

# Risk Evaluation and Mitigation Strategy (REMS) Document

## SUBOXONE<sup>1</sup> (buprenorphine and naloxone) and SUBUTEX (buprenorphine) REMS Program

*This REMS does not apply to Suboxone and Subutex products dispensed to patients admitted to an Opioid Treatment Program (OTP) under 42 CFR Part 8 because the care of OTP patients is subject to specific requirements under those regulations.*

### I. Administrative Information

Application Numbers: NDA 022410 (and Authorized Generic); NDA 020732; NDA 020733

Application Holder: Indivior Inc.

Initial REMS Approval: 08/2010

Most Recent REMS Update: 12/2020

### II. REMS Goals

The goals of the REMS for SUBOXONE and SUBUTEX are to:

- Mitigate the risks of accidental overdose, misuse and abuse.
- Inform prescribers, pharmacists and patients of the serious risks associated with SUBOXONE and SUBUTEX.

### III. REMS Requirements

**Indivior Inc. must ensure that prescribers and patients comply with the following requirements:**

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#### 1. Prescribers who prescribe or dispense SUBOXONE and SUBUTEX must:

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Before treatment initiation  
(first dose)

1. Assess the patient's condition to verify the patient meets the diagnostic criteria for opioid dependence.
  2. Counsel the patient on the risks described in the Prescribing Information and [Medication Guide](#).
  3. Counsel the patient on safe storage of the medication.
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During treatment; at the  
first visit following  
induction

4. Prescribe a limited amount of medication.
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<sup>1</sup> SUBOXONE<sup>®</sup> includes the sublingual film, Authorized Generic of SUBOXONE<sup>®</sup> sublingual film, and SUBOXONE<sup>®</sup> sublingual tablets.

During treatment; at visits scheduled at intervals commensurate with patient stability	<ol style="list-style-type: none"> <li>5. Assess the patient's compliance with the prescribed medication, appropriateness of the dosage prescribed, whether patient is receiving the necessary psychosocial support, and whether patient is making adequate progress towards treatment goals.</li> <li>6. Counsel the patient about compliance with their medication.</li> <li>7. Complete the <a href="#">Appropriate Use Checklist</a>. Retain a completed copy in the patient's record or by using another method (e.g., electronic health record) specific to the prescriber's office practice.</li> </ol>
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**2. Patients who are prescribed SUBOXONE and SUBUTEX:**

Before treatment initiation	<ol style="list-style-type: none"> <li>1. Receive counseling from the prescriber on the risks and safe storage of the medication.</li> </ol>
During treatment; at time intervals determined by your prescriber	<ol style="list-style-type: none"> <li>2. Be monitored for compliance with the prescribed medication, appropriateness of the dosage prescribed, assessment of whether receiving the necessary psychosocial support, and whether making adequate progress towards treatment goals.</li> </ol>

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

<b>Target Audience</b>	<b>Communication Materials &amp; Dissemination Plans</b>
Prescribers certified to treat opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA 2000)	<p>REMS Letter: <a href="#">Dear Prescriber Letter</a> with attachments <a href="#">Prescriber Brochure</a> and <a href="#">Appropriate Use Checklist</a>.</p> <ol style="list-style-type: none"> <li>1. E-mail or direct mail within 30 days of approval of the SUBOXONE and SUBUTEX REMS and annually thereafter.</li> </ol>
All prescribers certified to treat opioid dependence under DATA 2000 since the last dissemination	<p>REMS Letter: <a href="#">Dear Prescriber Letter</a> with attachments <a href="#">Prescriber Brochure</a> and <a href="#">Appropriate Use Checklist</a>.</p> <ol style="list-style-type: none"> <li>1. E-mail or direct mail monthly.</li> </ol>
Retail pharmacies on the National Technical Information Service mailing list authorized by the DEA to handle schedule III-controlled substances	<p>REMS Letter: <a href="#">Dear Pharmacist Letter</a> with attachment <a href="#">Pharmacist Brochure</a>.</p> <ol style="list-style-type: none"> <li>1. Direct mail within 30 days of approval of the SUBOXONE and SUBUTEX REMS and annually thereafter.</li> </ol>

**To support REMS Program operations, Indivior Inc. must:**

1. Establish and maintain a REMS Program website, [www.suboxoneREMS.com](http://www.suboxoneREMS.com). The REMS Program website must include the option to print the Prescribing Information, Medication Guides, 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 websites.

2. Make the REMS Program website fully operational and all REMS materials available through the website, through field personnel, and call-center within 60 calendar days of REMS modification.
3. Establish and maintain a REMS Program call center for REMS participants at 1-866-463-4846.

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

4. Maintain adequate records to demonstrate the REMS requirements have been met, including, but not limited to, records of mailings. These records must be readily available for FDA inspections.
5. Monitor compliance with the prescriber requirements to document prescribing and dispensing with the documentation of safe use conditions through surveys of patients and prescribers, evaluations of health care utilization databases, and ongoing surveillance (sources including, but not limited to, internet, national databases, and surveys conducted at substance abuse treatment programs).
6. Take reasonable steps to improve implementation of and compliance with the requirements in the SUBOXONE and SUBUTEX REMS Program based on monitoring and evaluation of the SUBOXONE and SUBUTEX REMS Program.

## **IV. REMS Assessment Timetable**

Indivior Inc. must submit REMS Assessments to FDA at 6 months and at 12 months for the first year from the date of initial approval of the REMS (30 August 2010), then annually thereafter. 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 Inc. must submit each assessment so it will be received by the FDA on or before the due date.

## **V. REMS Materials**

The following materials are part of the SUBOXONE and SUBUTEX REMS Program:

### **Training and Education Materials**

Patient:

1. [Medication Guide](http://www.suboxoneREMS.com) (available at [www.suboxoneREMS.com](http://www.suboxoneREMS.com))

### **Patient Care Form**

2. [Appropriate Use Checklist](#)

### **Communication Materials**

3. [Dear Prescriber Letter](#)
4. [Dear Pharmacist Letter](#)
5. [Prescriber Brochure: Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers](#)
6. [Pharmacist Brochure: Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists](#)

### **Other Materials**

7. [SUBOXONE/SUBUTEX REMS Website](http://www.suboxoneREMS.com) ([www.suboxoneREMS.com](http://www.suboxoneREMS.com))