Revised July 1, 2026

Long-Acting Injectable Buprenorphine in King County, WA

Implementation Barriers & Solutions

OVERDOSE PREVENTION & RESPONSE TEAM, PUBLIC HEALTH—SEATTLE & KING COUNTY | JUNE 2026

Contents

Purpose

This report is intended to inform healthcare practitioners, administrators, and policymakers of the challenges and potential solutions for long-acting injectable buprenorphine (LAIB) implementation across healthcare settings in Washington State, with a focus on King County. It summarizes and expands on input from 40 participants at a November 2025 LAIB implementation meeting hosted by Public Health—Seattle & King County's Overdose Prevention and Response team.

Disclaimer

The information in this report reflects available knowledge at the time of writing and has been verified where possible. Details are subject to change. This report does not serve as legal advice. Readers should consult primary sources and their own legal and risk management teams before making decisions based on this content.

Acronyms

The acronyms used in this report and their full forms are as follows:

- **CFR**: Code of Federal Regulations
- **CMS**: Centers for Medicare & Medicaid Services
- **DEA**: Drug Enforcement Administration
- **DRG**: Diagnosis-Related Group (hospital inpatient bundled payment)
- **ED**: Emergency Department
- **EHR**: Electronic Health Record
- **HCA**: Washington State Health Care Authority
- **HCE**: Healthcare Entity
- **LAIB**: Long-Acting Injectable Buprenorphine
- **MOUD**: Medications for Opioid Use Disorder
- **OBOT**: Office-Based Opioid Treatment
- **OIC**: Office of the Insurance Commissioner
- **OPPS**: Outpatient Prospective Payment System
- **OTP**: Opioid Treatment Program
- **OUD**: Opioid Use Disorder
- **PMP**: Prescription Monitoring Program
- **PQAC**: Pharmacy Quality Assurance Commission
- **REMS**: Risk Evaluation and Mitigation Strategy
- **RCW**: Revised Code of Washington
- **TA**: Technical Assistance

- **WAC**: Washington Administrative Code

Executive Summary

Long-acting injectable buprenorphine (LAIB) is an evidence-based treatment for opioid use disorder that maintains steady medication levels and removes the need for daily dosing. In King County, LAIB initiation rates have increased but remain low compared to daily oral (sublingual) buprenorphine. Regulatory, financial, and logistical barriers severely limit patient access, particularly for vulnerable populations who may benefit the most.

This report identifies barriers and potential solutions to LAIB implementation, organized into two primary categories: 1) Financial, including reimbursement structures, medication waste, and procurement challenges; and 2) Operational, including federal restrictions, Electronic Health Record (EHR) limitations, gaps in the Prescription Monitoring Program (PMP), and institutional approval processes. Each section describes the barriers, summarizes their impact, and proposes solutions. A summary table of described solutions is in *Appendix 1: Impact Table*.

Each described solution is accompanied by a preliminary assessment of its impact, current status, feasibility, and timeline. These preliminary assessments are best estimates determined with currently available information and may change as more is learned. Impact is assessed relative to regional-scale LAIB access and implementation; a solution rated as low impact regionally may still be meaningful for individual sites or specific patient populations.

Summary of Financial Barriers

LAIB is a high-cost medication, ranging from roughly $500-$2,000 per dose, and reimbursement structures vary significantly by care setting and payer, creating financial disincentives and administrative barriers that discourage adoption.

- Outpatient clinics may purchase a stock supply of LAIB and later bill for each dose administered (a process known as “Buy-and-Bill”). This allows immediate access for patients, but incurs significant up-front cost.
- Opioid Treatment Program (OTP) reimbursement is primarily based on a daily bundled rate per patient. These rates were built around methadone, which is inexpensive, and do not account for the significantly higher cost of LAIB.
- Mobile medical programs lack valid place-of-service codes for insurance reimbursement and have difficulty confirming patient insurance status in the field.
- Some private insurers require high copays that can be unaffordable, limiting access and causing financial burden for clinics who absorb the cost to ensure access.

- Hospital inpatient reimbursement is a bundled rate through the Diagnosis-Related Group (DRG) system. These rates do not accommodate the high cost of LAIB.
- Emergency department (ED) reimbursement is through the Outpatient Prospective Payment System (OPPS), which is similar to outpatient billing, and rates may not fully cover cost. EDs must also incur a high up-front cost to stock LAIB.
- Prescribed, patient-specific LAIB doses cannot be reassigned when a patient does not present to their appointment, resulting in disposal of expensive medication.
- Stock medications may expire before use, wasting expensive medication.

Summary of Operational Barriers

Multiple operational barriers make implementation challenging, including federal and state regulations and infrastructure limitations.

- The adoption of mobile medical LAIB delivery is slow, despite successful mobile delivery of sublingual buprenorphine and methadone, due to a lack of explicit local, state, and federal support. Mobile medical teams face uncertainty about licensing, registration, compliance procedures, funding mechanisms, and operational feasibility, limiting treatment for vulnerable populations with the greatest barriers to traditional clinic-based care.
- To prevent treatment delays, clinical settings may procure a stock supply of LAIB using the Buy-and-Bill method, instead of prescribing to a pharmacy; however, this requires significant infrastructure investment.
- OTP electronic health record (EHR) systems lack functionality for LAIB inventory management, creating compliance risk.
- Hospital formulary approval processes prevent or delay LAIB implementation for months, even where financial and clinical support exists.
- Prior authorization for LAIB, required by many private insurers, delays treatment.
- Prescription monitoring program (PMP) records are incomplete because Buy-and-Bill (stock supply) and inpatient hospital-administered doses are not consistently captured.

Summary of Solutions

A brief summary of the solutions proposed in this report are as follows, organized by estimated timeline for completion.

Near-Term (1-2 years)

- **1.A.** Extend the Washington State Health Care Authority (HCA) LAI Bup Funding Program, restore Medicaid patient eligibility, expand to hospital emergency

departments (EDs), and allow funds to be used to cover copays for patient that cannot afford them. (High impact, Moderate feasibility)

- **2.C.** Provide centralized technical assistance for LAIB implementation for all healthcare settings, including navigating DEA registration, licensing, inventory management, billing, and workflow development. (Moderate impact, High feasibility)
- **2.E.** Expedite hospital formulary approval processes for LAIB. (High impact, Moderate feasibility)

Moderate-Term (2-4 years)

- **1.G.** Extend Sublocade shelf-life labeling, if supported by stability data. (Low impact, Low feasibility)
- **2.A.** Establish explicit support for mobile medical LAIB delivery through healthcare leadership endorsement, operational guidance, technical assistance, secured funding, and peer networks; pursue federal amendments as longer-term strategy. (High impact, Moderate feasibility)
- **2.B.** Allow HCE LAIB Transport through PQAC rulemaking that permits Healthcare Entities to use the "black bag" rule to transport stock controlled substance medications to field sites through Pharmacy Quality Assurance Commission (PQAC) rulemaking. (High impact, Moderate feasibility)
- **2.D.** Improve OTP EHR capabilities for improved inventory management. (High impact, Moderate feasibility)
- **2.F.** Eliminate prior authorization for private insurance. (Moderate impact, Moderate feasibility)
- **2.G.** Standardize Prescription Monitoring Program (PMP) reporting mechanisms across all healthcare settings. (Moderate impact, Moderate feasibility)

Long-Term (5+ years)

- **1.B.** Adjust OTP reimbursement rates or create a separate LAIB add-on payment. (High impact, Low feasibility)
- **1.C.** Adjust hospital DRG rates or create a separate LAIB reimbursement mechanism outside the DRG. (High impact, Moderate feasibility)
- **1.D.** Adjust ED reimbursement rates within the OPPS payment structure. (High impact, Low feasibility)
- **1.E.** Eliminate private insurance copays. (Moderate Impact, Moderate Feasibility)

- **1.F.** Allow medication reassignment of prescribed doses to another eligible patient when the original patient does not receive the injection. (High impact, Low feasibility)

Background

Buprenorphine is an evidence-based treatment for Opioid Use Disorder (OUD) that significantly reduces morbidity and mortality. The long-acting injectable formulation (LAIB), given weekly or monthly, maintains steady medication levels and removes the need for daily dosing. This has clinical advantages over daily sublingual buprenorphine, particularly for treatment initiation and retention: LAIB eliminates daily medication burden, reduces variability in plasma levels, may improve treatment retention, and enhances patient-reported outcomes compared to daily sublingual dosing.[1] For patients initiating treatment in acute care settings (such as emergency departments), rapid access to LAIB can accelerate engagement and stabilization.[2]

Emergency departments and hospital inpatient units represent critical opportunities to engage patients in OUD treatment during acute crises. Many individuals with OUD lack ongoing primary care relationships and access healthcare only during emergencies or acute medical events. These moments create a treatment window: patients may be more willing to engage in treatment during periods of acute need, and the inpatient or post-ED discharge period is a vulnerable time with elevated overdose risk. Initiating LAIB during these acute care encounters can provide sustained medication coverage during the critical post-discharge transition, reducing overdose risk and improving treatment engagement. Reducing readmissions and ED returns also benefits healthcare system capacity and clinician burnout by decreasing demand on strained resources.

LAIB is particularly important for vulnerable populations who face structural barriers to daily medication adherence, including unstable housing, limited pharmacy access, and safe medication storage challenges. LAIB removes these barriers and enables access to treatment for individuals who might otherwise remain untreated. Expanding LAIB access in low-barrier clinics and mobile medical programs is essential for reaching these populations.

There are just two brand names of LAIB available, Sublocade and Brixadi. Each brand has different clinical advantages related to initiation, dose, and efficacy, making it important to have both available.

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[1] Lintzeris N, Dunlop AJ, Haber PS, et al. Patient-Reported Outcomes of Treatment of Opioid Dependence With Weekly and Monthly Subcutaneous Depot vs Daily Sublingual Buprenorphine: A Randomized Clinical Trial. JAMA Netw Open. 2021;4(5):e219041. doi:10.1001/jamanetworkopen.2021.9041

[2] D'Onofrio G, Herring AA, Hawk KF, et al. Emergency Department–Initiated Buprenorphine for Opioid Use Disorder: A Randomized Clinical Trial. JAMA. 2026;335(11):948–960. doi:10.1001/jama.2025.27019

In King County, LAIB initiation rates increased in 2024-2025, but remain low compared to daily sublingual buprenorphine.[3] Regulatory ambiguity, financial barriers, and logistical challenges severely limit patient access, particularly for vulnerable populations who may benefit the most.

On November 6, 2025, Public Health—Seattle & King County's Overdose Prevention and Response team hosted a virtual convening with more than 40 participants from clinics, hospitals, and emergency departments, as well as partners from King County, the Washington State Health Care Authority, and the University of Washington to discuss improving access to LAIB in King County. The session focused on regulatory uncertainty, procurement challenges, and cost barriers that make consistent access and utilization of the medication difficult. Across settings, attendees emphasized the need for regulatory changes, streamlined processes, and sustainable financial solutions.

This report presents critical LAIB implementation barriers, presents potential interim solutions, and proposes more permanent solutions to expand equitable access to this lifesaving treatment. For a summary of all potential solutions with impact and feasibility ratings, see *Appendix 1: Impact Table*. Impact and feasibility ratings are estimates based on what is currently known and may be revised as implementation efforts progress. Impact is assessed relative to regional-scale LAIB access and implementation, rather than the effect on any single site.

Section 1: Financial Barriers & Solutions

LAIB reimbursement structures vary significantly by care setting and payer, creating financial disincentives and administrative barriers that discourage adoption, particularly among safety-net providers serving high-need populations.

Financial Barriers

Financial structures in healthcare payment systems create barriers that make LAIB provision unsustainable for many providers. Hospital bundled payment models, fixed OTP reimbursement rates, and the risk of medication waste create cost pressures that disincentivize LAIB provision.

[3] kingcounty.gov/overdose/data

Outpatient Clinics

Outpatient clinics have two options for obtaining LAIB for their patients: through a prescription to a pharmacy or a Buy-and-Bill process. Each presents distinct challenges.

1. Pharmacy Delivery: This process involves a provider prescribing LAIB to patient; the prescription is sent to a specialty pharmacy to be filled. With an existing agreement in place, the pharmacy will then deliver the prescribed dose to the clinic for patient administration. This process avoids upfront purchasing costs, but creates treatment delays, requiring the patient to return at a later date when the dose is available on site. For patients with opioid use disorder, even short delays risk disengagement during the critical window when they are ready to initiate treatment. This also increases the burden on clinics who must hold a second appointment for dose administration.
2. Buy-and-Bill: This process involves a clinic purchasing a stock supply of the medication and later billing for each dose administered. This enables immediate administration to patients but requires significant up front cost and infrastructure investment.
    a. Upfront cost: Clinics must purchase a high-cost LAIB inventory before receiving reimbursement over time. In fiscal year 2025, the Washington State Health Care Authority (HCA) LAI Bup Funding Program alleviated this burden for eligible, nonprofit organizations, by paying for the initial supply. However, the program shifted in fiscal year 2026 making funds available only for patients without insurance, and the program end entirely on 6/30/2027.[4]
    b. Lack of reimbursement and under-reimbursement:
        i. The Medicaid reimbursement rate for Sublocade, one of only two available brands of LAIB, is less than the drug cost. The rate cannot be changed, according to the methodology listed in WAC 182-531-1850 4(b)(A) and the HCA's agreement with CMS.[5]
        ii. Clinics carry financial risk from doses administered that may ultimately not be reimbursed. For clinics with King County Integrated Care Network contracts, clinical staff verify network and Medicaid coverage in ProviderOne prior to administration, but human error can easily occur in this process. Additionally, because there is a lag time

[4] https://www.hca.wa.gov/assets/program/lai-bup-funding-program-faqs-fy25-26.pdf
[5] WAC 182-531-1850 4(b)(A)

in processing claims, there is no real-time feedback to identify and correct issues.[6]

There are also several operational barriers with Buy-and-Bill, outlined in Section 2; see *Buy-and-Bill Infrastructure*.

Additionally, private insurance presents financial barriers to LAIB access. First, restrictive formularies limit coverage to only one LAIB option (Sublocade or Brixadi), preventing clinicians from prescribing based on best clinical judgment. Second, expensive copayments delay or prevent patient access to treatment, particularly problematic during treatment initiation when rapid access to LAIB—rather than waiting to establish daily sublingual buprenorphine—accelerates stabilization and reduces relapse risk during the critical early treatment window.

Clinics also incur substantial operational costs for LAIB provision, including secure storage, refrigeration, handling, inventory management, and administrative overhead. When billing insurance, the total claim includes both the medication cost and these operational expenses. Insurance typically covers a percentage of this total claim, and patients pay a copayment. However, medication copay assistance programs cover only the medication, not the operational costs. This creates a coverage gap, with the remaining costs falling to clinics or their patients. For safety-net providers and patients with limited financial resources, this gap creates a significant barrier to access, often forcing clinics to absorb costs or patients to forgo treatment.

Opioid Treatment Programs (OTPs)

OTPs use a variety of different payment methodologies to reimburse for their services. A significant reimbursement mechanism is the bundled payment structure. OTP bundled rates were historically developed to cover the cost of methadone, which is inexpensive. Depending on the details of an individual OTP payment methodology with a payor, payments may be inadequate for the higher cost LAIB products.

Additionally, as most OTPs in WA use forms of bundled payment structures, many OTPs may lack systems and expertise to implement fee-for-service billing, which would allow for reimbursement, but poses a significant administrative hurdle. There are also issues with OTPs needing to work with many different insurance providers which all may have different

[6] King County Integrated Managed Care (IMC) and Integrated Care Network (KCICN) Overview

payment methodologies in place and private insurers, which have highly variable coverage and often require prior authorization.

Successfully addressing these gaps would require system and administrative resources for OTPs to negotiate with their various insurers to gain approval to bill for LAIB products as fee-for-service professionals administered drugs[7] in addition to bundled payments. Alternatively, payers could adopt a payment structure similar to Medicare, which offers weekly bundled rates under a G code that specifically covers the higher cost of LAIB products.

In addition to reimbursement challenges, OTPs face challenges to getting LAIB on site. The Buy-and-Bill process can be used to stock the medication, but OTPs encounter the same financial barriers described in the *Outpatient Clinics* section and the operational challenges described in the *Buy-and-Bill Infrastructure* section. Additionally, many OTP Electronic Health Record (EHR) systems lack the capability to accurately track LAIB inventory, increasing risks of reporting errors and DEA scrutiny.

Alternatively, OTPs may consider prescribing LAIB to a pharmacy using the prescriber's DEA license for delivery. However, this approach operates outside the OTP structure and would reclassify the patient as an office-based opioid treatment (OBOT) patient, with implications for bundled reimbursement. OTPs must evaluate the regulatory and billing impacts before pursuing this option.

Pharmacy-based delivery also introduces logistical barriers around delivery addresses. Although multiple clinic locations within an OTP may share a SAMHSA certification number, each maintains a separate facility DEA registration. Current regulations may restrict a pharmacy from delivering a controlled substance to a clinic address that differs from the prescribing provider's registered DEA address, creating barriers for multi-site OTPs and mobile medication units alike. Clear guidance from the Washington Pharmacy Quality Assurance Commission and the DEA is necessary to resolve these delivery and dispensing limitations.

[7] Provider billing guides and fee schedules | Washington State Health Care Authority see *Professional Administered drugs*.

Mobile Medical Programs

Mobile medical programs most often operate as an extension of an outpatient clinic or OTP, so the barriers described in those sections also apply those mobile medical programs. In addition, mobile medical programs face the following financial barriers:

- Service location billing issues: Street outreach and encampment-based care lack valid place-of-service codes, complicating insurance billing.
- Coverage verification: Confirming patient insurance status in the field is more difficult than in traditional clinical settings.
- A lack of secure, sustained funding to support operations.

Hospital Inpatient Units

Hospital payments for inpatient stays typically operate under a bundled payment model (Diagnosis-Related Groups, or DRG), which provides a fixed reimbursement regardless of the specific services delivered during hospitalization. Because LAIB is expensive and not separately reimbursed under this structure, hospitals lose money on every dose administered to an inpatient, creating a strong financial disincentive.

There are two pathways for administering LAIB outside of the DRG.

1. Discharge-day administration: Medicaid covers LAIB when administered from inpatient facility stock. If given on the day of discharge, it can be billed outside the DRG via the inpatient pharmacy using professional billing codes.
2. Specialty pharmacy delivery (known as "white-bagging"): A specialty pharmacy delivers the medication directly to the hospital, where it is then entered as a "home medication" by the inpatient pharmacy and administered to the patient. This is generally permitted by insurers and hospital pharmacies for specialty medications but requires an agreement and established workflows between the agencies.[8]

Emergency Departments

Emergency departments bill under the Outpatient Prospective Payment System (OPPS) and would bill LAIB as an outpatient drug. Buy-and-Bill is the only viable procurement option for EDs, as pharmacy delivery is not feasible given brief care encounters and delivery timelines. EDs thus encounter the same financial and operational barriers related

[8] O'Conor, Clarissa MD; Armstrong, Aria BA; Sai, Mistead MSW; Farhi, Shai MD; Klug, Emma MD; Fitzgerald, Ruchi MD; Shastry, Siri MD, MS. "Now It's Up to Me to Take Advantage of the Shot": Patient Perspectives on Hospital Initiation of Long-acting Injectable Buprenorphine. Journal of Addiction Medicine 20(2):p 168-175, March/April 2026. | DOI: 10.1097/ADM.0000000000001529

to Buy-and-Bill described in the *Outpatient Clinics* and *Buy-and-Bill Infrastructure* sections.

Additionally, EDs were not eligible for the HCA LAI Bup Funding Program to offset upfront costs and cite high medication cost as a primary barrier. As a result, EDs have deferred to oral (sublingual) buprenorphine as the inexpensive option, despite LAIB's clinical advantages.

Medication Waste

As described in previous sections, LAIB must either be prescribed to a pharmacy and delivered or picked up by clinical staff or procured through the Buy-and-Bill method for stock supply. Both of these methods can result in substantial waste of a medication that costs approximately $500 per weekly injection and $2,000 per monthly injection.

1. For pharmacy-filled LAIB, each dose is prescribed to a specific patient. If the original patient does not proceed with treatment, there is no existing mechanism to reassign the dose to a different patient.
2. For a Buy-and-bill stock supply, clinical sites must estimate the number of doses they may need, which is challenging with a relatively novel medication. When estimates are too high, unused doses expire and must be discarded. Sublocade has a much shorter shelf-life than Brixadi, increasing waste risk. Labeled expiration dates are conservative estimates that may not reflect actual stability, but clinics must discard products regardless.[9] Disposal adds another financial barrier. Specialized disposal vendors often charge minimum fees by weight. One site reported a vendor requiring a 30-pound minimum purchase, which would take most clinics years to accumulate given LAIB's low weight per dose.

Financial Solutions

Addressing financial barriers requires financial investment and payment reform to align incentives with equitable LAIB access. These solutions range from state-level insurance regulation to federal payment policy reform and require engagement with payers, regulators, and legislators.

[9] Zilker, M., Sörgel, F., & Holzgrabe, U. (2019). A systematic review of the stability of finished pharmaceutical products and drug substances beyond their labeled expiry dates. *Journal of pharmaceutical and biomedical analysis*, *166*, 222–235. https://doi.org/10.1016/j.jpba.2019.01.016

A. Extend and Expand HCA LAI Bup Funding Program

The most pressing financial barriers related to stocking LAIB for outpatient clinics, OTPs, and EDs would be alleviated through changes to the existing HCA LAI Bup Funding Program, including:

1. Extending the program beyond its current expiration
2. Expanding site eligibility to hospital outpatient settings, including EDs and hospital-affiliated clinics.
3. Revert to the original program parameters that allowed the funding to be used for Medicaid-enrolled patients.
4. Expand the program to allow funding to be used to cover private insurance copays for patients who cannot afford them.

Preliminary Assessment:

- **Impact:** High. These changes would enable EDs, OTPs, and outpatient clinics to offer LAIB, opening access for critical patient populations.
- **Feasibility:** Moderate. Builds on existing infrastructure and aligns with the program's access-expansion goals but requires additional funding allocation through legislation.
- **Timeline:** Near-term.
- **Status:** In fiscal year 2025, the program could be used for Medicaid and uninsured patients of outpatient clinics. In fiscal year 2026, funding can only be used for uninsured patients. The program is set to expire on 6/30/2027.

B. Adjust OTP Reimbursement

Enable OTPs to offer LAIB by adjusting their payment rates cover the high cost of these medications. Rate adjustments could be made either by increasing bundled rates or creating a separate LAIB add-on payment outside of the bundled rate structure.

Preliminary Assessment:

- **Impact:** High.
- **Feasibility:** Low. Rate changes have historically been challenging and often unsuccessful. Add-on payments outside of the bundled rate structure would be a significant change to the existing payment structure.
- **Timeline:** Long-term
- **Status:** No known effort underway.

C. Adjust Hospital DRG Rates

Remove the financial disincentive for hospitals to provide LAIB during inpatient stays by adjusting DRG bundled payments to reimburse for LAIB or create an add-on reimbursement mechanism outside the DRG. This would require an HCA DRG rate adjustment for Medicaid and a Centers for Medicare & Medicaid Services (CMS) rate adjustment for Medicare.

Preliminary Assessment:

- **Impact:** High. This would remove the primary financial disincentive for hospitals to administer LAIB during inpatient stays.
- **Feasibility:** Moderate for Medicaid (state); low for Medicare (federal).
- **Timeline:** Moderate-term for Medicaid; long-term for Medicare (federal CMS action).
- **Status:** No known effort underway.

D. Adjust ED Reimbursement Rates

Ensure EDs are fully reimbursed for the cost of LAIB administration. The gap between LAIB procurement costs and reimbursement across payers must be quantified as a necessary first step toward targeted rate or policy changes.

Preliminary Assessment:

- **Impact:** High. EDs are a critical access point for patients with OUD who may not engage with other care settings.
- **Feasibility:** Low. This requires negotiation with multiple payers.
- **Timeline:** Long-term
- **Status:** No known effort underway.

E. Eliminate Private Insurance Copays

Pursue state legislation requiring private insurers to eliminate copays for LAIB. As the governing body that establishes enforcement mechanism, the Office of the Insurance Commissioner (OIC) should be engaged early on for regulatory expertise and support.

This action would remove a significant access barrier for a minority of people with private health insurance plans; it would be limited to state-regulated commercial insurance (individual plans sold on the marketplace or small group plans) but would not apply to self-funded, employer-sponsored plans or federal programs, which provide coverage for the

majority of privately insured people in Washington State. Federal legislation is needed to eliminate copays for self-funded plans.

Preliminary Assessment:

- **Impact:** Low. This would remove a significant access barrier for some privately insured patients but would be limited to state-regulated commercial insurance plans, not self-funded employer plans or federal programs.
- **Feasibility:** Moderate for state-sponsored plans (requires state legislation and OIC support) either OIC rulemaking or state legislation). Low for self-funded, employer-sponsored plans or federal programs (required federal legislation)
- **Timeline:** Long-term (5+ years).
- **Status:** No known effort underway. This could be pursued in coordination with existing efforts on *2.E Eliminate Prior Authorization*, as both involve the same payer stakeholders and policy strategies.

F. Allow Medication Reassignment Through State Legislation

Enact state legislation allowing healthcare facilities to reassign prescribed LAIB doses to other eligible patients when the original patient does not receive the injection. This approach would operate within existing federal REMS requirements by establishing state-level procedures for secure transfer of unopened, sealed medications. Utah's Charitable Prescription Drug Recycling Act (Utah Code § 58-17b-P9) exists as precedent for this; it explicitly includes MOUD and permits transfer of injectable medications in sealed containers.[10]

Preliminary Assessment:

- **Impact:** High. This would significantly reduce medication waste and improve program financial sustainability.
- **Feasibility:** Moderate. Requires state legislation.
- **Timeline:** Moderate-term
- **Status:** No known effort underway.

G. Extend Sublocade Shelf-life Labeling

To reduce medication waste for sites using Buy-and-Bill, extend the window in which Sublocade can be used before expiring, if possible. Engage the manufacturer, Indivior, to

[10] Utah Charitable Prescription Drug Recycling Act, Utah Code § 58-17b-P9

determine whether the shelf-life can be extended based on existing stability data and, if so, update product labeling.

Preliminary Assessment:

- **Impact:** Low. Would reduce medication waste and reduce the financial risk of sites using the buy-and-bill method to maintain stock supply, as it is difficult to estimate medication demand.
- **Feasibility:** Low. The manufacturer, Indivior, may already have the data to support this. If so, they may be incentivized to change product labeling of expiration dates to make their product more competitive. If not, it would require data collection/review and possibly FDA approval of stability data, which may or may not demonstrate product viability beyond the existing shelf life.
- **Timeline:** Moderate-term (if data exists), long-term (if not).
- **Status:** No known effort underway.

Section 2: Operational Barriers & Solutions

Operational Barriers

Beyond financial constraints, operational barriers rooted in regulatory restrictions and system infrastructure gaps make consistent LAIB delivery logistically complex and resource-intensive. These barriers affect how and where providers can deliver LAIB, how they manage medication inventory, and their ability to coordinate care. They are particularly acute for field-based outreach programs serving the most vulnerable populations.

Mobile Medical LAIB Access

Mobile medical programs deliver treatment directly to vulnerable populations. Programs have successfully integrated sublingual buprenorphine and methadone into field-based care delivery, with early reports demonstrating clinical success and high engagement rates among unsheltered and unstably housed populations.

However, LAIB adoption by mobile medical programs has been slow. While the operational landscape for LAIB field delivery is complex, the primary barrier is the lack of explicit support for mobile medical LAIB services. Mobile medical teams report uncertainty about operational feasibility of different delivery models, required licensing, registration, and compliance procedures. This uncertainty has resulted in cautious adoption despite clinical demand.

Funder and healthcare leadership support, coupled with operational guidance and technical assistance, would accelerate LAIB adoption by mobile medical programs. Additionally, federal regulatory support, including amendments to the FDA REMS protocol and relevant statutes and regulations to explicitly support field-based provision of LAIB by healthcare teams, would remove federal barriers to this critical service delivery model.

Mobile medical programs also face regulatory challenges to transporting LAIB doses. These programs operate as an extension of a fixed-site clinic, which are typically licensed as HCEs and hold a DEA registration at the organizational level. This organizational registration is separate and distinct from the individual DEA registrations held by each prescribing provider employed there. Under 21 CFR 1301.25, the DEA's "black bag" rule allows a DEA-registered practitioner to transport controlled substances to field locations for use in their professional practice without obtaining a separate DEA registration for each site visited. However, the black bag rule as currently interpreted applies to individual DEA registrants, not to organizational or HCE-level registrations. This means that stock medications ordered under an HCE cannot be taken to a different location. It may be possible to take stock medications on outreach if they are ordered under an individual providers DEA registration.

When LAIB stock is ordered under the organization's DEA registration, as is standard and operationally appropriate for an HCE, it is not clearly permissible to transport that stock into the field under the black bag rule. The medication is attributed to the organization, not to an individual practitioner traveling with their personal supply. This gap means that mobile medical programs face legal ambiguity in transporting bulk, unassigned LAIB stock to sites where patients will be seen and dosed.

One pathway that appears to be legally available under current rules is for an individual DEA-registered provider at the organization to order LAIB stock medication under their own individual DEA registration, rather than under the organization's HCE registration. A provider doing so could then transport that stock to field sites under 21 CFR 1301.25, as they are a registered practitioner carrying controlled substances for use in their professional practice. This would allow mobile medical teams to bring unassigned, bulk LAIB into the field and administer it to patients at shelters, encampments, or supportive housing sites without requiring each dose to be a pre-labeled, patient-specific pharmacy prescription.

However, this workaround is operationally burdensome, introduces risk, and should not be understood as a solution. Several problems arise:

1. It creates a single point of failure in the organization's medication supply chain. When ordering, storage, and transport of LAIB stock are all tied to one individual's DEA registration, the entire field program's medication access is contingent on that person remaining employed, licensed, and available. If that provider leaves the organization, goes on leave, or has their DEA registration suspended or revoked for any reason, the program loses its legal pathway to bring stock medication into the field until another provider assumes that role and re-establishes the ordering relationship. This is a fragile operational foundation for a program serving high-acuity patients with serious overdose risk.
2. It places disproportionate regulatory and legal exposure on an individual provider. When medication ordering, transport, and field administration are all conducted under a single provider's DEA registration rather than distributed across the organization's institutional registration, that individual bears heightened personal liability if anything goes wrong, whether a diversion event, a documentation lapse, or a regulatory audit. This is a significant burden to ask of any provider and may deter qualified clinicians from taking on the role.
3. It inverts the organizational logic of the HCE registration structure. The purpose of an organizational DEA registration is to allow the institution, not any one person, to be the accountable entity for controlled substance ordering and management. Routing stock medication through an individual registration to circumvent a gap in HCE field-transport rules undermines that structure in ways that may create compliance complications and is inconsistent with how most health care organizations are designed to operate.

For these reasons, ordering under an individual DEA registration is a legally plausible but practically fragile workaround that is not a sustainable model for field-based LAIB delivery.

Buy-and-Bill Infrastructure

As previously described, Buy-and-Bill is a procurement model in which a clinic purchases a stock supply of LAIB and bills insurers after administering each dose. Clinics may choose Buy-and-Bill to provide immediate access without depending on specialty pharmacy delivery timelines. However, significant operational barriers exist before a clinic can establish Buy-and-Bill:

1. Licensing and certification:
    a. REMS certification: Site Risk Evaluation and Mitigation Strategy (REMS) certification is required to stock controlled substances. This is an

administrative burden that can take months to secure and requires ongoing compliance.

b. HCE license: Clinics must first obtain an HCE license from the Washington State Department of Health before they can register with the DEA to order and stock controlled substances.
c. DEA registration: Controlled substances must be ordered under a DEA registration, which can either be the clinical site registration or an individual prescribers' registration. It is generally preferred to order under a clinic registration to simplify compliance and ensure continuity when staff changes occur; however, there are restrictions on taking stock supplies into the field that that limit mobile medical teams (see *Mobile Medical Medication Transport*).

2. Storage and Security Requirements
    a. As controlled substances, LAIB formulations must be securely stored in locked medication storage units within locked rooms, requiring dedicated infrastructure. Sublocade additionally requires refrigeration if not used within 12 weeks, necessitating investment in appropriate refrigeration equipment and temperature monitoring.

OTP EHR Limitations

Many Electronic Health Record (EHR) systems lack adequate controlled substance inventory management functionality for LAIB, creating compliance challenges for clinics and OTPs attempting to track stock medications and meet requirements for 21 CRF and DEA recordkeeping.

This represents a significant barrier for OTPs in particular, where EHR's are tailored to the traditional methadone dosing. While the recordkeeping requirements themselves are manageable, EHR vendors serving OTPs have been slow to develop the necessary functionality for this formulation. The compliance risk is substantial enough to deter many OTPs from adopting LAIB altogether.

Hospital Formulary Approval Processes

A committee approval process is required for medications to be added to an inpatient or ED hospital formulary. This is a bureaucratic process requiring coordination across many departments that can take many months or longer, even when financial and clinical support exists. Formulary decisions are heavily influenced by medication cost and reimbursement models. Because LAIB carries high upfront costs and lacks clear reimbursement pathways outside the DRG (for inpatient) or within standard OPPS billing

(for ED), hospitals deprioritize LAIB formulary approval. See *Financial Barriers* for more information on reimbursement in these settings.

Prescription Monitoring Program (PMP) Gaps

Washington's PMP has significant gaps that limit its usefulness for LAIB care coordination. Current reporting requirements are unclear regarding Buy-and-Bill and hospital-administered doses, leading to inconsistent practices.

For buy-and-bill/stock supply: LAIB administered from clinic stock supply doesn't appear in the PMP because there's no prescription claim, only a provider order. The PMP was designed to automatically capture prescriptions filled at pharmacies with insurance claims, not medications administered from stock inventory. However, if stock doses were required to appear in PMP, it would be an additional administrative burden because each dose would either need to be entered manually, or significant changes to EHR systems would be necessary to automate it, as is done through pharmacy-filled doses. For OTPs, PMP reporting would also pose a CFR Part 2 privacy issue.

For hospitals: Under RCW 70.225.020, medications dispensed to a patient for more than a one-day supply should be reported to the PMP.[11] However, this statute has ambiguous language around hospital inpatient exceptions and "single dose" administration that predates LAIB. This creates uncertainty: while a LAIB injection is technically a single dose, it provides weeks of medication coverage. Different hospitals and providers have interpreted their reporting obligations differently, resulting in incomplete PMP records.

These gaps impact care transfers, particularly when patients cannot recall their dosing history. Providers at their new care site lack visibility of prior LAIB doses, making it difficult to determine appropriate dosing intervals and ensure continuity, and risks duplicate dosing.

Prior Authorization Requirement for Private Insurers

Private insurance plans (state-regulated commercial insurance plans have not e Self-funded, employer-sponsored plans) frequently require prior authorization (PA) before covering LAIB. PA requirements impose an administrative burden on providers, who must submit documentation, wait for insurer review, and often appeal denials, which can delay patient access by days or weeks. For patients with active substance use disorder, even

[11] RCW 70.225.020

brief delays during the critical window of treatment motivation can result in loss of opportunity, return to unsafe patterns of use, and overdose.

Additionally, PA requirements create unpredictable access barriers: some insurers approve rapidly while others impose lengthy review periods or request additional clinical justification, requiring providers to navigate inconsistent requirements across multiple payers. This administrative complexity is particularly burdensome for safety-net providers with limited billing and prior authorization staff, which may lack capacity to manage multiple payer requirements.

Prescription Monitoring Program (PMP) Reporting Gaps

The Washington PMP reliably captures LAIB doses dispensed by outpatient pharmacies through automatic reporting. However, they do not reliably capture LAIB doses administered from stock supplies at hospitals, emergency departments, opioid treatment programs, clinics, and mobile medical programs because the infrastructure for automatic reporting of stock medication administration has not been implemented across these settings. This significantly limits LAIB care coordination

LAIB administered from clinic stock does not appear in the PMP because there is no prescription claim, only a provider order. The PMP was designed to automatically capture prescriptions filled at pharmacies with insurance claims, not medications administered from stock inventory. Requiring stock doses to appear in the PMP would create substantial administrative burden; each dose would either require manual entry or significant changes to EHR systems to automate reporting, as is done for pharmacy-filled doses. For opioid treatment programs, PMP reporting raises additional concerns regarding CFR Part 2 privacy protections, creating reluctance to participate.

For LAIB administered in hospitals and emergency departments, RCW 70.225.020 states that medications dispensed to a patient for more than a one-day supply should be reported to the PMP. However, this statute contains ambiguous language regarding hospital inpatient exceptions and "single dose" administration that predates LAIB. While a LAIB injection is technically a single dose, it provides weeks of medication coverage. Different hospitals and providers have interpreted their reporting obligations differently, resulting in incomplete and inconsistent PMP records.

The inability for providers to see a record of prior LAIB doses creates significant care coordination challenges across multiple critical transitions. When patients cannot recall their dosing history and LAIB doses are not recorded in the PMP, providers must choose

between the possibility of duplicate dosing (primarily a financial, rather than clinical risk) or delay/discontinue treatment. Dose records are particularly important when patients transition to a carceral setting, as many of these institutions require proof of dosing to continue treatment. Treatment discontinuation is particularly problematic during these vulnerable transitions; gaps in coverage risk destabilization, disengagement from care, return to use, and overdose.

Operational Solutions

Addressing operational barriers requires regulatory clarification, state legislation, and system infrastructure improvements that streamline LAIB delivery. Solutions in this category focus on enabling providers to deliver care in diverse settings, manage medications efficiently, and operate sustainably. Some solutions can be pursued through state-level action, while others require federal regulatory guidance or legislative change.

A. Establish Explicit Support for Mobile Medical LAIB

Establish explicit support for mobile medical LAIB delivery through 1) explicit endorsement and operational guidance by state and local healthcare leadership entities, 2) technical assistance for licensing, registration, billing, and regulatory compliance, 3) secured funding available for programs through grants or other mechanisms, and 4) establishment of peer learning networks for mobile medical programs.

In tandem with this local approach, pursue longer term federal amendments to statutes and regulations to explicitly support field-based provision of LAIB.

Preliminary Assessment:

- **Impact:** High. Would directly address field-based delivery barriers.
- **Feasibility:** Moderate for state/local approach. Low for federal regulatory amendments.
- **Timeline:** Moderate-term for state/local approach. Long-term for federal.
- **Status:** No coordinated effort underway.

B. Allow Healthcare Entity (HCE) LAIB transport

Pursue targeted rulemaking with the Washington State Pharmacy Quality Assurance Commission (PQAC) to clarify that it is allowable for Healthcare Entities (HCE) to transport stock LAIB to mobile medical outreach locations using the "black bag rule." This would be the primary mechanism to eliminate the current requirement that individual clinical staff serve as couriers. The rule would place regulatory accountability at the institutional level

rather than concentrating it on individual clinicians and is consistent with how HCE registrations are intended to function.

PQAC previously initiated broader Alternative Distribution Models rulemaking (CR-101, October 2023), but withdrew it (WSR 26-10-040) due to opposition to unrelated provisions. However, the withdrawal does not reflect opposition to the access-expansion goal itself. A narrower, more targeted rulemaking focused specifically on critical controlled substances like LAIB would avoid the political and operational baggage that contributed to the prior withdrawal. Legal analysis of the Commission's authority under the federal DEA framework would be required.

Preliminary Assessment:

- **Impact:** High. Directly addresses the core barrier by enabling HCE-level stock transport and eliminating reliance on individual clinical staff as couriers.
- **Feasibility:** Moderate. Prior rulemaking withdrawal was driven by unrelated provisions; a narrower approach focused on critical controlled substances may face less resistance. Legal analysis required.
- **Timeline:** Moderate-term (if targeted rulemaking is initiated).
- **Status:** Prior effort withdrawn. No active effort underway; access-expansion goal remains viable through more targeted approach.

C. Provide Technical Assistance

Establish a coordinated, statewide technical assistance (TA) program to help clinical sites navigate the complex regulatory, licensing, and operational mechanisms for LAIB implementation. Given the multiple barriers outlined in this report, comprehensive TA could benefit all clinical settings and accelerate implementation timelines. Examples of TA needs include:

- Guidance on compliance with federal and state regulations applicable to the clinical setting (e.g., medication transport for mobile medical programs).
- Assistance applying for organizational DEA registration, HCE license, and REMS certification.
- Support developing setting-specific LAIB procurement, inventory management, and clinical workflows.
- Support developing medication reassignment protocols (if state legislation is enacted).
- Support for expedited hospital formulary approval.

- Assistance with automatic PDMP reporting implementation.
- Education for institutional leadership on why LAIB implementation is a priority investment despite implementation complexities.

D. Improve OTP EHR Capabilities

Remove the compliance barrier that deters OTPs from adopting LAIB by ensuring their EHR systems can track controlled substance inventory as required by DEA regulations. Advocate for EHR vendors serving OTPs to develop inventory management functionality that supports LAIB stock tracking and DEA 21 CFR compliance.

Preliminary Assessment:

- **Impact:** High. Would reduce administrative burden, improve DEA compliance, and remove a barrier that currently deters many OTPs from adopting LAIB.
- **Feasibility:** Moderate. Requires EHR vendor action; advocacy and market demand from OTPs may be needed to prioritize development.
- **Timeline:** Moderate-term
- **Status:** No known effort underway.

E. Expedite Hospital Formulary Approval

Reduce significant delays for hospital LAIB implementation by working with hospitals to streamline internal formulary review processes. Because formulary approval is an internal institutional decision, advocacy must take a capacity-building and engagement approach. Specific strategies may include:

- Engaging hospital pharmacy and therapeutics (P&T) committees directly with education on LAIB clinical efficacy, safety, and operational feasibility.
- Providing hospitals with evidence summaries, formulary submission templates, and implementation guidance to reduce review time.
- Sharing best practices and timelines from hospitals that have successfully expedited LAIB formulary approval.
- Collaborating with the Washington State Hospital Association and other relevant organizations to encourage adoption of streamlined approval timelines.
- Creating incentives or requirements for timely formulary approval.

Preliminary Assessment:

- **Impact:** Moderate. Removes a significant institutional barrier for hospitals, which are critical places for LAIB initiation.

- **Feasibility:** Moderate. Requires action by individual health systems action, which can be encouraged, but not enforced.
- **Timeline:** Near-term
- **Status:** No known effort underway, although some hospital systems may be pursuing this.

F. Eliminate Prior Authorization (PA) for Private Insurance

Pursue state legislation requiring private insurers to cover LAIB without prior authorization, preventing treatment delays during the critical window when patients are most motivated to initiate treatment. The OIC should be engaged early in the legislative process for regulatory expertise and support.

Preliminary Assessment:

- **Impact:** Moderate. This would reduce administrative burden and provide more rapid access to LAIB for patients with state-regulated private insurance plans. However, it would not apply to self-funded, employer-sponsored plans or federal programs, which provide coverage for the majority of privately insured people in Washington State.
- **Feasibility:** Moderate for state-regulated plans, which would require state legislation with OIC enforcement, for which there is precedent.[12] Low for self-funded, employer-sponsored plans, which may require federal legislation.
- **Timeline:** Moderate-term
- **Status:** No known effort underway.

G. Standardize PMP Reporting Across Settings

Improve care coordination and prevent treatment gaps or duplicate dosing by developing mechanisms to report all administered LAIB doses to the PMP, including doses from stock supplies at clinics, OTPs, and EDs. This would require updated EHR systems and reporting infrastructure, as well as support for OTPs to address CFR Part 2 privacy concerns. Implementing a statewide standardized reporting infrastructure.

Improve care coordination and prevent duplicate dosing by developing mechanisms to report all administered LAIB doses to the PMP, including doses from stock supplies at clinics, OTPs, hospitals, and EDs. Strategies include 1) implementing statewide

[12] Office of the Insurance Commissioner, Reproductive and Birth Control Health Rights, https://www.insurance.wa.gov/insurance-resources/health-insurance/how-health-insurance-works/reproductive-and-birth-control-health-rights.

standardized reporting infrastructure for stock medication administration reporting; 2) updating EHR systems to capture and transmit stock dose data; 3) regulatory clarification regarding how federal CFR Part 2 privacy requirements apply to PDMP reporting from OTPs, and 4) support for these settings to comply with updated reporting requirements.

Preliminary Assessment:

- **Impact:** Moderate. Improves care coordination across care settings.
- **Feasibility:** Moderate. Requires systems coordination, significant EHR and data infrastructure investment, and clarification of CFR Part 2 privacy concerns for OTPs.
- **Timeline:** Moderate-term
- **Status:** No known effort underway.

Conclusion

Expanding access to LAIB in King County will require coordinated action across regulatory, financial, and health system domains. While some identified barriers require federal action, substantial progress is possible through engagement with healthcare providers and payers, implementation support, and Washington State legislation and rulemaking.

Public Health—Seattle & King County is committed to working with clinical partners, state agencies, and policymakers to advance LAIB access. We invite stakeholders to engage on actionable solutions and to share additional insights that can inform this work.

For questions or comments, contact: Public Health—Seattle & King County Overdose Prevention and Response Team at overdose@kingcounty.gov

Appendix 1: Impact Table

Long-Acting Injectable Buprenorphine (LAIB) Access Initiative | Public Health—Seattle & King County | April 2026

Each solution is labelled with a reference number and letter that corresponds to sections in the document:

- Number 1 refers to *Section 1: Financial Barriers and Solutions*, and each letter corresponds to a solution in the *Financial Solutions* sub-section; e.g., *1.A.* refers to Financial Solution A: *Extend and Expand HCA LAID Bup Funding Program*.
- Number 2 refers to *Section 2: Operational Barriers and Solutions*, and each letter corresponds to a solution in the *Operational Solutions* sub-section.

The impact, status, feasibility, and timelines are based on a preliminary assessment of currently available information and may change as more is learned. Impact is assessed relative to regional-scale LAIB access and implementation; a solution rated as low impact regionally may still be meaningful for individual sites or specific patient populations.

Financial Solutions

Solution	Description	Setting	Impact	Feasibility	Timeline	Status
1.A. Extend & Expand HCA LAI Bup Funding Program	Extend the HCA LAI Bup Funding Program beyond 6/30/2027. Restore eligibility to Medicaid patients. Expand site eligibility to EDs. Allow funds to be used to copays.	Outpatient, Mobile medical, OTP, ED	**High**	**Moderate**	**Near-term (1–2 yrs)**	Program expires 6/30/27. No extension announced.
1.B. Adjust OTP Reimbursement	Adjust OTP bundled rate or creating a separate LAIB add-on payment outside the bundled rate structure.	OTP	**High**	**Low**	**Long term (5+ yrs)**	No known effort underway.
1.C. Adjust Hospital DRG Rates	Adjust bundled payments to separately reimburse for LAIB or create an add-on reimbursement outside the DRG	Inpatient	**High**	**Moderate**	**Long-term (5+ yrs)**	No known effort underway.

1.D. Adjust ED Reimbursement Rates	Adjust payer reimbursement rates for LAIB administered in the ED.	ED	**High**	**Low**	**Long-term (5+ yrs)**	No known effort underway.
1.E. Eliminate Private Insurance Copays	Pursue legislation requiring private insurers to eliminate copays for LAIB.	Outpatient	**Low**	**Moderate**	**Long-term (5+ yrs)**	No known effort underway.
1.F. Allow Medication Reassignment	Enact state legislation allowing dose reassignment to another eligible patient when the original patient does not receive the injection.	Outpatient, Mobile medical, OTP, ED	**High**	**Moderate**	**Long-term (5+ yrs)**	No known effort underway.
1.G. Extend Sublocade Shelf-life Labeling	Determine whether the shelf-life can be extended based on stability data, and if so, update labeling.	Outpatient, Mobile medical, OTP, ED	**Low**	**Low**	**Moderate-term (2–4 yrs)**	No known effort underway.

Operational Solutions

2.A. Establish Explicit Support for Mobile Medical LAIB	Establish explicit support through healthcare leadership endorsement, operational guidance, TA, funding; pursue federal regulatory amendments.	Mobile medical	**High**	**Moderate (local) Low (federal)**	**Moderate (local), Long-term (federal)**	No coordinated effort underway.
2.B. Allow HCE LAIB transport	Establish PQAC rule to allow HCEs to transport stock LAIB doses to outreach locations.	Mobile medical	**High**	**Moderate**	**Moderate-term (2–4 yrs)**	WSR 26-10-040 withdrawn. A new, targeted effort not yet initiated.

2.C. Provide Technical Assistance	Provide centralized TA for LAIB implementation for all healthcare settings.	All	**Moderate**	**High**	**Near-term (1–2 yrs)**	Various MOUD TA; not specific to LAI implementation
2.D. Improve OTP EHR Capabilities	Improve inventory management functionality within OTP EHRs for DEA and 21 CFR compliance.	OTP	**High**	**Moderate**	**Moderate-term (2–4 yrs)**	No known effort underway.
2.E. Expedite Hospital Formulary Approval	Work with hospitals to expedite formulary review process.	Inpatient	**High**	**Moderate**	**Near-term (1-2 yrs)**	No known effort underway.
2.F. Eliminate PA for private insurance	Pursue state legislation requiring private insurers to cover LAIB without prior authorization.	All	**Moderate**	**Moderate**	**Moderate-term (2–4 yrs)**	No known effort underway.
2.G. Standardize PMP Reporting Across Settings	Develop mechanisms to ensure all administered LAIB doses are reported to the PMP, including those from stock supplies.	All	**Moderate**	**Moderate**	**Moderate-term (2–4 yrs)**	No known effort underway.

Appendix 2: Methods and Contributing Perspectives

Origins of This Report

This report originated as an internal summary of a convening hosted by the Overdose Prevention and Response Team at Public Health — Seattle & King County (PHSKC) on November 6, 2025. The convening brought together more than 40 participants representing a broad range of perspectives on LAIB implementation, including staff from PHSKC and King County Department of Community and Human Services (DCHS), SUD treatment programs, hospitals, emergency departments, federally qualified health centers (FQHCs), academic partners, and the Washington State Health Care Authority (HCA).

The convening was structured around five discussion areas: regulations and compliance, procurement models, financial considerations, documentation and storage, and emerging practices. Participants were asked to share implementation challenges they had encountered, approaches they had used or were considering, and areas where they believed systemic change was needed. The questions that guided each discussion are listed below.

As the summary was developed, it became clear that the issues raised warranted deeper analysis than a meeting summary could provide. The report was expanded through follow-up communication with attendees to gather additional detail and clarification, independent review of relevant federal and state regulations, Washington Administrative Code (WAC), and Washington State Pharmacy Quality Assurance Commission (PQAC) rulemaking activity, and review of publicly available program documentation, published literature, and policy guidance.

The result is a report that builds on the perspectives shared at the convening but extends beyond them to provide regulatory context, identify specific barriers, and assess potential solutions. The convening participants provided the grounding for this work; the analysis and conclusions are those of the PHSKC Overdose Prevention and Response team.

Discussion Questions from the November 2025 Convening

The following questions guided discussion across the five agenda topics:

Regulations and Compliance

- What regulatory hurdles have you encountered in implementing LAIB?
- How have you interpreted or navigated regulatory ambiguity regarding administering LAIB at outreach sites?

- What workarounds have you developed, and what are their limitations?

Procurement Models

- What procurement model does your setting use (buy-and-bill, pharmacy-ordered, hospital formulary), and what challenges have you encountered?
- How has the HCA LAI Buprenorphine funding program, and its subsequent changes, affected your ability to serve patients?
- What barriers exist to establishing or maintaining a stock supply of LAIB?

Financial Considerations

- What reimbursement challenges have you encountered across payer types?
- How do procurement costs compare to reimbursement rates in your setting?
- What financial models or workarounds have you used to sustain LAIB access?

Documentation and Storage

- What documentation and recordkeeping challenges have you encountered, particularly related to DEA compliance and PDMP reporting?
- What storage challenges exist for LAIB, and how have you addressed them?

Emerging Practices

- What innovative or experimental approaches to LAIB delivery have you tried or are considering?
- What has worked, what has not, and what would you need to scale successful approaches?

Contributing Perspectives

This report was developed through input from 40 participants at a November 2025 LAIB implementation meeting hosted by Public Health—Seattle & King County's Overdose Prevention and Response team, and subsequent follow-up consultation for clarification and fact checking during the report's development. Meeting participants included medical providers and staff from hospitals, clinics, OTPs, mobile medical programs, King County agencies, and academic partners, including from:

- Public Health—Seattle & King County
- King County Behavioral Health and Recovery Division

- Washington State Health Care Authority
- University of Washington
- Downtown Emergency Services Center
- We Care Daily Clinics
- Kelley-Ross Pharmacy Group
- Swedish Health Services

Individual meeting participants include, but are not limited to:

- Mandy Sladky, MSN, RN, CARN, University of Washington, Addictions, Drug, and Alcohol Institute and Public Health—Seattle & King County (Primary Author)
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- James Darnton, MD, FASAM
- Cricket (Christine) Richards McCleary, BA
- Shivani Vaza, MD
- Laura Pugh, MD