Policy Considerations to Increase Buprenorphine Access in California

Key Context

Access to buprenorphine—a controlled substance used as a medication for opioid use disorder—is a critical tool in the continuum of substance use disorder and overdose prevention services. Like methadone (another common medication for opioid use disorder) buprenorphine has consistently been associated with substantial reductions in opioid-related morbidity and mortality, all-cause mortality, and opioid-related acute care.[1-5] However, buprenorphine affects the body differently than methadone, binding partially (rather than fully) to opioid receptors and generally not creating a "high." As a result, buprenorphine is less tightly regulated than methadone and can be prescribed in various settings beyond licensed Narcotic Treatment Programs, including primary care offices and clinics.

Historically, methadone has been more commonly used; however, buprenorphine uptake, especially among Medi-Cal patients, has risen steeply in the past decade.[4] Increased buprenorphine utilization has been driven, in part, by unprecedented financial investment and removal of state and federal regulatory barriers to buprenorphine dispensing. However, even with these policy changes, buprenorphine remains highly regulated (see Exhibit 1).

BUPRENORPHINE

- A medication for opioid use disorder that reduces morbidity and mortality
- Available as pill, film, or long-acting injectable
- Has low risk of diversion (being used outside of its prescribed purpose)
- Increasingly accessible in the past decade, yet ongoing regulations limit its full potential

Exhibit 1: Regulatory Patchwork for Buprenorphine Dispensing (federal and state)[i]

Drug approval & indication	• The U.S. Food and Drug Administration (FDA) approves medications for marketing and sale and sets Risk Evaluation and Mitigation Strategies (REMS) to support safe use of medication. • The U.S. Drug Enforcement Administration (DEA) makes final decision to place a medication in a controlled substance schedule, which impacts federal and state dispensing regulations.
Pharmacy procurement & dispensing	• State laws for controlled substances regulate buprenorphine dispensing. For example, the California Board of Pharmacy publishes "red flag" protocols that require pharmacists to scrutinize buprenorphine prescriptions in the same way as opioids, in line with DEA guidance. • The federal Controlled Substances Act requires pharmacies and pharmacists to ensure the validity of prescriptions for all controlled substances; the DEA enforces this. • Wholesalers must register with the DEA and report suspicious orders.
Provider certification	• DEA licensed providers otherwise eligible to prescribe in California can dispense buprenorphine. • California licensure for Narcotic Treatment Programs includes buprenorphine dispensing standards. Narcotic Treatment Programs must also be certified by the Substance Abuse and Mental Health Services Administration (SAMSHA) to dispense buprenorphine.[5]

[i] In addition, many insurance companies require providers to be accredited by nationally recognized entities (e.g., Joint Commission, Commission on Accreditation of Rehabilitation Facilities) as a condition of payment.[i]

CHALLENGE #1:

Many pharmacies do not stock buprenorphine, delaying medication access

Despite its efficacy, **only 46.8% of pharmacies in California stocked buprenorphine in 2023**,[6] with marked racial and ethnic disparities in pharmacy buprenorphine access.[7] The reasons for pharmacy variability in stocking and dispensing buprenorphine varies, requiring a number of interventions.[8] Stigma surrounding buprenorphine and the patients who need it have been voiced as key factors,[9] but there are also policy-related barriers to pharmacy dispensing.

An analysis by the USC Schaeffer Center found that people who live in majority **white neighborhoods in California were 2.6x more likely than those in majority Black or Latine neighborhoods** to have a local pharmacy that stocks buprenorphine.[7]

Policy Considerations	Rationale and Details
☑ **Mandate pharmacies to stock buprenorphine**	• Some states and cities (including San Francisco) have mandated that pharmacies carry at least one buprenorphine product.[10,11] • Notably, San Francisco's challenges with enforcement points to the need to pair laws with education and enforcement mechanisms.
☑ **Require pharmacies to honor valid prescriptions**	• Requiring pharmacies to honor any valid buprenorphine prescription could cut down on refusals to dispense based on stigma. (This requires a clear definition of a valid prescription; see below).
☑ **Clarify "red flag" protocols for buprenorphine in the context of opioid use disorder**	• Clinicians have noted Drug Enforcement Administration (DEA) and State Board of Pharmacy oversight as a barrier to buprenorphine dispensing.[12] • Pharmacists must assess for "red flags" that could indicate the prescription is not for a valid medical purpose. Red flags might include payment in cash, patients traveling long distances to obtain a prescription, or prescriptions for certain combinations of drugs.[13] • In February 2025, the California State Board of Pharmacy heard concerns from providers who felt that red flag protocols could jeopardize access to buprenorphine for opioid use disorder.[14] The State Board of Pharmacy agreed to pursue changes to training and provided a one-page educational material with examples of how buprenorphine patients may trigger red flags despite a valid medical purpose, such as if their provider address is far from the pharmacy due to use of telehealth. • In addition to education, changes to red flag guidelines are likely needed, such as specific guidance distinguishing flags for buprenorphine from flags for other opioid medications.
☑ **Clarify Suspicious Order Reporting System (SORS) triggers as they relate to buprenorphine**	• Some pharmacists may keep buprenorphine stocking or dispensing low due to fears of triggering a "Suspicious Order Reporting System" (SORS) flag, which would allow the DEA to investigate the pharmacy.[15] • While the DEA has no threshold number of buprenorphine prescriptions that triggers SORS, wholesalers must set up systems to monitor and report "suspicious" orders from pharmacies. Wholesalers could alleviate confusion by clearly communicating what could trigger SORS for buprenorphine to pharmacies monitored by their specific system. • The California State Board of Pharmacy could help to encourage more transparent wholesaler policies, for instance by inviting wholesalers to participate in discussions with providers and pharmacies.

CHALLENGE #2:

Providers, particularly smaller providers, face financial barriers procuring long-acting injectable buprenorphine

Long-acting injectable buprenorphine, administered weekly or monthly, removes the daily burden of taking the medication orally. However, injectable buprenorphine is subject to tighter regulation and higher costs than oral formulations. In terms of regulation, FDA's Risk Evaluation and Mitigation Strategies (REMS) program requires that injectable buprenorphine is administered by a healthcare professional in a healthcare setting or pharmacy; it cannot be dispensed to patients. [16,17] Participating healthcare settings and pharmacies must take administrative steps to enroll, become certified to receive the injectable formulation, and maintain their certification.[18]

With respect to cost, the wholesale acquisition cost of long-acting buprenorphine is approximately $1,600 per vial depending on the dosage.[18] Substance use disorder providers typically purchase long-acting buprenorphine from a wholesaler or specialty pharmacy and then bill insurance companies separately for the medication and the administration after each injection. Coupled with the additional administrative burdens associated with the FDA REMS requirements for long-acting buprenorphine, the high cost of the medication can be a barrier for providers – particularly smaller community clinics – who may have difficulty identifying resources to purchase the medication upfront and then waiting for reimbursement. As a result of these barriers, a relatively small number of SUD providers are able to provide long-acting injectable buprenorphine onsite.[19]

> "From a policy perspective, there are really tight regulations on injectable buprenorphine. It has to come from very specific pharmacies...They can only be ordered and picked up from one centralized outpatient pharmacy ...which is [in] the middle of a very large county. From edge to edge of the county, it will take you an hour and 15 minutes...and [the injectable buprenorphine is] in the middle, not accessible."
>
> *-Buprenorphine provider (suburban county)*

Policy Considerations	Rationale and Details
☑ **Explore creative financing models for long-acting injectable buprenorphine to support access in smaller clinics**	• California could consider using state general funds to enable safety net providers to purchase the medication through a public health group purchasing organization (GPO) that is able to secure significantly discounted prices.[20] • States have used GPOs for the purchase of other public health medications, including naloxone and vaccines, typically dispensed via public health channels.[21] • This type of arrangement might allow smaller providers to dispense long-acting injectable buprenorphine and could provide a stable funding source for providing this formulation to uninsured individuals.
☑ **Review public reimbursement rates for long-acting injectable buprenorphine**	• The Department of Health Care Services—the state agency that oversees California's Medicaid program, Medi-Cal—and counties who manage Medi-Cal substance use disorder service payment and delivery could review reimbursement models to ensure that the relatively high costs of long-acting injectable buprenorphine are adequately reflected in Medi-Cal provider reimbursement rates.

CHALLENGE #3:

Community-based organizations that are optimally positioned to provide lifesaving overdose prevention and response services lack sustainable funding mechanisms.

People who use opioids experience layered barriers to accessing buprenorphine—such as poverty, homelessness, co-occurring mental health conditions, polysubstance use, and medical systems distrust—and may not be engaged in formal clinic environments where buprenorphine is available. Community-based organizations who reach these populations with overdose prevention and response services are poised to support clients who seek buprenorphine in overcoming these layered barriers. These community-based organizations have demonstrated success through grant-funded buprenorphine programs—including those that use grant funding to overcome known barriers to buprenorphine, such as limited access or poor experiences in pharmacies.[22] However, grant funding for community-based opioid use treatment is temporary in nature and highly impacted by political and economic shifts, posing sustainability barriers to these unique programs. Additionally, these non-clinical providers often have a hard time meeting the credentialing and other administrative and capacity requirements to bill Medi-Cal for covered services provided to Medi-Cal beneficiaries.[23]

Policy Considerations	Rationale and Details
☑ **Continue to support community-based organizations with guidance on reimbursement opportunities**	• California's Department of Health Care Services has successfully expanded reimbursement opportunities for community-based organizations and Community Health Workers in Medi-Cal. • The Department of Health Care Services should continue its work to include community-based providers who provide buprenorphine and other overdose prevention services in Medi-Cal, including specific guidance for inclusion of these providers in Drug Medi-Cal (DMC) and Drug Medi-Cal Organized Delivery System (DMC-ODS) reimbursement structures.
☑ **Utilize innovative contracting models with community-based organizations to reduce administrative burden of Medi-Cal billing**	• Nimble contracts and reimbursement arrangements can help ensure that smaller overdose prevention and response organizations with strong ties to the communities they serve can participate as meaningful Medi-Cal partners. DMC-ODS counties should consider utilizing innovative contracting models with community-based overdose prevention and response organizations to ensure that Medi-Cal credentialing requirements and billing infrastructure do not become a barrier to reimbursing services that Medi-Cal covers. • For instance, other state Medicaid programs and managed care plans have successfully partnered with community-based organizations (including syringe services programs) through a per member per month financing agreement rather than a fee-for-service reimbursement structure.[24]
☑ **Embed sustainability planning into grants for community-based overdose prevention and response**	• In addition to opening up more pathways for Medi-Cal reimbursement, DHCS should ensure that grant funding for community-based buprenorphine encompasses sustainability planning so that grant-funded overdose prevention and response organizations can transition post-grant.[25]

Conclusion

Access to buprenorphine is a critical tool in the continuum of substance use disorder and overdose prevention services. Though California has taken notable steps to improve access to buprenorphine through policy change and unprecedented investment, there are opportunities to make buprenorphine more available and accessible, particularly for the long-acting injectable formulation. State regulating entities, including the California State Board of Pharmacy and the Department of Health Care Services, have an important role to play in better understanding the buprenorphine access gaps that persist across the state and identifying and implementing policy solutions to close those gaps. This is particularly important as the state prepares for a volatile federal funding landscape and potential public and private insurance coverage losses. It will be critical for the state to identify efficient, affordable, and low-threshold policies that enable a range of substance use disorder service providers – including retail pharmacies, clinics, and community-based overdose prevention and response organizations – to make buprenorphine available to anyone who might benefit from it.

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