Legislative and Regulatory Update 2016

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Alicia Kerry Mica, Michael Baxter 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 honoraria.

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

- Target Audience: Pharmacists & Technicians
- ACPE#: 0202-0000-16-165-L03-P/T
- Activity Type: Knowledge-based
At the completion of this activity, participants will be able to:

• Identify new federal legislative activity that will affect the practice of pharmacy

• Describe new federal regulations and regulatory activities that will affect the practice of pharmacy

• Recall the current status of federal reimbursement for pharmacist services
Assessment Question #1

Within which section of Medicare are pharmacists seeking to be recognized as “providers”?

a) Medicare Part A
b) Medicare Part B
c) Medicare Part C
d) Medicare Part D
Assessment Question #2

Which change did FDA announce for inspections of human compounders that will start on August 1, 2016?

a) FDA will no longer inspect 503A pharmacies
b) FDA will determine if compounders are 503A facilities before applying CGMP
c) FDA inspects only 503B facilities
d) A & C
Assessment Question #3

If a pharmacy generates 10kg of hazardous waste and 0.1kg of acute hazardous waste per month, according to EPA’s proposed rule, which generator category would the pharmacy be?

a) Conditionally exempt small quantity generator
b) Large quantity generator
c) Medium quantity generator
d) None of the above
Legislative Update
2016 Election

Senate
• Current Makeup
  – 54 Republicans
  – 44 Democrats
  – 2 Independents
• Up For Re-election
  – 10 Democrat Seats
  – 24 Republican Seats

House
• Currently there are 246 Republicans & 186 Democrats *
• All House seats are up for re-election this year

* 3 vacancies (KY-1, HI-1, PA-2)
House Leadership

• Republican Leadership
  – Speaker – Paul Ryan (WI)
  – 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)
House of Representatives

• Energy and Commerce Committee
  – Chairman Fred Upton (R-MI)
  – Ranking Member Frank Pallone (D-NJ)
• Ways and Means Committee
  – Chairman Kevin Brady (R-TX)
  – Ranking Member Sander Levin (D-MI)
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)
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)
Senate Key Committees

Senator

• 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)
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
  – Currently 292 cosponsors, more than 65% of the House

• Senators Chuck Grassley (R-IA), Sherrod Brown (D-OH), Robert Casey (D-PA), and Mark Kirk (R-IL) introduced on January 29, 2015
  – Currently 49 cosponsors, 50% of the Senate

• 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-licensed 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)
Patient Access to Pharmacists’ Care Coalition (PAPCC)

Nearly 40 organizations and growing!
PAPCC Successes

- Formed a results-oriented coalition that continues to grow
- Legislation has support from over 67% of the House, 50% of the Senate
- Support is bipartisan
  - Remarkable for health care legislation in a partisan Congress
- After almost 3 years, involving 2 sessions of Congress, no opposition to legislation
- Pharmacy unified in support
- Synergistic effects at state and federal level
  - Federal effort has helped state level efforts and vice versa
July 23, 2016: President Obama signed CARA into law. It is comprised of the 9 titles that aim to address the opioid epidemic:

**Title I – Prevention and Education**

- Pain management best practices inter-agency task force, required to include pharmacists and pharmacies and representatives from the VA, DoD and veteran services organizations
- Secretary may establish a program to pilot requirements and procedures to assist veterans with certain military emergency medical training to meet requirements for becoming civilian health care professionals
- Grants that may fund: training for pharmacists on prescribing of drugs or devices for emergency overdose treatment; strategies for pharmacists to dispense naloxone; and encourages states to allow and enable pharmacies to dispense naloxone pursuant to a standing order
Comprehensive Addiction and Recovery Act of 2016 (CARA)

Title II – Law Enforcement and Treatment
- Authorizes grants for treatment as alternatives to incarceration programs
- Requires a GAO study and report on federal agency programs and research relative to substance use and substance use disorders among adolescents and young adults
- Requires Attorney General to coordinate with covered entities, such as hospitals with onsite pharmacies, expansion or making available prescription drug disposal sites

Title III – Treatment and Recovery
- Grants for evidence-based prescription opioid and heroin treatment
- Allows nurse practitioners and physician assistants to prescribe schedule III drugs, such as buprenorphine, for medication-assisted treatment
- Directs VA to expand Opioid Safety Initiative to all VA medical facilities
Comprehensive Addiction and Recovery Act of 2016 (CARA)

Title IV – Addressing Collateral Consequences
• GAO report on recovery and collateral consequences one year after CARA’s enactment

Title V – Addiction and Treatment Services for Women, Families and Veterans
• Defines the “Veterans treatment court program” which involves intensive supervision and case management, full continuum of treatment services, alternatives to incarceration and other appropriate services, such as housing
• Provides grants for a veterans assistance programs which may be used for veterans treatment court programs, peer-to-peer services, best practices and training programs
Comprehensive Addiction and Recovery Act of 2016 (CARA)

Title VI – Incentivizing State Comprehensive Initiatives To Address Prescription Opioid Abuse

- Grants to states for education efforts around opioid use, treatment and recovery, prescription drug monitoring programs (PDMPs), treatment programs, prevention, disposal and detection of warning signs of opioid use disorder

Title VII – Miscellaneous

- Allows partial fills of schedule II controlled substances if not prohibited by state law and requested by the patient or practitioner who wrote the prescription

- Creates a “lock-in” program for Medicare Parts C and D prescription drug plans to tie at-risk beneficiaries to single prescriber and pharmacy for frequently abused drugs

Title VIII – Kingpin Designation Improvement
Comprehensive Addiction and Recovery Act of 2016 (CARA)

Title IX – Department of Veterans Affairs

- Requires expansion of the Opioid Safety Initiative of the VA to include all medical facilities of the Department
- VA health care providers, before initiating opioid therapy, to use the VA’s Opioid Therapy Risk Report tool
- Enhance standards for urine tests before and during opioid therapy
- Each VA medical facility must designate a pain management team of health care professionals to coordinate pain management therapy for non-cancer patients
- VA health care providers must report to state prescription drug monitoring programs
- Establishment of Office of Patient Advocacy Department of Veterans Affairs
- Pilot program on integration of complementary and integrative health and related issues for veterans and family members of veterans
Regulatory Update
The Drug Quality and Security Act

Signed into law on November 27, 2013

- Compounding Quality Act
  - Establishes Outsourcing Facilities
- Drug Supply Chain Security Act (DSCSA)
  - Also known as Track and Trace
April 15, 2016: 3 Draft FDA DQSA Guidance Documents
1. Prescription Requirement Under Section 503A
   • Prohibits office use under 503A
   • Limits anticipatory compounding to a 30-day supply
   • Attempts to define what constitutes a valid prescription
2. Hospital and Health System Compounding
   • Allows hospitals and health systems to distribute compounded drug products, without patient-specific prescriptions, for up to a 1-mile radius from their pharmacy within their own facilities
3. Facility Definition Under Section 503B
Recent Compounding Activities

July 11, 2016: Draft FDA Guidance on Compounded Drug Products/Essentially Copies of a Commercially Available Drug Products Under Section 503A

• Determination of a Commercially Available Drug: “…has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; the API(s) have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless a prescriber determines that there is a change, made for an identified individual patient, which produces for that patient a significant difference from the commercially available drug product”

• Significant Difference Exceptions: API (Inactive Ingredients); Drug Strength (i.e., Same, Similar or Easily Substitutable Strength) - within 10% of the strengths of the respective commercially available products; Same Route of Administration (e.g., Topical, Intravenous, Oral)

• Regularly/Inordinate Compounded Amounts: No action “…if the compounding fills four or fewer prescriptions for the relevant compounded drug product in a calendar month”
Recent Compounding Activities

July 11, 2016: Draft FDA Guidance on Compounded Drug Products/Essentially Copies of Approved Drug Products Under Section 503B

• Determination of Approved Drug Product: “The FDA approved drug have the same “active ingredients(s); route of administration; dosage form; dosage strength; and excipients.” (i.e., fillers)*
  
  – *Note: Essentially a copy of an approved drug, unless the approved drug appears on FDA’s drug shortage list at the time of compounding, distribution, and dispensing

• 60-Day Extension for Shortaged Products: No FDA action for filling orders that it received for a compounded drug that is identical to an approved drug that was on FDA’s drug shortage list “…at the time that the outsourcing facility received the order, provided the drug also appeared on the FDA drug shortage list within 60 days of the outsourcing facility distributing or dispensing the drug”**

  – **Note: The 60-day extension applies only to orders received while the product is on the shortage list
Recent Compounding Activities

July 12, 2016: FDA Inspections “Notice” Document

• New Procedure for Inspections of Human Drug Compounders
  – Agency will determine if compounders are 503A facilities before applying CGMPs
  – Effective August 1 (and does not apply to current or past inspections)
  – FDA intends to continue to inspect compounding facilities and to take action, as appropriate, when the agency identifies violations of Federal law that could put patients at risk
  – FDA will still undertake inspections of 503A facilities, and intends to include CGMPs on Form FDA-483s, potentially for 503A pharmacies
Recent Compounding Activities

August 3, 2016: Draft FDA Guidance on Insanitary Conditions at Compounding Facilities

• Examples of insanitary conditions
• Procedures that compounding facilities should employ to ensure that they do not have insanitary conditions and that they are capable of producing sterile drug products
• Actions that compounding facilities should take if they identify insanitary conditions at their facilities;
• Potential FDA regulatory actions if insanitary conditions are not adequately corrected
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

Phase 1: Lot Level Tracing
• 1/15: Authorized trading partner verification
• 3/16: Suspect/ illegitimate product identification and notification
• 1/15 & 3/16: Transaction data

Phase 2: Product Identifier (PI)
• 11/17: Manufacturers add PI to unit/case, and build a database
• 11/18: Re-packagers add PI to unit/case
• 11/19: Wholesaler transactions with identified products
• 11/20: Dispenser transactions with identified products

Phase 3: Unit Level Tracing
• 11/23: Unit-level traceability for all supply chain stakeholders
• 11/23: Track and exchange unit-level serialized data
Requirements already in effect (Phase 1):

- Authorized trading partner verification (Jan/2015)
- Suspect/illegitimate product identification and notification (Jan/2015)
- Transaction data
  - Only accept product if previous owner provides the “3Ts” (March/2016)
  - Provide the subsequent owner with the 3Ts (July/2015)
  - Trading partners, including pharmacies, capture and maintain the 3Ts for 6 years from the date of the transaction (March/2016)
DQSA: Track and Trace

Additional Provisions:
• 2020: Small pharmacy technology assessment on package-level tracing
• 2020: Establish and evaluate pilot projects on enhancing supply chain safety/security
• 2021: Regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level
• 2022: Final guidance on interoperable data exchange standards for secure package level product tracing
DQSA: Track and Trace Updates

- October 2015: FDA releases wholesaler and third-party logistics provider (3PL) facility licensure data to the public
- October 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
- Exception: 3Ts are not required for a specific patient need
- On October 21, APhA and other stakeholders met with FDA on this issue
DQSA: Track and Trace Updates

- April 2016: FDA holds a public workshop regarding proposed pilot project(s)
- May 2016: Comments due on a Request for Information regarding pilot projects
  - Pharmacy-related concerns emphasized the need to include variable pharmacies, technological barriers and cost
- October 2016: FDA holds public workshop regarding best practices for the product identifier
September 2015: EPA released the proposed rule “Management Standards for Hazardous Waste Pharmaceuticals”

- Unifies requirements for health care facilities, which includes pharmacies, that generate more than 100kg of hazardous waste or 1kg of acute hazardous waste monthly;
- Provides fewer requirements for facilities generating less waste are “conditionally exempt small quantity generators” (CESQGs);
- Outlines hazardous waste determinations, disposal options including a sewering ban, shipping requirements, training requirements, and on-site storage (among others).
EPA Proposed Rule: Hazardous Waste Pharmaceuticals

Pharmacies (unless CESQGs) 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 sewering (including CESQGs)
- Adhere to specific storage, shipping and recordkeeping requirements
APhA submitted comments addressing 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
August 2015: FDA released a draft guidance on biosimilars naming with comments due October 2015. FDA has yet to finalize the guidance document. In tandem with the draft guidance, FDA released a proposed rule changing the existing names of 6 related biologics and biosimilars. The proposed rule has yet to be finalized.

• 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”

• Suffix, as proposed, are random but some stakeholders believe the suffix should be meaningful, or the applicant should be provided an opportunity to suggest suffix

• FDA has yet to release guidance for interchangeable biological products
### FDA Biosimilar Naming Guidance

<table>
<thead>
<tr>
<th>Type of Biological Product</th>
<th>&quot;Brand&quot; Name</th>
<th>FDA &quot;Proper Name&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Product</td>
<td>Neupogen</td>
<td>Filgrastim-jcwp</td>
</tr>
<tr>
<td>Biosimilar</td>
<td>Zarxio</td>
<td>Filgrastim-bflm</td>
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</tbody>
</table>
Biosimilar Product Labeling Guidance

March 2016: FDA releases draft guidance on labeling for biosimilar products. Highlights from labeling guidance include:

• Information and data from a clinical study of a biosimilar product should be described in labeling only when necessary to inform safe and effective use by a health care practitioners

• Biosimilar labeling should include a description of the clinical data like that on the reference product’s label

• Biosimilar labeling to include a statement that the product is biosimilar to the reference product

• Content depends on whether the applicant seeks approval for all conditions of use

• Sections of biosimilar product label based on the reference product labeling should have similar text, need not be identical and certain differences may be appropriate

• Biosimilar product labeling may have differences such as administration, preparation, storage or safety information
The Guidance includes product identification preferences, as described below:

- The **biosimilar product name** (i.e. Zarxio) should be used in labeling specific to the biosimilar product of when referring solely to the biosimilar product.
  - The FDA proper name (i.e. Filgrastim-bfim) should be used when the product name is not available.

- The **reference product name** should be used: (1) when clinical studies or data derived from studies with the reference product are described in biosimilar product labeling; and (2) within the statement of biosimilarity.
- The **core name + “products”** (i.e. filgrastim products) used where risk applies to both the biosimilar product and the reference product, such as boxed warning, contraindications, warnings and precautions

- **More than one product name** may be used in a single paragraph. FDA provided the following example:

  Replicamab products can cause hepatotoxicity and acute hepatic failure. In clinical trials of replicamab-hjxf, 10% of patients developed elevated ALT or AST greater than three times the upper limit of normal and 5% progressed to acute hepatic failure. Evaluate serum transaminases (ALT and AST) and bilirubin at baseline and monthly during treatment with NEXSYMEO . . .
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, will include information regarding interchangeability of biosimilars and their reference products
Anticipated Policy/ Regulation Related to Biological Products

Naming

• S. 2700 – FDA and NIH Workforce Authorities Modernization Act passed the HELP Committee for inclusion the Senate’s Biomedical Innovation Project, the companion effort to the House’s July 2015 passage of 21st Century Cures (H.R. 6)
  – The bill includes a provision that would exempt biologic products from having to adhere to U.S. Pharmacopeial (USP) standards for quality, including naming
  – USP’s naming structure does not utilize a suffix
  – The Federal Food, Drug, & Cosmetic Act (501/502) has adulteration and misbranding provisions that contain a role for USP naming and quality, which applies to biological products
Other Regulatory Activity

- Nondiscrimination in Health Care Settings (final regulation issued)
- OTC Naloxone and Patient Medication Information (announced intent; no federal register activity recently)
- OTC / DTC Diagnostic Tests for Infectious Disease (Panel Meeting held)
- Value-based purchasing and insurance design (ongoing regulatory activity)
- Medication-assisted treatment (final regulation issued)
- Pharmacogenomics / genetic tests (ongoing regulatory activity)
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Helpful Resources

FDA Regulatory Compounding Information:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm

APhA’s Opioid Resource Center:
Questions?

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