State of Pharmacy 2017: Key Legislative and Policy Issues
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Chair, ASHP House of Delegates

Objectives
- Summarize changes in U.S. government
- Discuss key national and state legislative issues related to health care
- Describe ASHP’s progress on initiatives related to provider status, drug price increases, and controlled substances
- Review key ASHP policy recommendations

2016 Elections Produce Change
- New President: Donald Trump
- Senate: Rep 52; Dem 45; Ind 2
- House: Rep 241; Dem 194
- Dems close gap in both chambers, but Rep remains in control
Key Milestones

• January 3 – Election of Speaker
• January to February – Confirmation hearings: Cabinet positions, SCOTUS
• March 15 – Congressional budgets, reconciliation instructions, CHIP reauthorization, etc.
• April 16 – First 100 days
• July 1 – Beginning of many state fiscal years; Governors need to finalize Medicaid and CHIP budgets
• September 30 – Expiration of FDA User Fees, CHIP, Health Care Extenders (Medicare, Medicaid, Public Health)
• October 1 – New fiscal year begins

Potential Health-Related Legislation

• ACA repeal/replace
• Medicaid reform
• Medicare "extenders"
• SCHIP reauthorization
• UFAs (PDUFA, GDUFA, BsUFA)
• Drug pricing bills

21st Century Cures Act

• Signed into law December 13, 2016
• Includes the following funding provisions of interest
  - $5 billion for NIH funding
  - $500 million for FDA funding
  - $1 billion for Moonshot Cancer Initiative funding
  - $1 billion for Precision Medicine Initiative
  - $1 billion for new opioid prevention and treatment programs enacted in the Comprehensive Addiction and Recovery Act (CARA)
ACA Repeal/Replace

- GOP control of Congress and White House means repeal of much of the Affordable Care Act (ACA) within reach
- Some elements may be retained
- ASHP has a list of aspects of the ACA that we would like to see preserved
  - 340B and Medicaid enhancement
  - CMMI
  - Public health funding
  - MTM grant program

PROVIDER STATUS UPDATE

Provider Status is About Patients

Achieving provider status is about giving patients access to care that improves:
- Patient safety
- Healthcare quality
- Outcomes
- Decreases costs
What is Federal Provider Status?

Becoming a “provider” in the Medicare program means that pharmacists can participate in Part B of the Medicare program and bill Medicare for services that are within their state scope of practice to perform.

Who Has Provider Status?

- Physicians
- Nurse practitioners
- Physician assistants
- Certified nurse midwives
- Psychologists
- Clinical social workers
- Certified nurse anesthetists
- Speech-language pathologists
- Audiologists
- Registered dietitians
- Physical therapists

The Pharmacy and Medically Underserved Areas Enhancement Act

- Increases access to healthcare for patients in medically underserved areas.
- Promotes cost-effective healthcare by increasing opportunities for early interventions.
- Allows pharmacists to provide services authorized by state scope of practice.
Benefits of Enacting Legislation

- Services
  - Managing chronic diseases
  - Medication management
  - Manage care as patients transition from hospital to home
  - Health and wellness testing
  - Administering immunizations

- Overall impact
  - Improved health outcomes
  - Reduced hospital readmissions
  - Reduced emergency department visits

Patient Access to Pharmacists’ Care Coalition (PAPCC)

- Coalition pushing for passage of legislation
- Most pharmacy groups are active members
- Patient advocacy, special interest groups

Next Steps

- Reintroduction
  - S.109 introduced January 12, 2017
    - Sen. Grassley lead sponsor
    - Introduced with 26 original cosponsors (33 currently) KS
  - H.R. 592 reintroduced January 20, 2017
    - Rep. Guthrie lead sponsor
    - Introduced with 107 original cosponsors (138 currently)
    - Maintained bill number from 114th to 115th Congress
- Negotiation with Committee staff
- Appropriate vehicle to move bill over the goal line
State Provider Status and CDTM

- States are continuing to look at areas of opportunity to expand their state scope of practice and be recognized as providers on a state level.
- **Reminder**—Federal Legislation cites states scope of practice as reference point to reimbursement.
- Significant variation in scope—range from immunizing to prescribing oral contraceptives to reimbursement.

How is State Provider Status Defined?

- Listed as health care provider
- Allowed to enter into a Collaborative Drug Therapy Management (CDTM) Agreement with prescribers
- Distinct designation allowing specific patient care services with additional credentialing

Expanding Scopes of Practice

- CMCS released guidance on State Flexibility to Access to Drug Therapy
- Guidance outlines the need for expanding scopes of practices through CPAs, standing orders, and state-wide protocols
- CMCS guidance document and 2015 NGA white paper are good tools to lobby state boards and legislatures on expanding scope.
What Should A Good State Provider Status Law Have?

- Perform patient assessments
- Administer vaccinations and immunizations
- Initiate, adjust, and discontinue drug therapy pursuant to CDTM
- Perform Medication Therapy Management Services (MTM)
- Manage drug therapy for chronic disease states

Legislation Introduced in 2017

- Reimbursement/Coverage - MS, MT, NJ
- Immunizations/Vaccinations - IN, KS, KY, NH, NY, TX
- Oral Contraceptives - MO, NJ, SC

Keys to Success

- Pharmacy must maintain unified stance
- Grassroots efforts must be robust
- Focusing on the unmet need, new Medicare enrollees
- Election results do not change our message
Drug Price Spikes

- Media reports covering sudden spikes in pricing of brand and generic drugs
- Subject of investigations by Congress and the Administration
- Hearings in both the House and Senate
- Large settlement with Federal government over pricing practices

Campaign for Sustainable Rx Pricing

- Non-partisan coalition of organizations, including AHA, AARP, AHIP, ASHP, Greater NY Hospital Association, and Walmart
- Members span consumer, payer, and provider spectrum
- Exploring market-based solutions, not price controls
- Endorsing legislation aimed at addressing the high cost of drugs
Drug Prices Affect Access

- Pharmacists providing care in medically underserved areas rely on drug discounts, including the 340B program
- 340B program savings are used to:
  - Increase the number of indigent patients serviced.
  - Reduce the price of medications for patients.
  - Expand other services offered to patients.

Drug Pricing Legislation

- S. 297 and H.R. 749 - expedited approval of ANDA when a drug is in short supply or little or no competition exists
- S. 124 – Brand companies prohibited from paying generic manufacturers to delay generic version to market
- S. 92, S. 183 – allowance for drug importation from other countries where prices are significantly lower (not supported by ASHP)
- S. 348, H.R. 242, S. 41 - Allows government to negotiate drug prices directly with manufacturers for drugs covered by Medicare Part D. Doesn't have bipartisan support
- Prescription Drug User Fee Act (PDUFA) up for reauthorization this year and may serve as best legislative vehicle to address this problem - considered must-pass legislation

Drug Pricing

- Common Themes for Drug Transparency Legislation
  - Set price per dose (activates reporting)
  - List of drugs broken down into groups (activates reporting)
  - Mandates drug companies to release to regulating body all costs associated with drug (R&D, advertising, etc)
  - Drug reports would be in public record for anyone to access
Biosimilars Naming

- On January 12, 2017, FDA finalized its 2015 draft guidance regarding the nonproprietary naming of biologics and biosimilars
  - FDA will require that reference products and their biosimilars share a nonproprietary name (the “core name”), but that each product have a unique suffix
    - Suffixes must be devoid of meaning and sponsors can submit up to 10 suffixes for consideration
    - Core name + suffix = FDA “Proper Name”

<table>
<thead>
<tr>
<th>Proprietary or “Brand” Name</th>
<th>FDA “Proper Name”</th>
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<tbody>
<tr>
<td>Neupogen</td>
<td>Filgrastim-jcwp</td>
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<tr>
<td>Zarzio</td>
<td>Filgrastim-bfilm</td>
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Interchangeability

- FDA intends to determine interchangeability based on a “totality of the evidence”
  - Data and information required to demonstrate interchangeability will differ based on the characteristics of the reference product and the proposed interchangeable product
    - If a product is to be administered more than once, switching studies are expected
    - FDA is looking for clinical data that reduces “residual uncertainty” as to how the interchangeable product will function
- FDA is encouraging sponsors to apply for interchangeability for all of the reference product’s conditions of use, when possible
- Comments on the draft guidance were due March 20
Biosimilars

- The FDA finally released their guidance on interchangeability in mid January
- The “national coalition” compromise is still going strong with a 5 business day notification for physicians
- Already four states have introduced biosimilar legislation
- Another 10 states are rumored to be active on this issue.

State Biosimilar Legislation

- States with draft language or introduced legislation:
  - Montana – HB 233
  - Nebraska – LB 481
  - Nevada – BDR 504
  - South Carolina – HB 3438
  - New Mexico – Draft language
- States that are target by the “national coalition” are: AK, AL, AR, CT, IA, KS, MN, NY, and VT

OPIOID ABUSE
ASHP Initiatives

- Guidelines on Preventing Diversion of Controlled Substances
  - Ricky Ogden and Brian O’Neal
- Policy Recommendations 2017 HOD
  - Controlled Substance Diversion Prevention
  - Partial Filling of Schedule II Prescriptions
  - Drug Testing
- Support of Comprehensive Addiction and Recovery Act (CARA)
  - signed into law 7/22/16

State Opioid Abuse Legislation

- 46 states have laws that address access to Naloxone
- 49 states have Prescription Drug Monitoring Programs (PDMP)
  - Most of the PDMPs are not interoperable
- 21 states already have some type of legislation introduced in 2017

Themes in Opioid Legislation

- Prescription Drug Monitoring Programs
  - Bolster access and mandate the usage
- Opioid and Pain Management Training
  - Require prescribers and healthcare professionals CE
- Restricted Supply
  - Allowing for only a 7 day supply
- Drug Take Back Programs
- Naloxone Access Expansion
Legislation in 2017

- PDMP Creation or Expansion - AZ, AR, CO, FL, IN, IA, MO, MS, MT, NE, NV, NY, OR, SD, VA, WA
- Opioids Training - IN, NJ, NY, OR
- Restricted Supply - NJ, OR, VA, WA, UT
- Take Back Program – CT, NV, NJ, NY, OR, WA
- Naloxone Expansion - NJ, OK, WY

ASHP HOUSE OF DELEGATES

Kansas Delegates

- Chris Bell
- Joan Kramer
- Lindsay Massey
- Jeff Little - alternate
COUNCIL ON PHARMACY MANAGEMENT:
1. Ensuring Patient Safety and Data Integrity During Cyber-attacks

COUNCIL ON PHARMACY PRACTICE:
2. Reduction of Unused Prescription Drug Products

COUNCIL ON PUBLIC POLICY:
3. Collaborative Drug Therapy Management

COUNCIL ON THERAPEUTICS:
4. Drug Dosing in Diseases that Modify Pharmacokinetics or Pharmacodynamics
5. Pharmacist’s Leadership Role in Anticoagulation Management

Ensuring Patient Safety and Data Integrity During Cyber-attacks

To advocate that healthcare organizations include pharmacists in (1) assessing cyber-security systems and procedures for vulnerabilities, (2) implementing cyber-security strategies, and (3) reviewing cyber-security breaches and developing corrective actions; further,
To encourage the development of business continuity plans by pharmacy departments; further,
To advocate that healthcare organizations assess vendor systems to validate the security and integrity of data, including an assessment of the minimum amount of patient health information vendors require to provide services.
Reduction of Unused Prescription Drug Products

To recognize that unused prescription drug products contribute to drug misuse, abuse, and diversion; further,
To advocate for research, education, and best practices to ensure appropriate quantities of prescription drug products are prescribed, including but not limited to partial fills or refills; further,
To advocate that pharmacists take a leadership role in reducing excess quantities of unused prescription drug products.

Collaborative Drug Therapy Management

To pursue the development of federal and state laws and regulations that authorize collaborative drug therapy management by pharmacists; further,
To advocate expansion of federal and state laws and regulations that optimize pharmacists’ ability to provide the full range of professional services within their scope of expertise; further,
To advocate for state laws and regulations that would allow pharmacists to transmit prescriptions electronically under collaborative drug therapy management protocols; further,
To acknowledge that as part of these advanced collaborative practices, pharmacists, as active members in team-based care, must be responsible and accountable for medication-related outcomes; further,
To support affiliated state societies in the pursuit of state-level collaborative drug therapy management authority for pharmacists.

Drug Dosing in Diseases that Modify Pharmacokinetics or Pharmacodynamics

To encourage research on the pharmacokinetics and pharmacodynamics of drugs in acute and chronic disease states; further,
To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and systemwide documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic disease states; further,
To collaborate with stakeholders in enhancing aggregation and publication of and access to data on the effects of such pharmacokinetic and pharmacodynamic changes on drug dosing within these patient populations.
Pharmacist’s Leadership Role in Anticoagulation Management

To advocate that pharmacists provide leadership in caring for patients receiving medications for anticoagulant therapy management, further,

To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving medications for anticoagulation therapy management, further,

To encourage pharmacists who participate in anticoagulation therapy management to educate patients, caregivers, prescribers, and other members of the interprofessional healthcare team about anticoagulant medication uses, drug interactions, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

JUNE HOUSE OF DELEGATES

Joint Council Taskforce convened to address Resolution on Policy 9915: ASHP Position on Assisted Suicide

Medical Aid in Dying

To affirm that a pharmacist’s decision to participate or decline to participate in medical aid in dying for competent, terminally ill patients, where legal, is one of individual conscience; further,

To reaffirm that pharmacists have a right to participate or decline to participate in medical aid in dying without retribution; further,

To take a stance of studied neutrality on legislation that would permit medical aid in dying for competent, terminally ill patients
Other notable policies

- Workforce Diversity
- Any Willing Provider Status for Pharmacists and Pharmacies
- Restricted Drug Distribution
- Use of Patient’s Personal Technology Devices for Care
- Weight-based Drug Dosing
- Drug Testing
- Therapeutic and Psychosocial Considerations of Transgender Patients

Questions?