



## XYWAV and XYREM REMS Risk Management Report

Risk Management Reports (RMRs) are filled out by the central Certified Pharmacy to document and report events that give rise to a reasonable suspicion of abuse, misuse, diversion, or any behavior or information that may indicate the drug is not being used according to the prescriber's instructions. The RMR history of a patient allows for the review of prior events of suspected abuse, misuse, or diversion and gives the pharmacist a more complete picture of the patient's history. The availability of individual patient RMRs enables the pharmacist to track and monitor for trends suggesting abuse, misuse, or diversion in individual patients. A trend or pattern of behavior in a patient's RMR history can be an indicator of abuse, misuse, or diversion and identifies patients who may require additional scrutiny when another event, such as an early refill request, occurs. In these cases, the RMR history informs actions of the pharmacist.

Examples of events that would require completion of an RMR under the XYWAV and XYREM REMS include, but are not limited to, the following:

- Patient requests for early refills.
- Patient's loss/misuse of the product.
- Patient claim that he or she did not receive the product but the delivery service shows receipt of delivery, or that the shipment was lost or stolen or delivered to an incorrect address and was not returned.
- Tampering with or counterfeiting or contaminating the product.
- Inquiries and/or arrests by law and regulatory enforcement agencies associated with the misuse or diversion of the product, or crimes related to the product.
- Prescribers whose DEA and/or state license numbers cannot be validated and the prescriber is submitting a REMS Prescriber Enrollment Form, REMS Patient Enrollment Form, XYWAV Prescription Form, or XYREM Prescription Form.

To complete an RMR:

- Assign a unique Control Number to each report in the Central Database.
- Complete investigation of the event, which may include contacting the patient, prescriber, law enforcement agency, or other parties.
- Attach any additional documentation required to support the investigation, including but not limited to the following: DEA 106 Form, police or fire report, or report from the shipping service.
- Complete review, follow up, and sign-off on the RMR.
  - When the event involves suspected abuse, misuse, or diversion, the prescriber will be contacted and an alert may be placed in the prescriber or patient profile of the Central Database to ensure prescriber and pharmacist awareness.
  - The Certified Pharmacy will monitor any associated patient or prescriber activity in the XYWAV and XYREM REMS during the course of the investigation and for a period after the investigation, where appropriate.
  - The Certified Pharmacy will work with Jazz Pharmaceuticals to determine the need to notify local, state, or federal agencies.
- Ensure that the information contained in the RMR is maintained in the Central Database.
- Send the RMR to Jazz Pharmaceuticals within one business day.

If the RMR includes a potential adverse event, the potential adverse event is reported through the Jazz Pharmaceuticals adverse event reporting system. If the RMR includes a product complaint, the event is also reported through the Jazz Pharmaceuticals product complaint system.



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Date: \_\_\_\_\_ Control No.: JRM- \_\_\_\_\_

Addendum: Yes  No

Type of reporter (e.g., patient, pharmacist, physician): \_\_\_\_\_

If not patient, name of reporter: \_\_\_\_\_

Nature of report (e.g., early refill request, lost or stolen bottle, package not received, other):  
\_\_\_\_\_

Identification number(s) (patient and/or prescriber ID associated with RMR): \_\_\_\_\_

Date enrolled in program (from patient or prescriber record): \_\_\_\_\_

Reviewed alerts and RMR history for individual? Yes  No

RMR event (please provide detail): \_\_\_\_\_  
\_\_\_\_\_

Date(s) of RMR event: Start: \_\_\_\_\_ End: \_\_\_\_\_

Early refill requested? Yes  No

If yes, reason for early refill request (e.g., dose increase, spilled medication, lost/stolen product):  
\_\_\_\_\_

Prescriber contacted? Yes  No

If yes, outcome: \_\_\_\_\_ If no, reason: \_\_\_\_\_

Early refill status: Approved  Denied  Early refill status reason: \_\_\_\_\_

Potential adverse event associated with report? Yes  No  If yes, AE number: \_\_\_\_\_

Summary of investigation: \_\_\_\_\_  
\_\_\_\_\_

Attachments (check all that apply):

DEA 106 Form  Police/Fire Report  Shipping Service Report

Other  (specify) \_\_\_\_\_

Monitor (alert placed): Yes  No  N/A

Report closed: Yes  No

➤ Operations Director (or designee): \_\_\_\_\_ Signature (date/time) \_\_\_\_\_

➤ Pharmacist in Charge (or designee): \_\_\_\_\_ Signature (date/time) \_\_\_\_\_