END

BACKUP

ORDER MONITORING

Rhodes Pharmaceuticals
Order Monitoring System

Current Order Monitoring System Procedure analyzes the following 3 methods of purchase:

1. Wholesaler/Distributor Direct Sales
2. Indirect Contract Sales
3. State Medicaid usage

National Account Managers will visit any wholesalers, distributors or retailers (including physicians) that gets flagged by the order monitoring system and discuss our findings with their compliance officer, senior management or owner.

Wholesaler/Distributor Direct Sales

- Sales to customers purchasing directly are monitored and flagged if units exceed an average of prior months purchases

Indirect Contract Sales

- Indirect sales are tracked through chargeback data using iContracts Sales Tracking Software
- An indirect customer is flagged if indirect units exceed an average of previous usage
- Factors such as newly awarded contracts or changes to insurance are considered
- Accounts will be contacted by National Account Managers if suspicious activity is determined

State Medicaid Utilization

- State Medicaid agencies submit quarterly invoices to Rhodes Pharmaceuticals for calculation and payment of a rebate.
- Invoices are checked to ensure that the tablets per prescriptions do not exceed an established threshold
- Units are flagged that exceed the threshold are rejected for further documentation from the State Medicaid Agency
- The individual pharmacies may be contacted to validate the justification for the prescription.

Current FDA Thinking

- FDA CDER response to Center for Lawful Access and abuse-deterrence Citizen Petition
  - Letter in response to a citizen petition asking that the FDA take administrative action to transition to abuse-deterrent opioids
- Key Takeaways
  - FDA does not believe proposed restrictions for opioid drug products in solid oral dosage forms are either feasible, appropriate or in the interest of public health
  - FDA intends to continue to take a product-by-product approach to regulatory decisions concerning the safety and effectiveness of opioid products
  - Consistent with this product-by-product approach, FDA approved non-abuse-deterrent Zohydro ER after concluding that its benefits outweigh its risks
  - FDA recognizes that the most common form of abuse of prescription opioids is by swallowing intact tablets or capsules

FDA Recent Approvals

- In 2013 there were 20 opioid ANDA's approved without abuse-deterrent properties
- Zohydro ER approved October 25, 2013 without abuse-deterrent properties

FDA Approved Label