

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 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.

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- 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 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 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.



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

First Name _____ Last Name _____

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.