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NDA 22526 Addyi™ (flibanserin)

Serotonin 1A receptor agonist and a Serotonin 2A receptor antagonist

Sprout Pharmaceuticals, Inc.,

a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc.

400 Somerset Corporate Boulevard

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(s)

The goal of the Addyi REMS is to mitigate the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol by:

- Ensuring prescribers and pharmacists are educated about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol and the need to counsel patients about this risk.
- Informing patients of the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

II. ELEMENTS

A. Elements To Assure Safe Use

1. Healthcare providers who prescribe Addyi for outpatient use must be specially certified.
 - a. To become specially certified to prescribe Addyi in the Addyi REMS Program, healthcare providers must:
 - i. Review the Prescribing Information (PI) for Addyi.
 - ii. Review the *Addyi REMS Program Prescriber and Pharmacy Training* and successfully complete the *Addyi REMS Program Knowledge Assessment*.
 - iii. Enroll in the Addyi REMS Program by completing the *Addyi REMS Program Prescriber Enrollment Form*.

- b. As a condition of certification, prescribers must:
 - i. Counsel patients about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol, using the *Addyi REMS Program Patient-Provider Agreement Form*. Maintain the completed *Addyi REMS Program Patient-Provider Agreement Form* in the patient's records and provide the patient with the portion of the *Addyi REMS Program Patient-Provider Agreement* designated for patient receipt.
 - ii. Report any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals.
- c. Sprout Pharmaceuticals must:
 - i. Ensure that healthcare providers who prescribe Addyi for outpatient use are specially certified, in accordance with the requirements described above.
 - ii. Provide all the following mechanisms for healthcare providers to complete the certification process for the Addyi REMS Program: online, by email or by fax.
 - iii. Ensure that healthcare providers are notified when they have been certified in the Addyi REMS Program.
 - iv. Maintain a validated, secure database of healthcare providers who are certified to prescribe Addyi in the Addyi REMS Program.
 - v. Ensure that healthcare providers meet the REMS requirements and de-certify healthcare providers who do not maintain compliance with REMS requirements.
 - vi. Ensure that certified prescribers are provided access to the database of certified pharmacies.
 - vii. Provide the *Addyi REMS Program Prescriber Enrollment Form*, *Addyi REMS Program Prescriber and Pharmacy Training*, *Addyi REMS Program Knowledge Assessment*, and the PI to healthcare providers who (1) attempt to prescribe Addyi and are not yet certified, or (2) inquire about how to become certified.

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

- *Addyi REMS Program Prescriber Enrollment Form*
- *Addyi REMS Program Prescriber and Pharmacy Training*
- *Addyi REMS Program Knowledge Assessment*
- *Addyi REMS Program Website screenshots*
- *Addyi REMS Program Patient-Provider Agreement Form*

2. Pharmacies that dispense Addyi must be specially certified.

- a. To become specially certified to dispense Addyi in the Addyi REMS Program, pharmacies must:
 - i. Designate an authorized representative to complete the enrollment and certification processes by submitting the completed appropriate pharmacy enrollment form on behalf of the pharmacy.

- 1) Outpatient Pharmacy:
 - *Addyi REMS Program Multiple Location Pharmacy Enrollment Form*
 - *Addyi REMS Program Individual Location Pharmacy Enrollment Form*
 - 2) Inpatient Pharmacy: *Addyi REMS Program Inpatient Pharmacy Enrollment Form*
- ii. Ensure that the authorized representative oversees implementation and compliance with the Addyi REMS Program requirements by doing the following:
- 1) Review the *Addyi REMS Program Prescriber and Pharmacy Training* and the PI and successfully complete the *Addyi REMS Program Knowledge Assessment*.
 - 2) Ensure all relevant staff involved in the dispensing of Addyi are trained on the Addyi REMS Program requirements using the *Addyi REMS Program Prescriber and Pharmacy Training* and maintain a record of training.
 - 3) Put processes and procedures in place to ensure that prior to dispensing Addyi, the outpatient pharmacy verifies the prescriber is certified in the Addyi REMS Program and counsels the patient to avoid alcohol use with Addyi.
 - 4) Ensure all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals or MedWatch.
 - 5) Maintain appropriate documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide such documentation upon request to Sprout Pharmaceuticals, FDA, or a designated third party.
 - 6) Comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.
- b. As a condition of certification:
- i. Outpatient pharmacies:
 - 1) Must recertify in the Addyi REMS Program if the pharmacy designates a new authorized representative.
 - 2) A pharmacy that supports electronic communication verification with the Addyi REMS Program system must:
 - a) Ensure the pharmacy enables its pharmacy management system to support communication with the Addyi REMS Program system, using established telecommunication standards, and runs the standardized validation test transaction to validate the system enhancements.
 - b) Dispense Addyi to patients only after obtaining a predispense authorization (PDA) by processing each prescription through its pharmacy management system to electronically verify the prescriber is certified in the Addyi REMS Program.
 - c) Prior to dispensing, counsel patients to avoid alcohol use with Addyi. .

- 3) A pharmacy that does NOT support electronic telecommunication verification with the Addyi REMS Program system must:
 - a) Dispense Addyi to patients only after obtaining authorization by calling the REMS Program Support Center or by accessing the Addyi REMS Program website to verify the prescriber is certified in the Addyi REMS Program.
 - b) Prior to dispensing, counsel patients to avoid alcohol use with Addyi.
- ii. Inpatient Pharmacies must:
 - 1) Recertify in the Addyi REMS Program if the pharmacy designates a new authorized representative.
 - 2) Dispense Addyi only for inpatient use unless the pharmacy is enrolled as an outpatient pharmacy and can comply with the requirements under 2(b)(i).
- c. Sprout Pharmaceuticals must:
 - i. Ensure that pharmacies that dispense Addyi are specially certified, in accordance with the requirements described above.
 - ii. Provide all the following mechanisms for pharmacies to complete the certification process for the Addyi REMS Program: online, by email, or by fax.
 - iii. Ensure that pharmacies are notified when they have been certified by the Addyi REMS Program.
 - iv. Verify every 2 years that the authorized representative's name and contact information corresponds to that of the current designated authorized representative for the certified pharmacy. If different, the pharmacy will be required to re-certify with a new authorized representative.

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

- *Addyi REMS Program Multiple Location Pharmacy Enrollment Form*
- *Addyi REMS Program Individual Location Pharmacy Enrollment Form*
- *Addyi REMS Program Inpatient Pharmacy Enrollment Form*
- *Addyi REMS Program Prescriber and Pharmacy Training*
- *Addyi REMS Program Knowledge Assessment*

B. Implementation System

1. Sprout Pharmaceuticals must ensure that Addyi is only distributed to certified pharmacies by:
 - a. Ensuring that wholesalers/distributors who distribute Addyi comply with the program requirements for wholesalers/distributors. The authorized wholesalers/distributors must:

- i. Put processes and procedures in place to verify, prior to distributing Addyi, that the pharmacy is certified using the validated, secure database provided by the Addyi REMS Program.
 - ii. Train all relevant staff on the Addyi REMS Program requirements.
 - iii. Comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program. In addition, wholesalers/distributors must maintain appropriate documentation and make it available for audits.
 - iv. Provide distribution data to Sprout Pharmaceuticals.
 - b. Ensuring that authorized wholesalers/distributors maintain distribution records of all shipments of Addyi and provide the data to Sprout Pharmaceuticals.
2. Sprout Pharmaceuticals must audit the wholesalers/distributors within 60 calendar days after each wholesaler/distributor is authorized to distribute Addyi in order to ensure that all processes and procedures are in place and functioning to support the requirements of the Addyi REMS Program. Sprout Pharmaceuticals must ensure the authorized wholesalers/distributors meet the REMS requirements and institute corrective action for wholesalers/distributors who do not maintain compliance with the REMS requirements.
 3. Sprout Pharmaceuticals must maintain a validated, secure database of pharmacies that are certified to dispense Addyi in the Addyi REMS Program.
 4. Sprout Pharmaceuticals must maintain records of Addyi distribution and dispensing, certified prescribers, certified pharmacies, and authorized wholesalers/distributors to meet the REMS requirements.
 5. Sprout Pharmaceuticals must ensure that the pharmacies and authorized wholesalers/distributors meet the REMS requirements and will de-certify pharmacies and authorized wholesalers/distributors who do not maintain compliance with the REMS requirements.
 6. Sprout Pharmaceuticals must maintain an Addyi REMS Support Center (1-844-233-9415) and Addyi REMS Program Website (www.AddyiREMS.com). The REMS Program Website must include the capability to complete prescriber and pharmacy certification online, provide pre-dispense authorizations online, and include the option to print the PI, Medication Guide, and Addyi REMS materials. The Addyi product website for consumers and healthcare providers (www.Addyi.com) must include a prominent REMS-specific link to the Addyi REMS Program Website.
 7. Sprout Pharmaceuticals must ensure that within 30 calendar days of approval of the REMS modification the Addyi REMS Program Website (www.AddyiREMS.com) is fully operational and the REMS materials listed in or appended to the Addyi REMS document are available through the Addyi REMS Program Website or by calling the Addyi REMS Support Center.
 8. Sprout Pharmaceuticals must monitor the certified pharmacies to ensure the requirements of the Addyi REMS Program are being met. Sprout Pharmaceuticals must institute corrective action if noncompliance is identified.

9. Sprout Pharmaceuticals must audit 100 certified pharmacies or 1% of certified pharmacies, whichever is greater, within 180 calendar days after the pharmacy places its first order of Addyi to ensure that all processes and procedures are in place and functioning to support the requirements of the Addyi REMS Program. The certified pharmacies will also be included in Sprout Pharmaceuticals' ongoing annual audit plan. Sprout Pharmaceuticals must institute corrective action for certified pharmacies who do not maintain compliance with the REMS requirements.
10. Sprout Pharmaceuticals must take reasonable steps to improve implementation of and compliance with the requirements in the Addyi REMS Program based on monitoring and evaluation of the Addyi REMS Program.

III. Timetable for Submission of Assessments

Sprout Pharmaceuticals must ensure FDA receives REMS assessments 6 months and 12 months from the date of the initial approval of the REMS (August 18, 2015) and annually thereafter on or before the anniversary date of the initial REMS approval. 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 assessment due date.

APPENDIX A: ADDYI REMS PROGRAM PRESCRIBER ENROLLMENT FORM



Addyi™ REMS Program Prescriber Enrollment Form

The Food and Drug Administration has required a Risk Evaluation and Mitigation Strategy (REMS) for Addyi™ (flibanserin) to mitigate the increased risk of hypotension and syncope associated with flibanserin due to an interaction with alcohol. Addyi is only available from prescribers and pharmacies that have been certified through the Addyi REMS Program.

Completing prescriber certification can either be done online at www.AddyiREMS.com or by reviewing a hard copy of the *Addyi REMS Program Prescriber and Pharmacy Training Program*, completing the *Addyi REMS Program Knowledge Assessment*, and submitting this Enrollment Form. If you've received a hard copy of the *Addyi REMS Program Prescriber and Pharmacy Training Program*, successfully completing the prescriber certification process requires you to:

1. Read the Addyi Prescribing Information and *Addyi REMS Program Prescriber and Pharmacy Training Program*.
2. Review your knowledge and successfully complete the *Addyi REMS Program Knowledge Assessment*.
3. Enroll by completing the *Addyi REMS Program Knowledge Assessment* and this one-time *Addyi REMS Program Prescriber Enrollment Form* (all fields must be completed). This may be:
 - a. Faxed to the Addyi REMS Program Support Center at 1-844-694-3373 or
 - b. Scanned and e-mailed to AddyiREMS@AddyiREMS.com

Prescriber Attestations:

1. I understand that Addyi is only available through prescribers and pharmacies that are certified by the Addyi REMS Program and that I must comply with the program requirements to prescribe Addyi.
2. I understand that that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.
3. I have reviewed the Addyi Prescribing Information.
4. I have reviewed the *Addyi REMS Program Prescriber and Pharmacy Training Program* and successfully completed the *Addyi REMS Program Knowledge Assessment*.
5. I will counsel my patients about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol, using the *Addyi REMS Program Patient-Provider Agreement Form*.
6. I will maintain the completed *Addyi REMS Program Patient-Provider Agreement Form* in the patient's records and provide the patient with their portion of the *Patient-Provider Agreement* designated for the patient receipt.
7. I understand that the Addyi REMS Program may contact me via phone, mail, or email to survey me on the effectiveness of the REMS Program requirements.
8. I will report any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals at 1-844-746-5745.

Prescriber's Signature

Date

Print Name

NPI #

DEA#

Please Complete The Following Page



Addyi™ REMS Program Prescriber Enrollment Form

First Name: _____

Last Name: _____

Practice Name: _____

Street Address: _____

City: _____ ST: _____ Zip: _____

Are you a: MD DO PA NP Other _____

Clinical Specialty: Gynecology Family Medicine Internal Medicine Psychiatry Other _____

Practice Setting: Outpatient General Practice Outpatient Specialty Inpatient Specialty Other _____

NPI#: _____ DEA # (optional): _____

Telephone #: _____ Fax #: _____

E-mail: _____ Confirm E-mail: _____

Preferred Method of Communication (please select one): Fax Email

If manually completing, please fax all pages of this form to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com. Ensure your completed Knowledge Assessment and Enrollment Form is provided to the Addyi REMS Program Support Center.

APPENDIX B: ADDYI REMS PROGRAM PRESCRIBER AND PHARMACY TRAINING



Addyi™ REMS Program Prescriber and Pharmacy Training

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

Sprout Pharmaceuticals, Inc.
4208 Six Forks Rd, Suite 1010
Raleigh, NC 27609

Addyi™ REMS Program Overview

- The Food and Drug Administration (FDA) has required a **R**isk **E**valuation and **M**itigation **S**trategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.
- Prescribers and Pharmacies **must be certified** in the Addyi REMS program to prescribe and dispense Addyi.
- Outpatient Pharmacies will only fill an Addyi prescription written by a certified prescriber. This is verified electronically when each Addyi prescription is processed through the pharmacy's computer system or by calling the Addyi REMS Program Support Center.

Addyi™ REMS Program Prescriber and Pharmacy Training

- The information presented in this training program does not include a complete list of all risks and safety information on Addyi.
- Before prescribing or dispensing Addyi, please read the Addyi Prescribing Information and the Addyi Medication Guide available at www.AddyiREMS.com.
- Further information is also available at www.AddyiREMS.com.

Addyi™ REMS Program Certification Process

Complete the Addyi REMS Program Prescriber and Pharmacy Training in 3 easy steps*:

READ

Read the Addyi REMS Program Prescriber and Pharmacy Training and Prescribing Information

REVIEW

Review your knowledge by answering Knowledge Assessment questions

ENROLL

Enroll by completing the enrollment process online or by faxing the appropriate enrollment form

*For online enrollment first sign-up by creating an account and providing all requested contact information

Addyi™ REMS Goal

The goal of the Addyi REMS is to mitigate the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol by:

- Ensuring prescribers and pharmacists are educated about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol and the need to counsel patients about this risk.
- Informing patients of the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

Addyi™ is Indicated for HSDD

- Addyi is indicated for the treatment of premenopausal women with acquired generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
 - A co-existing medical or psychiatric condition,
 - Problems within the relationship, or
 - The effects of a medication or other drug substance.

Limitations of Use

- Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi is not indicated to enhance sexual performance.

Addyi™ and Alcohol: Increased Risk of Hypotension and Syncope

- Dedicated alcohol interaction study with Addyi in 23 men and 2 premenopausal women.
- All subjects were co-administered Addyi 100 mg and the equivalent of two or four glasses of wine* consumed over 10 minutes in the morning.
- Severe hypotension was observed.
- Therapeutic intervention was needed in some cases.
- There were no events requiring therapeutic intervention when Addyi or alcohol was administered alone.

*Each glass of wine containing 12% alcohol content = one can of beer containing 5% alcohol = 1.5 ounce shot of 80-proof spirit in a 70 kg person

Addyi™ and Alcohol: Increased Risk of Hypotension and Syncope

- Four of 23 subjects (17%) co-administered Addyi 100 mg and the equivalent of two glasses of wine had events of hypotension or syncope.
 - Systolic blood pressure reductions from 28 to 54 mmHg
 - Diastolic blood pressure reductions from 24 to 46 mmHg
- Six of the 24 subjects (25%) co-administered Addyi 100 mg and the equivalent of four glasses of wine experienced orthostatic hypotension when standing from a sitting position
 - Systolic blood pressure reductions from 22 to 48 mmHg
 - Diastolic blood pressure reductions from 0 to 27 mmHg

Addyi™ Contraindications

- **Alcohol**
- Moderate or strong CYP3A4 inhibitors
- Hepatic impairment

Addyi™ and Alcohol

- Patients must not take Addyi unless they can abstain from alcohol use for the full duration of treatment.
- Prescribers need to evaluate a patient's ability to abstain from using alcohol.
- Prescribers and Pharmacists must counsel their patients on the increased risk of hypotension and syncope with Addyi due to an interaction with alcohol and the need to abstain from alcohol.
- The **Addyi REMS Patient-Provider Agreement Form** is an important tool for healthcare providers to use with patients.

Addyi™ REMS Program Patient-Provider Agreement

- The **Addyi REMS Program Patient-Provider Agreement Form** must be used to counsel patients upon receiving their initial prescription for Addyi.
- After signing, this form should be kept in the patient's chart.
- The bottom portion can be torn off for the patient to take home.
- **This form may also be used for pharmacy counseling.**

addyi[®]
(flibanserin)

**Addyi™ REMS Program
Patient-Provider Agreement Form**

Healthcare Provider:

- Alcohol use is contraindicated in women taking Addyi™ (flibanserin).
- Addyi and alcohol interact and increase the risk of severe hypotension and syncope.
- I agree to:
 - Use this Patient-Provider Agreement Form to counsel my patients about these risks and the importance of abstaining from alcohol.
 - Sign this form along with my patient and place a copy in her chart.
 - **Tear off** the bottom portion and provide it to my patient to take home for her reference.

Prescriber Signature _____ Date _____

Pharmacist: This form may be used as an optional tool for counseling patients. No charting or signatures are required.

Patient:

I understand that I must not drink alcohol while taking Addyi. Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.
- I understand the instructions that my healthcare provider has given to me.

Patient Signature _____ Date _____

addyi™
(flibanserin) **Addyi™ Patient Information**

I understand that I must not drink alcohol while taking Addyi (flibanserin). Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.

For more information about Addyi please visit www.AddyiREMS.com

©2015 Sprout Pharmaceuticals, Inc. Addyi REMS Patient-Provider Agreement

Patient-Provider Agreement: Patient Information

Patients taking Addyi™ must express an understanding of the following:

- **I understand I must not drink alcohol while taking Addyi (flibanserin).**
- Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).
- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

APPENDIX C: ADDYI REMS PROGRAM KNOWLEDGE ASSESSMENT

Addyi™ REMS Program Knowledge Assessment

Confirm Your Understanding Through Knowledge Assessment (circle your answer)

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment questions.

Why is alcohol contraindicated with Addyi?	a) Hepatotoxicity b) Teratogenicity	c) Hypotension and syncope d) Hypersensitivity
What is the purpose of the Addyi REMS Patient-Provider Agreement Form?	a) For prescribers to counsel patients at the office visit. b) For patient charting	c) For the patient to take home the important safety messages d) For pharmacy counseling e) All of the above
How often must pharmacists counsel patients about the need to avoid alcohol?	a) Never b) Only if the patient asks about alcohol use	c) With the first prescription only d) With every prescription
What is the primary counseling message for the patient?	a) Do not drink alcohol while taking Addyi until you know how alcohol affects you. b) Limit your alcohol use while taking Addyi	c) You must not drink alcohol while taking Addyi d) Do not drink alcohol at night when you take your daily Addyi

First Name:

Last Name:

NPI#

DEA#

 addyi[®]
(flibanserin)

Print this page and complete Knowledge Assessment. This page, along with the appropriate enrollment form will need to be faxed to the Addyi REMS Support Center (1-844-694-3373) or print, scan and e-mail to AddyiREMSEnroll@AddyiREMS.com to complete certification.

APPENDIX D: ADDYI REMS PROGRAM WEBSITE SCREENSHOTS

Addyi REMS Program

Risk Evaluation and Mitigation Strategy

Website Screenshots

V1

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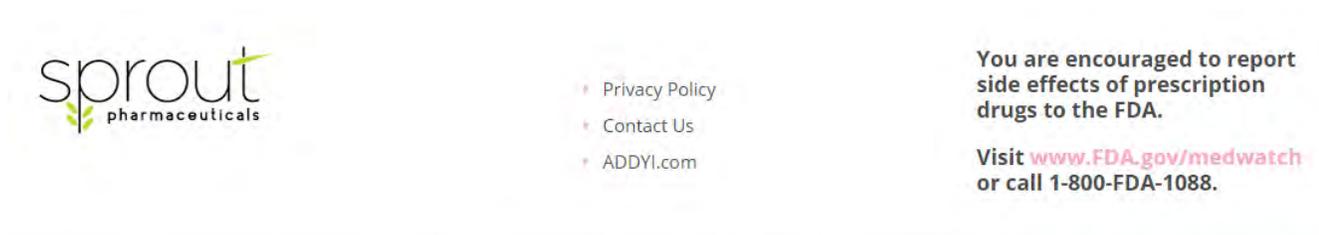
1. Header

1. Header is included on every web page. To reduce the length of the document, the screenshot is included once.



2. Footer

1. Footer is included on every web page. To reduce the length of the document, the screenshot is included once.



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2. Home Page

Prescriber Training, Enrollment, and Certification (3 Easy Steps) Pharmacy Training, Enrollment, and Certification (3 Easy Steps) Addyi Certified Pharmacy Network Log In

Addyi Risk Evaluation and Mitigation Strategy (REMS)

What is the Addyi REMS Program?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the Addyi REMS Program is to inform prescribers, outpatient pharmacies, inpatient pharmacies, and patients about the increased risk of:

- **Hypotension and Syncope** due to an interaction with alcohol

Addyi REMS Program Requirements

Prescribers	Outpatient Pharmacies	Inpatient Pharmacies
<ul style="list-style-type: none">• To be able to prescribe Addyi, prescribers must be trained, successfully complete a knowledge assessment, and enroll to be certified in the Addyi REMS program.• Before prescribing Addyi, prescribers must review and complete the Addyi REMS Patient-Provider Agreement Form with every patient.	<ul style="list-style-type: none">• To be able to dispense Addyi, the Authorized Representative of the outpatient pharmacy must be trained, successfully complete a knowledge assessment, and enroll their pharmacy to be certified in the Addyi REMS program.• To be able to dispense Addyi, outpatient pharmacies must train all relevant pharmacy staff involved in dispensing.• Before dispensing every prescription, pharmacies must counsel all patients on the need to avoid alcohol.	<ul style="list-style-type: none">• To be able to dispense Addyi, the Authorized Representative of the inpatient pharmacy must be trained, successfully complete a knowledge assessment, and enroll their pharmacy to be certified in the Addyi REMS program.• To be able to dispense Addyi, inpatient pharmacies must train all relevant pharmacy staff involved in dispensing.• Inpatient Pharmacies must not dispense Addyi for outpatient use.

Click on the appropriate button below to complete the certification process in 3 easy steps.

PRESCRIBERS

Click Here to Start the Addyi REMS Program Prescriber and Pharmacy Training

START

PHARMACIES

Click Here to Start the Addyi REMS Program Prescriber and Pharmacy Training

START

Indication:

Addyi is indicated for the treatment of premenopausal women with hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:

- A co-existing medical or psychiatric condition.
- Problems within the relationship, or
- The effects of a medication or other drug substance.

Limitations of Use:

- Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi is not indicated to enhance sexual performance.



Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

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Materials for Prescribers

- Addyi REMS Prescriber and Pharmacy Training Program (Including a Knowledge Assessment)
- Addyi REMS Prescriber Enrollment Form
- Addyi REMS Patient-Provider Agreement Form
- Prescribing Information
- Medication Guide

Materials for Pharmacies

- Addyi REMS Prescriber and Pharmacy Training Program (Including a Knowledge Assessment)
- Addyi REMS Program Individual Location Outpatient Pharmacy Enrollment Form
- Addyi REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form
- Addyi REMS Program Inpatient Pharmacy Enrollment Form
- Addyi REMS Program Patient-Provider Agreement Form
- Prescribing Information
- Medication Guide

Materials for Patients

- Addyi REMS Patient-Provider Agreement Form
- Medication Guide

Addyi REMS Program Support Center

Hours of Operation:
8:00 AM to 8:00 PM ET

Email:
help@addyirems.com

Phone:
1-844-233-9415

Fax:
1-844-694-3373

Sprout Customer Service

Phone:
1-844-746-5745

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3. Prescriber Page

Prescriber Training, Enrollment, and Certification (3 Easy Steps) | Pharmacy Training, Enrollment, and Certification (3 Easy Steps) | Addyi Certified Pharmacy Network | Log In

Home » Prescriber Training, Enrollment, and Certification (3 Easy Steps)

Prescriber Training, Enrollment, and Certification (3 Easy Steps)

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi™ (flibanserin) outweigh the increased risk of **hypotension and syncope** due to an interaction with alcohol.

Prescribers and Pharmacies must be certified in the Addyi REMS Program to prescribe and dispense Addyi. For prescribers to successfully become certified they must complete the following 3 easy steps*:

1. **Read** the Addyi REMS Program Prescriber and Pharmacy Training and Prescribing Information.
2. **Review** your knowledge by answering Knowledge Assessment questions.
3. **Enroll** by completing the enrollment process online or by faxing the appropriate enrollment form.

**For online enrollment first sign-up by creating an account and providing all requested contact information*

For prescribers the entire Addyi REMS Program certification process can be completed online or by downloading and following the directions in the Addyi REMS Program Prescriber and Pharmacy Training document, available on this website. You may also call the Addyi REMS Program Support Center (1-844-233-9415) to request that the requisite materials be sent to you.

PRESCRIBERS: CLICK THE BUTTON BELOW TO INITIATE THE ENTIRE ADDYI REMS PROGRAM TRAINING, ENROLLMENT AND CERTIFICATION PROCESS. COMPLETION SHOULD TAKE LESS THAN 10 MINUTES.



PRESCRIBERS
Click Here to Start
ADDYI REMS PROGRAM TRAINING, ENROLLMENT
AND CERTIFICATION PROCESS

 **START**

addyi™
(flibanserin)

Search for a Certified Pharmacy near you
Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Search

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Materials for Prescribers

- Addyi REMS Prescriber and Pharmacy Training Program (Including a Knowledge Assessment)
- Addyi REMS Prescriber Enrollment Form
- Addyi REMS Patient-Provider Agreement Form
- Prescribing Information
- Medication Guide

Materials for Pharmacies

- Addyi REMS Prescriber and Pharmacy Training Program (Including a Knowledge Assessment)
- Addyi REMS Program Individual Location Outpatient Pharmacy Enrollment Form
- Addyi REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form
- Addyi REMS Program Inpatient Pharmacy Enrollment Form
- Addyi REMS Program Patient-Provider Agreement Form
- Prescribing Information
- Medication Guide

Materials for Patients

- Addyi REMS Patient-Provider Agreement Form
- Medication Guide

Addyi REMS Program Support Center

- 🕒 **Hours of Operation:**
8:00 AM to 8:00 PM ET
- ✉ **Email:**
AddyiREMSenroll@AddyiREMS.com
- 📞 **Phone:**
1-844-233-9415
- 📠 **Fax:**
1-844-694-3373

Sprout Customer Service

- 📞 **Phone:**
1-844-746-5745

4. Pharmacy Page

Pharmacy Training, Enrollment, and Certification (3 Easy Steps)

Pharmacy Training, Enrollment, and Certification (3 Easy Steps)

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi™ (flibanserin) outweigh the increased risk of **hypotension and syncope** due to an interaction with alcohol.

Prescribers and Pharmacies must be certified in the Addyi REMS Program to prescribe and dispense Addyi. For pharmacies to successfully become certified they must complete the following 3 easy steps**:

- 1. Read** the Addyi REMS Program Prescriber and Pharmacy Training and the Prescribing Information for Addyi. The Addyi REMS Program Prescriber and Pharmacy Training Program and Prescribing Information are available for download from this website (www.AddyiREMS.com) or they can be requested by calling the Addyi REMS Program Support Center (1-844-233-9415). You can also launch the Addyi REMS Program Prescriber and Pharmacy Training** (including the Knowledge Assessment) and enrollment process by clicking the appropriate button at the bottom of this webpage. (See **Option 1: Online** below for a description of the different pharmacies)
- 2. Review** your knowledge by answering the questions contained within the Addyi REMS Program Knowledge Assessment.
- 3. Enroll** in the Addyi REMS Program by completing the appropriate pharmacy enrollment process. Enrollment can be completed in 2 ways, online or fax.

* For online enrollment first sign-up by creating an account and providing all requested contact information.

Option 1: Online
Click on the appropriate button below to complete the Addyi REMS Program Prescriber and Pharmacy Training, knowledge assessment and enrollment online. Choose the button that best meets your needs.

Individual Location Outpatient Pharmacy Training Program, Certification and Enrollment

This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

[CLICK HERE](#)

Multiple Locations Outpatient Pharmacy Training Program, Certification and Enrollment

This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Clicking this button will take the authorized representative through the entire training, enrollment and certification process.

[CLICK HERE](#)

Inpatient Pharmacy Training Program, Certification and Enrollment

This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

[CLICK HERE](#)

Pharmacy Staff Training Program for all pharmacy staff at Addyi REMS Program Certified Pharmacies.

Clicking on this button will take pharmacy staff through the appropriate training should they wish to take the Addyi REMS Program training online. After completion, pharmacy staff will be able to print a Certificate of Completion which an authorized representative can use as documentation of the training requirements of the Addyi REMS Program.

[CLICK HERE](#)

Option 2: Fax
Complete the appropriate enrollment form located on the right side of this page located under the heading Materials for Pharmacies and the Knowledge Assessment. Please fax all pages of the completed enrollment form and Knowledge Assessment to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to ADDYI@SPROUTPHARMACEUTICALS.COM. You may also call the Addyi REMS Program Support Center (1-844-233-9415) to request the appropriate materials be sent to you.

** Note the training program is also available to pharmacy staff to meet the training requirements of the Addyi REMS Program.



Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

[Search](#)

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Materials for Prescribers

- Addyi REMS Prescriber and Pharmacy Training Program (Including a Knowledge Assessment)
- Addyi REMS Prescriber Enrollment Form
- Addyi REMS Patient-Provider Agreement Form
- Prescribing Information
- Medication Guide

Materials for Pharmacies

- Addyi REMS Prescriber and Pharmacy Training Program (Including a Knowledge Assessment)
- Addyi REMS Program Individual Location Outpatient Pharmacy Enrollment Form
- Addyi REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form
- Addyi REMS Program Inpatient Pharmacy Enrollment Form
- Addyi REMS Program Patient-Provider Agreement Form
- Prescribing Information
- Medication Guide

Materials for Patients

- Addyi REMS Patient-Provider Agreement Form
- Medication Guide

Addyi REMS Program Support Center

- 🕒 **Hours of Operation:** 8:00 AM to 5:00 PM ET
- ✉ **Email:** ADDYI@SPROUTPHARMACEUTICALS.COM
- ☎ **Phone:** 1-844-233-9415
- 📠 **Fax:** 1-844-694-3373

Sprout Customer Service

- ☎ **Phone:** 1-844-746-5745

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5. Certified Network Page

Prescriber Training, Enrollment, and Certification (3 Easy Steps) Pharmacy Training, Enrollment, and Certification (3 Easy Steps) **Addyi Certified Pharmacy Network** Log In

[Home](#) » Addyi Certified Network

Addyi Certified Network

Addyi Certified Pharmacy Network

Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Search

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Addyi REMS Website

6. Create an Account Page

Prescriber Training, Enrollment, and Certification (3 Easy Steps) Pharmacy Training, Enrollment, and Certification (3 Easy Steps) Addyi Certified Pharmacy Network Log In

Home » Create Account

Create an Account

To create your web account for the Addyi™ (flibanserin) REMS Program, please complete the fields below. The Username you specify must be unique within the Addyi REMS Program website. All fields are required unless otherwise indicated.

First Name	Last Name
<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>
Email Address	
<input type="text" value="Email Address"/> 	
Certification ID	<i>Enter your certification ID if you have enrolled via fax or email. If you do not currently have a certification ID, one will be provided upon receipt of your enrollment confirmation.</i>
<input type="text" value="Certification ID"/>	
Username	<input type="button" value="Suggest Username"/> <input type="button" value="Check Username Availability"/>
<input type="text" value="Username"/>	<input type="checkbox"/> Use Email Address as Username
Password	Confirm Password
<input type="text" value="Password"/>	<input type="text" value="Confirm Password"/>

7. Stakeholder Identification Page

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- Prescriber** - This is for individuals prescribing Addyi to their patients.
- Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

Next

8. Stakeholder Identification Confirmation Message – Prescriber

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- Prescriber** - This is for individuals prescribing Addyi to their patients.
- Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

You have selected *Prescriber*. If this is correct, please choose **Next** to continue.

Next

9. Stakeholder Identification Confirmation Message – Individual Location Outpatient Pharmacy

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- Prescriber** - This is for individuals prescribing Addyi to their patients.
- Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

You have selected *Individual Location Outpatient Pharmacy*. If this is correct, please choose **Next** to continue.

Next

10. Stakeholder Identification Confirmation Message – Multiple Locations Outpatient Pharmacy

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- Prescriber** - This is for individuals prescribing Addyi to their patients.
- Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

You have selected *Multiple Locations Outpatient Pharmacy*. If this is correct, please choose **Next** to continue.

Next

11. Stakeholder Identification Confirmation Message – Inpatient Pharmacy

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- Prescriber** - This is for individuals prescribing Addyi to their patients.
- Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

You have selected *Inpatient Pharmacy*. If this is correct, please choose **Next** to continue.

Next

12. Stakeholder Identification Confirmation Message – Pharmacy Staff

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- Prescriber** - This is for individuals prescribing Addyi to their patients.
- Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

This selection enables the healthcare professional to view the Addyi REMS Program Prescriber and Pharmacy Training. This training allows you to complete the Knowledge Assessment. If this is correct, please choose **Next** to continue.

Next

13. Prescriber Intake Page

Prescriber Training, Enrollment, and Certification (3 Easy Steps)	Pharmacy Training, Enrollment, and Certification (3 Easy Steps)	Addyi Certified Pharmacy Network
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Dilasha Hudson | [Log out](#)
[Change Password](#)

[Home](#) » Addyi REMS Program Prescriber Information Intake Form

Addyi REMS Program Prescriber Information Intake Form

Complete All Fields Below

First Name	<input type="text"/>	Last Name	<input type="text"/>
Telephone Number	<input type="text"/>	Fax Number	<input type="text"/>
Email	<input type="text" value=""/>	Preferred Method of Contact	<input type="checkbox"/> Fax <input type="checkbox"/> Email
NPI	<input type="text"/>	DEA	<input type="text"/>

Professional Designation	Your Clinical Specialty	Practice Setting:
<input type="radio"/> MD <input type="radio"/> DO <input type="radio"/> PA	<input type="radio"/> Gynecology <input type="radio"/> Internal Medicine	<input type="radio"/> Outpatient General Practice
<input type="radio"/> NP <input type="radio"/> Other	<input type="radio"/> Family Medicine <input type="radio"/> Psychiatry	<input type="radio"/> Outpatient Specialty
	<input type="radio"/> Other	<input type="radio"/> Inpatient Specialty <input type="radio"/> Other

Name of Practice/Clinic

Address

City	State	Zip Code
<input type="text"/>	<input type="text"/>	<input type="text"/>

[Submit to Continue to Addyi REMS Program Prescriber and Pharmacy Training](#)

14. Individual Location Outpatient Pharmacy Intake Form

[Home](#) » Addyi REMS Program Individual Location Outpatient Pharmacy Information Intake Form (for Authorized Representative)

Addyi REMS Program Individual Location Outpatient Pharmacy Information Intake Form (for Authorized Representative)

Complete All Fields Below

First Name	Last Name	
<input type="text"/>	<input type="text"/>	
Email	Phone Number	Fax Number
<input type="text" value=""/>	<input type="text"/>	<input type="text"/>
Title	Your Profession	Preferred Method of Contact
<input type="text"/>	<input type="radio"/> R.Ph. <input type="radio"/> PharmD <input type="radio"/> Tech <input type="radio"/> Other	<input type="checkbox"/> Fax <input type="checkbox"/> Email
NPI	NCPDP	DEA
<input type="text"/>	<input type="text"/>	<input type="text"/>
Pharmacy Name	Pharmacy Store # (optional)	
<input type="text"/>	<input type="text"/>	
Address 1		
<input type="text"/>		
Address 2		
<input type="text"/>		
City	State	Zip Code
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="button" value="Submit to Proceed to Addyi REMS Program Prescriber and Pharmacy Training"/>		

15. Multiple Locations Outpatient Pharmacy Intake Form

[Home](#) » Addyi REMS Program Multiple Locations Outpatient Pharmacy Information Intake Form (for Authorized Representative)

Addyi REMS Program Multiple Locations Outpatient Pharmacy Information Intake Form (for Authorized Representative)

Complete All Fields Below

First Name	Last Name	
<input type="text"/>	<input type="text"/>	
Email	Phone Number	Fax Number
<input type="text" value=""/>	<input type="text"/>	<input type="text"/>
Title	Your Profession	Preferred Method of Contact
<input type="text"/>	<input type="radio"/> R.Ph. <input type="radio"/> PharmD <input type="radio"/> Tech <input type="radio"/> Other	<input type="checkbox"/> Fax <input type="checkbox"/> Email
Pharmacy Name		
<input type="text"/>		
Address 1		
<input type="text"/>		
Address 2		
<input type="text"/>		
City	State	Zip Code
<input type="text"/>	<input type="text"/>	<input type="text"/>

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16. Inpatient Pharmacy Intake Form

[Home](#) » Addyi REMS Program Inpatient Pharmacy Information Intake Form

Addyi REMS Program Inpatient Pharmacy Information Intake Form

Complete All Fields Below

First Name

John

Last Name

Doe

Email

john@gmail.com 

Phone Number

Telephone Number

Fax Number

Fax Number

Your Profession

R.Ph. PharmD Tech Other

Preferred Method of Contact

Email Fax

NPI

NPI

Pharmacy License Number

Pharmacy License Number

DEA

DEA

Facility Name

Facility Name

Address 1

Address

Address 2

Address 2

City

City

State

State

Zip Code

Zip Code

[Submit to Proceed to Addyi REMS Program Pharmacy Training](#)

Home » Addyi REMS Program Prescriber and Pharmacy Training

Addyi REMS Program Prescriber and Pharmacy Training

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Addyi™ REMS Program Prescriber and Pharmacy Training

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

Sprout Pharmaceuticals, Inc.
4208 Six Forks Rd, Suite 1010
Raleigh, NC 27609

18. Education Page 2

Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ REMS Program Overview

- The Food and Drug Administration (FDA) has required a **R**isk **E**valuation and **M**itigation **S**trategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.
- Prescribers and Pharmacies **must be certified** in the Addyi REMS program to prescribe and dispense Addyi.
- Outpatient Pharmacies will only fill an Addyi prescription written by a certified prescriber. This is verified electronically when each Addyi prescription is processed through the pharmacy's computer system or by calling the Addyi REMS Program Support Center.


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19. Education Page 3

Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ REMS Program Prescriber and Pharmacy Training

- The information presented in this training program does not include a complete list of all risks and safety information on Addyi.
- Before prescribing or dispensing Addyi, please read the Addyi Prescribing Information and the Addyi Medication Guide available at www.AddyiREMS.com.
- Further information is also available at www.AddyiREMS.com.

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HOME » Addyi REMS Program Prescriber and Pharmacy Training

Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ REMS Program Certification Process

Complete the Addyi REMS Program Prescriber and Pharmacy Training in 3 easy steps*:

READ

Read the Addyi REMS Program Prescriber and Pharmacy Training and Prescribing Information

REVIEW

Review your knowledge by answering Knowledge Assessment questions

ENROLL

Enroll by completing the enrollment process online or by faxing the appropriate enrollment form

*For online enrollment first sign-up by creating an account and providing all requested contact information

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(flibanserin)

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21. Education Page 5

Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ REMS Goal

The goal of the Addyi REMS is to mitigate the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol by:

- Ensuring prescribers and pharmacists are educated about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol and the need to counsel patients about this risk.
- Informing patients of the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

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22. Education Page 6

Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ is Indicated for HSDD



- Addyi is indicated for the treatment of premenopausal women with acquired generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
 - A co-existing medical or psychiatric condition,
 - Problems within the relationship, or
 - The effects of a medication or other drug substance.

Limitations of Use

- Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi is not indicated to enhance sexual performance.


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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ and Alcohol: Increased Risk of Hypotension and Syncope

- Dedicated alcohol interaction study with Addyi in 23 men and 2 premenopausal women.
- All subjects were co-administered Addyi 100 mg and the equivalent of two or four glasses of wine* consumed over 10 minutes in the morning.
- Severe hypotension was observed.
- Therapeutic intervention was needed in some cases.
- There were no events requiring therapeutic intervention when Addyi or alcohol was administered alone.

*Each glass of wine containing 12% alcohol content = one can of beer containing 5% alcohol = 1.5 ounce shot of 80-proof spirit in a 70 kg person

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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ and Alcohol: Increased Risk of Hypotension and Syncope

- Four of 23 subjects (17%) co-administered Addyi 100 mg and the equivalent of two glasses of wine had events of hypotension or syncope.
 - Systolic blood pressure reductions from 28 to 54 mmHg
 - Diastolic blood pressure reductions from 24 to 46 mmHg
- Six of the 24 subjects (25%) co-administered Addyi 100 mg and the equivalent of four glasses of wine experienced orthostatic hypotension when standing from a sitting position
 - Systolic blood pressure reductions from 22 to 48 mmHg
 - Diastolic blood pressure reductions from 0 to 27 mmHg

 
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Prescriber Training, Enrollment, and Certification (3 Easy Steps) Pharmacy Training, Enrollment, and Certification (3 Easy Steps) Addyi Certified Pharmacy Network

John Doe | [Log out](#)
[Forgot Password](#)

[Home](#) » Addyi REMS Program Prescriber and Pharmacy Training

Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ Contraindications

- **Alcohol**
- Moderate or strong CYP3A4 inhibitors
- Hepatic impairment

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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ and Alcohol



- Patients must not take Addyi unless they can abstain from alcohol use for the full duration of treatment.
- Prescribers need to evaluate a patient's ability to abstain from using alcohol.
- Prescribers and Pharmacists must counsel their patients on the increased risk of hypotension and syncope with Addyi due to an interaction with alcohol and the need to abstain from alcohol.
- The **Addyi REMS Program Patient-Provider Agreement Form** is an important tool for healthcare providers to use with patients.


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Addyi REMS Program Prescriber and Pharmacy Training

Addyi™ REMS Program Patient-Provider Agreement

- The **Addyi REMS Program Patient-Provider Agreement Form** must be used to counsel patients upon receiving their initial prescription for Addyi.
- After signing, this form should be kept in the patient's chart.
- The bottom portion can be torn off for the patient to take home.
- **This form may also be used for pharmacy counseling.**

Addyi™ REMS Program Patient-Provider Agreement Form

Healthcare Provider:

- Alcohol use is contraindicated in women taking Addyi™ (flibanserin)
- Addyi and alcohol interact and increase the risk of severe hypotension and syncope
- I agree to:
 - Use this Patient-Provider Agreement Form to counsel my patients about the risks and the importance of abstaining from alcohol.
 - Sign this form along with my patient and place a copy in the chart.

Tear off the bottom portion and provide it to my patient to take home for her reference.

Provider Signature _____ Date _____

Pharmacist: This form may be used as an optional tool for counseling patients. No charting or signatures are required.

Patient:

I understand that I must not drink alcohol while taking Addyi. Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I have side effects (nausea), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.
- I understand the instructions that my healthcare provider has given to me.

Patient Signature _____ Date _____

addyi™ (flibanserin) Addyi™ Patient Information

I understand that I must not drink alcohol while taking Addyi (flibanserin). Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I have side effects (nausea), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.

For more information about Addyi please visit www.AddyiREMS.com

©2015 Sprout Pharmaceuticals, Inc. Addyi REMS Patient-Provider Agreement



Addyi REMS Program Prescriber and Pharmacy Training

Patient-Provider Agreement: Patient Information

Patients taking Addyi™ must express an understanding of the following:

- **I understand I must not drink alcohol while taking Addyi (flibanserin).**
- Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).
- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.

addyi[™]
(flibanserin)

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12

Addyi REMS Program Prescriber and Pharmacy Training

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

Take the Knowledge Assessment



30. Knowledge Assessment Landing Page

Prescriber Training, Enrollment, and Certification (3 Easy Steps) Pharmacy Training, Enrollment, and Certification (3 Easy Steps) Addyi Certified Pharmacy Network

John Doe | (Account) (Logout) (Settings)

Home » Addyi REMS Program Prescriber and Pharmacy Training

Addyi REMS Program Prescriber and Pharmacy Training

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

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(flibanserin)

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31. Knowledge Assessment

Prescriber Training, Enrollment, and Certification (3 Easy Steps) Pharmacy Training, Enrollment, and Certification (3 Easy Steps) Addyi Certified Pharmacy Network Log In

• Addyi REMS Program Knowledge Assessment

Addyi REMS Program Knowledge Assessment

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment questions.

1. Why is alcohol contraindicated with Addyi?

- Hepatotoxicity
- Teratogenicity
- Hypotension and syncope
- Hypersensitivity

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

- For prescribers to counsel patients at the office visit
- For patient charting
- For the patient to take home the important safety messages
- For pharmacy counseling
- All of the above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

- Never
- Only if the patient asks about alcohol use
- With the first prescription only
- With every prescription

4. What is the primary counseling message for the patient?

- Do not drink alcohol while taking Addyi until you know how alcohol affects you
- Limit your alcohol use while taking Addyi
- You must not drink alcohol while taking Addyi
- Do not drink alcohol at night when you take your daily Addyi

[Click to Submit and Continue Enrollment](#)

32. Knowledge Assessment – Success Page for Prescriber

Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

John Doe | [Logout](#)
[Change Password](#)

[Home](#) » Addyi REMS Program Knowledge Assessment

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 4 out of 4 correct.

[PROCEED TO PRESCRIBER ATTESTATION](#)

1. Why is alcohol contraindicated with Addyi?

Answer Provided: Hypotension and syncope

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

Answer Provided: With every prescription

4. What is the primary counseling message for the patient?

Answer Provided: You must not drink alcohol while taking Addyi

33. Knowledge Assessment – Success Page for Individual Location Outpatient Pharmacy

Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

John Doe | [Log out](#)
[Change Password](#)

[Home](#) » Addyi REMS Program Knowledge Assessment

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 4 out of 4 correct.

[PROCEED TO INDIVIDUAL LOCATION OUTPATIENT PHARMACY ATTESTATIONS](#)

1. Why is alcohol contraindicated with Addyi?

Answer Provided: Hypotension and syncope

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

Answer Provided: With every prescription

4. What is the primary counseling message for the patient?

Answer Provided: You must not drink alcohol while taking Addyi

34. Knowledge Assessment – Success Page for Multiple Locations Outpatient Pharmacy

Prescriber Training, Enrollment, and Certification (3 Easy Steps)

Pharmacy Training, Enrollment, and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

John Doe | [Log out](#)
[Change Password](#)

[Home](#) » Addyi REMS Program Knowledge Assessment

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 4 out of 4 correct.

[PROCEED TO MULTIPLE LOCATIONS OUTPATIENT PHARMACY ATTESTATIONS](#)

1. Why is alcohol contraindicated with Addyi?

Answer Provided: Hypotension and syncope

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

Answer Provided: With every prescription

4. What is the primary counseling message for the patient?

Answer Provided: You must not drink alcohol while taking Addyi

35. Knowledge Assessment – Success Page for Inpatient Pharmacy

[Home](#) » Addyi REMS Program Knowledge Assessment

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 4 out of 4 correct.

[PROCEED TO INPATIENT PHARMACY ATTESTATIONS](#)

1. Why is alcohol contraindicated with Addyi?

Answer Provided: Hypotension and syncope

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

Answer Provided: With every prescription

4. What is the primary counseling message for the patient?

Answer Provided: You must not drink alcohol while taking Addyi

36. Knowledge Assessment – Success Page for Pharmacy Staff

Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

John Doe | [Log out](#)
[Change Password](#)

[Home](#) » Addyi REMS Program Knowledge Assessment

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 4 out of 4 correct.

[CLICK TO COMPLETE TRAINING](#)

1. Why is alcohol contraindicated with Addyi?

Answer Provided: Hypotension and syncope

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

Answer Provided: With every prescription

4. What is the primary counseling message for the patient?

Answer Provided: You must not drink alcohol while taking Addyi

37. Knowledge Assessment – Failure Attempt Page

[Home](#) » Addyi REMS Program Knowledge Assessment

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 3 out of 4 correct.

[RESTART TRAINING](#)

[RETAKE KNOWLEDGE ASSESSMENT](#)

Incorrect Result(s) Below:

1. Why is alcohol contraindicated with Addyi?

Answer Provided: Hypersensitivity

Correct Result(s) Below:

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?

Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?

Answer Provided: With every prescription

4. What is the primary counseling message for the patient?

Answer Provided: You must not drink alcohol while taking Addyi

38. Prescriber Attestation

Prescriber Training, Enrollment, and Certification (3 Easy Steps)	Pharmacy Training, Enrollment, and Certification (3 Easy Steps)	Addyi Certified Pharmacy Network
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John Doe | [Logout](#)
[Change Password](#)

[Home](#) » [Prescriber Attestations](#)

Prescriber Attestations

Please click to attest to each of the following statements:

Please click to attest to each of the following statements:

	Attest
I understand that Addyi is only available through prescribers and pharmacies that are certified by the Addyi REMS Program and that I must comply with the program requirements to prescribe Addyi.	<input type="radio"/>
I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.	<input type="radio"/>
I have reviewed the Addyi Prescribing Information.	<input type="radio"/>
I have reviewed the Addyi REMS Program Prescriber and Pharmacy Training and successfully completed the Addyi REMS Program Knowledge Assessment.	<input type="radio"/>
I will counsel my patients about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol, using the Addyi REMS Program Patient-Provider Agreement Form.	<input type="radio"/>
I will maintain the completed Addyi REMS Program Patient-Provider Agreement Form in the patient's records and provide the patient with their portion of the Patient-Provider Agreement designated for the patient receipt.	<input type="radio"/>
I understand that the Addyi REMS Program may contact me via phone, mail, or email to survey me on the effectiveness of the REMS Program requirements.	<input type="radio"/>
I will report any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals at 1-844-233-9415.	<input type="radio"/>

[Submit Attestations](#)

39. Individual Location Outpatient Pharmacy Attestation

Individual Location Outpatient Pharmacy Attestations (for Authorized Representative)

Please click to attest to each of the following statements:

	Attest
1. I have reviewed the Addyi REMS Program Prescriber and Pharmacy Training, the Addyi Medication Guide, and the Prescribing Information; and successfully completed the Addyi REMS Program Knowledge Assessment.	<input type="radio"/>
2. I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.	<input type="radio"/>
3. My certified pharmacy must complete training of pharmacists and staff involved with the dispensing of Addyi using the Addyi REMS Program Prescriber and Pharmacy Training and must comply with the REMS requirements. This training will be documented and is subject to audit.	<input type="radio"/>
4. I will ensure my certified pharmacy counsels patients to abstain from alcohol use with Addyi prior to dispensing.	<input type="radio"/>
5. My certified pharmacy will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.	<input type="radio"/>
6. I will ensure that all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope where an interaction with alcohol cannot be ruled out to either Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).	<input type="radio"/>
7. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative to maintain certification to order and dispense Addyi.	<input type="radio"/>
8. I will maintain such documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.	<input type="radio"/>
9. I will comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.	<input type="radio"/>
10. I understand Addyi REMS Program personnel may contact pharmacists at certified outpatient pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.	<input type="radio"/>
11. I will oversee compliance with the Addyi REMS Program requirements.	<input type="radio"/>
12. I understand that my certified outpatient pharmacy must verify the prescriber is certified in the Addyi REMS Program prior to dispensing Addyi and will ensure verification through the following option (Click either Option A or B and indicate the NCPDP# as noted on the next page).	<input type="radio"/>

[Click to Submit Attestations and Select Your Verification Option](#)

40. Multiple Locations Outpatient Pharmacy Attestation

Multiple Locations Outpatient Pharmacy Attestations (for Authorized Representative)

Please click to attest to each of the following statements:

Attest

- 1. I have reviewed the Addyi REMS Program Prescriber and Pharmacy Training Program, the Addyi Medication Guide, and the Prescribing Information and have successfully completed the Addyi REMS Program Knowledge Assessment.
- 2. I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.
- 3. I will establish processes and procedures for all my certified outpatient pharmacy dispensing locations to ensure compliance with the requirements of the Addyi REMS Program before dispensing Addyi, including the following: (A) All certified outpatient pharmacy dispensing locations will complete training of pharmacists and staff involved with the dispensing of Addyi using the Addyi REMS Program Prescriber and Pharmacy Training Program and will comply with the REMS requirements. This training will be documented and is subject to audit. (B) All certified outpatient pharmacy dispensing locations will verify the prescriber is certified in the Addyi REMS Program prior to dispensing Addyi. (C) All certified outpatient dispensing locations will counsel patients prior to dispensing the drug to abstain from alcohol consumption while undergoing treatment with Addyi. (D) All certified outpatient pharmacy dispensing locations will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.
- 4. I will ensure that all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope where an interaction with alcohol cannot be ruled out to either Sprout Pharmaceuticals (1-844-746- 5745) or MedWatch (1-800-FDA-1088).
- 5. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative to maintain certification to order and dispense Addyi.
- 6. I will maintain such documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.
- 7. I will comply with the audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.
- 8. I understand Addyi REMS Program personnel may contact pharmacists at certified outpatient pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.
- 9. I will oversee compliance with the Addyi REMS Program requirements.
- 10. I will ensure the following Pharmacy Management System requirements will be in place for all certified outpatient pharmacy dispensing locations. (A) The Pharmacy Management System configuration and/or updates will be in place and verified with the Addyi REMS Program Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements. (B) The Pharmacy Management System configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol consumption with every dispensed prescription. (C) The Pharmacy Management System configuration must process all Addyi prescriptions, regardless of the method of payment, through our pharmacy management system and "pharmacy claims routing switch" for Addyi REMS verification of prescriber certification prior to dispensing every prescription.
- 11. Proper authorization or provision of data rights to my switch provider are in place to meet Addyi REMS Program requirements.

Complete Addyi REMS Program Prescriber and Pharmacy Training

41. Inpatient Pharmacy Attestation

Prescriber Training, Enrollment, and Certification (3 Easy Steps) Pharmacy Training, Enrollment, and Certification (3 Easy Steps) Addyi Certified Pharmacy Network

John Doe | [Logout](#)
[Change Password](#)

[Home](#) » Inpatient Pharmacy Attestations

Inpatient Pharmacy Attestations (for Authorized Representative)

Please click to attest to each of the following statements:

	Attest
I have read the Addyi REMS Program Prescriber and Pharmacy Training, the Addyi Medication Guide and the full Prescribing Information and have successfully completed the Addyi REMS Program Knowledge Assessment.	<input type="radio"/>
I understand that there is an increased risk of syncope and hypotension associated with Addyi due to an interaction with alcohol.	<input type="radio"/>
I will ensure that my inpatient pharmacy does not dispense Addyi for outpatient use.	<input type="radio"/>
I understand that pharmacies within or associated with my healthcare facility that dispense drugs to outpatients must be separately certified as a certified outpatient pharmacy and comply with the Addyi REMS Program requirements to dispense Addyi to outpatients.	<input type="radio"/>
I understand that a prescriber who wants to discharge a patient with an Addyi prescription, intended to be dispensed by an outpatient pharmacy, will be required to enroll in the Addyi REMS Program.	<input type="radio"/>
My certified pharmacy will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.	<input type="radio"/>
I will ensure all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).	<input type="radio"/>
I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative.	<input type="radio"/>
I will maintain such documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.	<input type="radio"/>
I will comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.	<input type="radio"/>
I understand Addyi REMS Program personnel may contact pharmacists at certified inpatient hospital pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.	<input type="radio"/>
I will oversee compliance with the Addyi REMS Program requirements.	<input type="radio"/>

[Submit Attestations](#)

42. Individual Location Outpatient Pharmacy Verification Options

Prescriber Training, Enrollment, and Certification (3 Easy Steps)	Pharmacy Training, Enrollment, and Certification (3 Easy Steps)	Addyi Certified Pharmacy Network
John Doe Log out Change Password		
Select the option that best matches your Pharmacy Management System (A or B)		
OPTION A <input type="radio"/>	OPTION B <input type="radio"/>	
<input type="text" value="0113388"/>	<input type="text" value="0113388"/>	
My pharmacy utilizes a Pharmacy Management System (PMS) to transmit prescriptions electronically and will utilize this technology to verify prescriber certification.	My pharmacy <u>does not</u> utilize a Pharmacy Management System (PMS) to transmit prescriptions electronically and will verify prescriber certification through the Addyi REMS Program website or the Addyi REMS Program Support Center.	
I will ensure the following Pharmacy Management System requirements will be in place for my pharmacy.		
<ol style="list-style-type: none">1. The pharmacy management system configuration and/or updates will be in place and verified with the Addyi REMS Program Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements.2. The pharmacy management system configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol with every dispensed prescription.3. The pharmacy management system configuration must process all Addyi prescriptions, regardless of the method of payment, through the pharmacy management system and "pharmacy routing switch" for Addyi REMS verification of prescriber certification prior to dispensing every prescription.4. I acknowledge that prior to Addyi REMS pharmacy certification, the Addyi REMS Program Support Center will contact me if an agreement is needed to permit the switch provider to use prescription data from this pharmacy to conduct the REMS.	I will ensure my pharmacy staff will access the Addyi REMS Program website at www.AddyiREMS.com or call the Addyi REMS Program Support Center (1-844-233-9415) to confirm the authorizing prescriber is certified (as outlined in attestation 12) before dispensing each Addyi prescription. A complete authorization requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber's NPI or DEA.	
Complete Addyi REMS Program Prescriber and Pharmacy Training		

43. Individual Location Outpatient Pharmacy Verification Options – With Option Selected

Prescriber Training, Enrollment, and Certification (3 Easy Steps)	Pharmacy Training, Enrollment, and Certification (3 Easy Steps)	Addyi Certified Pharmacy Network
John Doe Log out Change Password		
Select the option that best matches your Pharmacy Management System (A or B)		
OPTION A <input checked="" type="radio"/>	OPTION B <input type="radio"/>	
<input type="text" value="0113388"/>	<input type="text" value="0113388"/>	
<p>My pharmacy utilizes a Pharmacy Management System (PMS) to transmit prescriptions electronically and will utilize this technology to verify prescriber certification.</p> <p>I will ensure the following Pharmacy Management System requirements will be in place for my pharmacy.</p> <ol style="list-style-type: none">1. The pharmacy management system configuration and/or updates will be in place and verified with the Addyi REMS Program Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements.2. The pharmacy management system configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol with every dispensed prescription.3. The pharmacy management system configuration must process all Addyi prescriptions, regardless of the method of payment, through the pharmacy management system and "pharmacy routing switch" for Addyi REMS verification of prescriber certification prior to dispensing every prescription.4. I acknowledge that prior to Addyi REMS pharmacy certification, the Addyi REMS Program Support Center will contact me if an agreement is needed to permit the switch provider to use prescription data from this pharmacy to conduct the REMS.	<p>My pharmacy <u>does not</u> utilize a Pharmacy Management System (PMS) to transmit prescriptions electronically and will verify prescriber certification through the Addyi REMS Program website or the Addyi REMS Program Support Center.</p> <p>I will ensure my pharmacy staff will access the Addyi REMS Program website at www.AddyiREMS.com or call the Addyi REMS Program Support Center (1-844-233-9415) to confirm the authorizing prescriber is certified (as outlined in attestation 12) before dispensing each Addyi prescription. A complete authorization requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber's NPI or DEA.</p>	
Complete Addyi REMS Program Prescriber and Pharmacy Training		

44. Prescriber Enrollment Confirmation

Prescriber Training, Enrollment, and Certification (3 Easy Steps) Pharmacy Training, Enrollment, and Certification (3 Easy Steps) Addyi Certified Pharmacy Network

John Doe | [Log out](#)
[Change Password](#)

[Home](#) » Addyi REMS Program Prescriber and Pharmacy Training Certification

Addyi REMS Program Prescriber and Pharmacy Training, Enrollment and Certification Complete.



Congratulations!

You've completed the certification process.

Thank you for completing the
Addyi REMS Program certification process!

Certification ID: PR50766683184

Addyi REMS Program Support Center
1-844-233-9415

[Return to Addyi Rems Home](#)

45. Individual Location Outpatient Pharmacy Enrollment Confirmation

Prescriber Training, Enrollment,
and Certification (3 Easy Steps)

Pharmacy Training, Enrollment,
and Certification (3 Easy Steps)

Addyi Certified Pharmacy Network

John Doe | [Log out](#)
[Change Password](#)

Addyi REMS Program Prescriber and Pharmacy Training, Enrollment and Certification Complete.



Congratulations!

**You've completed the certification
process. Please see the directions below
for the remaining steps.**

Once your submission is successfully processed, you will receive a fax or e-mail with instructions on how to submit test transaction(s) to the Addyi REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Addyi REMS Program. Upon successful verification of connectivity, you will be provided with the Terms & Conditions to become certified. Once this process is complete your pharmacy will receive a confirmation from the Addyi REMS Support Center and you will be considered certified and permitted to order, receive, and dispense Addyi.

Certification ID: PHY0766682260

**If you have any questions or require additional information, please
contact the Addyi REMS Program Support Center at 1-844-233-9415.**

[Return to Addyi REMS Home](#)

46. Multiple Location Outpatient Pharmacy Enrollment Confirmation

Prescriber Training, Enrollment, and Certification (3 Easy Steps)	Pharmacy Training, Enrollment, and Certification (3 Easy Steps)	Addyi Certified Pharmacy Network
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John Doe | [Log out](#)
[Change Password](#)

[Home](#) » Addyi REMS Program Prescriber and Pharmacy Training Certification

Addyi REMS Program Prescriber and Pharmacy Training, Enrollment and Certification Complete.



Congratulations!

You've completed the certification process.

Upon receipt of all enrollment materials, you will receive a fax or email with instructions on how to submit test transaction(s) to the Addyi REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Addyi REMS Program. After successful completion of test transaction(s) you will receive a multiple pharmacy enrollment confirmation via fax and/or email from the Addyi REMS Support Center. Your multiple pharmacy entity will be considered certified and your retail chain dispensing locations will be eligible to complete their certification procedures.

Certification ID: CHQ0766683376

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415.

[Return to Addyi Rems Home](#)

47. Inpatient Pharmacy Enrollment Confirmation

Prescriber Training, Enrollment, and Certification (3 Easy Steps)	Pharmacy Training, Enrollment, and Certification (3 Easy Steps)	Addyi Certified Pharmacy Network
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John Doe | [Logout](#)
[Change Password](#)

[Home](#) » Addyi REMS Program Prescriber and Pharmacy Training Certification

**Addyi REMS Program
Prescriber and Pharmacy
Training, Enrollment and
Certification Complete.**



Congratulations!

You've completed the certification process.

Upon receipt the Addyi REMS Program Support Center will contact you to complete the certification process.

Certification ID: IHF0766681447

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415 or visit www.AddyiREMS.com.

[Return to Addyi Rems Home](#)

48. Pharmacy Staff Enrollment Confirmation

Prescriber Training, Enrollment, and Certification (3 Easy Steps) | Pharmacy Training, Enrollment, and Certification (3 Easy Steps) | Addyi Certified Pharmacy Network

John Doe | [Log out](#)
[Change Password](#)

Addyi REMS Program Prescriber and Pharmacy Training, Enrollment and Certification Complete.



John Doe
03/10/2016

Congratulations!
You've completed the Addyi REMS Program
Prescriber and Pharmacy Training and
Knowledge Assessment.

[Click here to print](#)

[Return to Addyi Rems Home](#)

49. Pre-dispensing Authorization Intake

» Predispense Authorization

Predispense Authorization

To determine if the safe use conditions have been met for your patient to receive Addyi, please complete the Predispense Authorization Information below and Submit. All fields are required unless otherwise indicated.

First Name	Last Name
<input type="text"/>	<input type="text"/>
Prescriber Identifier Information <i>At least one identifier is required.</i>	
Prescriber DEA	Prescriber NPI
<input type="text"/>	<input type="text"/>

50. Pre-dispensing Authorization Confirmation

Home » Predispense Authorization Confirmation

Predispense Authorization Confirmation



You are now authorized to dispense Addyi. Please counsel the patient and provide a medication guide.

Predispense Authorization Code: XXXXXXXXXXXXXXXX

NPI: XXXXXXXXXXXX

DEA: XXXXXXXXXXXX

Close

51. Contact Us

Prescriber Training, Enrollment, and Certification (3 Easy Steps) Pharmacy Training, Enrollment, and Certification (3 Easy Steps) Addyi Certified Pharmacy Network Log In

[Home](#) » Contact Us

Contact Us

Addyi REMS Program Support Center

-  **Hours of Operation** : 8:00 AM – 8:00 PM ET
-  **Phone** : 1-844-233-9415
-  **Fax** : 1-844-694-3373
-  **Email** : AddyiREMSEnroll@AddyiREMS.com

For questions or requests pertaining to the Addyi REMS Program please contact the Addyi REMS Support Center.

Sprout Pharmaceuticals, Inc. Customer Service

-  **Phone** : 1-844-233-9415
-  **Email** : AddyiREMS@sproutpharma.com

Mailing Address:

4208 Six Forks Road
Suite 1010
Raleigh, NC 27609

52. Important Safety Information – Page 1



Indication and Important Safety Information

Indication

- Addyi is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
 - A co-existing medical or psychiatric condition,
 - Problems within the relationship, or
 - The effects of a medication or other drug substance.

Acquired HSDD refers to HSDD that develops in a patient who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation or partner.

Limitations of Use

- Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi is not indicated to enhance sexual performance.

Important Safety Information

WARNING: HYPOTENSION AND SYNCOPE IN CERTAIN SETTINGS
See full prescribing information for complete boxed warning.

- **Use of Addyi and alcohol increases the risk of severe hypotension and syncope; therefore alcohol use is contraindicated. Before prescribing Addyi, assess the likelihood of the patient abstaining from alcohol. Counsel patients prescribed Addyi about the importance of abstaining from alcohol.**
- **Addyi is available only through a restricted program called the Addyi REMS Program.**
- **Severe hypotension and syncope can occur when Addyi is used with moderate or strong CYP3A4 inhibitors or in patients with hepatic impairment; therefore, Addyi use in these settings is contraindicated.**

Contraindications

Addyi is contraindicated:

- With use of alcohol.
- With concomitant use with moderate or strong CYP3A4 inhibitors.
- In patients with hepatic impairment.

Summary of Warnings and Precautions

- **Hypotension and Syncope due to an Interaction with Alcohol.** An interaction between Addyi and alcohol increases the risk of severe hypotension and syncope. Alcohol use is contraindicated. Before prescribing Addyi, the healthcare provider should assess the likelihood of the patient abstaining from alcohol use.
- **Addyi Risk Evaluation and Mitigation Strategy (REMS) Program.** Addyi is available only through a restricted program called the Addyi REMS Program, because of the increased risk of severe hypotension and syncope due to an interaction between Addyi and alcohol. The Addyi REMS requires that prescribers are certified by enrolling and completing training; and, pharmacies are certified and will not dispense Addyi unless it is prescribed by a certified prescriber. More information is available at www.AddyiREMS.com.

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53. Important Safety Information – Page 1

- **Hypotension and Syncope with CYP3A4 Inhibitors.**
 - Moderate and strong CYP3A4 inhibitors significantly increase Addyi concentrations, which can lead to hypotension and syncope. Concomitant use of Addyi with a moderate or strong CYP3A4 inhibitor is contraindicated.
 - Concomitant use of multiple weak CYP3A4 inhibitors that may include herbal supplements (e.g., ginkgo, resveratrol) or non-prescription drugs (e.g., cimetidine) could also lead to clinically relevant increases in flibanserin concentrations that may increase the risk of hypotension and syncope.
- **Central Nervous System Depression.** Addyi can cause CNS depression (e.g., somnolence, sedation). In five 24-week, randomized, placebo-controlled, double blind trials of premenopausal women with HSDD the incidence of somnolence, sedation or fatigue was 21% and 8% in patients treated with 100 mg of Addyi at bedtime and placebo, respectively. The risk of CNS depression is increased if Addyi is taken during waking hours, or if Addyi is taken with alcohol or other CNS depressants, or with medications that increase flibanserin concentrations.

Patients should not drive or engage in other activities requiring full alertness until at least 6 hours after taking Addyi and until they know how Addyi affects them.

- **Hypotension and Syncope with Addyi Alone.** The use of Addyi – without other concomitant medications known to cause hypotension or syncope – can cause hypotension and syncope. In five 24-week, randomized, placebo-controlled, double-blind trials of premenopausal women with HSDD, hypotension was reported in 0.2% and <0.1% of Addyi-treated patients and placebo-treated patients, respectively; syncope was reported in 0.4% and 0.2% of Addyi-treated patients and placebo-treated patients, respectively. The risk of hypotension and syncope is increased if Addyi is taken during waking hours. Consider the benefits of Addyi and the risks of hypotension and syncope in patients with pre-existing conditions that predispose to hypotension. Patients who experience pre-syncope should immediately lie supine and promptly seek medical help if the symptoms do not resolve. Prompt medical attention should also be obtained for patients who experience syncope.
- **Syncope and Hypotension in Patients with Hepatic Impairment.** Any degree of hepatic impairment significantly increases flibanserin concentrations, which can lead to hypotension, syncope, and CNS depression. Therefore, Addyi is contraindicated in patients with hepatic impairment.

Most Common Adverse Reactions

- The most common adverse reactions among patients treated with Addyi were dizziness (Addyi 11.4%; Placebo 2.2%), somnolence (Addyi 11.2%; Placebo 2.9%), nausea (Addyi 10.4%; Placebo 3.9%), fatigue (Addyi 9.2%; Placebo 5.5%), insomnia (Addyi 4.9%; Placebo 2.8%) and dry mouth (Addyi 2.4%; Placebo 1.0%).

Summary of Drug Interactions

- Addyi is primarily metabolized by CYP3A4 and, to a lesser extent, by CYP2C19.
- Addyi is contraindicated in women taking a moderate (e.g., fluconazole) or strong (e.g., ketoconazole) CYP3A4 inhibitor.
- Patients using Addyi with combined oral contraceptives or with weak CYP3A4 inhibitors may experience a higher incidence of adverse reactions.
- CYP2C19 inhibitors (e.g. proton pump inhibitors, selective serotonin reuptake inhibitors, benzodiazepines, antifungals) may increase Addyi exposure, which may increase the risk of hypotension, syncope, and CNS depression.
- Do not use Addyi with strong CYP3A4 inducers (e.g., rifampin, St. John's Wort) as this will substantially reduce the concentration of Addyi.
- Addyi inhibits P-glycoprotein (P-gp). Monitoring of drug concentrations of any narrow therapeutic index drugs that are substrates for P-gp (e.g., digoxin) should be increased if co-administered with Addyi. The concomitant use of Addyi with digoxin, a drug that is transported by P-gp, increases the digoxin concentration. This may lead to digoxin toxicity.

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54. Privacy Policy

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Privacy Policy

By using or accessing one of the websites ("Sites") owned by Sprout Pharmaceuticals Incorporated ("we", "us" or "Company"), you agree to the terms of this Privacy Policy. Because you may submit your contact information or other personally identifiable information to us through our Sites or via email, we feel you should fully understand the terms and conditions relating to the collection, use and possible disclosure of that information. The term "Personal Information" as used throughout this Privacy Policy, applies to any information that we may collect, and which can be used to identify or to locate an individual.

Your privacy and security are important to us. Our Privacy Policy is clear: we will collect no Personal Information about you when you visit our Sites unless you elect to provide that information to us. This Privacy Policy discloses what Personal Information (as described below) we collect from you when you visit and use our Sites, how we use that Personal Information, and how you can correct or make changes to that information. If you do not consent to the terms of our Privacy Policy you do not have the right to use the Sites in any way, including REMS Certification. However, you can complete REMS certification by contacting the Addyi™ (fibanserin) REMS Support Center (☎ 1-844-233-9415); this will bypass providing any person information via the internet. We reserve the right to change our Privacy Policy at any time, in the event we decide to make material changes to our Privacy Policy, we will attempt to notify you and other users of the Sites by sending a notice to the primary email address provided to us and/or by placing a notice on our Sites. You should periodically check our Sites for such notices. This Privacy Policy only applies to information we collect at our Sites and via the electronic communications technologies that we use. It does not apply to information collected through other means, including Personal Information you provide in e-mail messages you send to us or Personal Information we may collect from you offline. This Privacy Policy is intended for all visitors to the Company Sites including consumers, healthcare professionals and Company business partners.

At some of our Sites, we may use Personal Information in a manner not described in this Privacy Policy, in those instances, the different uses of Personal Information will be disclosed to you at the web page where your Personal Information is collected, prior to such collection.

Capitalized terms not defined in this Privacy Policy have the meanings set forth in the Terms of Use.

Your California Privacy Rights

As further discussed in this Privacy Policy, we may from time to time provide you with the opportunity to receive information about our products and services and/or those of our Affiliates (as defined below) or third party partners. You can prevent future disclosures of your Personal Information to our Affiliates and third parties for their direct marketing purposes, at no charge, by exercising your "opt out" rights through any of the means described below in our Privacy Policy.

The Information We Collect

When you visit the Sites you may provide us with two types of information: (i) information regarding your use of the Sites automatically collected by us as you interact with the Sites, even if you do nothing during your visit but browse the Sites, and (ii) information you submit voluntarily via the Sites.

(i) When you enter the Sites, we may collect your browser type, your operating system (e.g., Windows 7), the domain name of your internet service provider (e.g., Comcast), the date and time of your visit, the pages viewed, the time spent at our Sites, and the websites visited just before and just after our Sites (including any third-party website that links to our Sites, if you followed a link to our Sites), and your IP address.

Even when you visit areas of the Sites anonymously, we may collect IP addresses automatically. An IP address is a number that is automatically assigned to your computer whenever you begin service with an internet service provider. Each time you access the Sites and each time you request one of our pages, our server logs your IP address. Standing alone, your IP address is not necessarily personally identifiable. We may use your IP address to administer the Sites, to assist in diagnosing problems with our server, to monitor our system performance and/or to make it easier and more convenient for you to navigate and use the Sites.

In addition, we store certain information from your browser using "cookies." A cookie is a piece of data stored on the user's computer tied to information about the user. We may use session ID cookies to confirm that users are logged in. Any and all of this information may be associated with your Personal Information. Most web browsers automatically accept cookies, but you can usually configure your browser to prevent this. Not accepting cookies may make certain features of the Sites unavailable to you.

(i) When you enter the Sites, we may collect your browser type, your operating system (e.g., Windows 7), the domain name of your internet service provider (e.g., Comcast), the date and time of your visit, the pages viewed, the time spent at our Sites, and the websites visited just before and just after our Sites (including any third-party website that links to our Sites, if you followed a link to our Sites), and your IP address.

Even when you visit areas of the Sites anonymously, we may collect IP addresses automatically. An IP address is a number that is automatically assigned to your computer whenever you begin service with an internet service provider. Each time you access the Sites and each time you request one of our pages, our server logs your IP address. Standing alone, your IP address is not necessarily personally identifiable. We may use your IP address to administer the Sites, to assist in diagnosing problems with our server, to monitor our system performance and/or to make it easier and more convenient for you to navigate and use the Sites.

In addition, we store certain information from your browser using "cookies." A cookie is a piece of data stored on the user's computer tied to information about the user. We may use session ID cookies to confirm that users are logged in. Any and all of this information may be associated with your Personal Information. Most web browsers automatically accept cookies, but you can usually configure your browser to prevent this. Not accepting cookies may make certain features of the Sites unavailable to you.

(ii) Through the use of certain functionality of the Sites, including but not limited to emails you send to us directly via hyperlink, you may provide us with your name, company affiliation, email address, telephone number, physical address, and other information that may be required for you to use such functionality. Additionally, if you are an employment applicant, you may provide us with information regarding your prior employment, education, gender, and ethnicity. This includes information provided in emails and cover letters we receive electronically. You may always choose not to provide us with your Personal Information, and we will disclose to you at the time we collect your Personal Information whether it is required for you to receive the information or services you have requested. To better understand and address your interests, and to keep the Personal Information we have about you accurate, we may correct or add to the Personal Information you provide to us at our Sites with Personal Information we receive from you offline or from other sources. You have several choices regarding your use of our Sites. You could decide not to submit any Personal Information at all. Although certain Sites may ask for permission to use your Personal Information for certain purposes, you can agree or decline to provide your Personal Information. If you subscribe for particular communications or services such as e-mail updates, you will be able to unsubscribe at any time by: (x) following any opt-out instructions contained in communications you receive from Company; (y) un-subscribing at specific areas of the Sites where you registered, if available, or (z) sending a written request to the Company contact address, which appears at the end of this Privacy Policy.

In addition, we store certain information from your browser using "cookies." A cookie is a piece of data stored on the user's computer tied to information about the user. We may use session ID cookies to confirm that users are logged in. Any and all of this information may be associated with your Personal Information. Most web browsers automatically accept cookies, but you can usually configure your browser to prevent this. Not accepting cookies may make certain features of the Sites unavailable to you.

(ii) Through the use of certain functionality of the Sites, including but not limited to emails you send to us directly via hyperlink, you may provide us with your name, company affiliation, email address, telephone number, physical address, and other information that may be required for you to use such functionality. Additionally, if you are an employment applicant, you may provide us with information regarding your prior employment, education, gender, and ethnicity. This includes information provided in emails and cover letters we receive electronically. You may always choose not to provide us with your Personal Information, and we will disclose to you at the time we collect your Personal Information whether it is required for you to receive the information or services you have requested. To better understand and address your interests, and to keep the Personal Information we have about you accurate, we may correct or add to the Personal Information you provide to us at our Sites with Personal Information we receive from you offline or from other sources. You have several choices regarding your use of our Sites. You could decide not to submit any Personal Information at all. Although certain Sites may ask for permission to use your Personal Information for certain purposes, you can agree or decline to provide your Personal Information. If you subscribe for particular communications or services such as e-mail updates, you will be able to unsubscribe at any time by: (x) following any opt-out instructions contained in communications you receive from Company; (y) un-subscribing at specific areas of the Sites where you registered, if available, or (z) sending a written request to the Company contact address, which appears at the end of this Privacy Policy.

(ii) Through the use of certain functionality of the Sites, including but not limited to emails you send to us directly via hyperlink, you may provide us with your name, company affiliation, email address, telephone number, physical address, and other information that may be required for you to use such functionality. Additionally, if you are an employment applicant, you may provide us with information regarding your prior employment, education, gender, and ethnicity. This includes information provided in emails and cover letters we receive electronically. You may always choose not to provide us with your Personal Information, and we will disclose to you at the time we collect your Personal Information whether it is required for you to receive the information or services you have requested. To better understand and address your interests, and to keep the Personal Information we have about you accurate, we may correct or add to the Personal Information you provide to us at our Sites with Personal Information we receive from you offline or from other sources. You have several choices regarding your use of our Sites. You could decide not to submit any Personal Information at all. Although certain Sites may ask for permission to use your Personal Information for certain purposes, you can agree or decline to provide your Personal Information. If you subscribe for particular communications or services such as e-mail updates, you will be able to unsubscribe at any time by: (x) following any opt-out instructions contained in communications you receive from Company; (y) un-subscribing at specific areas of the Sites where you registered, if available, or (z) sending a written request to the Company contact address, which appears at the end of this Privacy Policy.

55. Privacy Policy - continued

Children; Parental Consent Policy

The Children's Online Privacy Protection Act imposes certain requirements on websites directed toward children under 13 that collect information on those children, or on websites that know they are collecting Personal Information from children under the age of 13. The Sites are not intended for children under the age of 13, and it currently is our policy not to collect Personal Information from any person under 13, and we request that children under the age of 13 not submit any Personal Information to us via the Sites. If we learn that we have inadvertently gathered Personal Information from children under 13, we will use reasonable efforts to notify such child's parent or guardian and erase such information from our records, unless the child's parent or guardian consents to our maintaining such information.

Use of Information Obtained by Company

Information collected automatically when you access the Sites is used to administer the Sites and to analyze trends and gather statistical information for aggregate use. We may disclose any such information for our legitimate business purposes.

In general, Personal Information you provide to us is used to respond to requests that you make (For example, we may use your Personal Information to process your Addyi REMS certification. Company may also send you service-related announcements from time to time through the general operation of the Sites. Generally, you may opt out of such communications, although Company reserves the right to send you service-related notices even if you opt out of all voluntary notifications.

Policy on Use of Social Security Numbers Note to Healthcare Professionals and Business Partners

If you have a business or professional relationship with Company, we may use your Personal Information, including Personal Information we may collect about you from other sources, to develop our business relationship with you and your organization.

Sharing Your Information with Third Parties

You may choose to provide information about you and your company or organization to other users and to the public by providing such information on public areas of the Sites ("Public Information"). Public information does not include information you submit to us but do not post on areas of the Sites accessible by other users or the public ("Non-Public Information"). Non-Public Information may include Personal Information.

We share your Non-Public Information with third parties only in limited circumstances, such as the information required to successfully complete Addyi REMS certification, where we believe such sharing is reasonably necessary to operate the Sites, legally required or, permitted by you. For example:

- We may share your Non-Public Information with a parent company, any subsidiaries, joint ventures, or other companies under common control with Company now or in the future (collectively, "Affiliates"), in which case we will require our Affiliates to honor this Privacy Policy with respect to such shared information.
- We may provide Non-Public Information to service providers who help us bring you the services we offer, such as hosting the service at a co-location facility, sending email updates about Company, removing repetitive information from our user lists, or to provide search results or links. In connection with these offerings and business operations, our service providers may have access to your Non-Public Information for use for a limited time in connection with these business activities. Where we utilize third parties for the processing of any of your Non-Public Information, we implement reasonable contractual protections limiting the use of that Non-Public Information to the provision of services to Company.
- We may offer to provide services jointly with other companies on the Sites, and we may share Non-Public Information with that company in connection with such offer or your use of that service.
- We may share your Non-Public Information if you request such a disclosure, to enforce an agreement we have with you, or to comply with the terms of an agreement with a product-related co-promotion partner. If the ownership of all or substantially all of the Company business, or individual business units or assets owned by Company that are related to the Sites, were to change, your Non-Public Information may be transferred to the new owner. In such event, Company will notify you by posting such notice on one or more of the Sites before information about you is transferred and becomes subject to a different privacy policy in order to give you a reasonable opportunity to opt out of such different privacy policy, provided however, in the event Company fails to notify you, your Personal Information will still be transferred but subject to this Privacy Policy.
- Account or other Non-Public Information (i) pursuant to lawful requests, such as subpoenas or court orders, or in compliance with applicable laws, or (ii) when we believe it is necessary to comply with law, to protect our interests or property, including, but not limited to, in the context of a legal dispute, to protect the rights, property or safety of our employees or others, to prevent fraud or other illegal activity perpetrated through the Sites or using the Company name, or to prevent imminent harm. This may include sharing Non-Public Information with other companies, lawyers, agents or government agencies or where needed, for corporate audits or to investigate or respond to a complaint or security threat.

Third Party Links

Company Sites may contain links to other websites which may collect information directly from you. Each of the websites linked to the Sites may have separate privacy and data collection practices, independent of Company. Once you link to another site from ours, you are subject to the Privacy Policy and Terms of Use of the new site, and Company has no responsibility or liability for these independent policies or actions and is not responsible for the privacy practices or the content of such websites, nor does Company endorse or make any warranties or representations about the contents, products or services offered on such websites or the security of any information you provide to them. If you have any questions about how these other sites use your information, you should contact them directly. This Privacy Policy applies solely to information collected by Company via the Sites.

Security

Although we use reasonable efforts to safeguard the security of your Personal Information, transmissions made on or through the Internet are inherently vulnerable to attack and cannot be guaranteed to be secure. Consequently, we cannot and do not guarantee that unauthorized access, hacking, data loss, or other breaches will never occur. In addition, submissions made via email are not protected by encryption and are vulnerable to interception during transmission. You are solely responsible for safeguarding and maintaining the secrecy of your Personal Information. Please be careful and responsible whenever you are online. We urge you to take steps to keep your Personal Information safe. Our hosting provider's computer systems employ software to monitor network traffic in order to identify unauthorized attempts to upload or change information, or otherwise cause damage. Unauthorized attempts to upload information or change information on the Sites are strictly prohibited and may be punishable under the Computer Fraud and Abuse Act of 1986 and the National Information Infrastructure Protection Act.

56. Privacy Policy - continued

Protecting Yourself; Updating Your Information

You can learn more about Internet privacy from government websites such as www.ftc.gov/privacy/. In addition, it is important to keep us updated with your most current contact information. You can review and make changes to the information we have on file about you by emailing us your updated information. To the extent we maintain your email address or other information about you, you may ask us via email at compliance@Company.com to have such information deleted, updated or corrected, and/or to request us to cease collecting Personal Information about you in the future.

Changing Your Preferences; Opt-Out of Receiving Communications

When you provide us with your Personal Information, you may be given some choices about how we use that Personal Information. You may change these preferences later. For example, if you sign up for an e-mail newsletter, you may opt out of receiving future e-mail newsletters at any time. If you opt in to receive communications from Company, we will always provide you with one or more of the following ways to opt out: (i) by following any opt-out instructions contained in communications you receive from Company, (ii) by un-subscribing at specific areas of the Site(s) where you registered, if available, or (iii) by sending a written request to the Company contact address immediately below.

Changes to Our Policy

This Privacy Policy is effective with respect to any information collected on or after the date below. Company reserves the right to modify or supplement this Privacy Policy at any time. If we make any changes, we will update the Sites and Privacy Policy to include such change and notice thereof. Please review this Privacy Policy often to review any changes that may affect your use of the Sites. Your continued use of the Sites once the revised Privacy Policy has been posted on any of the Sites with the updated date affirms your agreement to such changes. If you do not agree to abide by this Privacy Policy, do not use or access (or continue to use or access) the Sites.

Contacting Company

If you have any questions about this Privacy Policy or Company's privacy practices in general, or if you need help accessing your Personal Information or changing your preferences, please contact us at:

Phone : 919-882-0850
Fax : 919-882-0855
Email : info@sproutpharma.com

You may also contact us by mail at Sprout Pharmaceuticals, 4208 Six Forks Road Suite 1010 Raleigh, NC 27609. Or, you can visit our Contact Us section at www.sproutpharma.com/contact-us for more information.

Make sure to provide the name of the Site(s) applicable to your request, and your name and contact information. If you do not provide us with this information, we may not be able to respond.

APPENDIX E: ADDYI REMS PROGRAM PATIENT-PROVIDER AGREEMENT FORM

Addyi™ REMS Program Patient-Provider Agreement Form

Healthcare Provider:

- Alcohol use is contraindicated in women taking Addyi™ (flibanserin)
- Addyi and alcohol interact and increase the risk of severe hypotension and syncope.
- I agree to:
 - Use this Patient-Provider Agreement Form to counsel my patients about these risks and the importance of abstaining from alcohol.
 - Sign this form along with my patient and place a copy in her chart.
 - **Tear off** the bottom portion and provide it to my patient to take home for her reference.

Prescriber Signature _____ Date _____

Pharmacist: This form may be used as an optional tool for counseling patients. No charting or signatures are required.

Patient:

I understand that I must not drink alcohol while taking Addyi. Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.
- I understand the instructions that my healthcare provider has given to me.

Patient Signature _____ Date _____

----- tear here -----

addyi™
(flibanserin)

Addyi™ Patient Information

I understand that I must not drink alcohol while taking Addyi (flibanserin). Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).

- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.

For more information about Addyi please visit www.AddyiREMS.com

APPENDIX F: ADDYI REMS PROGRAM MULTIPLE LOCATION PHARMACY
ENROLLMENT FORM



Addyi™ REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form

The Food and Drug Administration has required a Risk Evaluation and Mitigation Strategy (REMS) for Addyi™ (flibanserin) to mitigate the increased risk of hypotension and syncope associated with flibanserin due to an interaction with alcohol. For outpatient use, Addyi is only available from certified outpatient prescribers and certified outpatient pharmacies through the Addyi REMS Program. For inpatient use, Addyi is only available from certified inpatient pharmacies through the Addyi REMS Program.

Only certified pharmacies can dispense Addyi. This helps ensure that patients starting or continuing treatment with Addyi are counseled appropriately about the increased risk of hypotension and syncope associated with flibanserin due to an interaction with alcohol.

As the **Authorized Pharmacy Representative** for your multiple locations outpatient pharmacy, you must do the following:

- Ensure all your outpatient pharmacy dispensing locations utilize a pharmacy management system to submit all Addyi prescriptions in accordance with the Addyi REMS program requirements.
- Review the *Addyi REMS Program Prescriber and Pharmacy Training Program*, *Addyi Medication Guide*, and *Prescribing Information* for Addyi.
- Successfully complete and submit the *Addyi REMS Program Knowledge Assessment* and this *Addyi REMS Multiple Locations Outpatient Pharmacy Enrollment Form*. This may be done online at www.AddyiREMS.com or by completing both in hard copy and submitting via fax or email to the Addyi REMS Program Support Center.
- Implement the necessary staff training and processes at both a headquarters level and at each dispensing location to comply with the Addyi REMS Program requirements.

Authorized Multiple Locations Outpatient Pharmacy Representative Acknowledgement

I understand that Addyi can only be dispensed by certified pharmacies and, to become certified, all my outpatient pharmacy dispensing locations must comply with the Addyi REMS Program requirements. As an Authorized Pharmacy Representative, I acknowledge that:

1. I have reviewed the *Addyi REMS Program Prescriber and Pharmacy Training Program*, the *Addyi Medication Guide*, and the *Prescribing Information* and have successfully completed the *Addyi REMS Program Knowledge Assessment*.
2. I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.
3. I will establish processes and procedures for all my certified outpatient pharmacy dispensing locations to ensure compliance with the requirements of the Addyi REMS Program before dispensing Addyi, including the following:
 - a. All certified outpatient pharmacy dispensing locations complete training of pharmacists and staff involved with the dispensing of Addyi using the *Addyi REMS Program Prescriber and Pharmacy Training Program* and will comply with the REMS requirements. This training will be documented and is subject to audit.
 - b. All certified outpatient pharmacy dispensing locations verify the prescriber is certified in the Addyi REMS Program prior to dispensing Addyi.



Addyi™ REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form

- c. All certified outpatient dispensing locations will counsel patients prior to dispensing drug to abstain from alcohol consumption while undergoing treatment with Addyi.
- d. All certified outpatient pharmacy dispensing locations will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.
4. I will ensure that all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope *where an interaction with alcohol cannot be ruled out* to either Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).
5. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative to maintain certification to order and dispense Addyi.
6. I will maintain such documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.
7. I will comply with the audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.
8. I understand Addyi REMS Program personnel may contact pharmacists at certified outpatient pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.
9. I will oversee compliance with the Addyi REMS Program requirements.
10. I will ensure the following Pharmacy Management System requirements will be in place for all certified outpatient pharmacy dispensing locations:
 - a. The Pharmacy Management System configuration and/or updates will be in place and verified with the Addyi REMS Program Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements.
 - b. The Pharmacy Management System configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol consumption with every dispensed prescription.
 - c. The Pharmacy Management System configuration must process all Addyi prescriptions, regardless of the method of payment, through our pharmacy management system and “pharmacy claims routing switch” for Addyi REMS verification of prescriber certification prior to dispensing every prescription.
11. Proper authorization or provision of data rights to my switch provider are in place to meet Addyi REMS Program requirements.

Please complete all the information requested on the next page.



Addyi™ REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form

Authorized Multiple Locations Outpatient Pharmacy Representative to complete (all fields required):

First Name _____ Last Name _____ Title _____

Phone Number _____ Fax _____

Email _____

Multiple Locations Pharmacy Name _____

Chain ID # _____

Address _____ City _____

State _____ Zip Code _____

Signature _____ Date _____

Authorized Multiple Locations Outpatient Pharmacy Representative

Preferred Method of Communication (please select one): Fax Email

Please fax all pages of this form and the completed *Addyi REMS Program Knowledge Assessment* to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com.

Once this form is successfully processed, you will receive a fax or e-mail with instructions on how to submit test transaction(s) to the Addyi REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Addyi REMS program.

After successful completion of the test transaction(s) you will receive a multiple pharmacy enrollment confirmation via fax and/or email from the Addyi REMS Program Support Center. Your multiple pharmacy entity will be considered certified and your retail chain dispensing locations will be eligible to complete their certification procedures.

The *Addyi REMS Program Prescriber and Pharmacy Training Program* for your pharmacy dispensing locations will be made available through the Addyi REMS Support Center. Once the training program and knowledge assessment are completed at a pharmacy dispensing location within your organization, it is your responsibility to capture the pharmacy dispensing location information noted below and provide this information to the Addyi REMS Program Support Center. Once the Addyi REMS Program Support Center receives, processes, and confirms the required pharmacy dispensing location information from you, this pharmacy dispensing location will be considered certified and permitted to order, receive, and dispense Addyi.

The following required pharmacy dispensing location fields must be provided to the Authorized Multiple Pharmacy Representative for each trained pharmacy dispensing location: Responsible Pharmacist first and last name, dispensing pharmacy address with zip code, phone and fax numbers, pharmacy NCPDP ID, NPI and DEA numbers; and pharmacy store # (if applicable).

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415.

APPENDIX G: ADDYI REMS PROGRAM INDIVIDUAL LOCATION PHARMACY
ENROLLMENT FORM



Addyi™ REMS Program Individual Location Outpatient Pharmacy Enrollment Form

The Food and Drug Administration has required a Risk Evaluation and Mitigation Strategy (REMS) for Addyi™ (flibanserin) to mitigate the increased risk of hypotension and syncope associated with flibanserin due to an interaction with alcohol. For outpatient use, Addyi is only available from certified outpatient prescribers and certified outpatient pharmacies through the Addyi REMS Program.

Only certified pharmacies can dispense Addyi. This helps ensure that patients starting or continuing treatment with Addyi are counseled appropriately about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

As the **Authorized Pharmacy Representative** for this outpatient pharmacy, you must do the following:

- Read the *Addyi REMS Program Prescriber and Pharmacy Training Program*, *Addyi Medication Guide*, and *Prescribing Information* for Addyi.
- Successfully complete and submit the *Addyi REMS Program Knowledge Assessment* and the *Addyi REMS Program Individual Location Outpatient Pharmacy Enrollment Form*. This may be done online at www.AddyiREMS.com or by completing both in hard copy and submitting via fax or email to the Addyi REMS Support Center.
- Implement the necessary staff training and processes at your outpatient pharmacy to comply with the Addyi REMS Program requirements.

Authorized Individual Location Outpatient Pharmacy Representative Acknowledgement

I understand that Addyi can only be dispensed by certified pharmacies and, to become certified, my outpatient pharmacy must comply with the Addyi REMS Program requirements. As an Authorized Pharmacy Representative, I acknowledge that:

1. I have reviewed the *Addyi REMS Program Prescriber and Pharmacy Training Program*, the *Addyi Medication Guide*, and the *Prescribing Information*; and successfully completed the *Addyi REMS Program Knowledge Assessment*.
2. I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.
3. My certified pharmacy must complete training of pharmacists and staff involved with the dispensing of Addyi using the *Addyi REMS Program Prescriber and Pharmacy Training Program* and must comply with the REMS requirements. This training will be documented and is subject to audit.
4. I will ensure my certified pharmacy counsels patients to abstain from alcohol use with Addyi prior to dispensing.
5. My certified pharmacy will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.
6. I will ensure that all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope where an interaction with alcohol cannot be ruled out to either SproutPharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).



Addyi™ REMS Program Individual Location Outpatient Pharmacy Enrollment Form

7. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative to maintain certification to order and dispense Addyi.
8. I will maintain such documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.
9. I will comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.
10. I understand Addyi REMS Program personnel may contact pharmacists at certified outpatient pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.
11. I will oversee compliance with the Addyi REMS Program requirements.
12. I understand that my certified outpatient pharmacy must verify the prescriber is certified in the Addyi REMS Program prior to dispensing Addyi and will ensure verification through the following option (**Place a check next to either Option A or B and indicate the NCPDP# as noted on the next page**).

Please complete all the information requested on the following pages.



Addyi™ REMS Program Individual Location Outpatient Pharmacy Enrollment Form

Please indicate your Pharmacy NCPDP# next to your preferred Option A or B based on how you will process dispensing transactions for the Addyi REMS Program.

<input type="checkbox"/> Option A NCPDP# _____	<input type="checkbox"/> Option B NCPDP# _____
<p>My pharmacy utilizes a Pharmacy Management System (PMS) to transmit prescriptions electronically and will utilize this technology to verify prescriber certification.</p>	<p>My pharmacy <u>does not</u> utilize a Pharmacy Management System (PMS) to transmit prescriptions electronically.</p>
<p>I will ensure the following Pharmacy Management System requirements will be in place for my pharmacy.</p> <ol style="list-style-type: none"> a. The pharmacy management system configuration and/or updates will be in place and verified with the Addyi REMS Pharmacy Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements. b. The pharmacy management system configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol with every dispensed prescription. c. The pharmacy management system configuration must process all Addyi prescriptions, regardless of the method of payment, through the pharmacy management system and “pharmacy routing switch” for Addyi REMS verification of prescriber certification prior to dispensing every prescription. d. I acknowledge that prior to Addyi REMS pharmacy certification, the Addyi REMS Support Center will contact me if an agreement is needed to permit the switch provider to use prescription data from this pharmacy to conduct the REMS. 	<p>I will ensure my pharmacy staff will access the Addyi REMS Program website at www.AddyiREMS.com or call the Addyi REMS Program Support Center (1-844-233-9415) to confirm the authorizing prescriber is certified (as outlined in attestation 12) before dispensing each Addyi prescription. A complete authorization requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber’s NPI or DEA.</p>

Please proceed to next page and provide required information.



Addyi™ REMS Program Individual Location Outpatient Pharmacy Enrollment Form

Authorized Individual Location Outpatient Pharmacy Representative to complete (all fields required):

First Name _____ Last Name _____ Title _____

Phone Number _____ Fax _____

Email _____

Address _____ City _____

State _____ Zip Code _____

Pharmacy Name _____

Pharmacy NCPDP ID _____ DEA Number _____

Pharmacy NPI _____ Pharmacy Store # (optional) _____

Signature _____ Date _____

Authorized Individual Location Outpatient Pharmacy Representative

Preferred Method of Communication (please select one): Fax Email

Please fax all pages of this form and the completed *Addyi REMS Program Knowledge Assessment* to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail both documents to AddyiREMSEnroll@AddyiREMS.com.

Once this form is successfully processed and the knowledge assessment has been successfully completed, you will receive a fax or e-mail with further information.

If you selected Option A above: You will receive instructions on how to submit test transaction(s) to the Addyi REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Addyi REMS Program. Upon successful verification of connectivity, you will be provided with the Terms & Conditions to become certified. Once this process is complete your pharmacy will receive a confirmation from the Addyi REMS Program Support Center and you will be considered certified and permitted to order, receive, and dispense Addyi.

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415.

APPENDIX H: ADDYI REMS PROGRAM INPATIENT PHARMACY ENROLLMENT
FORM



Addyi™ REMS Program Inpatient Pharmacy Enrollment Form (for use in facilities that dispense for inpatient use)

The Food and Drug Administration has required a Risk Evaluation and Mitigation Strategy (REMS) for Addyi™ (flibanserin) to mitigate the increased risk of hypotension and syncope associated with flibanserin due to an interaction with alcohol. For inpatient use, Addyi is only available from certified inpatient pharmacies through the Addyi REMS Program. For outpatient use, Addyi is only available from certified outpatient prescribers and certified outpatient pharmacies through the Addyi REMS Program.

Only certified pharmacies can dispense Addyi. This helps ensure that patients starting or continuing treatment with Addyi are counselled appropriately about the risks of hypotension and syncope associated with flibanserin due to an interaction with alcohol.

As the **Authorized Pharmacy Representative** for your facility's inpatient pharmacy, you must do the following:

- Review the *Addyi REMS Program Prescriber and Pharmacy Training Program*, *Addyi Medication Guide*, and *Prescribing Information for Addyi*.
- Successfully complete and submit the *Addyi REMS Program Knowledge Assessment* and this *Addyi REMS Program Inpatient Pharmacy Enrollment Form*. This may be done online at www.AddyiREMS.com or by completing both in hard copy and submitting via fax or email to the Addyi REMS Program Support Center.
- Implement the necessary staff training and processes in the facility's inpatient pharmacy to comply with the Addyi REMS Program requirements.

Authorized Inpatient Pharmacy Representative Acknowledgement

I understand that Addyi can only be dispensed by certified pharmacies and, to become certified, all my inpatient pharmacy must comply with the Addyi REMS Program requirements. As an Authorized Pharmacy Representative, I acknowledge that:

1. I have read the *Addyi REMS Program Prescriber and Pharmacy Training Program*, the *Addyi Medication Guide* and the full *Prescribing Information* and have successfully completed the *Addyi REMS Knowledge Assessment*.
2. I understand that there is an increased risk of syncope and hypotension associated with Addyi due to an interaction with alcohol.
3. I will ensure that my inpatient pharmacy does not dispense Addyi for outpatient use.
4. I understand that pharmacies within or associated with my healthcare facility that dispense drugs to outpatients must be separately certified as a certified outpatient pharmacy and comply with the Addyi REMS Program requirements to dispense Addyi to outpatients.
5. I understand that a prescriber who wants to discharge a patient with an Addyi prescription, intended to be dispensed by an outpatient pharmacy, will be required to enroll in the Addyi REMS Program.
6. My certified pharmacy will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.



Addyi™ REMS Program Inpatient Pharmacy Enrollment Form
(for use in facilities that dispense for inpatient use)

7. I will ensure all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).
8. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative.
9. I will maintain such documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.
10. I will comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.
11. I understand Addyi REMS Program personnel may contact pharmacists at certified inpatient hospital pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.
12. I will oversee compliance with the Addyi REMS Program requirements.

Authorized Inpatient Pharmacy Representative

Name* (please print): _____ Date: _____

NPI #: _____

Complete all information requested on the following page.



Addyi™ REMS Program Inpatient Pharmacy Enrollment Form
 (for use in facilities that dispense for inpatient use)

Authorized Inpatient Pharmacy Representative

Signature* _____ Date _____
 First Name* _____ Last Name* _____ Title _____
 Phone Number* _____ Email* _____

*Required Fields

Inpatient Pharmacy Information

Pharmacy Name* _____ NPI Number* _____
 Address* _____ Pharmacy License Number* _____
 City* _____ DEA Number* _____
 State* _____ ZIP* _____ Phone Number* _____
 Required Fields Fax Number _____

Preferred Method of Communication (please select one): Fax Email

Please fax all pages of this form and the completed Addyi REMS Program Knowledge Assessment to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSenroll@AddyiREMS.com.

Once processed, the Addyi REMS Program Support Center will contact you to complete the certification process.

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415 or visit www.AddyiREMS.com.