Risk Evaluation and Mitigation Strategy (REMS) Document

SUBLOCADE (buprenorphine extended-release) REMS Program

I. Administrative Information

Application Number: NDA 209819
Application Holder: Indivior Inc.
Initial REMS Approval: [11/2017]
Most Recent REMS Update: [12/2020]

II. REMS Goal

The goal of the SUBLOCADE REMS is to mitigate the risk of serious harm or death that could result from intravenous self-administration by:

- Ensuring healthcare settings and pharmacies are certified and only dispense SUBLOCADE directly to a healthcare provider for administration by a healthcare provider

III. REMS Requirements

Indivior must ensure that healthcare settings, pharmacies, and wholesalers/distributors comply with the following requirements:

1. Healthcare settings and pharmacies that dispense SUBLOCADE must:

To become certified to dispense	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting or pharmacy. 2. Have the authorized representative enroll in the REMS Program by completing the Healthcare Setting and Pharmacy Enrollment Form and submitting it to the REMS Program. 3. Train all relevant staff involved in dispensing that the drug must be dispensed directly to a healthcare provider for administration by a healthcare provider, and the drug must not be dispensed to the patient. 4. Establish processes and procedures to verify SUBLOCADE is dispensed directly to a healthcare provider and the drug is not dispensed to the patient. 5. Establish processes and procedures to notify the healthcare provider not to dispense the drug directly to patients.
Before dispensing	6. Verify that SUBLOCADE is dispensed directly to a healthcare provider and the drug is not dispensed to the patient. 7. Notify the healthcare provider not to dispense the drug directly to patients.

To maintain certification to dispense	8. Have a new authorized representative enroll in the REMS Program by completing the Healthcare Setting and Pharmacy Enrollment Form if the authorized representative changes.
At all times	9. Not distribute, transfer, loan or sell SUBLOCADE. 10. Maintain records of all processes and procedures including compliance with those processes and procedures. 11. 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.

2. Wholesalers/Distributors that distribute SUBLOCADE must:

To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings and pharmacies. 2. Train all relevant staff involved in distributing SUBLOCADE on the process and procedures to verify the healthcare settings and pharmacies are certified.
At all times	3. Distribute only to certified healthcare settings and pharmacies. 4. Maintain and submit records of all shipments of SUBLOCADE to Indivior. 5. Comply with audits carried out by Indivior or a third party acting on behalf of Indivior to ensure that all processes and procedures are in place and are being followed.

To inform healthcare providers about the REMS Program and the risks and safe use of SUBLOCADE, Indivior must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials-& Dissemination Plans
All prescribers certified to treat opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA 2000); all pharmacies authorized by DEA to handle schedule III controlled substances on a national mailing list from the National Technical Information Service; all Opioid Treatment Programs certified under 42 CFR 8	REMS Letter: Healthcare Provider REMS Letter with attachment: Fact Sheet: How to Obtain SUBLOCADE 1. Mail within 60 calendar days of the date SUBLOCADE is first commercially distributed and again 6 months later, or 2. eMail within 60 calendar days of the date SUBLOCADE is first commercially distributed and again 6 months later. 3. Make available via a link from the SUBLOCADE REMS Program Website. 4. Disseminate through professional societies and request the content be provided to their members. 5. Disseminate at Professional Meetings for 1 year from the date SUBLOCADE is first commercially distributed.
All prescribers certified to treat opioid dependence under	REMS Letter: Healthcare Provider REMS Letter with attachment: Fact Sheet: How to Obtain SUBLOCADE

Target Audience	Communication Materials-& Dissemination Plans
DATA 2000 since the last dissemination; all pharmacies authorized by DEA to handle schedule III controlled substances since the last dissemination; all Opioid Treatment Programs certified under 42 CFR 8 since the last dissemination	6. Mail annually from the date SUBLOCADE is first commercially distributed, or 7. eMail annually from the date SUBLOCADE is first commercially distributed.

To support REMS Program operations, Indivior must:

1. Establish and maintain a REMS Program website, www.SUBLOCADEREMS.com. The REMS Program website must include the capability to complete healthcare setting and pharmacy certification online, the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website.

2. Make the REMS Program website fully operational and all REMS materials available through website and call center by the date SUBLOCADE is first commercially distributed.

3. Establish and maintain a REMS Program call center for REMS participants at 1-866-258-3905.

4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the SUBLOCADE REMS Program.

5. Ensure healthcare settings and pharmacies are able to enroll by fax, mail, email, and online.

6. Provide Healthcare Provider REMS Letter, Fact Sheet: How to Obtain SUBLOCADE, Healthcare Setting and Pharmacy Enrollment Form and the Prescribing Information to REMS participants who (1) attempt to dispense SUBLOCADE and are not yet certified or (2) inquire about how to become certified.

7. Notify healthcare settings and pharmacies, confirming certification, within 7 calendar days after they become certified in the REMS Program.

8. Provide wholesalers/distributors access to the database of certified healthcare settings and pharmacies.

To ensure REMS participants' compliance with the REMS Program, Indivior must:

9. Verify annually that the authorized representative's name and contact information correspond to those of the current designated authorized representative for the certified healthcare setting or pharmacy. If different, the healthcare setting and pharmacy must be required to re-certify with a new authorized representative.

10. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: SUBLOCADE distribution and dispensing; certification of pharmacies and healthcare settings; and audits of REMS participants.

11. Establish a plan for addressing non-compliance with REMS Program requirements.

12. Monitor healthcare settings, pharmacies, and wholesalers/distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.

13. Audit 10% of healthcare settings no later than 90 calendar days after they become certified, and 10% annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. Annual audits must include healthcare settings that have received at least one shipment of SUBLOCADE in the past 12 months and not have been audited in the past 3 years.

14. Audit pharmacies no later than 90 calendar days after the pharmacy receives its first shipment, and 10% annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. Annual audits must include pharmacies that have received at least one shipment of SUBLOCADE in the past 12 months and not have been audited in the past 3 years.

15. Audit wholesalers/distributors no later than 90 calendar days after they become authorized or from the date SUBLOCADE is first commercially distributed (whichever is later), and annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.

16. Take reasonable steps to improve implementation of and compliance with the requirements in the SUBLOCADE REMS Program based on monitoring and evaluation of the SUBLOCADE REMS Program.

IV. REMS Assessment Timetable

Indivior must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS (11/30/2017). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Indivior must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the SUBLOCADE REMS and are appended**:**

Enrollment Forms:

Healthcare Setting and Pharmacy:

1. Healthcare Setting and Pharmacy Enrollment Form

Communication Materials

2. Healthcare Provider REMS Letter
3. Fact Sheet: How to Obtain SUBLOCADE

Other Materials

4. REMS Program Website

INDIVIOR™

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use Ⓒ

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)*

INDIVIOR™

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use Ⓒ

AUTHORIZED REPRESENTATIVE INFORMATION

(*REQUIRED FIELDS)

Credentials*:

- ◯ Pharmacist
- ◯ Nurse Practitioner
- ◯ Practice Manager
- ◯ Other _____
- ◯ Physician
- ◯ Nurse
- ◯ Physician Assistant

First Name* (please print) | MI | Last Name* (please print)

Position/Title | Email Address* or Fax Number* | Phone Number* Ext

Preferred Method of Communication for Correspondence* (please select **one**)

◯ Email ◯ Fax

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

INDIVIOR™

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use Ⓒ

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

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

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

SUBLOCADE is a registered trademark of Indivior UK Limited.
© Indivior PLC | INDIVIOR is a registered trademark of Indivior UK Limited | All rights reserved.
P-BAG-US-00620 November 2019

INDIVIOR™

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use Ⓒ

FDA-REQUIRED REMS SAFETY INFORMATION

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY
• **Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.** • **Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.**

November 2019

Dear Healthcare Provider:

The purpose of this letter is to inform you about **the risk of serious harm or death that could result from intravenous self-administration of SUBLOCADE and its restricted distribution program**. The FDA has determined that a **Risk Evaluation and Mitigation Strategy (REMS)** is necessary to ensure that the benefits of SUBLOCADE outweigh this serious risk.

SUBLOCADE is available only through a restricted distribution program called the SUBLOCADE REMS Program because of **the risk of serious harm or death that could result from intravenous self-administration. SUBLOCADE is intended for abdominal subcutaneous injection only by a healthcare provider.**

What are the SUBLOCADE REMS Program requirements?

- All healthcare settings and pharmacies that dispense SUBLOCADE must be certified in the SUBLOCADE REMS Program.
- Healthcare providers, healthcare settings, and pharmacies must obtain SUBLOCADE through a restricted distribution program.
- **SUBLOCADE should never be dispensed directly to a patient.**

Please see the attached non-promotional ***SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE***, reviewed by the FDA, for information about **how your healthcare setting or pharmacy can obtain SUBLOCADE.**

Please visit www.SUBLOCADEREMS.com for information about **how your healthcare setting or pharmacy can certify** in the SUBLOCADE REMS Program.

INDIVIOR™

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use Ⓒ

Where can I find more information about the SUBLOCADE REMS Program?

- Visit www.SUBLOCADEREMS.com to access the following materials:
  - ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form***
  - ***SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE***
  - ***Prescribing Information***
  - ***Medication Guide***
- Contact the SUBLOCADE REMS Program at 1-866-258-3905 for SUBLOCADE REMS materials and for additional information about the SUBLOCADE REMS Program.
- Visit the REMS@FDA website at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.
- Call Indivior's Medical Information line (1-877-782-6966).

Indication

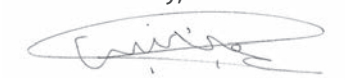
SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Reporting Adverse Events

You are encouraged to report negative side effects to the FDA. 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 or to Indivior at 1-877-782-6966.

Sincerely,



Baher Mankabady, MD
Vice President, Global Patient Safety

Indivior Inc.

Enclosed:

SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE

List of SUBLOCADE REMS Program-certified Pharmacies

Note: Once SUBLOCADE is delivered for a named patient or is obtained for a healthcare setting's bulk supply, it should be kept in a secure place per state and federal regulations. Store refrigerated. Once outside the refrigerator, this product may be stored in its original packaging at room temperature for up to seven (7) days prior to administration. Discard SUBLOCADE if left at room temperature for longer than seven (7) days.

SUBLOCADE is a registered trademark of Indivior UK Limited.
© Indivior PLC | INDIVIOR is a registered trademark of Indivior UK Limited | All rights reserved.
P-BAG-US-00618 November 2019

INDIVIOR™

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use ℞

SUBLOCADE REMS Program Fact Sheet
How to Obtain SUBLOCADE

What is the SUBLOCADE REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. **SUBLOCADE is intended for abdominal subcutaneous injection only by a healthcare provider.** SUBLOCADE is available only through a restricted distribution program called the SUBLOCADE REMS Program because of **the risk of serious harm or death that could result from intravenous self-administration**.

What are the SUBLOCADE REMS Program requirements?

Any pharmacy that dispenses SUBLOCADE as well as any healthcare setting* (including a prescriber office) that purchases SUBLOCADE from a distributor must be certified prior to dispensing/purchasing SUBLOCADE. Prescriber offices that only order SUBLOCADE from a certified pharmacy for a specific patient are exempt from certification.

How can DATA 2000-waivered prescribers obtain SUBLOCADE for their patients?

Prescribers who are DATA 2000-waivered can obtain SUBLOCADE for their patients in two ways.

1. Through a certified pharmacy for a specific patient:

In advance of the patient's appointment, send a prescription for your named patient to a certified pharmacy. The certified pharmacy will send SUBLOCADE to you to administer it directly to that patient. SUBLOCADE should never be dispensed directly to the patient. It should be administered by a healthcare professional in your office or clinic. Your healthcare setting **does not need to be certified** in the SUBLOCADE REMS Program for you to administer SUBLOCADE to an individual named patient obtained through a certified pharmacy. A list of certified pharmacies is appended to each mailing of the ***SUBLOCADE REMS Program Dear Healthcare Provider Letter***. Additionally, the current list may be obtained on the SUBLOCADE REMS website or from the SUBLOCADE REMS Program at 1-866-258-3905. **SUBLOCADE should never be dispensed directly to a patient.**

2. By ordering SUBLOCADE directly through a distributor:

To order SUBLOCADE through a distributor, the healthcare setting in which you practice must first become certified.

*Examples of healthcare settings include: group practice, independent practice, institution, Department of Defense (DoD) facility, outpatient clinic, hospital, Veterans Administration (VA) facility, opioid treatment program (OTP), closed healthcare system, other healthcare setting.

INDIVIOR™

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use Ⓒ

How can healthcare settings* obtain SUBLOCADE for potential patients?

To receive and store a supply of SUBLOCADE for a healthcare setting, all healthcare settings and pharmacies that dispense SUBLOCADE* must:

1. Be certified in the SUBLOCADE REMS Program.
2. Designate an "authorized representative" to complete the ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form*** and submit it to the SUBLOCADE REMS Program for certification.
3. Train relevant staff involved in the dispensing of SUBLOCADE, to ensure that it is dispensed directly to a healthcare provider.
4. Establish processes and procedures to verify that SUBLOCADE is dispensed directly to a healthcare provider. **SUBLOCADE should never be dispensed directly to a patient**.

How should SUBLOCADE be stored?

- Once SUBLOCADE is delivered for a named patient or is obtained for a healthcare setting's bulk supply, it should be kept in a secure place per state and federal regulations. Store refrigerated. Once outside the refrigerator, this product may be stored in its original packaging at room temperature for up to seven (7) days prior to administration. Discard SUBLOCADE if left at room temperature for longer than seven (7) days.

Where can I find more information about the SUBLOCADE REMS Program?

- Visit www.SUBLOCADEREMS.com to access the following materials:
  - ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form***
  - ***SUBLOCADE REMS Program Dear Healthcare Provider Letter***
  - ***Prescribing Information***
  - ***Medication Guide***
- Contact the SUBLOCADE REMS Program at 1-866-258-3905 for SUBLOCADE REMS materials and for additional information about the SUBLOCADE REMS Program.
- Visit the REMS@FDA website at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.
- Call Indivior's Medical Information line (1-877-782-6966).

*Examples of healthcare settings include: group practice, independent practice, institution, Department of Defense (DoD) facility, outpatient clinic, hospital, Veterans Administration (VA) facility, opioid treatment program (OTP), closed healthcare system, other healthcare setting.

SUBLOCADE is a registered trademark of Indivior UK Limited.
© Indivior PLC | INDIVIOR is a registered trademark of Indivior UK Limited | All rights reserved.
P-BAG-US-00617 November 2019

Risk Evaluation and Mitigation Strategy (REMS)

What is the SUBLOCADE REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. **SUBLOCADE is intended for abdominal subcutaneous injection only by a healthcare provider.** SUBLOCADE is available only through a restricted distribution program called the SUBLOCADE REMS Program because of the risk of **serious harm or death that could result from intravenous self-administration.**

What are the SUBLOCADE REMS program requirements?

- All healthcare settings and pharmacies that dispense SUBLOCADE must be certified in the SUBLOCADE REMS program
- Healthcare providers, healthcare settings, and pharmacies must obtain SUBLOCADE through a restricted distribution program
- **SUBLOCADE should never be dispensed directly to a patient.**

Which healthcare settings MUST BE certified in the SUBLOCADE REMS program?

All healthcare settings and pharmacies that dispense SUBLOCADE must be certified. Examples of healthcare settings include: group practice, independent practice, institution, Department of Defense (DoD) facility, outpatient clinic, hospital, Veterans Administration (VA) facility, opioid treatment program (OTP), closed healthcare system, other healthcare setting.

How does my healthcare setting or pharmacy become certified in the SUBLOCADE REMS program?

1. **Get Started here**

   Designate an **authorized representative.** 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.

2. **Review REMS Materials**

   Review the SUBLOCADE REMS Program materials, including ***SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE***, the Prescribing Information, and the Medication Guide.

3. **Complete the Enrollment Process**

   Complete, sign, and submit the ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form.***

   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
   - "Authorized Representative Information" section
   - "Healthcare Setting Information" section

   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 ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form*** may be completed via one of the following enrollment options below:

   - To enroll **online**, please **click here**.
   - 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.

4. **Implement the REMS Program**

   - Establish processes and procedures to verify that SUBLOCADE is dispensed directly to a healthcare provider for administration to a patient. **SUBLOCADE should never be dispensed directly to a patient.**
   - Implement the necessary staff training and processes to comply with the SUBLOCADE REMS Program requirements.

How can certified healthcare settings obtain SUBLOCADE for potential patients?

In advance of the patient's appointment, order SUBLOCADE from an authorized distributor. SUBLOCADE should be administered by a healthcare professional in your office or clinic directly to the patient. **SUBLOCADE should never be dispensed directly to a patient.**

How can DATA 2000-waivered prescribers obtain SUBLOCADE for their patients?

Prescribers who are DATA 2000-waivered can obtain SUBLOCADE for their patients in two ways.

1. Through a certified pharmacy for a named patient:

   In advance of the patient's appointment, send a prescription for your named patient to a certified pharmacy. The certified pharmacy will send SUBLOCADE to you to administer it directly to that patient. SUBLOCADE should never be dispensed directly to the patient. It should be administered by a healthcare professional in your office or clinic. Your healthcare setting **does not need to be certified** in the SUBLOCADE REMS Program for you to administer SUBLOCADE to an individual named patient obtained through a certified pharmacy. A list of certified pharmacies is appended to each mailing of the ***SUBLOCADE REMS Program Dear Healthcare Provider Letter***. Additionally, the current list may be obtained on the SUBLOCADE REMS website or from the SUBLOCADE REMS Program at 1-866-258-3905. **SUBLOCADE should never be dispensed directly to a patient.**

2. By ordering SUBLOCADE directly through a distributor:

   To order SUBLOCADE through a distributor, the healthcare setting in which you practice must first become certified.

How should SUBLOCADE be stored?

Once SUBLOCADE is delivered for a named patient or is obtained for a healthcare setting's bulk supply, it should be kept in a secure place per state and federal regulations. Store refrigerated. Once outside the refrigerator, this product may be stored in its original packaging at room temperature for up to seven (7) days prior to administration. Discard SUBLOCADE if left at room temperature for longer than seven (7) days.

Where can I find more information about the SUBLOCADE REMS Program?

- Review the following materials:
  - ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form***
  - ***SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE***
  - ***SUBLOCADE REMS Program Dear Healthcare Provider Letter***
  - ***Prescribing Information***
  - ***Medication Guide***
- Contact the SUBLOCADE REMS Program at 1-866-258-3905 for REMS materials and for additional information about the SUBLOCADE REMS Program.
- Visit the REMS@FDA website at: **https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm**.
- Call Indivior's Medical Information line (1-877-782-6966).

Please click **here** for a list of the certified pharmacies where SUBLOCADE can be obtained. A list of certified pharmacies is also appended to each mailing of the ***SUBLOCADE REMS Program Dear Healthcare Provider Letter***. Additionally, the current list may be obtained by calling the SUBLOCADE REMS Program at 1-866-258-3905.

Indication

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Reporting Adverse Events

You are encouraged to report negative side effects to the FDA. 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** or to Indivior at 1-877-782-6966 or **PatientSafetyNA@indivior.com**.

Materials for SUBLOCADE REMS:

- **SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form**
- **SUBLOCADE REMS Program Dear Healthcare Provider Letter**
- **SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE**

CERTIFICATION PORTAL

SUBLOCADE is a registered trademark of Indivior UK Limited.
© Indivior PLC | INDIVIOR is a registered trademark of Indivior UK Limited | All rights reserved.
This site is sponsored by Indivior Inc. and intended solely for residents of the United States only.

P-BAG-US-00833

You are now leaving the SublocadeREMS.com website.

Links to other websites are provided for your convenience and general informational purposes only. The terms of use and privacy statement on the SublocadeREMS.com website will not apply to other websites. Indivior Inc. does not endorse websites that are not owned or operated by Indivior Inc. Indivior Inc. recommends you carefully review the terms of use and privacy statement of any other websites, and reminds you that you are solely responsible for your interactions on any other websites. By clicking "Continue" you will exit Indivior Inc.'s SublocadeREMS.com website.

CONTINUE → Cancel

Risk Evaluati

What is the SUBL Program?

A REMS is a strate required by the Foc drug outweigh its ri **injection only by a healthcare provider.** SUBLOCADE is available only through a restricted distribution program called the SUBLOCADE REMS Program because of the risk of **serious harm or death that could result from intravenous self-administration.**

What are the SUBLOCADE REMS program requirements?

- All healthcare settings and pharmacies that dispense SUBLOCADE must be certified in the SUBLOCADE REMS program
- Healthcare providers, healthcare settings, and pharmacies must obtain SUBLOCADE through a restricted distribution program
- **SUBLOCADE should never be dispensed directly to a patient.**

Which healthcare settings MUST BE certified in the SUBLOCADE REMS program?

All healthcare settings and pharmacies that dispense SUBLOCADE must be certified. Examples of healthcare settings include: group practice, independent practice, institution, Department of Defense (DoD) facility, outpatient clinic, hospital, Veterans Administration (VA) facility, opioid treatment program (OTP), closed healthcare system, other healthcare setting.

How does my healthcare setting or pharmacy become certified in the SUBLOCADE REMS program?

1. **Get Started here**

   Designate an **authorized representative.** 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.

2. **Review REMS Materials**

   Review the SUBLOCADE REMS Program materials, including ***SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE***, the Prescribing Information, and the Medication Guide.

3. **Complete the Enrollment Process**

   Complete, sign, and submit the ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form.***

   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
   - "Authorized Representative Information" section
   - "Healthcare Setting Information" section

   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 ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form*** may be completed via one of the following enrollment options below:

   - To enroll **online**, please **click here**.
   - 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.

4. **Implement the REMS Program**

   - Establish processes and procedures to verify that SUBLOCADE is dispensed directly to a healthcare provider for administration to a patient. **SUBLOCADE should never be dispensed directly to a patient.**
   - Implement the necessary staff training and processes to comply with the SUBLOCADE REMS Program requirements.

How can certified healthcare settings obtain SUBLOCADE for potential patients?

In advance of the patient's appointment, order SUBLOCADE from an authorized distributor. SUBLOCADE should be administered by a healthcare professional in your office or clinic directly to the patient. **SUBLOCADE should never be dispensed directly to a patient.**

How can DATA 2000-waivered prescribers obtain SUBLOCADE for their patients?

Prescribers who are DATA 2000-waivered can obtain SUBLOCADE for their patients in two ways.

1. Through a certified pharmacy for a named patient:

   In advance of the patient's appointment, send a prescription for your named patient to a certified pharmacy. The certified pharmacy will send SUBLOCADE to you to administer it directly to that patient. SUBLOCADE should never be dispensed directly to the patient. It should be administered by a healthcare professional in your office or clinic. Your healthcare setting **does not need to be certified** in the SUBLOCADE REMS Program for you to administer SUBLOCADE to an individual named patient obtained through a certified pharmacy. A list of certified pharmacies is appended to each mailing of the ***SUBLOCADE REMS Program Dear Healthcare Provider Letter***. Additionally, the current list may be obtained on the SUBLOCADE REMS website or from the SUBLOCADE REMS Program at 1-866-258-3905. **SUBLOCADE should never be dispensed directly to a patient.**

2. By ordering SUBLOCADE directly through a distributor:

   To order SUBLOCADE through a distributor, the healthcare setting in which you practice must first become certified.

How should SUBLOCADE be stored?

Once SUBLOCADE is delivered for a named patient or is obtained for a healthcare setting's bulk supply, it should be kept in a secure place per state and federal regulations. Store refrigerated. Once outside the refrigerator, this product may be stored in its original packaging at room temperature for up to seven (7) days prior to administration. Discard SUBLOCADE if left at room temperature for longer than seven (7) days.

Where can I find more information about the SUBLOCADE REMS Program?

- Review the following materials:
  - ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form***
  - ***SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE***
  - ***SUBLOCADE REMS Program Dear Healthcare Provider Letter***
  - ***Prescribing Information***
  - ***Medication Guide***
- Contact the SUBLOCADE REMS Program at 1-866-258-3905 for REMS materials and for additional information about the SUBLOCADE REMS Program.
- Visit the REMS@FDA website at: **https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm**.
- Call Indivior's Medical Information line (1-877-782-6966).

Please click **here** for a list of the certified pharmacies where SUBLOCADE can be obtained. A list of certified pharmacies is also appended to each mailing of the ***SUBLOCADE REMS Program Dear Healthcare Provider Letter***. Additionally, the current list may be obtained by calling the SUBLOCADE REMS Program at 1-866-258-3905.

Indication

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Reporting Adverse Events

You are encouraged to report negative side effects to the FDA. 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** or to Indivior at 1-877-782-6966 or **PatientSafetyNA@indivior.com**.

SUBLOCADE

E REMS
althcare Setting
cy Enrollment
Form

SUBLOCADE REMS Program Dear Healthcare Provider Letter

SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE

CERTIFICATION PORTAL

SUBLOCADE is a registered trademark of Indivior UK Limited.
© Indivior PLC | INDIVIOR is a registered trademark of Indivior UK Limited | All rights reserved.
This site is sponsored by Indivior Inc. and intended solely for residents of the United States only.

P-BAG-US-00833