strategy to lower the cost of naloxone and to increase the amount of naloxone available in the state.

3. Expand availability of naloxone to social programs

In the context of this report, social programs are organizations that provide or distribute free naloxone to clients and community partners. Currently, OEND is limited to funding secured through grants, which is distributed to social service and community organizations. These funds purchase naloxone kits which may be made available to anyone. Naloxone kits provided by the OEND program that are dispensed to patients with Apple Health and commercial insurance are not eligible for reimbursement as there is not an infrastructure in place for social programs to do so. Therefore, it would be advantageous for these social service and community organizations to be able to purchase naloxone directly and bill Apple Health or commercial insurance for reimbursement. This would free up grant funds to purchase additional naloxone for the uninsured.

In addition to lacking billing infrastructure, many low barrier programs serving people who use drugs do not collect any identifiable information from their clients. While some clients may be willing to share their information in these settings, others would not. This could lead people at high risk of overdose to not seek services at all. This strategy appears to be an option to increase and expand the amount of naloxone distributed through OEND and through these community organizations, but it would require funding to build and maintain an infrastructure for agencies to use.

4. Expand to manage denied claims

The fourth policy option would have HCA establish a clearinghouse to manage claims for naloxone that are denied by private insurance. Section 7 of 2SSB 5195 (2021) provides HCA with the authority to "…[b]ill, charge, and receive payment from health carriers, managed health care systems, and to the extent that any self-insured health plans choose to participate, self-insured health plans…" when creating a bulk purchasing and distribution program. Under this option, HCA would be able to reimburse pharmacies and health systems for naloxone due to a denied claim or potentially high out-of-pocket cost.

Ideally, HCA would not need to create an entire new pharmacy purchasing and distribution system for health carriers, pharmacy benefit managers (PBMs), wholesalers, manufacturers, health systems, prescribers, pharmacies, and patients to navigate, as the existing private insurance system does cover naloxone for many Washingtonians. However, access is an issue for certain patients, and health insurers or PBMs may deny a claim if the naloxone is dispensed to the patient pursuant to a visit to the emergency department or office visit. Patients may also forego filling a prescription for naloxone if they are not able to afford their cost-share for naloxone. Option 4 would be used as a means to increase access by reimbursing for naloxone in these instances to either the provider or patient by applying a dosage-based assessment for improperly denied claims or excessive cost-shares.

For this strategy to work, providers would need to submit claims denied by a private insurer to a clearinghouse contracted by HCA to review and determine eligibility for reimbursement. If the claim was denied for a reason outlined in an established policy, such as naloxone not being eligible to be reimbursed separately when provided as part of an emergency department visit, then the clearinghouse could bill the private insurer on behalf of HCA for the amount invoiced by the provider. A policy would need to be created that outlines appropriate and inappropriate denials, as some denials may be justified (e.g., patient not covered by health plan at the time of dispensing). An alternative to the clearing house model is for the legislature to mandate coverage of naloxone when dispensed in an emergency department or pursuant to an office visit.

HCA would also need to explore patient cost-shares as a barrier to access, since some patients may be uninsured, have high copays or coinsurances when receiving naloxone from a pharmacy. For patients with high cost-shares, HCA may be able to cap the price of certain naloxone cost-shares through this program, similar to how the cost-share for insulin was capped with SSB 5546 (2021). Additionally, certain high-deductible health plans are managed by the IRS and are eligible to provide preventive health care services before satisfying an annual deductible, as described in 26 USC Section 223(c)(2)(C) and clarified in IRS Notice 2004-23. However, these options around cost-share would need to be explored legally and operationally before being considered a viable option.

5. HCA operates a statewide naloxone program

The fifth and final policy option that HCA may consider is establishing a statewide bulk purchasing and distribution program for naloxone. This new program would have a significant impact on how naloxone is purchased and accessed in the state, but it may create some operational and funding challenges that could disrupt existing pharmacy purchasing systems.

Under this strategy, HCA would have the authority to purchase and distribute naloxone to various entities, collect funding through dosage-based assessments, or provide reimbursement to health care providers for dispensing naloxone. The assessment could also be based on an estimation of covered lives that would receive naloxone through the bulk purchasing program. Providers would not need to submit claims to health insurers or PBMs, as all purchasing and reimbursement for naloxone would be coordinated through this new program.

However, this strategy faces some significant challenges, and HCA received clear indication from payers and providers that disrupting the current purchasing and distribution systems would compromise operations. For example, creating a new purchasing and distribution system could cause issues for patients and practices that currently do not experience any affordability or access issues. The investment and funding necessary to establish and administer this program could also increase the cost of dispensing naloxone to patients given the new administrative costs and potentially increased costs due to lost discounts, if a purchaser could receive naloxone for less than what is available through the new program.

The creation of a bulk purchasing and distribution program is being considered as it could provide an option as long as it corrects the access and affordability issues without increasing costs, creating new access issues, or adding to provider and health system burden.

Next steps

HCA is in the process of evaluating the current challenges facing health systems, communities, providers, and patients in accessing affordable naloxone. Depending on the issues facing these health care entities, HCA will evaluate how the different strategies best provide solutions for both the short-term and long-term problems in Washington.

Conclusion

Over the last year, HCA and the Center have worked with soliciting feedback from stakeholders, researching policy options, and considering the authority granted to HCA under Section 7 of 2SSB 5195 (2021). HCA and the Center have identified five policy options that could provide solutions for naloxone access and affordability in Washington, as detailed in the report.

HCA is actively working to better understand the current challenges and barriers that patients and providers face when attempting to provide naloxone to those in need. Going forward, HCA will continue working with other agencies and the community in identifying problems that people face and how the five options, either independently or in combination, may address these issues.