



SUBLOCADE REMS Program

Healthcare Setting and Pharmacy Enrollment Form

Instructions:

SUBLOCADE is only available through the SUBLOCADE Risk Evaluation and Mitigation Strategy (REMS) Program. Before SUBLOCADE is provided, healthcare settings or pharmacies must:

1. Designate an authorized representative.
2. Complete and sign this **SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form** and submit it to the REMS Program.
3. 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.
4. Agree to verify that SUBLOCADE is dispensed directly to a healthcare provider. **Do not dispense SUBLOCADE directly to a patient.**
5. Agree to notify the healthcare provider not to dispense directly to patients.

Only one (1) form is needed per healthcare setting. A pharmacy is covered under their healthcare setting's enrollment in the SUBLOCADE REMS Program.

The **SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form** contains three sections:

- "Authorized Representative Signature" section – page 2
- "Authorized Representative Information" section – page 3
- "Healthcare Setting Information" section – page 4

For the initial enrollment, all three sections noted above must be submitted. To add an additional healthcare setting after the initial enrollment, you may submit just the "Healthcare Setting Information" section for each dispensing site where SUBLOCADE will be shipped within your healthcare system.

If a designated authorized representative changes, the new authorized representative must complete and sign a new **SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form**, including a "Healthcare Setting Information" section for each healthcare setting with which he/she is now affiliated.

The authorized representative will ensure that each dispensing location that meets the REMS requirements will be permitted to purchase, receive, and dispense SUBLOCADE. The certification will be confirmed prior to shipping SUBLOCADE.

Enrollment can be done via the online portal, fax, email, or mail.

- To enroll **online**, please go to www.SUBLOCADEREMS.com.
- For enrollment via **fax**, please complete all required fields on the form and one "Healthcare Setting Information" section for each dispensing site, and fax the section(s) to 1-866-823-9549.
- For enrollment via **E-mail**, please complete all required fields on the form and one "Healthcare Setting Information" section for each dispensing site, and email the section(s) to certify@SublocadeREMS.com.
- For enrollment via **mail**, please complete all required fields on the form and one "Healthcare Setting Information" section for each dispensing site, and mail the section(s) to SUBLOCADE REMS Program, 200 Pinecrest Plaza, Morgantown, WV 26505-8065.

For questions regarding the SUBLOCADE REMS Program or how to enroll, visit www.SUBLOCADEREMS.com or contact the SUBLOCADE REMS Program at 1-866-258-3905.



Authorized Representative Responsibilities

I am the authorized representative designated by my healthcare setting or pharmacy to coordinate the activities of the SUBLOCADE REMS Program. On behalf of the healthcare setting or pharmacy, I agree that we will comply with the following program requirements:

- Become certified with the SUBLOCADE REMS Program to order SUBLOCADE.
- Understand that there is a risk of serious harm or death that could result from intravenous self-administration. **Do not dispense SUBLOCADE directly to a patient.**
- Establish processes and procedures to verify SUBLOCADE is dispensed to a healthcare provider, and SUBLOCADE is not dispensed to a patient.
- Ensure that all relevant staff involved in dispensing SUBLOCADE are trained that SUBLOCADE must be dispensed directly to a healthcare provider for administration by a healthcare provider, and that SUBLOCADE must not be dispensed directly to a patient.
- Establish processes and procedures to notify the healthcare provider not to dispense directly to patients. Notifications may be accomplished through a variety of mechanisms based on the healthcare setting. Phone calls, an auxiliary label printed automatically and affixed to the dispensed prescription, or reminders in the electronic medical record are potential mechanisms to communicate the alert.
- Establish processes and procedures to not distribute, transfer, loan, or sell SUBLOCADE.
- Maintain records of all processes and procedures including compliance with those processes and procedures.
- Comply with audits by Indivior Inc. or a third party acting on behalf of Indivior to ensure that all processes and procedures are in place and are being followed for the SUBLOCADE REMS Program.
- Ensure each dispensing site location has policies and procedures and will provide the following information (site name, DEA number, address, phone, fax, email, and primary point of contact if not the authorized representative) to the SUBLOCADE REMS Program, to enable those sites to purchase, receive, and dispense SUBLOCADE.

I understand that this enrollment applies to my healthcare setting(s) or pharmacy for which I am the designated authorized representative.

Healthcare Setting or Pharmacy Authorized Representative Signature*

Date (MM/DD/YYYY)*





HEALTHCARE SETTING INFORMATION

(*REQUIRED FIELDS)

Authorized Representative Name*

Phone Number* or Fax Number* or Email Address*

Healthcare Setting Name*

DEA Number (on file with distributor account)*

Primary Point of Contact (if person is not the authorized representative)*

Address*

Address Line 2

City* State* ZIP*

Phone Number* Fax Number* or Email Address*

Setting Type*

Pharmacy:
Specialty Pharmacy Other

Healthcare Setting:
Group Practice Hospital
Independent Practice Veterans Administration (VA) Facility
Institution Opioid Treatment Program (OTP)
Department of Defense (DoD) Facility Closed Healthcare System
Outpatient Clinic Other

I am the designated authorized representative for this healthcare setting or pharmacy.

Healthcare Setting or Pharmacy Authorized Representative Signature* Date (MM/DD/YYYY)*