Legislative and Regulatory Update
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Supporter

- Supported by the Pharmacy Technician Certification Board.

Disclosures

Michael Spira, Jillanne Schulte, and Jenna Ventresca: "declare 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 honors.

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

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 status of federal, state, and private payer reimbursement for pharmacists' services.

Self Assessment Questions

APhA has provided comments to Congress that recommend which of the following?
- Increasing prescriber and patient education
- Standardizing and integrating real-time prescription drug monitoring programs
- Increasing access to reversal agents such as naloxone
- All of the above
At the federal level, APhA is requesting legislative changes to which government program in an effort to provide coverage for pharmacists' services:

a) Medicaid  
b) Medicare Part A  
c) Medicare Part B  
d) Affordable Care Act and the federal and state health exchanges

According to EPA’s Proposed Rule: Management Standards for Hazardous Waste Pharmaceuticals, if a pharmacy generates 50 kg of hazardous waste pharmaceuticals per month, which generator category would the facility be in?

a) Conditionally exempt small quantity generator  
b) Large Quantity Generator  
c) Small Quantity Generator  
d) Medium Quantity Generator  
e) None of the above

**CONGRESSIONAL MAKE-UP**

- **House of Representatives**
  - 246 Republicans
  - 188 Democrats
  - 2 vacancies

- **Senate**
  - 54 Republicans
  - 44 Democrats
  - 2 Independents

**HOUSE LEADERSHIP**

- Speaker of the House - Paul Ryan (WI)
- **Republican Leadership**
  - Majority Leader - Kevin McCarthy (CA)
  - Majority Whip - Steve Scalise (LA)
  - Conference Chairman - Cathy McMorris Rodgers (WA)
  - Policy Committee Chairman - Luke Messer (IN)
- **Democratic Leadership**
  - Minority Leader - Nancy Pelosi (CA)
  - Minority Whip - Steny Hoyer (MD)
  - Assistant Leader - James Clyburn (SC)
  - Caucus Chairman - Xavier Becerra (CA)

**SENATE LEADERSHIP**

- **Senate President - Vice President Joe Biden**
- President Pro Temp - Orrin Hatch (UT)
- **Republican Leadership**
  - Majority Leader - Mitch McConnell (KY)
  - Majority Whip - John Cornyn (TX)
  - Conference Chair - John Thune (SD)
  - Policy Committee Chair - John Barrasso (WY)
  - Conference Vice Chair - Roy Blunt (MO)
Senate Leadership
Democratic Leadership
• Minority Leader – Harry Reid (NV)
• Minority Whip – Richard Durbin (IL)
• Conference Committee Chair – Harry Reid (NV)
• Conference Committee Vice Chair & Policy Committee Chair – Charles Schumer (NY)
• Conference Secretary – Patty Murray (WA)

House of Representatives Key Committees
House of Representatives
– Energy and Commerce Committee
  • Chairman Fred Upton (R-MI)
  • Ranking Member Frank Pallone (D-NJ)
– Ways and Means Committee
  • Chairman Paul Ryan (R-WI)
  • Ranking Member Sander Levin (D-MI)

Senate Key Committees
Senate
– Finance Committee
  • Chairman Orrin Hatch (R-UT)
  • Ranking Member Ron Wyden (D-OR)
– Health, Education, Labor & Pensions Committee
  • Chairman Lamar Alexander (R-TN)
  • Ranking Member Patty Murray (D-WA)

Provider Status Legislation
H.R.592 / S.314
Pharmacy and Medically Underserved Areas Enhancement Act
• Representatives Brett Guthrie (R-KY), G.K. Butterfield (D-NC), Todd Young (R-IN), and Ron Kind (D-WI) introduced on January 28, 2015
• Senators Chuck Grassley (R-IA), Sherrod Brown (D-OH), Robert Casey (D-PA), and Mark Kirk (R-IL) introduced on January 29, 2015
• Amends section 1861 of the Social Security Act to recognize pharmacists’ services within Medicare Part B

H.R.592 / S.314 – Scope of Proposal
• Pharmacists – State-licenced pharmacists with a B.S. Pharm. or Pharm. D. degree who may have additional training and certificates depending on state laws
• Services – Services authorized under state pharmacy scope of practice laws
• Patients – Services provided in/ for Medically Underserved Areas (MUA), Medically Underserved Populations (MUP), or Health Professional Shortage Areas (HPSA)
Pharmacy Collaboration

- APhA is part of a broad coalition of pharmacy organizations and stakeholders united in promoting patient access and coverage to pharmacists’ patient care services
- Coalition seeking provider status for pharmacists including advocacy for:
  - Consumer/patient access and coverage for pharmacists’ patient care services
  - Payers and policy makers to recognize pharmacists as health care providers who improve access, quality, and value of health care
  - Enhanced inclusion of pharmacists as members of patient health care teams

Patient Access to Pharmacists’ Care Coalition (PAPCC)

- Albertsons LLC and New Albertsons Inc.
- American Association of Colleges of Pharmacy
- American Pharmacists Association
- American Society of Consultant Pharmacists
- American Society of Health-System Pharmacists
- AmerisourceBergen
- Association of Clinicians for the Underserved
- BI-LO Pharmacy
- Cardinal Health
- CVS Health
- Food Marketing Institute
- fred’s Pharmacy
- Fruth Pharmacy
- Healthcare Distribution Management Association
- Healthcare Leadership Council
- Hematology/Oncology Pharmacy Association
- International Academy of Compounding Pharmacists
- Kroger
- McKesson
- National Alliance of State Pharmacy Associations
- National Association of Chain Drug Stores
- National Center for Farmworker Health
- National Community Pharmacists Association
- National Consumers League
- National Pharmaceutical Association
- National Patient Advocate Foundation
- National Rural Health Association
- Omnicell
- Pediatric Pharmacy Advocacy Group
- Rite Aid Pharmacy
- Safeway
- SUPERVALU Pharmacies
- Target
- Thrifty White Pharmacy
- Walgreens
- WalMart
- Winn-Dixie Pharmacy

Are only a limited number of pharmacists eligible under H.R.592 / S.314?

Feedback from Hill

- Positive feedback overall but cost is important
  - Need to “score” low by Congressional Budget Office (CBO)
  - Pharmacy challenged to be “saver, not coster”
  - Concern by pharmacy that savings, especially those that are long-term, are not considered when scoring
- Hill equates provider status with “fee-for-service”
  - Current focus is on new payment models (e.g. ACOs)
- There is not a good understanding of “Pharmacists’ Services”
  - Will they occur in isolation (i.e. coordination with other providers)

Provider Status Legislation

Congressional action

- Since introduction 1 year ago, we have more than 40% of the Senate and 60% of the House supporting our provider status legislation
- APhA & partner organizations remain staunchly committed; however, 2016 is a presidential election year so limited window of opportunity
  - Congress has an abbreviated schedule
  - Moving legislation narrowly focused on “must pass” legislation and/or noncontroversial issues
  - Legislation passed will need to identify offsets (i.e. ways to pay for costs related to legislation)
Provider Status Legislation

Next Steps in Congress
• CBD Score –
  – Process underway; APhA and PAPCC are working with Members of Congress to obtain score, which may be in an unofficial form
  o E.g. Lead House Sponsor, Cong. Guthrie, Vice Chair, Subcommittee on Health, House Energy and Commerce Committee
  o An unofficial/ back of the envelope score sufficient
• House Hearing – House leadership indicated this is a necessary step for legislation to move through the House
  – Simultaneous working on hearing and score
  – Working with bipartisan leads on requesting hearing

Provider Status Legislation

• Federal efforts is just one of our profession’s pathway to success
  – Pharmacy-related associations and pharmacists’ progress in helping patients receive better coordinated care has been impressive at the state level
  o States demonstrating impact pharmacists can have on patients and health care, including helping to fulfill needs of patients
  o These efforts are valuable to our federal level efforts as well
• APhA will continue to work with pharmacists and pharmacy associations across the country to make the case for increasing access to pharmacists’ patient care services

Pathways to Provider Status
• Federal Sector
  – Social Security, Medicare Part B & D, CMS, ACOs
  – Federal Regulations (CMS, AHRQ, HRSA)
• State
  – Medicaid
  – Health Insurance Exchanges, state health plans
  – Existing provider status and collaborative practice
• Private Payer
  – Accountable Care Organizations (ACOs)
  – Private or Employer-based Insurers
  – Medical Homes

Prescription Drug Abuse – Congressional Activity

Congressional Hearings:
• House of Representatives:
  – Energy and Commerce Subcommittee on Oversight and Investigations
  – House Energy and Commerce Subcommittee on Health
• Senate:
  – Health, Education, Labor and Pensions (HELP) Committee
  – Finance Committee
  – Special Aging Committee
• Hearings discussed
  – Enormity of the problem; problem at federal, state and local levels
  – Potential solutions

Numerous bills in House and Senate addressing prescription drug abuse, misuse and treatment; areas addressed include:
• Increasing access to buprenorphine by easing requirements to prescribe and dispense the drug
• Establishing an inter-agency tasking force to develop best practices for pain management and pain medication prescribing
• Expand access to opioid overdose reversal drugs, such as naloxone

Prescription Drug Abuse – APhA Comments
APhA’s comments to congressional members and committees included the following recommendations:
• Advancing team-based care by encouraging pharmacist inclusion to improve care management and outcomes
• Improving communication and access to information by standardizing and integrating real-time prescription drug monitoring programs (PDMPs)
• Encouraging the development, dissemination, and incentivization of naloxone-related education to patients and caregivers as well as to all members of the health care team
Prescription Drug Abuse - APhA Comments

- Enhancing education for health care professionals, including pharmacists and physicians about prescription drugs abuse, and preventive methods
- Increasing patient access to medication-related services and education by utilizing pharmacists’ expertise and accessibility
- Making prescription drug take back programs more publically accessible

Other Issues to Monitor - PBM’s

- Pharmacy Benefit Manager
- The House Committee on Oversight and Government Reform has held multiple hearings on PBM transparency
- APhA has stated:
  - Some PBM’s limit pharmacy participation even when pharmacies are willing to meet network terms and conditions
  - Cost containment provisions, which may restrict patient choice or access, must be scrutinized to ensure they actually produce savings
  - The unpredictable, direct and indirect remuneration (“DIR”) rates

Other Issues to Monitor - 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

Other Issues to Monitor - 21st Century Cures

- APhA submitted comments
  - Support for the goals of the legislation and lauded provisions that improve patient access to new technologies, support young clinicians, and enhance public health programs, including adult immunization programs
  - Concerns with patient access issues that could arise from two Medicare Part D provisions
    - A “lock in” provision for substance abusers
    - A provision that provides Part D plans unilateral authority to suspend pharmacy claims payment indefinitely based on unsubstantiated fraud allegations

Other Issues to Monitor – User Fee Acts

- Congress has started to discussion the next user fee acts
  - Prescription Drugs
  - Generics
  - Biosimilars
  - Medical Device

Other Issues to Monitor – Drug Pricing

- APhA comments have focused on:
  - Push for increasing the transparency and clarity of plan formulary information and improving plan communication with patients
  - Pharmacists, with more medication expertise than any other provider, can assist patients and other providers in optimizing the impact of medications so the investment in medications translates to better outcomes
  - For most patients, drug pricing itself is not the problem—what impacts them is their insurance plan’s copay amount. In many cases, pharmacists can assist patients in identifying safe and effective alternatives that may lower a patient’s costs

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On December 18, 2015, the Senate Finance Committee’s Chronic Care Working Group released a policy options document.

**Background on Working Group:**
- July 15, 2014: Committee on Finance held a hearing to educate lawmakers about the issues chronic pain suffers face.
- May 15, 2015: Committee’s second hearing focused on current chronic care coordination programs. Chairman Hatch and Ranking Member Wyden announced the formation of a chronic care working group to analyze current policy and develop solutions.
  - In May, they requested input on methods for improving outcomes for Medicare beneficiaries with multiple chronic health conditions.

On January 26, 2016, APHA provided support and feedback regarding the following topics:
- Developing a high severity code for chronic care management (CCM).
- Encouraging beneficiary use of CCM services.
- Expanding and making permanent the Independence at Home Model of Care.
- Beginning studies on medication synchronization, obesity drugs and integrating behavioral health and primary care among ACOs.
- Developing quality measures for chronic conditions.
- Expanding access to prediabetes education.

**Health Care Reform**
- **King v. Burwell**: Second challenge to Affordable Care Act (ACA)
  - Decided June 25, 2015; Subsidies upheld for plans purchased from federal exchange/marketplace.
  - Case revolved around the question of whether subsidies are available to individuals who purchase coverage from the federal exchange/marketplace.
- **Move to Value-Based Payment Models**: In January 2015, CMS announced that by 2018, it intends to transition 50% of Medicare fee-for-service payments to value-based models and to tie 95% of payments to quality/value.

**CMS Value-Based Payment Transitions**
- **Fee-for-Service 2016**: 85% All Medicare FFS, 30% fee-for-service tied to quality, 30% Alternative Payment Models.
- **Fee-for-Service 2018**: 90% Fee-for-Service 2016, 50% Alternative Payment Models.

**CMS Annual Part D Changes Process**
- **Part D Proposed Rule**: CMS Proposes Technical Changes to Medicare Part D.
- **Part D Final Rule**: Final Call Letter released, plans use this to structure plan bids that must be submitted to CMS.
- **Part D Call Letter**: Final Call Letter published, plans use this to structure plan bids that must be submitted to CMS.
CMS Draft Call Letter CY 2017

- CMS published the draft Call Letter on February 19, 2016; comments are due March 4, 2016
- CY 2017 Call Letter does not propose major revisions to Part D plan requirements and patient benefits, but does propose minor changes on issues that are of interest to pharmacists and technicians, including:
  - Coverage determination timelines
  - Formulary tier labeling and composition
  - Point-of-Sale edit rules

Medication Therapy Management (MTM)

- 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)
  - CMMI Enhanced MTM Model Test

CMMI Enhanced MTM Model Test

- CMMI Model Test for Innovation
  - Announced in late September 2015 and scheduled to begin January 1, 2017
  - Model Test participation is limited to stand-alone, individual-market prescription drug plans in certain geographic areas
  - Intended to provide flexibility in MTM; targeting and interventions
  - Participating plans receive a per member/per month payment (varies by model tested) for all enrollees
  - 5 year initial program period, with option to extend performance-based payments for an additional 2 years

CMS Physician Fee Schedule (PFS) CY 2016 Final Rule

- On November 16, 2015, CMS published its Physician Fee Schedule (PFS) CY 2016 final rule (with comment period)
- In follow-up to comments on the PFS proposed rule submitted September, 2015, APhA submitted comments to CMS regarding the final rule on December 29, 2015
- APhA comment highlights - Incident To Regulatory Changes: Thanked CMS for clarifying a concern APhA raised regarding a language change in the proposed rule related to billing and supervising physician of incident to services
  - In the final rule, CMS stated the change was only meant to clarify that the physician supervising incident to services would be the physician billing for those services

APhA comment highlights, cont.:

- Practice Expense Calculation: Responded to CMS’ request for feedback regarding the inclusion of pharmacists in direct practice expense (PE) costs, voicing support for compensation structures that support pharmacists’ services, but noting concern with PE being the only payment mechanism
- Reimbursement: Encouraged CMS to maximize patient access by focusing on reforming overall payment structures to create new opportunities for incidental to billing and to adjust reimbursement under HCPCS codes to provide reimbursement commensurate with the value of pharmacists’ services

CCM and TCM Services

- Recent loosening of incident-to requirements for chronic care management (CCM) and transitional care management (TCM) services
  - 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
- CY 2016 Physician Fee Schedule:
  - Requested general feedback from clinicians regarding provision of CCM and TCM services
  - Proposed revising general incident-to regulations to require that the billing physician/clinician also be the supervising physician/clinician
CMS Hospital Discharge Proposed Rule

- On October 29, 2015, CMS released its proposed rule setting out discharge planning requirements that hospitals must meet to participate in the Medicare and Medicaid programs
  - Implements the discharge planning requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014, aimed at improving consumer transparency and beneficiary experience during the discharge planning process
  - Proposed rule included a requirement that hospitals and critical access hospitals provide medication reconciliation with the "goal of improving patient safety" as part of every patient’s discharge plan

CMS Hospital Discharge Rule, cont.

- On January 4, 2016, APhA and NCPA submitted joint comments on the proposed rule
  - Comment highlights:
    - Medication Reconciliation: Agreed with CMS that medication reconciliation should be a standard element of discharge planning in hospitals and critical access hospitals
      - Suggested that in order to provide meaningful, high-quality medication reconciliation services, pharmacists should be actively engaged in the discharge planning process and in medication management processes generally
    - Burden Estimates for Medication Reconciliation: Encouraged CMS to revisit its burden estimates for medication reconciliation to ensure the estimates reflect services that will actually improve patient safety

ACA Benefit and Payment Parameters CY 2017

- On November 21, 2015, CMS released its annual proposed rule to amend and update its policies for the Affordable Care Act marketplaces for 2017 and beyond
- New policies of particular interest to pharmacists include:
  - Development of network adequacy standards for marketplace plans
  - Solicitation of comment on six standardized plan options

ACA Benefit and Payment Parameters CY 2017, cont.

- APhA submitted comments to CMS on December 21, 2015, which included:
  - Network Adequacy Standards: Urged CMS to develop and adopt robust network adequacy standards that expand patient access by integrating pharmacists’ patient care services
  - Transparency/Reporting Requirements: Encouraged the incorporation of transparency and reporting requirements for network access and benefits/coverage information
    - Better information is necessary for patients to have accurate information and metrics about qualified health plans’ benefits (e.g., actual access and copays)

CMS “AMP” Rule

- On February 1, 2016, CMS published the final rule for Medicaid covered outpatient drugs (the proposed rule was published on February 2, 2012)
  - Most provisions of the rule are effective April 1, 2016, but states have until April 1, 2017 to implement new pharmacy reimbursement provisions
  - CMS is accepting comments regarding the definition and identification of “line extension” drugs
  - The rule is the result of years of sustained advocacy by the pharmacy profession for fairer Medicaid reimbursement

Highlights of CMS “AMP” Rule

- Average Manufacturer Price (AMP): AMP calculated for multiple-source outpatient drugs “generally dispensed” in retail pharmacies based on net sales to wholesalers and retail pharmacies
  - Excluded from AMP calculation:
    - Specialty, home infusion, and home health pharmacy sales
    - Injected, infused, inhaled, implanted or instilled (“5i”) drugs not generally sold at retail pharmacy
    - Bona fide service fees
  - Federal Upper Limits (FULs): Created for nationally available, multiple-source drugs and will be updated and published monthly (lists due to be finalized in late March 2016)
    - FULs based on AMP, but when actual acquisition cost (AAC) exceeds AMP for a specific therapeutic class, the National Average Drug Acquisition Cost (NADAC) will serve as a reimbursement floor
• **AAC-Based Reimbursement**: State Medicaid fee-for-service pharmacy reimbursement must be based on AAC
  - Must be, in aggregate, the lower of AAC + "sufficient professional dispensing fee" or the pharmacy's usual and customary charges to the public

• **Professional Dispensing Fees**: CMS instructed states to consider pharmacy costs when setting the professional dispensing fee
  - CMS included a robust list of costs related to the pharmacist’s time as well as pharmacy overhead for necessary equipment and facilities

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**HHS Nondiscrimination Proposed Rule**

On September 8, 2015, HHS released a proposed rule regarding nondiscrimination in certain health care programs and activities

• The proposed rule is a result of Section 1557 of the Affordable Care Act which prohibits discrimination on the basis of race, color, national origin, sex (including gender identity), age, or disability in certain health care programs and activities.

• In general, the regulation applies to any health entity, program or activity receiving federal financial assistance
  - Medicaid, Medicare Part D and other government programs make pharmacies subject to the regulation

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**HHS Nondiscrimination Proposed Rule Highlights**

• Covered entities (e.g., pharmacies) are required to:
  - Provide notice to patients on accessing aids and services, contact information for the entity’s responsible employee, and the availability of a grievance procedure
  - Offer patients language assistance services to individuals with limited English proficiency, unless doing so would impose undue financial burden or would result in a fundamental alteration in an entity’s health program or activity
  - Provide auxiliary aids and services, and the accessibility of programs offered through electronic and information technology; unless doing so would impose undue financial burden or would result in a fundamental alteration in an entity’s health program or activity

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**HHS Nondiscrimination Proposed Rule Comments**

APhA provided comments on November 9, which included the following recommendations and concerns:

• Considering the amount of Federal financial assistance covered entities receive when imposing requirements and making determinations related to nondiscrimination claims
• Complying with the proposed rule adds costs and burdens beyond pre-existing Federal civil rights laws
• Underestimated cost burdens regarding language assistance services and auxiliary aids and services
• Restricting minor children from interpreting or facilitating communication may negatively impact care for those with limited English proficiency

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**HHS Nondiscrimination Proposed Rule Comments**

• The standard for effective communication for individuals with disabilities should be the same as private business/places of public accommodation opposed to standards for State and local governments
• Grievance procedures and designation of a responsible employee should be voluntary, not mandatory, for covered entities with fewer than 15 employees
• Notice requirements should be clarified and take into consideration limited space in pharmacies for posting
• Extending the compliance deadline by at least one year
The Drug Quality and Security Act

Signed into law on November 27, 2013

Drug Quality and Security Act

Compounding Act

Drug Supply Chain Security Act (DSCSA)

DQSA Implementation

• During Congressional deliberations and in its 503A Guidance document, FDA stated that it would take a “risk-based” approach to enforcement
  – APhA’s understanding was that the DQSA represented a maintenance of the status quo
  • Office-use compounding would not be affected
  • Enforcement patterns for compounding would not change significantly
  • FDA’s interpretation of DQSA has been broader and more comprehensive than initially anticipated

DQSA: Compounding Regulation & Guidance

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)
• The Memorandum of Understanding between FDA and states regarding interstate distribution of compounded products (MOU) and four Draft Guidelines were published for comment in 2015; they include:
  – Considerations for entities considering 503B registration
  – Adverse event reporting for 503B outsourcing facilities
  – Repackaging by 503A pharmacies and 503B outsourcing facilities
  – Mixing, diluting, or repackaging of biologics

Concerns with new guidance documents and the MOU

• For 503B, all drugs compounded in a 503B facility are subject to FDA oversight, so the same standards will apply to both sterile and non-sterile 503B products
• 503B facilities must compound at least some sterile products (no guidance as to amounts required)
• MOU between States and the FDA
  – No protections for contiguous/border states or for shortage situations;
  – Definition of “distribution” differs from the definition in the Food, Drug, and Cosmetic Act; and
  – Percentage limitations associated with interstate distribution are arbitrary and may result in serious patient access issues.

Other Compounding Activities

• APhA continues to work with the DQSA Coalition to address ongoing issues related to FDA’s implementation of the DQSA
  – On January 13, 2016, APhA signed on to a DQSA Coalition (representing more than 20 organizations) letter to state Boards of Pharmacy and Medicine requesting that the Boards hold any action on state office-use laws until FDA issues guidance specific to compounding for office-use
  – In a House Report on the Appropriation bill for HHS, Congress recently directed FDA to publish guidance regarding office-use compounding within 90 days
• Stakeholders are awaiting guidance documents on a number of compounding issues

DQSA: Track and Trace

Purpose of the Drug Supply Chain Security Act (DSCSA):

• Enable verification of the legitimacy of the drug product identifier down to the package level
• Enhance detection and notification of illegitimate products in the drug supply chain
• Facilitate more efficient recalls of drug products

Pharmacy Specific Provisions:

• Pharmacies are included in the definition of “dispenser”
• A dispenser is a type “trading partner”
**DQSA: Track and Trace**

Requirements already in effect as of March 1, 2016 (Phase 1):
- Authorized trading partner verification (January 1, 2015)
- Suspect/legitimate product identification and notification (April 1, 2015)
- Transaction data
  - Only accept product if the previous owner provides the “3Ts” (March 1, 2016)
  - Provide the subsequent owner with the “3Ts” (July 1, 2015)
- Trading partners, including pharmacies, capture and maintain the “3Ts” for 6 years from the date of the transaction (March 1, 2016)

**DQSA: Track and Trace**

- October 2015: FDA releases wholesaler and third-party logistics provider (3PL) facility license data to the public.
- October 29, 2015: FDA delays enforcement from the already extended November 1, 2015 deadline to March 1, 2016 requiring a pharmacy to:
  - 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
  - Enforcement delay did not extend to products transferred from pharmacy to pharmacy – meaning that “3Ts” must be included
- On October 21, APhA and other stakeholders met with FDA on this issue
- December 14: CDC posts notice seeking public comment; 30 day comment period
- January: CDC releases draft guideline via webinar; 2 day comment period
- CDC assembles workgroup, which included APhA’s Vice President, Anne Burns, to assess the Guideline’s evidence and recommendations; workgroup report submitted January 28 suggested relatively few modifications to CDC’s guideline

**Prescription Drug Abuse: CDC Draft Guideline**

- Provides recommendations for primary care providers who are prescribing opioids for chronic care outside of active cancer treatment, palliative care, and end-of-life care
- 12 recommendations address three subjects:
  - When to initiate or continue opioids for chronic pain (3 recommendations)
  - Opioid selection, dosage, duration, follow-up, and discontinuation (4 recommendations)
  - Assessing risk and addressing harms of opioid abuse (5 recommendations)

**Prescription Drug Abuse: CDC Draft Guideline**

- CDC Draft Guideline for Prescribing Opioids for Chronic Pain
  - September 16: CDC released draft guideline via webinar; 2 day comment period
  - APHA and NASPA submitted joint comments on September 18, 2015 regarding CDC’s process
  - December 14: CDC posts notice seeking public comment; 30 day comment period
  - APHA submitted comments January 13 regarding the draft guideline’s content; over 4000 comments were submitted
  - January: CDC assembles workgroup, which included APHA’s Vice President, Anne Burns, to assess the Guideline’s evidence and recommendations; workgroup report submitted January 28 suggested relatively few modifications to CDC’s guideline

APhA submitted comments on January 13, which:
- Encouraged an update when stronger evidence is released
- Emphasized that the Guidelines should take a team-based approach to care and pharmacists should be included
- Noted that lowest-effective dose should be patient-specific
- Suggested improvements to the recommendation on prescription drug monitoring programs
- Encouraged development of additional guidance and support regarding storage and disposal of unused opioids
- Requested more education and referral resources for health care professionals
Prescription Drug Abuse: White House

- **October 21:** The White House convened stakeholders in Charleston, West Virginia where the President announced new public and private efforts.
  - APhA’s commitment was to develop Opioid Use, Abuse, and Misuse Resource Center.
  - President’s Memorandum to Federal Departments and Agencies directs prescriber training and improving access to treatment.
- **February 2:** President Obama proposes $1.1 billion in new funding to address prescription drug abuse and heroin use epidemic.
  - $920 million of the $1.1 billion will be used to support cooperative agreements with States to expand access to medication-assisted treatment for opioid use disorders.

Prescription Drug Abuse: Resource Center

- Result of APhA’s October commitment to the White House.
- Serves as a “one-stop shop” for resources regarding opioid use, abuse and misuse.
- Includes input from members, APhA staff, and FDA.

EPA Proposed Rule: Hazardous Waste Pharmaceuticals

- On September 25, 2015, EPA formally released the proposed rule “Management Standards for Hazardous Waste Pharmaceuticals”.
  - Unifies requirements for health care facilities, which includes pharmacies, that generate more than 100 kg of hazardous waste or 1 kg of acute hazardous waste monthly.
  - Provides fewer requirements for facilities generating less waste are “conditionally exempt small quantity generators” (CESQG’s).
  - Outlines hazardous waste determinations, disposal options, including a sewer ban, shipping requirements, training requirements, and on-site storage (among others).
- APhA submitted comments to EPA on December 24, 2015.

EPA Proposed Rule: Hazardous Waste Pharmaceuticals

- Pharmacies (unless CESQG’s) will need to:
  - Determine whether pharmaceutical waste is hazardous.
  - Determine their generator category and submit one-time notice to EPA.
  - Sort potentially creditable hazardous waste and non-creditable hazardous waste.
  - Potentially creditable waste may be disposed of using a pharmaceutical reverse distributor or treatment, storage & disposal facility (TSDF).
  - Non-creditable hazardous waste may be disposed of using a TSDF.
  - Stop sewer ban (including CESQG’s).
  - Adhere to specific storage, shipping and recordkeeping requirements.

EPA Proposed Rule: Hazardous Waste Pharmaceuticals

- APhA comments addressed the following areas:
  - Pharmaceutical definition: Recommended that EPA exempt dietary supplements and pharmaceuticals with a radioactive component.
  - Hazardous Waste Pharmaceutical: Recommended development of a hazardous waste pharmaceutical list and reconsider counting potentially creditable pharmaceuticals as waste.
  - Residue: Requested EPA clarify exemptions.
  - Sewering ban: Recommended exempting run-off from cleaning.
  - Additional requests:
    - Harmonize regulations with other federal agencies and their regulations, such as DQSA/ DSCSA and DEA e.g., disposal options for controlled substances.
    - Increase education and awareness initiatives before the rule is effective.

FDA Biosimilar Naming Guidance

- FDA released a draft guidance on biosimilars naming on August 28, 2015, with comments due October 27, 2015.
- FDA proposed that reference products and their biosimilars share a nonproprietary name (the “core name”), but that each product have a unique suffix.
- Core name + suffix = FDA “Proper Name”

<table>
<thead>
<tr>
<th>Proprietary or “Brand” Name</th>
<th>FDA “Proper Name”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neupogen</td>
<td>Filgrastim-jwcp</td>
</tr>
<tr>
<td>Zarzio</td>
<td>Filgrastim-bfm</td>
</tr>
</tbody>
</table>
Pending FDA Naming Guidance, cont.

- FDA stated that the need for improved pharmacovigilance and safe use was the basis for its proposed naming policy, and highlighted the following:
  - Reference products and biosimilars may not be approved for all routes of administration and may have different delivery systems;
  - Shared INN might create the mistaken impression that reference products and biosimilars are interchangeable; and
  - Existing pharmacovigilance systems do not allow for adequate tracking of products with shared INNs.

- FDA questions to stakeholders:
  - Should suffixes be random or "meaningful" (meaning they are keyed to a manufacturer’s name, like -sndz)?
  - Should reference products and their interchangeable biosimilars share suffixes?

Pending Biosimilar FDA Naming Regulation

- In tandem with the draft guidance, FDA also released a proposed rule changing the existing names of 6 related biologics and biosimilars.
- Comments were due November 12, 2015

<table>
<thead>
<tr>
<th>Current Name</th>
<th>Proposed Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>filgrastim-sndz</td>
<td>filgrastim-bflm</td>
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<tr>
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</tr>
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<td>epoetin alfa-cgkn</td>
</tr>
<tr>
<td>infliximab</td>
<td>infliximab-hjmt</td>
</tr>
</tbody>
</table>

Highlights of APhA Biosimilars Comments

- APhA’s comments on both FDA’s biosimilars naming guidance and its proposed rule advocated for a consistent naming policy for all biologics and biosimilars:
  - Suffixes: Opposed the use of suffixes, but noted that if FDA imposes them, it is preferable that they convey information about the product without being keyed to a manufacturer’s name
  - Interchangeable Biosimilars: Supported shared names for interchangeable biosimilars that share the same name as their reference products
  - Education: Encouraged FDA and other stakeholders to develop objective educational programs to foster public awareness and understanding of biologic products

Anticipated FDA Biosimilar Policy/Regulation

Interchangeability

- FDA has not yet laid out the framework for interchangeability determinations
  - An interchangeable biological product:
    - In addition to meeting the biosimilarity standard, is expected to produce the same clinical result as the reference product in any given patient
    - Risks associated with alternating or switching between reference product and biosimilar are not greater than the risks associated with use of the reference product alone
  - FDA has created a “Purple Book”, which lists biologics and biosimilars and will eventually include information regarding interchangeability of biosimilars and their reference products

HRSA: 340B Draft Guidance

- August 28, 2015: HRSA released the long-awaited draft 340B “mega-guidance”
- Draft guidance addresses most aspects of the program, including:
  - Definition of “patient”;
  - Covered entity eligibility;
  - Duplicate discounts; and
  - Contract pharmacy compliance
- Final Rule publication scheduled for September 2016
• The HHS Office of the Inspector General outlined action items in its CY 2016 Investigative Plan that directly relate to pharmacy practice.

• In 2016, HHS plans to:
  – Analyze drug-related hospitalizations of Medicare beneficiaries to identify the role of beneficiaries’ pharmacies and prescribers.
  – Conduct a drug traceability test to gauge the efficacy of Drug Supply Chain and Security Act (“DSCSA”) requirements currently in effect.
  – Evaluate states’ Medicaid Drug Utilization Review (“DUR”) programs for clinical misuse or possible fraud.
  – Review Medicare and Medicaid payment policies and trends for specialty drugs.

Increasing Oversight and Scrutiny

Pharmacogenomics

• January 2, 2015: President Obama announced the Precision Medicine Initiative (PMI) which aims to incorporate precision medicine into clinical practice.

• December 2015: FDA launches precisionFDA, a web platform that aspires to foster innovation related to next generation sequencing and improve genomic test quality and accuracy.

• March 2, 2016: In response to President Obama’s PMI, FDA held a public workshop and is accepting comments to understand patient and provider perspectives on receiving potentially medically relevant genetic test results.

Self Assessment Questions

APhA has provided comments to Congress that recommend which of the following?

a) Increasing prescriber and patient education
b) Standardizing and integrating real-time prescription drug monitoring programs
c) Increasing access to reversal agents such as naloxone
d) All of the above

At the federal level, APhA is requesting legislative changes to which government program in effort to provide coverage for pharmacists’ services?

a) Medicaid
b) Medicare Part A
c) Medicare Part B
d) Affordable Care Act and the federal and state health exchanges

text