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# Drug Shortages in the Department of Veterans Affairs

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# Disclosure

- Vincent Calabrese does not have any conflicts of interest. His travel and accommodations to participate in this conference are funded by VA Pharmacy Benefits Management Services and he is not accepting an honorarium.

# Topics

- VA Background
- Shortage effects on VA outpatients and inpatients
- Shortage resources used by VA
- VA actions to manage shortages
- Recommendations

# VA Statistics

## ■ Facilities

- 152 hospitals
- 958 clinics (791 CBOCs)

## ■ Veterans

- 22.7 million total (8% women)
- 8.3 million enrollees
- 6.0 million patients treated
- 4.7 million pharmacy users

# VA Statistics

- 258 million outpatient prescriptions (30-day Equivalent)
  - 82% via mail order (CMOP)
  - 18% via local facility pharmacies
- VA Consolidated Mail Outpatient Pharmacy
  - Efficiency and Accuracy
  - 7 physical plants located across continental USA

# Shortage Effect on Outpatients

- Veterans request prescription refills 10-14 days prior to running out of medications
- Routed to CMOP to fill and mail to Veterans so they receive them within 10 days

# Shortage Effect on Outpatients

- CMOP must have prescription filled and turned over to parcel delivery vendor within 48 hours
  - If CMOP cannot fill order it is cancelled back to Medical Center
  - Delays Veterans from receiving needed medications

# Shortage Effect on Inpatients

- Anesthesia Drugs (e.g., Succinylcholine)
  - Surgery cancellations
- Anesthesiology Guidance
  - Therapeutic alternatives
- E.g. Rocuronium, where appropriate
  - Strategies to conserve existing supplies
- Reserve Succinylcholine for emergency use, when other options in the Guidance are not appropriate
- Drawing up Succinylcholine in syringes under pharmacy hood for extended stability/shelf life

# Web Resources

- National Shortage Websites:
  - Food and Drug Administration (FDA):  
<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm>
    - Company/Products
    - Reason
    - Related Information

# Web Resources

- National Shortage Websites:
  - American Society of Health-System Pharmacists (ASHP):  
<http://www.ashp.org/DrugShortages/Current/>
    - Products Affected - Description
    - Reason for the Shortage
    - Estimated Resupply Dates
    - Implications for Patient Care
    - Safety
    - Alternative Agents & Management
    - Related Shortages

# VA Actions

- Borrowing from private hospitals that may have excess stock due to contracts
- Coordination of sharing between VA hospitals
- Consolidation of dispensing to one VA CMOP
- Reduction in prescription quantity from 90-day supply to 30-day supply

# VA Actions

- VA Specific Shortages Report
  - Published as part a weekly pharmaceutical procurement newsletter
    - Econo # / Description
    - Generic Name / NDC
    - Vendor Name
    - Comments
    - Actions to Handle Shortages
    - Expected Return

# VA Actions

- Actions to Handle Shortages
  - Call companies for more information / resolution dates
  - Look in Prime Vendor to see available alternative sources
  - Look elsewhere if not in Prime Vendor (e.g., direct)
  - Action may be, in part, for providers to consider alternatives, where appropriate
- Work with Subject Matter Experts on Guidance
  - Therapeutic alternatives
  - Strategies to conserve supplies

# Recommendations

- Foreign Importation
  - VA (federal government) may not be able to procure due to Federal Acquisition Regulation (FAR) regarding foreign acquisition
  - FAR is a additional layer of regulation that creates a disadvantage compared to private sector during shortages
  - Recommend that FDA include appropriate waivers for federal agencies to be able to take advantage of this solution

# Recommendations

- Market Withdrawal Regulation
  - Recommend that FDA seek additional regulatory authority
  - 1) Require manufacturers to get approval from FDA before voluntarily withdrawing from the market for specified drugs or drug classes
    - Allows FDA to work with remaining manufacturers to adjust to increased market demand

# Recommendations

- 2) Require manufacturers to get approval from FDA before re-entering the market after voluntarily withdrawing from the market for specified drugs or drug classes
  - Allows FDA to work with remaining manufacturers to adjust to reduced market demand
  
- Early warning to public