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Heading to Decision 2012: Primaries and Policy for Pharmacy

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Political Landscape
- Presidential Campaign
  - Primaries
  - General Election
- Senate Races
- House Contests
- Governors and State Legislatures

Overarching Issues
- Deficit Reduction
- Economic Growth
- Unemployment
- October Surprise

Health System Pharmacy Policy
- Entitlement Reform
  - Medicare
  - Medicaid
- Affordable Care Act Implementation
  - Supreme Court Ruling
  - Quality Measures
  - Value Based Purchasing
  - Accountable Care Organizations
- Drug Shortages
  - Current Legislation
- Pharmacy Practice Model Initiative
  - Pharmacist Prescribing
  - Pharmacy Technician Licensure

Long Term Trends
- Push for Quality Measures
- Drive to Reduce Payment and Cost
- Pay for Performance Toward Patient Outcomes
- Essential Member of Interdisciplinary Team
Congressional Outlook for 2012: Drug Shortages and Prescription Drug User Fee Act (PDUFA)

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Issues
- Drug Shortages
- 340-B Expansion Bill
- Medication Therapy Management Bill
- Super Committee Cuts
- Drug Safety/PDUFA

Drug Shortages
- ASHP, larger stakeholder group recommendations on drug shortages
  - Enhanced communication/early warning
  - Ensure FDA has adequate resources
  - Establish contingency plans for drugs vulnerable to shortages, including incentives for manufacturers
  - Require collaboration between FDA and DEA to adjust quotas for controlled substances, as needed
  - Expedite approval for medically necessary, unapproved drugs
- Presented them to FDA at 9/26 public workshop

Preserving Access to Life-Saving Medications Act (S 296, HR 2245)
- Both bills
- Establish an early warning system
- Manufacturers would have to notify FDA of an interruption in production; 6 months for discontinuation, ASAP for production problem
- Notification would be confidential, FDA would only post information on actual shortages

Preserving Access to Life-Saving Medications Act (S 296, HR 2245)
- Bipartisan bills in Congress:
  - S. 296 (Klobuchar/CASEY)
  - H.R. 2245 (DeGette/Rooney)
- Bills establish early warning systems
- Both have bipartisan support
- House bill is supported by Hospira
### Differences between the Bills

- **S. 296:**
  - Only applies to drugs, not biologics
  - Does not spell out fines for failure to report
- **H.R. 2245** does both of the above
- Neither bill applies to unapproved drugs
- House bill is supported by a manufacturer (Hospira)
- Both bills now have bipartisan support
- **H.R. 2245** has 55 coponsors
- **S. 296** has 19

### Drug Shortages

- ASHP member Kevin Colgan testified before Congress on 9/23
- Expressed support for the bills
- Referenced larger list of recommendations
- **GAO report**
- FDA stakeholder meeting, 9/26
- Executive Order signed on 10/31
  - Provides "surge" staffing for FDA Drug Shortage Program
  - Directs Department of Justice and FDA to collaborate to address price gauging
  - Supports bipartisan legislation
  - Timed with release of:
    - FDA report on approach to addressing shortages
    - HHS analysis of economic factors

### 340-B Expansion Bill

- **H.R. 2674** (Rush, McMorris-Rodgers, Emerson)
  - Would extend 340-B discounts to inpatient
- ASHP supports, submitted a letter
  - Issue was one of two for legislative day

### Medication Therapy Management Bill

- **S. 274** (Hagan), **H.R. 891** (McMorris-Rodgers)
  - Would increase access to MTM programs based upon medical need under Part D
  - Would include MTM as part of the transitions of care activities also under Part D
  - ASHP sent letter supporting the bill
  - Impact is largely in the community setting

### Super Committee

- Cuts to Medicare, Medicaid
- Eliminate rural hospital payment add ons: essentially eliminate the special payments
- Cuts to GME:
  - Lower reimbursement for indirect graduate medical education
  - Lower or freeze direct graduate medical education
- Reduce payments for drugs in a physician’s office:
  - ASP plus 6 to ASP plus 3
  - Raise Medicare eligibility to 67
Drug Safety

- Legislation to ensure the safety of the US drug supply
- H.R. 3026 (Matheson)
  - Bill would establish a national electronic pedigree (track and trace) system
- S.B. 1584, Drug Safety (Bennet)
  - To improve the safety of the drug supply, look to manufacturers to ensure suppliers of raw materials/API are pure, legit
  - Also gives FDA mandatory recall authority
  - ASHP submitted letter of support
- PDUFA, awaiting FDA recommendations in January

Health System Pharmacy and the Administration’s Health Agenda

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Required Initiatives:
- Implementation of Quality Improvement Initiatives
- Inpatient/Outpatient Rulemaking

Voluntary Opportunities
- Accountable Care Organizations
- Payment Reform Models (CMMI)

"...The Road Ahead":
- Biosimilars and interchangeability
- 340B Program
- PDUFA

Quality Improvement

CMS Implementation of Affordable Care Act (ACA) Provisions

Quality Improvement (QI) Initiatives

- Value Based Purchasing
- Reduction of Readmissions
- Hospital Acquired Conditions
Value Based Purchasing

- Value Based Purchasing
  - Effective October, 2012
  - Clinical Processes of Care
  - Hospital Consumer Assessment of Healthcare Providers and Systems
  - Hospital Compare

Reducing Readmissions

- Applicable Conditions in 2013
- Additional Conditions for 2015

Healthcare Acquired Conditions

- Implemented July 1, 2011 for a limited number of conditions
- Medicare DRG to be reduced beginning FY 2015

Inpatient/Outpatient Medicare Rules

- Medicare Hospital Inpatient Prospective Payment System
  - Hospital Inpatient Quality Reporting Program
  - Interaction with Value Based Purchasing
- Medicare Outpatient Prospective Payment System
  - Payment for Separately Covered Outpatient Drugs
  - Non-Physician Supervision

Accountable Care Organizations – 1 of 2

- Integration of hospital and physician care to align incentives to meet quality measures and reduce spending growth
- Promote evidence based medicine
- Report quality and cost measures
- Coordinate Care
- Shared Savings

Voluntary Opportunities
### Accountable Care Organizations – 2 of 2
- Proposed Rule Issued March 31, 2011
- ASHP Comments
- Final Rule Issued October 20, 2011
- Changes between Proposed and Final Rules

### Payment Reform Initiatives
- Bundled Payments initiative
  - Announced August 23, 2011
  - Providers select conditions to bundle
  - Reorganizes the health care delivery structure
  - Determines how payments will be allocated among participating providers

### Bundled Payment Initiative
- Retrospective Bundling
  - Model 1
  - Model 2
  - Model 3
- Prospective Bundling
  - Model 4

### Challenges in Reconciling Payment and Quality Initiatives
- ACA Provisions
- Inpatient & Outpatient Rules
- ACOs, CMMI Initiatives

### Biosimilars: 2012
- FDA Proposed Rule on Biosimilars
  - Clinical Submission Guidelines
  - Biosimilarity versus Interchangeability
- ASHP and its members participated in a series of nationwide, roundtable meetings on the implementation of biosimilars legislation
PDUFA Proposals: 2012

- Expediting Drug Review
- Consumer Medication Information
- Biomarkers and Pharmacogenomics
- Patient Reported Outcomes
- Drugs for Rare Diseases
- Standardizing REMS
- Electronic REMS Data Submission

PDUFA V Should Address

- REMS
  - Standardization and burden
  - Mandatory recall authority
  - Single source and consistent communication
- Consumer Medication Information
  - Quality
  - Evidence-based and unbiased
  - Validated
- Promotion and dissemination of off-label use
  - Peer-reviewed scientific information
  - Supplemental drug application submission
- Direct-to-Consumer Advertising
- Globalization of Clinical Trials

340B

- GAO Report
- Orphan Drug Rule
- Definition of Patient
- User Fees

State Policy Issues:
A Look Back to 2011 and a Look Ahead to 2012

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Contents

- A look back – 2011:
  CDTM
  Tech Check Tech and Technician Regulation
  Other Issues
- A look ahead – 2012:
  Scope of Practice
  Technician Regulation
  Emerging Issues

CDTM

Collaborative Drug Therapy Management

State Activity and Progress
Current CDTM Landscape

Collaborative drug therapy management is currently allowed in 43 states

Source: NABP 2011 Survey of Pharmacy Law

CDTM: 2011 Victories and Current Progress

- NEW YORK: Establishes CDTM for first time: AB 4579
- INDIANA: CDTM Expansion: HB 1111 (inserted into HB 1233)
- NEVADA: CDTM Expansion: AB 199
- KANSAS: Board of Pharmacy Task Force created to explore establishing CDTM in Kansas
- ALABAMA: Possible CDTM legislation in 2012

Pharmacy Technicians

- Recent AJHP studies on Tech Check Tech
- Principles and Goals
  Pharmacy Technician Initiative (PTI)
  Pharmacy Practice Model Initiative (PPMI) Summit Recommendations
- State activity
  Tech Check Tech: NC, MA, OH
  Pharmacy Technician Certification Board (PTCB) Certification: MO

Two Recent AJHP Studies – Tech Check Tech


Pharmacy Technicians: Principles and Goals

- Pharmacy Technician Initiative (PTI)
- Pharmacy Practice Model Initiative (PPMI)

Pharmacy Technician Initiative

The Three Components of the Pharmacy Technician Initiative

1) ASHP-accredited training and education
2) PTCB certification
3) Board of Pharmacy registration
**Pharmacy Practice Model Initiative**

**PPMI Summit Recommendations – Objectives, Imperatives, and Advancing Technicians**

1) Objectives of PPMI
2) Imperatives for the New Pharmacy Practice Models
3) Advancing the Use of Pharmacy Technicians

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**PPMI Summit Recommendations**

**Objectives of PPMI:**

#5 -- Identify specific actions pharmacy leaders and staff should take to implement practice model change including determination of the necessary staff (pharmacy leaders, pharmacists, and technicians) skills and competencies required to implement this model.

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**Imperatives for New Pharmacy Practice Models:**

A1 -- There is opportunity to significantly advance the health and well being of patients in hospitals and health systems by changing how pharmacists, pharmacy technicians, and technology resources are deployed.

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**D. Advancing the Use of Pharmacy Technicians**

Beliefs and Assumptions

D1. Pharmacy technicians who have appropriate education, training, and credentials could be used much more extensively to free pharmacists from drug distribution activities.

D2. Assigning medication distribution tasks to pharmacy technicians would make it possible to redeploy pharmacists' time to drug therapy management activities.

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**Recommendations**

D3. The following tasks can be assigned to pharmacy technicians who have appropriate education and training:

D3c. Checking dispensing by other technicians (i.e., “tech-check-tech”).

D3n. Supervising other pharmacy technicians.

D9. All distributive functions that do not require clinical judgment should be assigned to technicians.
Pharmacy Technicians: State Activity

- NORTH CAROLINA – ASHP Advocacy Letter Opposing Legislation to Nullify Tech Check Tech Rule (SB 112 and Rule 21 NCAC 46.1418)
- MISSOURI – ASHP Advocacy Letter Supporting PTCB Certification of Pharmacy Technicians to MO BoP Technician Working Group
- MASSACHUSETTS – Members are working with the MA Board of Registration in Pharmacy to try to establish Tech Check Tech
- OHIO – Members are working with OH Board of Pharmacy to try to establish Tech Check Tech

A Look Ahead – 2012

The inextricable link between the optimal use of pharmacists and the optimal use of technicians:
- **Scope of Practice**
  Enabling pharmacists to practice “at the top of their license”
- **Technician Regulation**
  A properly trained technician workforce allows pharmacists’ to re-direct their time to drug therapy management activities
- **Emerging Issues**
  Biosimilars

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Questions?