

Qsymia[®] 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 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.
 - b. All certified retail pharmacy dispensing locations will not distribute, transfer, loan, or sell Qsymia to another pharmacy or distributor.
 - c. 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* each time Qsymia is dispensed.
 - d. I will maintain all records of certified retail pharmacy dispensing location training and acknowledgement forms.
 - e. 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.
 - f. 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 annual 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 corporate pharmacy enrollment confirmation via fax and/or email from VIVUS. 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 VIVUS. 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 it to VIVUS. Once VIVUS 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.

