

Recommendations on alternative models for long-acting injectable buprenorphine

Engrossed Substitute Senate Bill 5950; Section 215(126) (b); Chapter 376; Laws of 2024

October 15, 2024

Purpose

ESSB 5950 Section 215(126) (b) directs HCA to:

“...study alternative models that will ease access to long-acting injectable buprenorphine products and report recommendations to the office of financial management and the appropriate committees of the legislature by October 15, 2024.”

This report responds to that direction and includes background information about the opioid epidemic, considerations about long-acting injectable (LAI) buprenorphine affordability and access, and recommendations to the Office of Financial Management (OFM) on opportunities to expand access.

Background

The opioid epidemic continues to negatively impact Washington, requiring the state and its leaders to explore new ways of identifying and treating people living with opioid use disorder (OUD). HCA has partnered with other agencies and more information can be found on HCA’s website regarding:

- [State Opioid and Overdose Response \(SOOR\)](#)
- [HCA’s efforts](#) to address OUD and substance use disorder (SUD)

Addressing the opioid epidemic requires, among other strategies, access to medications that can reverse opioid overdose and medications to treat the condition. Medications like buprenorphine and methadone are the treatments of choice for OUD. Multiple studies have shown that they **reduce the risk of overdose death by at least 50 percent**. This report focuses on expanding access to one of the medications for opioid use disorder (MOUD), LAI buprenorphine.

LAI buprenorphine acts by binding to and partially activating opioid receptors in the body. Unlike oral formulations of buprenorphine which are taken daily, the LAI formulations can be administered weekly or monthly. Eliminating the need to take daily medication is particularly important for people living unhoused and others who face challenges taking medications daily.

Despite its effectiveness for patients, access to and affordability of LAI buprenorphine is challenging. LAI buprenorphine is primarily obtained through specialty pharmacies. This medication is subject to a Risk and Evaluation Mitigation Strategy (REMS) program under the Food and Drug Administration (FDA), meaning it cannot be given to patients to possess for themselves. Rather, the medication must always be delivered directly to clinics. Once delivered, it can only be handled and administered by certified health care providers. Medication can be ordered via prescription for a specific individual from the specialty pharmacy. It takes about a week for delivery. If the patient is not able to make their follow-up

appointment, the medication—which costs about \$2,000 per dose—cannot be used on anyone else and must be discarded.

An alternate path is for the clinic to purchase an inventory of medication to be available for same-day use when a patient is seen and requesting MOUD. Most clinics do not have funds available to purchase several thousand dollars' worth of these medications up front. ESSB 5950 Section 215(126) (a) provided HCA with funding to help purchase LAI buprenorphine for these providers as one way of expanding and making available same-day access to MOUD for Washingtonians. This is just **one of many existing mechanisms** through which HCA and other state agencies are working to address the opioid epidemic in our state.

Barriers to alternative models

HCA identified three major barriers the state must understand and address when considering alternative models through which patients could access LAI buprenorphine: federal regulations, staffing and facilities, and costs and purchasing.

Federal regulations

LAI buprenorphine has a REMS program under the FDA that mandates how the drug can be accessed, handled, and administered. The program is designed to prevent the medication from ever being physically handed over to the patient due to safety risks. Serious harm or death may occur if the medication is used improperly.

Providers who want to order and stock LAI buprenorphine must undergo REMS certification before ordering the drug from wholesalers or distributors. REMS certification is managed through drug manufacturers.

Staffing and facilities

The REMS-certification process requires proper storage equipment and staff training protocols. Providers who do not already have lockable refrigeration may need to purchase it to store some versions of this Schedule III controlled substance.

Costs and purchasing

The wholesale acquisition cost of LAI buprenorphine is a little over \$2,000 per 28-day supply per patient. Providers or clinics with tight cash-flows may be reluctant to purchase and stock the medication, especially if they do not see many patients with OUD who are appropriate candidates for LAI buprenorphine.

Reimbursement from private insurance may not incentivize providers to start offering LAI buprenorphine over other treatment options, like oral buprenorphine/naloxone. Uninsured patients are unable to reimburse LAI buprenorphine, meaning clinics would be absorbing these costs.

Findings on alternative models

HCA found three alternative models that may prove beneficial for improving access and affordability to LAI buprenorphine in Washington: small clinics, community pharmacies, and specialty pharmacies.

Small clinics

Small clinics are an option because they have a large community presence throughout the state, including urban and rural areas. Helping these clinics purchase an initial stock of LAI buprenorphine could increase access across Washington.

In the 2024 supplemental operating budget, the Legislature allocated \$3,000,000 for small providers to purchase LAI buprenorphine.

HCA has created a Participating Provider Agreement and a process for enrolling appropriate clinics to access these funds through our existing contract with MMCAP Infuse. HCA has also developed documents with policies and procedures to ensure clinics can set up their facilities to meet qualifications for ordering, storing, and administering. This program is launching in 2024.

Community pharmacies

HCA identified community pharmacies around the state offering and administering LAI buprenorphine at their locations, creating alternative sites of care for patients. In addition to offering these medications to the general population, these pharmacies were identified as potential partners for patients being released from jails or correctional facilities.

Community pharmacies are also the subject of research to better understand their effectiveness and impact in treating populations in our state. The University of Washington School of Pharmacy and Washington State Pharmacy Association are studying implementing new care models that would allow MOUD, including LAI buprenorphine, in community pharmacies. One chain of pharmacies is studying the effectiveness of LAI buprenorphine at community pharmacies across multiple states, including Washington.

Currently, these community pharmacies are primarily located in urban areas of Washington, meaning there is an opportunity to expand this model to rural areas of our state, where access to LAI buprenorphine at clinics may also be inadequate.

Specialty pharmacies

HCA has worked with Ardon Health, the specialty pharmacy for ArrayRx and the state's self-funded health plan, Uniform Medical Plan (UMP), to begin offering LAI buprenorphine statewide.

Since specialty pharmacies can ship medications anywhere in Washington, this strategy can help expand access to areas where community pharmacies are unable to provide access. Clinics do not have the ability to buy-and-bill for LAI buprenorphine.

Ardon Health has successfully contracted with one drug manufacturer for LAI buprenorphine.

Conclusions and recommendations

HCA identified three alternative models where patients may be able to access LAI buprenorphine. Since community pharmacies and specialty pharmacies are already able to buy LAI buprenorphine from wholesalers and bill health plans for reimbursement, the state may not need to take any action for these models to serve our communities.

There continue to be significant access limitations for those who are uninsured and unable to pay for the medication. **Therefore, HCA recommends the Legislature consider HCA's proposed Decision Package that requests \$3,000,000 for continuing to provide small clinics with funding to purchase LAI buprenorphine.**

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