Formulary Management

Jennifer L. Zacher, PharmD, BCPP
VA Pharmacy Benefits Management Service
Ellen A. Roska, PharmD, MBA
Defense Health Agency Pharmacy Operations Division

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CPE Information and Disclosures

Jennifer L. Zacher, PharmD, BCPP declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.”

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CPE Information

• Target Audience: Pharmacists and Technicians
• ACPE#: 0202-0000-15-209-L04-P/T
• Activity Type: Knowledge-based

Learning Objectives

1. Compare and contrast the Veteran’s Affairs (VA) formulary management process and benefit design with the Department of Defense (DoD) formulary management process and benefit design
2. Discuss the formulary management tools the VA and DoD use to manage the benefit
3. State the joint VA/DoD formulary alignment initiatives
4. Describe the impact federal legislation has/will have on future management and payment practices of both benefits

Self-Assessment Question 1

Which of the following statements accurately describes the VA Formulary Management process?

A. There is very little utilization of non-formulary medications within the VA system.
B. Each VA Medical Center is charged with developing its own local formulary.
C. VA clinical staff at the facility level are not involved in the national formulary review process.
D. Prescription copays are not dependent on VA National Formulary status.
Self-Assessment Question 2
Which groups provide formulary management input in the DoD?
A. Beneficiaries
B. Providers
C. Public Health Service, Defense Logistics Agency, DoD, VA
D. All of the above

Self-Assessment Question 3
How many pharmacy point of service options are there in the DoD?
A. One
B. Two
C. Three
D. Four

Overview
• Discuss the VA system
• Discuss the DoD system
• Joint formulary initiatives
• Impact of legislation

DEPARTMENT OF VETERANS AFFAIRS (VA) SYSTEM

VA Profile
• Staff Model (Health Maintenance Organization)
  – Comprehensive health care system
  – Direct provider of care
  – Providers are employees
  – Own and operate infrastructure
  – Prescription drug benefit is integrated, not added on or contracted out

VA Statistics (FY 2014)
• Facilities
  – 150 hospitals
  – 830 community based outpatient clinics
• Veterans
  – 22.0 million total (10% women)
  – 9.1 million enrollees
  – 6.2 million patients treated
  – 4.9 million pharmacy users
VA Statistics (FY 2014)

- 271 million outpatient RXs (30-day equivalents)
  - 85% via mail order
  - 15% via local facility pharmacies
- $3.7 billion outpatient drug expenditures
  - Cost per 30-day equivalents RXs nearly flat for 15 years
  - Cost low for population (elderly, male, comorbidities)

VA Pharmacy Benefits Management Services (PBM)

- Formulary Management
- VAMedSAFE
- Emergency Pharmacy Services
- VA Consolidated Mail Outpatient Pharmacy
- Pharmacy Re-engineering and Clinical Informatics
- PBM National Pharmacy Efficiency Program
- Pharmacy Residency
- VA Medication Reconciliation Initiative
- Pharmacy Recruitment and Retention
- Clinical Pharmacy Practice
- Pharmaceutical Compounding and Hazardous Drugs
- Academic Detailing

Key PBM Functions

- PBM Office (Formulary Management)
  - Evidence-based medicine
    - Clinical reviews, clinical algorithm and guideline development, pharmaceutical contracting
  - DoD collaboration
    - Clinical practice guideline development, pharmaceutical contracting
  - Education
    - Live Meeting programs
  - Data management
    - Pharmaceutical prime vendor PPV purchases and prescription data
  - Administration of Public Law 102-585
    - Federal drug pricing

Veterans Health Administration (VHA) Handbook 1108.08: VHA Formulary Management Process

- Formulary Management Process
  - Purpose, Background, Definitions, Scope
  - Responsibilities
  - Procedures
- Compassionate Use of Nutraceuticals
- Cosmetic and Enhancement Drugs
- Tablet Splitting
- Inventory Management
- Compounding of Non Sterile Pharmaceutical Preparations

Key Objectives

- Promote formulary decisions that are evidenced-based, not preference-based
- Promote appropriate drug therapy and discourage inappropriate drug therapy
- Reduce the geographic variability in utilization of pharmaceuticals across the VA system
- Promote portability and uniformity of the drug benefit
### Key Objectives

- Initiate patient safety improvements
- Design and implement relevant outcomes assessment projects
- Improve the distribution of pharmaceuticals
- Reduce inventory carrying costs, drug acquisition costs and the overall cost of care

### Formulary Overview

- **VA National Formulary (VANF)** is the sole drug formulary used in VA
- Dosage form specific (e.g. aspirin tab, etc)
- Co-pay: $8 per 30-day supply ($9 for P7/8s)
  - Affects only ~50% of Veterans based on eligibility
  - Same co-pay for Formulary vs. Non-Formulary
  - Different than Private Sector (tiers)
- Non-Formulary Process

### Formulary Overview

- **Formulary Progression**
  - Local (Veterans Affairs Medical Center (VAMC)) Formularies (173, <1996)
  - Added Veterans Integrated Service Network (VISN) Formularies (22, 1996)
  - Added National Formulary (1997)
  - Removed Local Formularies (2001)
  - Froze VISN Formularies (2006)
  - Abolished VISN Formularies (2009)

### Formulary Mgt Infrastructure

- **Office of the Under Secretary for Health**
- **VA Medical Advisory Panel (MAP)**
- **VISN Pharmacist Executives Committee**
- **VA Clinical Subject Matter Experts**
- **VA PBM**
- Regional (VISN) Pharmacy and Therapeutics (P&T) Committees
- Local (VAMC) P&T Committees
- Procurement / Acquisition Staff

### VA National “P&T” Committee

- **Medical Advisory Panel (MAP)**
  - 11 physicians
  - 11 PBM Clinical Pharmacists
  - 1 VPE member
- **VISN Pharmacist Executives Committee (VPE)**
  - 21 pharmacists
  - 1 MAP member
- **Meetings**
  - Monthly conference calls
  - Face-to-Face quarterly meetings (combined)
  - MAP vote prevails when consensus cannot be reached

### Formulary Development

- **New Molecular Entity Review (NME)**
- Local Provider (via VISN P&T Committee)
- **VISN P&T Committee, the VISN Pharmacist Executive Committee (VPE), the Medical Advisory Panel (MAP), a VHA Chief Medical Consultant or VHA Chief Medical Officer**
- Contracting Standardization
### New Molecular Entity (NME) Review Process

- NME approved by Food and Drug Administration (FDA)
- Literature search and draft review completed
- Presented to VPE/MAP committees and changes incorporated
- Disseminated widely to clinical staff for comment
- Presented to VPE/MAP committees and changes incorporated
- VA National Formulary decision
- National criteria for use developed when indicated

### Contracting

- Clinical review may lead to a national contract
- Review will determine type of contract
  - Evaluation factors vs. price alone
- Therapeutic Interchange contract
  - Therapeutic equivalence - evaluated by price alone
  - Evaluation factors - evaluated by best value
- Standardization contract
  - Generic contract - evaluated by price alone

### Standardization Contract

- Market conditions
  - Adequate competition (vendors, package sizes)
  - Sufficient raw materials
  - Price reduction and stabilization
- Contracting requirements
  - Minimum requirements (volume)
  - Vendors and package sizes

### VA FORMULARY MANAGEMENT TOOLS

### Formulary Mgt Strategy

- Clinical Staff Buy-In
  - Before formulary decisions are made and implemented, each VA clinician has an opportunity to provide input.
  - Due to up front buy-in and evidence based reviews, contract adherence for “closed” classes is rapid and extensive. Adherence can reach 90% in 3 months and >98% within 6 months.

### Non-Formulary Drug Use

- Prescribing guidance (evidence-based Criteria for Use) for non-formulary drugs is developed to ensure access to medically necessary drugs not listed on VANF.
- For illustration, in FY 2014 VA dispensed prescriptions for the following non-formulary drugs:

<table>
<thead>
<tr>
<th>Drug</th>
<th>30-day Eqv RXs</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crestor®</td>
<td>4,052,637</td>
<td>$57 million</td>
</tr>
<tr>
<td>Actos®</td>
<td>369,474</td>
<td>$48 million</td>
</tr>
<tr>
<td>Lipitor®</td>
<td>284,493</td>
<td>$9 million</td>
</tr>
<tr>
<td>Cymbalta®</td>
<td>249,611</td>
<td>$30 million</td>
</tr>
<tr>
<td>Zetia®</td>
<td>237,489</td>
<td>$14 million</td>
</tr>
</tbody>
</table>
**Broad Objectives:**

Formulary Management

- Lower Cost with Same Outcomes
  - or, better still...
- Same Cost with Better Outcomes
  - or, best....
- Lower Cost with Better Outcomes

**MILITARY HEALTH SYSTEM**

**DEPARTMENT OF DEFENSE**

**(DOD)**

**DoD Profile**

- Patients
  - Active duty, active duty dependents, retirees and retiree dependents, other
  - 9.53 million eligible / 7.52 million users
- Structure
  - Purchased care
    - Retail pharmacy
    - Mail order pharmacy
  - Direct care
    - Military treatment facilities

**DoD Statistics (2014)**

- Various health plan options (Tricare)
- Facilities
  - 56 medical centers and inpatients facilities
  - 360 ambulatory clinics
  - 262 dental clinics
  - 58,535 civilian contracted pharmacies
- Personnel (153,616 total)
  - 86,039 military personnel
  - 67,577 civilian personnel

**DoD Statistics (2014)**

DoD Prescription Volume (30 day equivalents) by Point of Service 2002-2014

**DOD FORMULARY MANAGEMENT**
DoD Pharmacy Operations Division (POD)

- **Purpose:** Improve readiness by increasing value, quality, and access to medical care and pharmacotherapy within the available resources of the Military Health System (MHS)
- **Mission:** Improve the clinical, economic, and humanistic outcomes of drug therapy in support of the readiness and managed health care missions of the MHS

DoD Pharmacy Operations Division (POD) Services

- Monitor drug usage and cost trends
- Perform pharmacoeconomic analyses
- Administrative and technical support for the DoD P&T Committee
- Support the Pharmacy Data Transaction Service
- Develop and manage information systems that support the pharmacy benefit
- Establish national pharmaceutical contracts with Defense Logistics Agency, VA PBM Strategic Health Group, and National Acquisition Center
- DoD/VA clinical practice guideline workgroup

Legal Basis & Congressional Oversight

  - Procedures for UF
  - DoD P&T Committee, BAP, Uniform Formulary (UF)
- 2008 NDAA
  - Federal Ceiling Price applies to retail network Rxs
- 2013 NDAA
  - Innovator drugs
  - Mail order
  - Over the counter

TRICARE Formulary

<table>
<thead>
<tr>
<th>Pharmacy Type</th>
<th>Formulary Drugs</th>
<th>Non-Formulary Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Generic (Tier 1)</td>
<td>Brand Name (Tier 2)</td>
</tr>
<tr>
<td>Military Pharmacy</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>(up to a 90-day supply)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRICARE Pharmacy</td>
<td>$0</td>
<td>$16</td>
</tr>
<tr>
<td>Home Delivery (up to 90 days)</td>
<td>$20</td>
<td>$46</td>
</tr>
<tr>
<td>TRICARE Retail Network Pharmacy (up to 90 days)</td>
<td>$8</td>
<td>$141 per 90 days</td>
</tr>
</tbody>
</table>

Pharmacy Copayments FY15

Higher co-insurance amounts apply to out-of-network claims.
No copay for Active Duty at any point of service.
**Organization**

- **DHA**
- **BAP**
- **HCO**
- **DoD P&T**
- **POD**

DHA = Defense Health Agency  
BAP = Beneficiary Advisory Panel  
HCO = Health Care Operations  
POD = Pharmacy Operations Division

**DoD P&T Committee**

- **DoD P&T Committee**
  - Military physicians (range of specialties) from each Service  
  - Pharmacy consultants from each Service  
  - Representatives/attendees from VA, Coast Guard, US Public Health Service, Defense Logistics Agency, Patient Safety, legal counsel, etc.
- **Comparative analysis**
  - Clinical effectiveness and safety  
  - Economic analysis
- **Meets quarterly**

**Formulary Management Strategy**

- **Beneficiary Advisory Panel**
  - Beneficiary input
- **Clinical**
  - Provider input

**DOD FORMULARY MANAGEMENT TOOLS**

**Formulary Tools**

- **Tier status**
- **Quantity limits**
  - Safety, costs, wastage
- **Warning messages**
  - Safety issues
- **Prior authorization**
- **Step therapy**
- **Age and gender**

**Side-by-Side Comparison**

<table>
<thead>
<tr>
<th></th>
<th>VA</th>
<th>DOD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient population</strong></td>
<td>Veterans, family member coverage through CHAMPVA program if eligible</td>
<td>Active duty and their families, Retirees and their families</td>
</tr>
<tr>
<td><strong>Beneficiaries</strong></td>
<td>9.1 million eligible</td>
<td>9.57 million eligible</td>
</tr>
<tr>
<td><strong>Structure</strong></td>
<td>Closed system</td>
<td>Direct care and purchased care</td>
</tr>
</tbody>
</table>
VA AND DOD FORMULARY ALIGNMENT

DoD/VA Formulary Alignment Initiatives

- Joint pharmaceutical contracting
  - 140 national contracts currently
- Joint Clinical Practice Guidelines
- VA/DoD formulary alignment
  - Goal: Continue the appropriate use of medication during transition from DoD to VA benefits
  - Identify medications with different formulary status in each system

DoD/VA Formulary Alignment Initiatives

- VA/DoD formulary reconciliation
  - VA added duloxetine, dextroamphetamine/amphetamine, dextroamphetamine/amphetamine SA, and bupropion extended-release to VA national formulary
  - Further alignment expected under proposed 2016 NDAA

Impact of Impending Legislation

- Continue collaboration efforts to ensure the continuity of care for transitioning Service members
- Strive to jointly provide safe, clinically appropriate, and effective therapies
- Develop formal transition policy including a current medication list
- Identify best practices in existing transition programs
  - Reduce errors, adverse events, number of medications
  - Improve patient outcomes
- Minimize patient disruption during transition by streamlining both DoD and VA processes and formulary alignment

Conclusion

- VA and DoD formulary management processes are patient centered and evidence based
- Our differences allow us to best deliver care to our unique patient populations
- Our collaboration efforts will continue to benefit both systems

THE FUTURE
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Answer to Self-Assessment Question 1

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Closing Remarks

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Jennifer.z

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Defense Health Agency Pharmacy Operations Division
ellen.a.roska.mil@mail.mil