Federal Legislative and Regulatory Update

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Disclosures
Stacie Maass 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.

Learning Objectives
At the completion of this activity, participants will be able to:
• Describe new federal legislative activity that will impact the practice of pharmacy
• Describe new federal regulations and activities that will affect the practice of pharmacy
• Discuss the current movement of health care and how it will impact the future of pharmacy

Assessment Questions
Which of the following is true regarding congressional activities related to prescription drug abuse:
 a) This issue is under the FDA/Administration’s purview so there is no congressional activity
 b) Since the rescheduling of hydrocodone combination products to Schedule II, prescription drug abuse/misuse is no longer a top concern
 c) Congress has established work groups, held hearings and continue to introduce legislation in effort to curb this problem
 d) Congress’ efforts are focused on only illicit drugs

Assessment Questions
Which change did CMS propose in the draft CY 2016 Call Letter:
 a) Loosening of MTM eligibility criteria
 b) An “any willing pharmacy” requirement for preferred networks
 c) A requirement that plans have only one generics drug tier, with the additional option of having a “preferred generics” tier
 d) None of the above

Assessment Questions
After the King v. Burwell ruling, which of the following is true:
 a) The Affordable Care Act (ACA) is no longer in effect
 b) Premium subsidies will not be available for anyone
 c) Premium subsidies will continue to be available to individuals who purchase coverage from the federal exchange
 d) The debate over health care is over and now Congress will turn its attention to non health care issues

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**21st Century Cures**

A new Congressional initiative that aims to accelerate the pace of cures and medical breakthroughs in the United States
- House Energy and Commerce Committee
- Senate Health, Education, Labor and Pensions Committee

- Seeks to:
  - Streamline clinical trials
  - Include patient perspective
  - Better access and sharing of data
  - New drugs and devices
  - Improvement of scientific research

- Lay the ground work for the next iteration of the Prescription Drug User Fee Act (PDUFA)

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**Prescription Drug Abuse**

- In 2014, the Senate HELP Committee formed a prescription drug abuse working group led by then Chairman Tom Harkin (D-IA) and Ranking Member Lamar Alexander (R-TN). Now, Chairman Alexander and Ranking Member Patty Murray (D-WA) have maintained the working group as a priority for the committee.

- APhA has been an active participant in the working group offering solutions, such as:
  - Increasing collaboration between health care professionals and regulators
  - Expanding e-prescribing
  - Building infrastructure to access patient electronic health records
  - Real time upload, workflow integration, and the interoperability of Prescription Drug Monitoring Programs, provider and patient education, take back programs
  - Expanding access to opioid reversal agents

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**Preferred Pharmacy Network**

- H.R. 793, Ensuring Seniors Access to Local Pharmacies Act introduced by Reps. Morgan Griffith (R-VA) and Peter Welch (D-VT)

- Bill would amend the Social Security Act to ensure that Medicare patients have equal access to community pharmacies in medically underserved areas as network pharmacies under Medicare prescription drug coverage

- Mirrors the approach of H.R. 592
Medication Therapy Management

• On Wednesday, March 18, Senators Pat Roberts (R-KS), Jeanne Shaheen (D-NH), Mark Kirk (R-IL) and Sherrod Brown (D-OH) introduced S. 776, legislation which would improve access to MTM under Medicare Part D
• The new legislation would allow beneficiaries with a single chronic condition to be eligible for MTM services but it would be limited to cases of diabetes, cardiovascular disease, COPD and high cholesterol
  - Currently MTM is limited to those who have two or more chronic conditions

Regulatory Activity

CMS Annual Part D Changes Process

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CMS Part D Final Rule CY 2015

Medicare enrollment for Part D prescribers and suppliers
• Requirement included in Part D CY 2015 Final Rule
  – For a Medicare prescription to be considered valid, the prescriber must be enrolled in Medicare and pharmacists, but pharmacists cannot enroll
  – Stemmed from the GAO Report that indicated widespread prescribing of pain medication by inappropriate providers, including massage therapists and veterinarians

CMS Part D Final Rule CY 2015

In response to advocacy from APhA and other pharmacy organizations, CMS published an interim final rule with a "pharmacist fix"
• In states where pharmacists are able to prescribe, pharmacists with valid NPIs will be able to register as "other authorized professionals" and prescriptions they write will be considered valid
• The changes do not make pharmacists Medicare providers
• Requirement goes into effect on June 1, 2016, and CMS has asked that clinicians submit applications to Medicare Administrative Contractors by January 1, 2016 to allow sufficient processing time

CMS: Part D Final Rule CY 2016

• Instead of releasing a new proposed rule for CY 2016, CMS opted to finalize provisions included in the CY 2015 Part D Proposed Rule (released January 10, 2014) that were never finalized in 2014
• CY 2016 Final Rule is focused on program efficiency and clarification of program requirements
**CMS: Part D Final Rule CY 2016**

- Changes to the efficient dispensing requirements in long-term care facilities
  - Encouraging the use of efficient techniques and clarifying that payments for these techniques do not require prorated dispensing fees
- Expanded Quality Improvement Program regulations
  - Reinforcing requirements for the implementation of Quality Improvement Projects (QIPs) and Chronic Care Improvement Programs (CCIPs) annually
- Improved MA-PD Coordination for Covered Drugs
  - Requiring Medicare Part D plans to “establish and maintain” a process for network pharmacies that will help ensure continuity of care and coordination between Part D drug benefits and Parts A/B drug benefits administered by the plan

**CMS: Other Issues**

- Incident-to Billing Changes for Certain Services
  - Recent loosening of incident-to requirements for chronic care management (CCM) and transitional care management (TCM) services
    - Not included in the CY 2015 Physician Fee Schedule Final Rule (published November 13, 2014)
  - For CCM and TCM services, there is no physician presence requirement nor are providers required to be employed by the physician or the physician’s office
  - Change only applies to CMS-defined CCM and TCM services

**CMS: CY 2016 Call Letter**

- CMS draft CY 2016 draft Call Letter was published on February 20, 2015 and the final was published on April 6, 2015
- CMS proposed relatively minimal changes for CY 2016
  - Quality
  - Preferred Networks
  - Drug Tier Labeling
  - Value-Based Payment Models
  - Maximum Allow Cost (MAC) Data
  - Mail Order and Auto-Ship Policy Changes

**CMS CY 2016 Call Letter**

- CMS's analysis of preferred networks in the draft Call Letter revealed that in some areas, fewer than half of plans meet CMS “convenient access” standards
- In the final Call Letter, CMS required that plans provide beneficiaries with more information about actual rates of access to pharmacies offering preferred cost sharing
  - In comments to CMS, APhA supported this change, but noted that beneficiaries need access to data relevant to access in their own communities, not just access across the plan
- CMS noted that it would continue to monitor beneficiary access to preferred cost sharing and would follow up with “outlier” plans

**CMS CY 2016 Call Letter**

- In comments to CMS, APhA supported CMS’s proposal in the draft Call Letter to require plans to include generics drugs in a single tier, with the option of employing a “preferred generics” tier
  - CMS finalized this proposal in the final Call Letter
- There have been complaints about plans moving generics into higher cost sharing tiers, and coupled with spikes to generics prices, pharmacy reimbursement and patient cost sharing requirements have been impacted
- Additionally, in its comments to CMS, APhA requested that CMS continue to look at options to address ongoing generics price spikes
**FDA: Biosimilars**

- At the January 7th Oncologic Drug Advisory Committee meeting, the Committee unanimously recommended approval of Sandoz’s biosimilar, Zarxio.
- On March 6th, FDA approved Zarxio.
  - Not designated as interchangeable.
  - Sandoz has not announced pricing yet.
- Zarxio’s entry into the market has been delayed by ongoing litigation.
- FDA has stated that it will release naming guidance shortly.

**FDA: Biosimilars**

<table>
<thead>
<tr>
<th>Biosimilar Applicant</th>
<th>Reference Drug</th>
<th>Nonproprietary Name</th>
<th>Approved Date</th>
<th>Approval Status</th>
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<tr>
<td>Sandoz</td>
<td>Neupogen (Amgen)</td>
<td>Filgrastim</td>
<td>March 6, 2015</td>
<td>Approved</td>
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<td>Celltrion</td>
<td>Remicade (Janssen)</td>
<td>Infliximab</td>
<td>TBD</td>
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<tr>
<td>Apotex</td>
<td>Neulasta (Amgen)</td>
<td>Pegfilgrastim</td>
<td>TBD</td>
<td>Application Pending</td>
</tr>
</tbody>
</table>

**US Biosimilar Pipeline**

- Adalimumab
- Etanercept
- Rituximab
- Epoetin-alfa
- Peg-Filgrastrim
- Trastuzumab
- Insulin Glargine
- Bevacizumab
- Ranibizumab
- Darbepoetin alfa
- Coagulation factor VIIa

**Biosimilars: Areas of Contention**

- Naming
  - Unique names versus International Nonproprietary Names (INNs)
  - Adverse Drug Event (ADE) tracking
- Substitutability
  - FDA determines biosimilarity and interchangeability
  - FDA “Purple Book”
  - State efforts

**FDA: Drug Importation**

- Importation of drugs for personal use.
  - Maine law allowing importation of drugs for personal use was struck down by U.S. District Court on the basis of pre-emption.
  - According to the ruling, FDA retains full control over importation of drugs based on the Food, Drug, & Cosmetic Act.
  - Some U.S. Senators have stated that they will seek to change existing federal law to allow importation.
The Drug Quality and Security Act

Signed into law on November 27, 2013

Compounding Quality Act
Drug Supply Chain Security Act (DSCSA)

Status of DQSA Implementation

- To date, FDA has published final guidance for:
  - 503A compounding (July 2014)
  - 503B outsourcing facility registration (November 2014)
  - 503B outsourcing fees (November 2014)
- Draft Guidelines and the MOU have been published for comment:
  - Comments on guidance documents were due May 13, 2015
  - Comments on the MOU are due July 20, 2015

Drug Supply Chain Security Act

- Purpose of the DSCSA (i.e. track and trace provisions):
  - Enable verification of the legitimacy of the drug product identifier down to the package level
  - Enhance detection & notification of illegitimate products
  - Facilitate more efficient recalls of drug products
- Pharmacy-Specific Provisions
  - A Pharmacy is defined as a “Trading Partner”
  - Requirements already in effect as of January 2015:
    - Pharmacies must only accept product from licensed manufacturers, wholesale distributors, or other pharmacies.
    - Pharmacies are required to develop processes to inspect, quarantine, investigate and notify FDA and immediate trading partners of suspect product
In June 2014, FDA released Draft Industry Guidance regarding identification of suspect product and notification:

- Identifies specific scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain
- Provides recommendations on how pharmacies can identify the product and determine whether the product is a suspect product as soon as practicable
- Sets forth the process by which pharmacies are to notify FDA and immediate trading partners of illegitimate product and how they may terminate the notifications in consultation with FDA

APhA Comments to FDA Draft Industry Guidance:

- Recognized pharmacies should develop processes to inspect, quarantine, and notify FDA and immediate trading partners of suspect product
- Pharmacies should not be required to develop processes to investigate and make the determination of whether a suspect product is illegitimate

Beginning November 1, 2015 (on June 30, FDA delayed enforcement from original 7/1/2015 deadline), a pharmacy shall:

- Not accept ownership of a product, unless the previous owner provides Transaction History (TH), Transaction Information (TI), and a Transaction Statement (TS) (i.e., product 3Ts)
- Capture and maintain such information, history, and statements for 6 years after the transaction
- With FDA’s delayed enforcement, pharmacies have an additional 4 months to comply with the above requirements

Beginning July 1, 2015; FDA did not extend the deadline for the following:

- Pharmacies shall provide the subsequent owner with TH, TI, and TS for the product
- Exception – 3Ts are not required for pharmacy to pharmacy sales to fulfill a specific patient need
- Specific patient need = Prescription for an identified patient

Expect guidance soon clarifying what form and manner pharmacies must provide the TH, TI, and a TS for the transferred product

Upcoming Key Dates

- By 11/27/2017, manufacturers shall place a unique product identifier (2D bar code) on certain prescription drug packages; repackagers have until 11/27/2018
  - Product identifier includes:
    - National Drug Code
    - Serial number
    - Lot number
    - Expiration date
- By 11/27/2020, participants will only trade products with product identifiers

Upcoming Key Dates

- FDA to conduct and complete a technology and software assessment on the feasibility of small pharmacies to conduct tracing at the package level by 2020
- FDA to establish pilot projects in coordination with stakeholders to explore and evaluate methods to enhance the safety and security of the supply chain by 2020
- FDA to develop regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level by 2021
- FDA to publish final guidance on standards for interoperable data exchange to enhance secure tracing of product at the package level by 2022
Pharmacist’s Role in Opioid Abuse, Addiction, and Diversion

It is critical to find the right balance!

Enforcement: Prevent diversion

Patient Care: Pain Management Addiction treatment

Collaboration with other healthcare professionals (e.g. 2013 AMA policy)

Prescription Drug Abuse

Abuse-Deterrent Formulations of Opioids
- October 30-31, 2014, FDA hosted a public meeting on abuse-deterrent formulations
- DEA supports FDA’s vision of a future where all opioids are formulated with abuse-deterrent technology
- APhA submitted written comments on January 9, 2015
- Comments incorporated membership and SIG survey feedback, offered general support, but cautioned that transition to all opioids with abuse-deterrent technology may:
  - Increase patient out-of-pocket costs
  - Limit ability to individualize doses and dosage forms (i.e. compounding)

Prescription Drug Abuse

DEA Finalizes Take-Back Rule
- In September 2014, DEA published the final rule on the take-back and disposal of controlled substances
  - The proposed rule was published in December 2012
- Regulation provides expanded options for discarding unused, unwanted or expired controlled substances
  - Mail-Back Programs
  - Pharmacy-Maintained Collection Receptacles
- Expands participation in take-back events
  - Previously only law enforcement-sponsored events allowed

Prescription Drug Abuse

DEA Take-Back Rule (cont.)
- Pharmacies (retail, hospital/clinics), manufacturers, distributors among those who may be an “authorized collector” by modifying their registration with DEA
- Concerns (e.g. logistics, liability) regarding participation due to program requirements
  - Receptacles to be accessible to the public AND also in an area where controlled substances are stored and where an employee is present
  - Receptacles to be for disposal of legal non-controlled and controlled prescription drugs from patients

Marijuana

Legalization of marijuana for medicinal and/or recreational purposes has been taking place at the state level
Marijuana
Controlled Substances Act 8 factor test
(1) Its actual or relative potential for abuse.
(2) Scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the drug or other substance.
(4) Its history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) What, if any, risk there is to the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Electronic Prescribing Information
• In December 2014, FDA issued a proposed rule to require electronic distribution of the package insert which is currently distributed in paper form on or within the package of stocked drug products.
• Elements of the proposal
  – Manufacturers must submit the most up-to-date label to an FDA controlled electronic repository
  – Allowances made for situations where electronic access is not feasible
• APhA recommended that FDA require manufacturers to provide paper PI in addition to electronic PI while assessing the costs associated with providing and accessing electronically-available PI.
  – Determination of electronic-only system depending on results of assessment.

Future of Health Care

Health Care Reform
• King v. Burwell: Second challenge to Affordable Care Act (ACA)
  – Subsidies upheld for Exchange
  – Case revolved around the question of whether subsidies are available to individuals who purchase coverage from the federal marketplace.
• Focus of Congress may move to improvements; also accomplished SGR
  – E.g., Looking at efficiencies of care, coordination, and value.

Fee-For-Service
...from encounters...to ongoing management

Pre-Ere-Service
Pre-Encounter | Encounter | Post-Encounter | Disengaged
X | $$$$ | X | X

Population Management
Pre-Encounter | Encounter | Post-Encounter | Disengaged
$ | $ | $ | $
Opportunity for pharmacists
- Expansion of the coverage of pharmacists patient care services [i.e., provider status efforts]
  - Efforts to improve and expand MTM services continue
  - These efforts are taking place in several different arenas
  - MTM Technical Expert Panel (TEP)
  - Discussions with House Energy & Commerce Committee and other stakeholders
  - CMS comment opportunities (e.g., the Call Letter)

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For more information on APhA’s provider status activities
Visit www.pharmacistsprovidecare.com