

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



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

pharmacy, institution, distributor, or prescriber.

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.



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**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.