

Vigabatrin REMS Inpatient Pharmacy (IP) Training

Version 8.0 30Sep2025

Agenda

- REMS Overview, Goals and General Requirements
- Pharmacy REMS Requirements
 - Pharmacy Enrollment Process
 - General Pharmacy Requirements
 - Inpatient Pharmacy REMS Requirements
 - Types of Non-compliance
- REMS Verification Portal
- Pharmacy User Management

Vigabatrin REMS Overview

- The Vigabatrin REMS is a single shared REMS for all approved vigabatrin products which launched on June 1st, 2017, replacing the SABRIL REMS Program
- The purpose of the Vigabatrin REMS is to mitigate the risk of vision loss associated with vigabatrin:
 - Ensuring that healthcare providers are educated about the risk of vision loss, the need to counsel patients about the risk, and the need for periodic visual monitoring
 - Ensuring that vigabatrin is dispensed only to patients with documentation that they are informed about the risk of vision loss associated with vigabatrin and the need for periodic visual monitoring
- Compliance with the Vigabatrin REMS is required for initiating and continuing a vigabatrin prescription, and through the entirety of patient support

REMS Requirements

Prior to prescribing vigabatrin, healthcare providers will:

- Review the Prescribing Information for vigabatrin, and submit a completed Prescriber Enrollment and Agreement Form (online, fax/mail)
- Educate and counsel patients about the benefits and risks associated with vigabatrin, including vision loss and the need for periodic visual monitoring
- Ensure that patients or parents/legal guardians sign the Patient/Parent/Legal Guardian – Physician Agreement Form

Prior to dispensing vigabatrin certified pharmacies will:

- Verify prescribers are certified and patients are enrolled prior to each dispensing
- Ensure appropriate records are maintained of all ‘Eligible’ Prescription Verifications, which should include: prescriber **REMS IDs**, patient **REMS IDs** and the **authorization codes** provided by the Vigabatrin REMS



Pharmacy REMS Requirements

Pharmacy Enrollment Process

- Vigabatrin is available to:
 - REMS Certified inpatient pharmacies
 - REMS Certified outpatient pharmacies who have contracted with at least one manufacturer
- A pharmacy must designate an Authorized Representative
- The Authorized Representative must:
 - Complete and submit the Pharmacy Enrollment Form
 - *Online (Inpatient option only) or fax*
 - Oversee implementation and compliance with REMS requirements
 - Ensure all pharmacy staff supporting the REMS are trained and aware of REMS requirements
- Upon REMS Certification, confirmation is sent via email to the Authorized Representative
 - Includes username and password to access the REMS verification portal (www.vigabatrinREMS.com)
 - Note: This should be kept on file by the Authorized Representative (i.e., for audit purposes, etc.)

VIGABATRIN REMS Pharmacy Enrollment Form

INSTRUCTIONS

- Review and complete this Pharmacy Enrollment Form (this is a one-time enrollment)
- Enroll online at www.vigabatrinREMS.com or complete all required fields below and fax all pages to Vigabatrin REMS at 1-866-205-3072. You will receive confirmation of your certification and log-in credentials for the assigned authorized representative via e-mail.

*Authorized Representative Name: First Name, Middle Initial, Last Name

*Authorized Representative Title/Position

*Telephone Number: Area Code, Telephone Number; *Office Fax Number: Area Code, Fax Number

*E-mail

*Preferred Method of Communication (please select one): Fax E-mail Phone

*Authorized Representative Signature; *Date: Month/Day/Year

Pharmacy Location Information

*Pharmacy Name

*Pharmacy Address: Street, City, State, ZIP Code

*Pharmacy Phone Number: Area Code, Telephone Number; *Pharmacy Fax Number: Area Code, Fax Number

*Select either inpatient or outpatient below and provide the appropriate identifier(s).

Inpatient Pharmacy Identifiers; Outpatient Pharmacy Identifiers

*NPI: ; NCPDP:

If you are enrolling more than one pharmacy location, check this box and provide the information on page 3 for each site. Use as many forms as necessary.

By completing and submitting this form as directed above and receiving certification confirmation, your pharmacy will be certified in the Vigabatrin REMS.

Phone: 1-866-244-8175; www.vigabatrinREMS.com; Fax: 1-866-205-3072

REMS Requirements for Pharmacies

The Authorized Representative must oversee implementation and compliance with the Vigabatrin REMS requirements by:

- Ensuring that all relevant staff involved in dispensing vigabatrin are trained on the Vigabatrin REMS requirements
- Verifying that the prescriber is certified and the patient is enrolled prior to each dispense
 - If a prescriber is not Certified and/or patient is not enrolled, the pharmacy should direct the prescriber to the REMS website (www.vigabatrinREMS.com) for enrollment information or to contact the Vigabatrin REMS to facilitate prescriber enrollment
- Record each 'Eligible' Prescription Verification, capturing:
 - Patient REMS ID
 - Prescriber REMS ID
 - Authorization Code (unique code provided by the Vigabatrin REMS)
 - Date of dispense

Note: The Authorized Representative and any confirmed Pharmacy staff can access the REMS Verification portal to view historical authorization code information

REMS Requirements for Pharmacies

- Complying with requests to be audited by the vigabatrin Sponsors, FDA, and/or a designated third party to ensure that:
 - All Vigabatrin REMS processes and procedures are documented, in place and are being followed
 - The Authorized Representative is responsible for establishing processes and procedures
 - All authorizations to dispense are documented and maintained
 - This includes: REMS authorization codes, Prescriber REMS IDs, and Patient REMS IDs

Note: 180-day audits are required upon REMS Certification. Annual audits are also conducted on a sample of pharmacies each year. Additionally, risk-based audits may be required if REMS compliance is not maintained

- If compliance with the requirements of the Vigabatrin REMS are not maintained, the pharmacy may no longer be able to dispense vigabatrin
- If the Authorized Representative changes, a new Pharmacy Enrollment form must be submitted to the REMS

REMS Requirements for Inpatient Pharmacies

During treatment, **prior to initial dispensing:**

- Verification of patient enrollment is required, prior to dispense. Obtain authorization to dispense by contacting the REMS or via the REMS Website to verify a patient is enrolled. **Document the confirmed patient identification number and Authorization Code**

During treatment, **within 15 days of inpatient admission:**

- Obtain authorization to continue dispensing by contacting the REMS or via the REMS Website to verify a certified prescriber authorizes continuing vigabatrin treatment, and to verify a patient is enrolled
 - Document the confirmed prescriber and patient identification numbers and Authorization Codes
 - **Note: Inpatient Pharmacies may confirm prescriber is certified, and patient is enrolled prior to initial dispensing**

Upon discharge:

- Do not dispense more than a 15 day temporary supply

REMS Requirements for Inpatient Pharmacies

Prescription Verification and Documentation options:

1. Trained pharmacy staff may complete initial prescription verification solely on the patient, ***prior to initial dispensing***. If verification is completed: the **Patient REMS ID** and unique **Authorization Code** must be properly documented in internal pharmacy records.
 - In this scenario, if vigabatrin will be dispensed to the patient *beyond 15 days* of a continuous inpatient admission, a *second verification* must be completed for both the patient and inpatient prescriber prior to the 15-day mark. Once completed, the **Patient REMS ID**, **Prescriber REMS ID**, and unique **Authorization Code** must be properly documented in internal pharmacy records.

OR

2. Trained pharmacy staff may complete prescription verification on both the patient and the inpatient prescriber ***prior to initial dispensing***. If verification is completed: the **Patient REMS ID**, **Prescriber REMS ID**, and unique **Authorization Code** must be properly documented in internal pharmacy records.
 - If the prescriber is certified prior to initial dispensing, no additional verification is required for the duration of the inpatient admission (unless the prescriber changes during the admission)
 - Refer to REMS Verification Portal section for examples

REMS Requirements for Inpatient Pharmacies

- Certified inpatient pharmacies may dispense vigabatrin during the duration of the admitted patient's care
 - REMS verification must be performed via the REMS verification portal for each admission
 - Verifications do not need to be performed daily
- Certified inpatient pharmacies will only be able to purchase vigabatrin through wholesalers/distributors contracted with the Vigabatrin Sponsors
 - To obtain information on contracted wholesalers/distributors, contact the REMS
 - Vigabatrin REMS
 - Phone: 1-866-244-8175
 - Hours: M-F 8:00AM-8:00PM EST

Pharmacy Non-Compliance Events

- Dispensing an ineligible prescription
 - Prescription dispensed to patient not enrolled
 - Prescription dispensed using prescription written by a non-certified prescriber
 - Prescription dispensed using prescription written by a non-certified prescriber to a patient not enrolled
- Dispensing vigabatrin without obtaining an Authorization Code
- Dispensing vigabatrin using an invalid Authorization Code
- Dispensing vigabatrin using an Authorization Code generated for the incorrect patient or prescriber

The REMS Coordinating Center monitors for potential non-compliance and contacts pharmacies to obtain information. Please ensure prompt response when potential non-compliances are being investigated

**Non-compliance related to improper documentation of Prescriber and Patient REMS IDs and Authorization Codes will be verified during REMS audits.*



REMS Verification Portal

REMS Verification Portal

- Pharmacy staff must verify that a patient is enrolled prior to the initial dispensing
- If the patient will continue vigabatrin in the inpatient setting beyond 15 days of the patient's admission, the inpatient pharmacy must ensure that the original Authorization Code verified both a certified prescriber and the enrolled patient; if a certified prescriber was not authorized, a new Authorization Code with a certified prescriber and the enrolled patient must be obtained (and documented) prior to the 15 day mark
- Verification is performed via the REMS Website (www.vigabatrinREMS.com)
- Pharmacy users may login from the home screen or by selecting the 'Pharmacy' page and login



- If a prescriber is not Certified and/or patient is not enrolled, the pharmacy should direct the prescriber to the REMS website or to contact the Vigabatrin REMS for assistance

REMS Verification Portal

[Continued]

- Once logged in, the pharmacy user will be presented with the following screen for data entry (note, patient information fields must be entered in the order displayed):

The screenshot shows a web form titled "REMS VERIFICATION" with a blue header bar. Below the header, the title "REMS VERIFICATION" is repeated in a light blue font. A note states: "Please provide patient information to verify enrollment in the REMS. Required fields are denoted by ***".

The form contains the following fields:

- A text input field containing "ABC Pharmacy" on the left and "NPI: 9999999999" on the right.
- A section titled "PATIENT INFORMATION" with three required fields: "*Last Name", "*First Name", and "*Date of Birth". The "Date of Birth" field includes a calendar icon.
- A section titled "PRESCRIBER INFORMATION" with one required field: "Prescriber NPI".
- At the bottom right, there are two buttons: "CLEAR" and "SUBMIT".

Note: Patient's last name is entered first, followed by first name

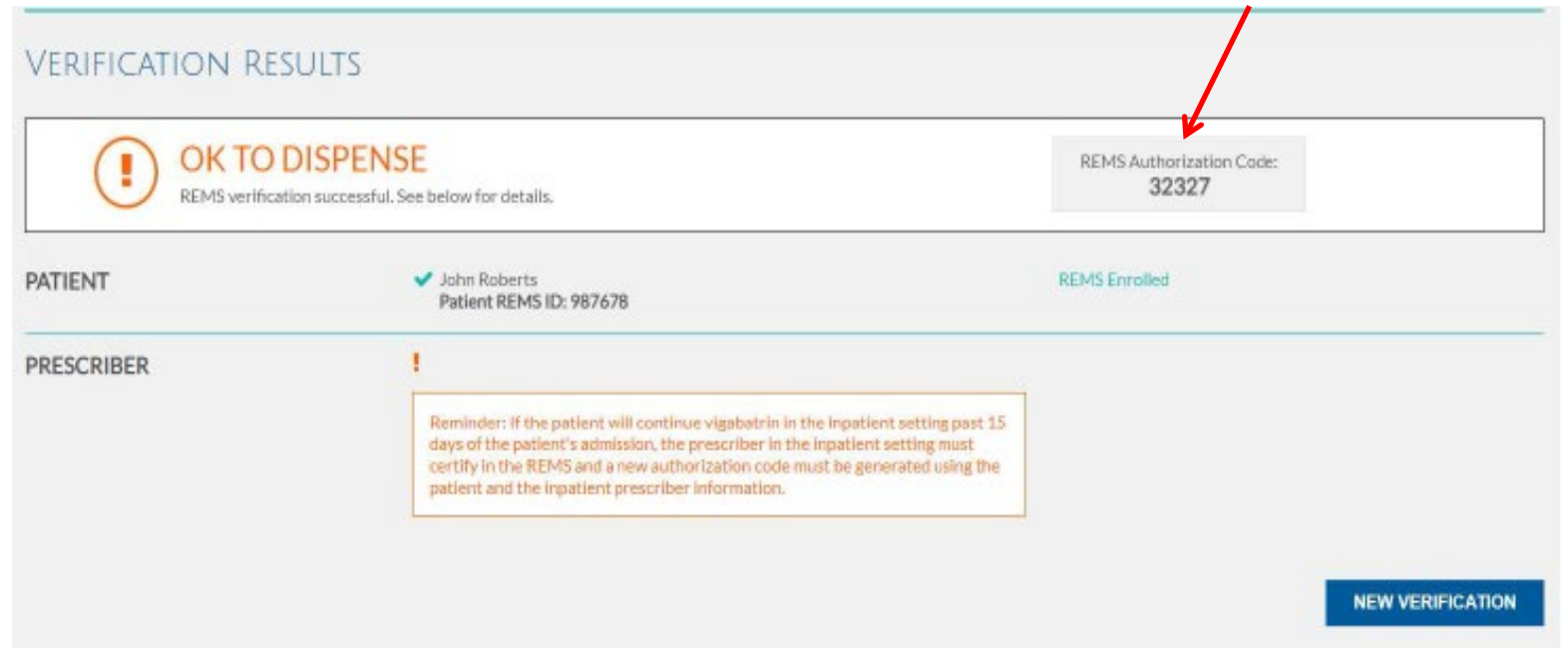
REMS Verification Portal – Successful Verification

- Once verification is completed and pharmacy user is ready to dispense, click the “Generate Authorization Code” button
- **IMPORTANT:** Pharmacy user must click on the “Generate Authorization Code” button and obtain/record an authorization code prior to dispensing vigabatrin

The screenshot displays the 'VERIFICATION RESULTS' section of the REMS portal. At the top, a status bar indicates 'OK TO DISPENSE' with a warning icon and the text 'REMS verification successful. See below for details.' To the right of this bar is a teal button labeled 'GENERATE AUTHORIZATION CODE', which is pointed to by a red arrow. Below the status bar, the 'PATIENT' section shows a checkmark next to 'John Roberts' and 'Patient REMS ID: 987678', with 'REMS Enrolled' noted to the right. The 'PRESCRIBER' section features a warning icon and a text box containing a reminder: 'Reminder: If the patient will continue vigabatrin in the inpatient setting past 15 days of the patient's admission, the prescriber in the inpatient setting must certify in the REMS and a new authorization code must be generated using the patient and the inpatient prescriber information.' A blue button labeled 'NEW VERIFICATION' is located at the bottom right of the page.

REMS Verification Portal – Obtain Authorization to Dispense

- The Authorization Code is displayed.
- Pharmacy staff must record and save the following in Patient ID and Prescriber ID (where applicable), as well as the Authorization Code in pharmacy records:
 - Prescriber REMS ID (when applicable)
 - Patient REMS ID
 - Authorization code
- These fields are required for audits



The screenshot displays the 'VERIFICATION RESULTS' section of the REMS Verification Portal. At the top, a status bar indicates 'OK TO DISPENSE' with a warning icon and the text 'REMS verification successful. See below for details.' To the right of this bar, a red arrow points to a box containing the 'REMS Authorization Code: 32327'. Below the status bar, the 'PATIENT' section shows a checkmark next to 'John Roberts' and 'Patient REMS ID: 987678', with 'REMS Enrolled' to the right. The 'PRESCRIBER' section features a warning icon and a text box with a reminder: 'Reminder: If the patient will continue vigabatrin in the inpatient setting past 15 days of the patient's admission, the prescriber in the inpatient setting must certify in the REMS and a new authorization code must be generated using the patient and the inpatient prescriber information.' A 'NEW VERIFICATION' button is located in the bottom right corner.

REMS Verification Portal – Successful Verification

- If only patient information is entered, or, if a non-certified prescriber's NPI is entered, the following reminder will be present on the “Ok to Dispense” screen:
 - If the patient will continue vigabatrin in the inpatient setting past 15 days of the patient’s admission, the prescriber in the inpatient setting may certify in the REMS and a new Authorization Code must be generated using the patient and the certified prescriber information

The screenshot displays the 'VERIFICATION RESULTS' page. At the top, a box with an orange exclamation mark icon and the text 'OK TO DISPENSE' indicates successful verification. Below this, the 'PATIENT' section shows 'Mary Stevens' with a green checkmark and 'Patient REMS ID: 99999', and 'REMS Enrolled' status. The 'PRESCRIBER' section shows 'Mark Connors (NPI 2222222222)' with an orange exclamation mark icon and 'Prescriber REMS ID: 323232', and 'Not REMS Certified' status. A reminder box states: 'Reminder: If the patient will continue vigabatrin in the inpatient setting past 15 days of the patient's admission, the prescriber in the inpatient setting must certify in the REMS and a new authorization code must be generated using the patient and the inpatient prescriber information.' A 'NEW VERIFICATION' button is located at the bottom right.

Section	Status	Details
Overall	OK TO DISPENSE	REMS verification successful. See below for details.
PATIENT	REMS Enrolled	Mary Stevens Patient REMS ID: 99999
PRESCRIBER	Not REMS Certified	Mark Connors (NPI 2222222222) Prescriber REMS ID: 323232


Reminder: If the patient will continue vigabatrin in the inpatient setting past 15 days of the patient's admission, the prescriber in the inpatient setting must certify in the REMS and a new authorization code must be generated using the patient and the inpatient prescriber information.

NEW VERIFICATION

REMS Verification Portal – Successful Verification

Example: both the patient is enrolled and the prescriber is certified

VERIFICATION RESULTS

**OK TO DISPENSE**
REMS verification successful. See below for details

REMS Authorization Code
W53782

PRESCRIBER ✓ Dr. Mark Smith (NPI 1234567890)
Prescriber REMS ID: 123434 **REMS Certified**


PATIENT ✓ John Roberts
Patient REMS ID: 987678 **REMS Enrolled**

NEW VERIFICATION

Unsuccessful Verification

- Pharmacy must not dispense.
- If prescriber is not certified and/or patient is not enrolled, the pharmacy should direct the prescriber to the REMS website to enroll or to contact the Vigabatrin REMS for assistance
- Pharmacy staff may also contact the REMS directly for support

VERIFICATION RESULTS

 **DO NOT DISPENSE**
REMS verification failed.

PLEASE CALL FOR ASSISTANCE
1-866-244-8175

PATIENT ✘ Mary Stevens
Patient REMS ID: 99999 Not REMS Enrolled

PRESCRIBER ✘

Reminder: If a patient is not previously enrolled in the REMS, the patient needs to enroll and the inpatient prescriber needs to certify before vigabatrin can be dispensed.

[NEW VERIFICATION](#)



Pharmacy User Management

User Access

- The Authorized Representative (AR) will automatically receive two separate emails with a unique username and password to access the REMS verification portal upon pharmacy certification in the REMS ARs may request access for additional pharmacy staff that will use the REMS verification portal by submitting a User Access Form
 - Contact the Vigabatrin REMS to obtain a User Access Form
 - Upon receipt of a completed User Access Form, including valid AR signature, the users will be added to the application
 - Username and password will be sent to each user in separate emails
 - Upon initial login users will be prompted to change their password
- The REMS will reach out to ARs biannually to confirm users still require access
 - If the AR becomes aware of users who no longer require access, they should notify the Vigabatrin REMS to have their access removed

User Access Form



Vigabatrin REMS Program Inpatient Pharmacy User Access Form

Please complete this form in order to receive access to the pharmacy portal for the Vigabatrin REMS Application. This form must be signed and dated by the Authorized Pharmacy Representative. Please submit the completed form, via fax, to the Vigabatrin REMS Program at 866-205-3072.

Vigabatrin REMS Program Authorized Representative Approval:

By signing this form as the Authorized Representative, I verify that the user(s) listed below is a representative of my Pharmacy and that she/he may be granted access permissions to Vigabatrin REMS application to confirm prescriber certification and patient enrollment prior to dispensing vigabatrin. I verify that it is my responsibility to notify the Vigabatrin REMS team immediately if a User should no longer require access to the Vigabatrin REMS application and request the user be deactivated.

**Unique log on credentials are solely intended for the identified individual user. Usernames and passwords must not be shared. An Authorized Representative may submit additional User Access Forms, at any time, to request new user accounts.*

Pharmacy Name: _____

Authorized Representative Name: (print) _____

Authorized Representative Signature _____ Date: _____

User Access Request: (print the following information)

First Name	Last Name	Title	Email	Phone #

Change in Authorized Representative

- In the event the Authorized Representative leaves the pharmacy or contact information is updated, the pharmacy must inform the Vigabatrin REMS
 - Outreach by the Vigabatrin REMS to confirm the Authorized Representative on record is accurate will be performed annually
 - If the Authorized Representative has changed, the pharmacy is required to submit a new Pharmacy Enrollment Form with the new/current Authorized Representative
 - If an Authorized Representative is not identified, the pharmacy may be inactivated in the REMS and unable to dispense until a representative is identified
- Be proactive and communicate any changes in Authorized Representative to the Vigabatrin REMS

Support

- www.vigabatrinREMS.com
 - Pharmacy Page
 - REMINDER: New Prescribers may enroll online anytime
 - REMINDER: Certified Prescribers may enroll new Patients online anytime
- Vigabatrin REMS
 - Phone: 1-866-244-8175
 - Fax: 1-866-205-3072
 - Hours: M-F 8:00AM-8:00PM EST



Thank you for attending!

Questions?

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