

### SUBLOCADE® REMS

There is a risk of serious harm or death that could result from intravenous self-administration of Sublocade®. Sublocade® should never be dispensed directly to a patient and is only intended for abdominal subcutaneous injection by a healthcare provider. To avoid self-administration and ensure patient safety, Sublocade® is available only through a restricted distribution program called the SUBLOCADE REMS (Risk Evaluation and Mitigation Strategy) Program.

### OPTIONS FOR OBTAINING SUBLOCADE®



#### CERTIFIED PHARMACY

- A list of certified pharmacies can be found:
  - At <https://www.sublocaderems.com/> under *Where can I find more information about the SUBLOCADE REMS Program?*
  - Appended to each mailing of the SUBLOCADE REMS Program Dear Healthcare Provider Letter
  - By calling the SUBLOCADE REMS Program at 1-866-258-3905
- DATA 2000-waivered prescribers submit a Sublocade® prescription for a named patient to the pharmacy. Follow rules and regulations for prescribing controlled substances.
- Sublocade® is dispensed to the healthcare provider for administration to the patient

#### DIRECT ORDERING

- Sublocade® can be ordered directly through a distributor
- The healthcare setting in which you practice must first become certified. To become certified you must:
  - Select an authorized representative
  - Complete and submit the SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form
  - Train relevant staff to ensure Sublocade® is dispensed only to healthcare providers
  - Establish processes and procedures to verify that Sublocade® is never dispensed directly to a patient

### SUGGESTED POLICIES AND PROCEDURES

Policies and procedures must be established to verify Sublocade® is dispensed to a healthcare provider, and Sublocade® is not dispensed to a patient.

- Staff training\*
- Notifying healthcare providers not to dispense directly to patients\*
- Not distributing, transferring, loaning, or selling Sublocade®\*
- Patient selection
- Patient education/Medication guide
  - Brochure available to download at <https://www.sublocade.com/Content/pdf/sublocade-patient-brochure.pdf> or at <https://www.sublocade.com/preparing-for-treatment>
- Medication administration
  - Video available at <https://www.sublocade.com/hcp/buprenorphine>
- Missed appointments, missed doses
- Refill procedures
- Refrigerator temperature monitoring
- Controlled substance inventory\*
- Coordination of submitting prescriptions to a certified pharmacy, medication delivery, and patient appointments if applicable
- Patient labs/tests (e.g., liver function, HCG)
- MAINTAIN APPROPRIATE RECORDS

### SUGGESTED SUPPLIES & EQUIPMENT

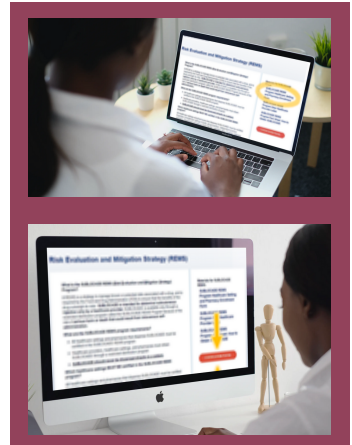


- Refrigerator
- Lock box
- Temperature gauge
- Temperature log
- Storage log
- Sublocade® log
- Location for patient to lie supine
- Injection supplies
  - Bandages
  - Gauze pads
  - Alcohol prep pads
  - Gloves
  - Sharps container
  - Ice packs

\*For certified healthcare facilities

# HOW TO BECOME CERTIFIED

1. Designate an authorized representative. This person will complete the enrollment form, coordinate the activities of the SUBLOCADE REMS Program, and ensure that the facility complies with the program requirements.
2. Complete the three sections of the SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form. The form can be accessed at <https://www.sublocaderems.com/Content/pdf/enrollment-form.pdf> or found at <https://www.sublocaderems.com/>
  - “Authorized Representative Signature” section – page 2
  - “Authorized Representative Information” section – page 3
  - “Healthcare Setting Information” section – page 4
    - The DEA number on file with the distributor account is required
3. Submit the form to the REMS Program by:
  - Online portal: <https://www.sublocaderemsc.com/#Public> or access via <https://www.sublocaderems.com/>
  - Fax: 1-866-823-9549
  - Email: [certify@SublocadeREMS.com](mailto:certify@SublocadeREMS.com)
  - Mail: SUBLOCADE REMS Program, 200 Pinecrest Plaza, Morgantown, WV 26505-8065
4. Agree to train all relevant staff at each dispensing location involved in dispensing the drug directly to a healthcare provider, to ensure that the drug is not dispensed directly to a patient.
5. Agree to verify that Sublocade® is dispensed directly to a healthcare provider. Do not dispense Sublocade® directly to a patient.
6. Agree to notify the healthcare provider not to dispense directly to patients. This may be accomplished via:
  - Phone calls
  - Auxiliary label affixed to the dispensed prescription
  - Reminders in the electronic medical record



*Indivior Inc. is required to notify healthcare settings and pharmacies, confirming certification, within 7 calendar days after they become certified in the REMS Program.*

## STORAGE

- Refrigeration required (2-8°C, 35.6-46.4°F)
- Store securely (e.g., locked refrigerator, lock box secured in refrigerator) in a room that can be locked
- Product can be stored in its original packaging outside the refrigerator at room temperature for up to 7 days

## ADDITIONAL INFORMATION

- Only one form is needed per healthcare setting. A pharmacy is covered under their healthcare setting's enrollment in the SUBLOCADE REMS Program.
- Multiple sites within a healthcare setting is possible (must have site name, DEA number, address, phone, fax, email, and primary point of contact if not the authorized representative). Add settings by submitting just the “Healthcare Setting Information” section for each dispensing site where Sublocade® will be shipped.
- Audits by Indivior Inc. or a third party acting on behalf of Indivior Inc. may occur.
- Physicians waived under the Drug Addiction Treatment Act of 2000 (DATA 2000) and DATA 2000-waivered Nurse Practitioners and Physician Assistants qualified under the Comprehensive Addiction and Recovery Act of 2016 may elect to list their practices in the Indivior Treatment Provider Locator.
- Check federal, state, local, and facility regulations to determine which healthcare providers may administer Sublocade®.
- The INSUPPORT™ Copay Assistance Program is available to help eligible patients (forms also available in Spanish).
- Healthcare providers should report all cases of intravenous administration and suspected adverse events associated with Sublocade® to the FDA at 1-800-FDA-1088 or online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) or to Indivior at 1-877-782-6966.

## Questions?

[www.SUBLOCADEREMS.com](http://www.SUBLOCADEREMS.com) or contact the SUBLOCADE REMS Program at 1-866-258-3905.