

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

### **Pharmacy Enrollment Form**

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

#### **As the Authorized Representative, I must:**

- Carry out the certification process and oversee implementation and compliance with the Qsymia REMS on behalf of the pharmacy
- Complete the Qsymia REMS Pharmacy Training
- Complete the Pharmacy Enrollment Form and fax or email the form to the Qsymia REMS Pharmacy Support Center
- Train all relevant staff involved in dispensing on the risks associated with Qsymia and the requirement to provide the Medication Guide and the *Risk of Birth Defects with Qsymia* patient brochure using the Qsymia REMS Pharmacy Training
- Establish processes and procedures to provide the Medication Guide and the *Risk of Birth Defects with Qsymia* patient brochure to each patient each time Qsymia is dispensed

#### **Before dispensing, all pharmacy staff must:**

- Provide the patient with the Medication Guide and the *Risk of Birth Defects with Qsymia* patient brochure through the processes and procedures established as a requirement of the REMS program

#### **At all times, all pharmacy staff must:**

- Not distribute, transfer, loan, or sell Qsymia
- Maintain records of standard operating procedures, training, and providing the Medication Guide and the *Risk of Birth Defects with Qsymia* patient brochure
- Maintain and submit annual compliance reports to the Qsymia REMS
- Comply with audits carried out by VIVUS to ensure that all processes and procedures are in place and are being followed
- Have a new Authorized Representative enroll in the Qsymia REMS by completing the Qsymia REMS Pharmacy Training and the Pharmacy Enrollment Form

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

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

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

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

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

**Pharmacy Type (Corporate, Independent, Mail Order, Closed System)** \_\_\_\_\_

**Pharmacy DEA** \_\_\_\_\_ **Pharmacy NCPDP** \_\_\_\_\_ **Pharmacy NPI** \_\_\_\_\_

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

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

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

**Authorized Representative**

**Please fax the completed form to the Qsymia REMS Pharmacy Support Center at 855-302-6699 or email the form to VivusUSREMS.sm@ppd.com.**

Once this form is successfully processed, you will receive a pharmacy enrollment confirmation via email from VIVUS. Your pharmacy will be considered certified to order, receive, and dispense Qsymia.

***Important Enrollment Information for Corporate Chain Entities with Retail Chain Pharmacy Dispensing Locations***

The Qsymia REMS Pharmacy Training for retail chain pharmacy dispensing locations is available through the Qsymia REMS website ([www.QsymiaREMS.com](http://www.QsymiaREMS.com)). Once the Training and Knowledge Assessment are completed at a pharmacy dispensing location within your organization, it is the responsibility of the Authorized Representative to capture the following required pharmacy dispensing location information for each trained retail chain pharmacy dispensing location and submit the information to VIVUS:

- Dispensing pharmacy address
- Phone and fax numbers
- Pharmacy DEA, NCPDP, and NPI numbers

Once VIVUS receives, processes, and confirms the required retail chain pharmacy dispensing location information from the Authorized Representative, the pharmacy dispensing location will be considered certified and permitted to order, receive, and dispense Qsymia.

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