

## 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](http://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).

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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"/> <b>Option A</b> <b>NCPDP# _____</b>	<input type="checkbox"/> <b>Option B</b> <b>NCPDP# _____</b>
<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"> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ol>	<p>I will ensure my pharmacy staff will access the Addyi REMS Program website at <a href="http://www.AddyiREMS.com">www.AddyiREMS.com</a> 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](mailto: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.**