



October 4, 2023

Rahul Gupta, MD, MPH, FACP, MBA
Director
Office of National Drug Control Policy
750 17th Street NW, Room 810
Washington, DC 20503

Dear Dr. Gupta:

On behalf of the American Association of Psychiatric Pharmacists (AAPP), providers committed to addressing the ongoing opioid crisis, we write to call your attention to a significant barrier to treatment for those with opioid use disorders (OUD). In particular, the Risk Evaluation and Mitigation Strategies (REMS) for Sublocade hinders patient access to this life-saving medication. Given that increasing access to substance use treatment is one of the pillars of the National Drug Control Strategy, we seek your assistance in addressing cross-agency policies that impede access to this important medication.

AAPP is a professional association of nearly 3,000 members who envision a world where all individuals living with mental illness, including those with substance use disorders (SUDs), receive safe, appropriate, and effective treatment. Pharmacist members specialize in psychiatry, substance use disorders (SUD), and psychopharmacology and most are residency trained and Board certified in psychiatric pharmacy holding the BCPP credential (Board Certified Psychiatric Pharmacist).

As you know the once-monthly Sublocade injection is a critical OUD treatment option and must be prescribed and dispensed as part of REMS. Specifically, Sublocade is provided to healthcare providers through a restricted program, only administered in a health care setting, and requires health settings and pharmacies that dispense Sublocade to certify they have procedures in place to ensure that Sublocade is dispensed only to health care providers (and not directly to patients).

Overall, we strongly support the goal of the REMS program to mitigate the risk of serious harm or death that could result from intravenous self-administration. We agree that Sublocade should not be dispensed directly to patients and must only be administered by a health care provider in a healthcare setting. **However, the requirements of the REMS program go far beyond the measures needed to mitigate the risk of self-administration.**

The issue is most concerning when Sublocade is dispensed from REMS certified pharmacies. Certifying a health care setting or practice in the Sublocade REMS to stock and order Sublocade directly from an authorized distributor creates the barrier as it does not allow for utilization of a patient's pharmacy insurance benefits to cover the medication, and thus is cost prohibitive for most practices.

We would like to highlight the following challenges with the current guidance we are receiving from the FDA REMS.

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Issue #1 – The REMS specifies that dispensing or delivery of Sublocade from a REMS certified pharmacy must be directly to a prescriber or practitioner administering Sublocade. This requirement has the following impact:

- Limits accessibility by requiring high-cost health care providers to take time to pick-up the prescription personally from the pharmacy.
- Limits a health system's ability to utilize lower cost alternatives that also ensure medication is not dispensed to a patient via:
 - Medication delivery through courier services to non-licensed clinic staff; or
 - Medication pick-up by clinic non-healthcare providers.

Issue #2 –The REMS requires that the pharmacy verify that the prescriber's DEA address exactly match the practice address where Sublocade is delivered. This requirement has the following impact:

- Limits access when a provider has recently changed practices, as there is generally a lag time after a prescriber updates their address with the DEA; and
- Limits access when a provider works at multiple locations, as a provider generally has only one primary practice address on file with the DEA.

As such, we urge the following clarifications be adopted to the Sublocade REMS program:

- Allow pharmacies to utilize courier services to deliver Sublocade to clinics and allow non-medical staff at the clinics to receive the deliveries on behalf of the prescriber or practitioner administering Sublocade.
- Allow pharmacies to store Sublocade securely as they do for other clinic-administered medications.
- Allow non-licensed clinic staff acting under the supervision of prescriber or practitioner administering Sublocade (including but not limited to patient navigators, counselors or care coordinators) to pick up Sublocade from the REMS certified pharmacy for transportation to the clinic where the medication will be administered.
- Require pharmacies to verify that the medication is delivered to a licensed medical facility.
- Remove the requirement for pharmacies to verify that the prescriber address exactly matches the DEA address on file.

We understand that addressing the access challenges of the Sublocade REMS may require changes in DEA policy and hope that your office can work with the DEA and the FDA to mitigate these barriers. Patient lives are at stake.

We appreciate your attention to this matter, and welcome an opportunity to discuss this with you or your staff. Thank you for your consideration of this meeting request. Please do not hesitate to contact me at bschimenti@aapp.org should you have any questions.

Sincerely,



Brenda K. Schimenti
Executive Director
American Association of Psychiatric Pharmacists