



Specialty Pharmacy and REMS Experiences and Challenges in VA

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VA Healthcare System

- The Veterans Health Administration is home to the United States' largest integrated health care system
- Comprehensive care provided by more than 53,000 independent licensed health care practitioners



Statistics at a Glance

- Number of VA Health Facilities
 - VA Community-Based Outpatient Clinics – 817
 - VA Hospitals – 152

*As of 3/31/12



Statistics at a Glance

- Total Enrollees in VA Healthcare System – 8.6 million
- Outpatient Visits – 79.8 million
- Inpatient Admissions – 692,000

*Fiscal Year 2011



Statistics at a Glance

- Total Outpatient Prescriptions Dispensed by VA Facilities in FY2011
 - > 139 million prescriptions
 - 78.5% dispensed by VA Consolidated Mail Outpatient Pharmacies (CMOP)




VA Pharmacy Considerations

- Electronic health records are available to providers and pharmacists
- Pharmacist disease state specialists actively participate in patient care and collaborate with providers
- Continuum of care guides and tracks health services
- All prescriptions are routed through the VA pharmacy, regardless of procurement source



VA Pharmacy Considerations

- Non-formulary prescriptions are reviewed for approval locally
- VA is the payor for the majority of prescriptions
- Contract for product purchase is between VA and the manufacturer, not between VA and specialty distributor/pharmacy



General Challenges Posed by Specialty Pharmacy Models

- VA healthcare system often not considered when restricted distribution models for medications are created. Need earlier involvement
- Those involved in the design of distribution models are at times not familiar with the unique operational, clinical and contractual processes
- Private sector models cannot always be successfully implemented in the VA
- Especially problematic when medication has REMS Elements to Assure Safe Use (ETASU)



General Challenges Posed by Specialty Pharmacy Models

- Participation as a specialty pharmacy closed to VA when dispensing and procurement is limited to contracted pharmacies
- Specialty pharmacy not contracted by manufacturer to service VA and extend upfront applicable Federal Supply Schedule pricing
- Manufacturer unaware of FSS terms and contractual responsibilities



Specialty Pharmacy Challenges

- Specialty Pharmacy or distributor unaware of FSS pricing and payment by VA
- Prescription dispensing delayed by SP when Veteran is unnecessarily contacted for payment or insurance information
- Benefits investigation by outside service does not apply
- SP doesn't have process in place to accept a credit card for payment and/or "buy and bill" transaction



Specialty Pharmacy Challenges

- Use of program Hub that first receives the patient's prescription or enrollment form
 - Unnecessary patient contact
 - Marketing
 - Patient assistance programs, benefit or formulary research
 - Privacy concerns
 - Increases delays and possibility of routing to SP not contracted by manufacturer to service VA



Specialty Pharmacy Challenges

- Review of all documents by VA Federal Supply Schedule (FSS) and Pharmacy Benefits Management (PBM) for compliance and acceptability. VA Privacy Office and Ethics Office involvement when necessary
- Includes program prescription forms, enrollment or registration documents, acknowledgments, release of information, distributor or specialty pharmacy account applications, counseling materials, etc.
- Creation of VA specific distribution model forms is often necessary



Specialty Pharmacy Challenges – Specific to SP Dispensing

- VA pharmacy needs to be made aware of all medication changes, dispensing dates, discontinuation of therapy and adverse events
- SP must contact VA pharmacy before subsequent refills are dispensed.
 - Therapy or condition may have changed
 - Medication interaction screening
 - Prescriber consultation
 - Payment



Specialty Pharmacy Challenges – Specific to SP Dispensing

- VA must have the option to have SP dispensed prescriptions shipped either directly to the patient or to the VA pharmacy for relay to the patient. Document must reflect those options
- Prescriptions sent directly to a patient – SP required to provide a delivery confirmation summary to VA pharmacy)
- Monthly sales data reporting



Transmucosal Immediate-Release Fentanyl (TIRF) Model

- Program design- Outpatient pharmacy and patient enrollment transmitted to the program via the pharmacy electronic management system to obtain dispensing approval
- VA pharmacy unable to implement
- Resulted in a lengthy REMS revision with significant time commitment and cost to the REMS sponsors
- Earlier VA involvement is critical



Goals

- Continue to drive awareness of VA requirements with all stakeholders and encourage earlier involvement in the distribution model planning phase
- History of successfully working together with industry to meet all requirements
- Dedicated to continue making these important medication options available to our Veterans



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