

## **Qsymia<sup>®</sup> Risk Evaluation and Mitigation Strategy (REMS)**

### **Pharmacy Enrollment Form - Corporate Entity of Retail Chain Pharmacy**

Because of the teratogenic risk associated with Qsymia therapy, Qsymia is available through a limited program under the REMS. Under the Qsymia REMS, only certified pharmacies may distribute Qsymia. I understand that my certified retail pharmacy dispensing locations must comply with the program requirements for certified pharmacies and the terms contained in this form. As the Authorized Corporate Pharmacy Representative, I acknowledge that:

1. I have reviewed and successfully completed the Qsymia Pharmacy Training Program and the knowledge assessment questions.
2. I understand the risks associated with Qsymia.
3. I understand and agree to comply with the requirements of the Qsymia REMS program for pharmacies.
  - a. The pharmacy management system configuration and/or updates will be in place and verified with the Qsymia REMS Pharmacy Support Center to ensure that Qsymia prescription claims are submitted in accordance with the program requirements.
  - b. The pharmacy management system will be in place to systematically direct that all certified retail pharmacy dispensing locations provide a Medication Guide and the *Risk of Birth Defects with Qsymia* patient brochure to each patient each time Qsymia is dispensed.
  - c. All certified retail pharmacy dispensing locations will refrain from reselling or transferring Qsymia to another pharmacy or distributor.
  - d. All certified retail pharmacy dispensing locations will complete training of pharmacists and staff involved with the dispensing of Qsymia and will comply with the REMS requirement to provide a Medication Guide and the *Risk of Birth Defects with Qsymia* patient brochure each time Qsymia is dispensed.
  - e. I will maintain all records of certified retail pharmacy dispensing location training and acknowledgement forms.
  - f. All certified retail pharmacy dispensing locations will be made aware that all Qsymia prescription claims, regardless of the method of payment, must be processed through our pharmacy management system and “pharmacy claims routing switch” for Qsymia REMS verification.



- g. I will ensure proper authorization or provision of data rights to my switch provider are in place to meet Qsymia REMS program requirements.
  - h. All certified retail pharmacy dispensing locations are subject to, and must comply with, surveys to assess compliance with the REMS requirements in order to maintain pharmacy certification.
  - i. Each corporate entity of a certified retail chain pharmacy is subject to, and must comply with, audit requirements to ensure that the REMS requirements are being followed to maintain their pharmacy certification under the Qsymia REMS.
4. I will oversee compliance with the Qsymia REMS program requirements and will provide quarterly compliance reports back to VIVUS to assess effectiveness and comply with all audit requirements.

**Authorized Corporate Pharmacy Representative to complete (all fields required):**

**First Name** \_\_\_\_\_ **Last Name** \_\_\_\_\_

**Phone Number** \_\_\_\_\_ **Fax** \_\_\_\_\_

**Email** \_\_\_\_\_

**Corporate Pharmacy Name** \_\_\_\_\_

**Address** \_\_\_\_\_ **City** \_\_\_\_\_

**State** \_\_\_\_\_ **Zip Code** \_\_\_\_\_

**Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

**Authorized Corporate Pharmacy Representative**

**Please fax completed form to the Qsymia REMS Pharmacy Support Center (855-302-6699).**

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 Qsymia REMS program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Qsymia REMS program.

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





The Qsymia Pharmacy Training Program for your pharmacy dispensing locations will be made available through the Qsymia REMS Pharmacy 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 to the Qsymia REMS Pharmacy Support Center. Once the Qsymia REMS Pharmacy 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 Qsymia.

The following required pharmacy dispensing location fields must be provided to the Authorized Corporate 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 DEA, NCPDP ID and NPI numbers; and pharmacy store # (optional).

**If you have any questions or require additional information, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698.**

