Legislative and Regulatory Update

Michael Spira
APhA Senior Lobbyist
Jillanne Schulte, JD
APhA Director, Regulatory Affairs

CPE Information

- Target Audience: Pharmacists & Technicians
- ACPE#: 0202-0000-15-221-L03-P/T
- Activity Type: Knowledge-based

Disclosures

Michael Spira and Jillanne Schulte 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 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:
• State new federal legislative activity that will affect 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 payor 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

After the King v. Burwell ruling, which of the following is true?
a) All US citizens are eligible for insurance premium subsidies
b) Premium subsidies will not be available for anyone
c) The Affordable Care Act is no longer in effect
d) Premium subsidies will continue to be available to individuals who purchase coverage from the federal exchange
Assessment Question #3
Which of the following is true for 503B outsourcing facilities?

a) Registration for 503B designation is free
b) Certain pharmacies are required by law to register as outsourcing facilities
c) An entity registering under 503B must do some sterile compounding
d) An entity that does only non-sterile compounding can register

Assessment Question #4
Which change did CMS implement in the final 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 Question #5
Which of following prescription drug take-back options can be facilitated by pharmacies?

a) The placement of a receptacle in the pharmacy for patients to discard unwanted, unused or expired prescription drugs
b) Accepting prescription drugs from the public and placing them in the trash
c) Accepting prescription drugs and placing them in the damaged inventory pile to be reverse distributed
d) All of the above

Congressional Make-up

• House of Representatives
  – 247 Republicans
  – 188 Democrats
• Senate
  – 54 Republicans
  – 44 Democrats
  – 2 Independents

House Leadership

• 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 – Problems and Opportunities

- Total health care spending in the United States is expected to reach $4.8 trillion in 2021, up from $2.6 trillion in 2010 and $75 billion in 1970
  - Health care spending will account for nearly 20% of GDP by 2021
- The US spends almost $300 billion annually on medication problems including medication non-adherence
- Chronic diseases costs the US health care system $1.7 trillion annually (more than 75% of health care spending)

Provider Status – 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
  - 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
- Association of Clinic Pharmacists
- Bi-Lo Pharmacy
- Cardinal Health
- CVS Health
- Food Marketing Institute
- 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 Pharmacy Association
- National Rural Health Association
- Omnicell
- Pediatrics Pharmacy Advocacy Group
- Rite Aid Pharmacy
- Safeway
- SUPERVALU Pharmacies
- Target
- Thrifty White Pharmacy
- Winn-Dixie Pharmacy
- Walgreens
- Walmart

Patient Access to Pharmacists’ Care Coalition

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

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

Patient Access to Pharmacists’ Care Coalition

- Positive feedback overall but cost is important
  - Need to “score” low by Congressional Budget Office (CBO)
  - Pharmacy challenged to be “saver, not coster”
- Hill equates provider status with “fee-for-service”
  - Current focus is on new payment models (e.g. ACOs)
- View from other health care providers
• On Wednesday, March 18 the Senate Budget Committee included S. 314 language in the Chairman’s Mark – recommendation by the committee chair.
• Great news!!
  – Shows our message is resonating
  – Helps make case for undecided Senators
• But…
  – It was included without funding
  – And the budget will not be signed into law

March 2015 Launched Media Campaign

Print and radio ads targeted to DC policymakers
  – Not a consumer campaign

Overall message is the need for Seniors’ access to healthcare

Some ads highlighted different problems
  – E.g. urban - difficult to get appointments and need for multiple bus lines

Ads also focused on different services and needs (e.g. diabetes, heart conditions, asthma)

A new Congressional initiative that aims to accelerate the pace of cures and medical breakthroughs in the United States

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

Lay the groundwork for the next iteration of the Prescription Drug User Fee Act (PDUFA)
21st Century Cures

On February 13, 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.

Prescription Drug Abuse

In 2014, the SenateHELP Committee formed a prescription drug abuse working group led by then Chairman Tom Harkin (D-IA) and Ranking Member Patty Murray (D-WA). 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.

Prescription Drug Abuse

The House Energy and Commerce Subcommittee on Oversight and Investigations has held a series of hearings focused on reducing prescription drug abuse:
- Chairman Tim Murphy (R-PA)
- Ranking Member Diana DeGette (D-CO)

Committee looked at:
- State Response
- Federal Response
- Growing problem of prescription drug and heroin abuse

APhA continues to work with the committee to provide input and feedback.

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.

APhA continues to work with the committee to provide input and feedback.

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.

APhA sent a letter of support to the sponsors.

Infusion Therapy

Medicare Home Infusion Site of Care Act
- Introduced in the House by Reps. Engel (D-NY) and Tiberi (R-OH)
- Introduced in the Senate by Sens. Isakson (R-GA) and Warner (D-VA)

Infusion therapy is fully covered by Medicare in hospitals, physician offices, and many other places but not in the home, which is the setting that is the most desirable, convenient, and by far the most cost effective.

The bill provides a pathway for reimbursement for the professional services, supplies and equipment associated with infusion therapy in the home under Medicare Part B, thus enabling the current Part D coverage of infusion drugs to become meaningful for Medicare beneficiaries.

APhA sent a letter of support to the sponsors.
Regulatory Update

Health Care Reform

• King v. Burwell: Second challenge to Affordable Care Act (ACA)
  – 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 (i.e., ACOs, PCMHs):
  – 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

Centers for Medicare & Medicaid Services (CMS)

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 Model Test for Innovation
  – Announced in late September 2015 and scheduled to begin January 1, 2017
  – Intended to provide flexibility in MTM targeting and interventions

CMS: Medication Therapy Management

Current Eligibility Criteria
• 2 – 3 chronic conditions; and
• 2 – 8 Part D medications; and
• Drug spend > $3,138 (CY ’14)
  – Current utilization rate remains extremely low
  – Approximately 8% of beneficiaries are currently eligible, despite a CMS goal of 25% eligibility
  – Criteria vary vastly among plans

APhA Proposed Changes
• Standardizing criteria to reduce plan variation and increase eligibility
• Lower thresholds for all three major eligibility criteria
• Improved targeting, including allowing pharmacists and prescribers to refer patients

CMS Annual Part D Changes Process

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
• 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
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.

CY 2016 Final Rule provisions include:
- 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.

The following provisions are included in the CY 2016 Final Rule:

- 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
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- 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.

The CY 2016 Final Rule provisions include:
- Part D Notice of Changes
  - Requiring plans to provide annual notice of changes to CMS and to enrollees at least 15 days prior to the election period
- P & T Committee Conflicts of Interest Changes
  - Requiring plan sponsors to create and document processes for handling conflicts of interests for P & T Committee members, including a determination by an objective party that disclosed financial interests are not actual conflicts of interest
- Plan Enrollment for Individuals Not Lawfully Present in the U.S.
  - Establishing that legal presence or U.S. citizenship is a prerequisite for enrollment in cost, Medicare Advantage, and Part D plans

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

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.

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.
CMS: Other Issues

CY 2015 Incident-to Billing Changes and CY 2016 Proposals
- 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 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

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
  - Contract pharmacy compliance
- Comments are due October 27, 2015

Pending 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
  - If this approach is adopted, suffixes must be devoid of meaning
  - Core name + suffix = FDA “Proper Name”

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<th>Proprietary or “Brand” Name</th>
<th>FDA “Proper Name”</th>
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<tr>
<td>Neupogen</td>
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<tr>
<td>Zanzio</td>
<td>Filgrastim-bflm</td>
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</table>

Pending FDA Naming Guidance, cont.

- FDA justified the proposed policy on the basis of improved pharmacovigilance and safe use
  - 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
  - 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 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 are due November 12, 2015

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<th>Proposed Name</th>
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<td>infliximab</td>
<td>infliximab-lymx</td>
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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
 Pending CMS Biosimilar Regulation

- In the Physician Fee Schedule FY 2016 proposed rule, CMS sets out a framework for reimbursing biosimilars under Part B
- CMS proposes to bundle all of a reference product’s biosimilars, including interchangeable biosimilars, under a single HCPCS code and Average Sales Price (ASP)
  - The reference product would not be included in the ASP calculation
  - ASP of biosimilar + 6% of reference product’s ASP = biosimilar reimbursement
- Pharmaceutical companies and physicians’ groups have expressed concerns about excluding the reference product from ASP calculations and including interchangeable biosimilars in the same category as non-interchangeable biosimilars

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

**Drug Quality and Security Act**

- Signed into law on November 27, 2013
- Establishes Outsourcing Facilities
- Also known as Track and Trace

DQSA Implementation

- 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

FDA: 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)
- Draft Guidelines and the MOU have been published for comment:
  - Comments on guidance documents were due May 13, 2015
    - 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
  - Comments on the MOU were due July 20, 2015

Concerns with new guidance documents and the MOU

- 503B Outsourcing Facilities
  - For 503B, all drugs compounded in a 503B facility are subject to FDA oversight (both sterile and non-sterile)
  - 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
  - Percentage limitations associated with interstate distribution are arbitrary and may result in serious patient access issues
FDA: Compounding Regulation & Guidance

Ongoing APhA Compounding Activities
- FDA recently opened a docket for comments on compounding issues not yet addressed in guidance, such as "office use", and APhA will be submitting comments
- In follow up to the nuclear listening session, nuclear pharmacy groups are considering options for additional comments
- APhA is a member of DQSA Coalition – coalition of 20+ organizations
  - Working at both Congressional and Agency level
  - Developing joint comments on MOU
  - Developing joint comments on ancillary DQSA issues
    - E.g., inspections, definitions, and "office-use"

TRICARE: Compounding Reimbursement

- Effective May 1, 2015, TRICARE covers a compounded medication (regardless of point-of-sale), only if its ingredients are:
  - FDA-approved, safe and effective, and medically-necessary; and
  - Cost-effective for the patient
- Express Scripts instituted an "enhanced" claims process to screen prescriptions at the ingredient level

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 and notification of illegitimate products in the drug supply chain
  - 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 to develop processes to inspect, quarantine, investigate and notify FDA and immediate trading partners of suspect product

Track and Trace Implementation

- 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

DSCSA Pharmacy-Specific Provisions

- Beginning November 1, 2015 (on June 30th, 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
- Enforcement delay did not extend to products transferred from pharmacy to pharmacy – meaning that 3Ts must be included
  - 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
Drug Supply Chain Security Act

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

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

Federal agencies continue to actively engage with stakeholders on this issue:
• June 24, 2015: HHS convened Healthcare Pharmacy Roundtable to discuss opioids
• June 2015: HHS OIG released a report on problematic patterns of dispensing and billing in Part D, with a particular focus on dispensing of, and billing for, "commonly abused opioids"
  – OIG will be investigating 1400+ pharmacies to determine if fraud and/or abuse are occurring
• July 1-2, 2015: FDA held a public meeting related to naloxone uptake and use
• September 16, 2015: CDC released draft Guidelines for Prescribing Opioids for Chronic Pain

Track and Trace Regulation

Additional Provisions Affecting Pharmacy
• 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!

Key Points
• Federal legislators and regulators remain highly engaged on issues of interest to the pharmacy profession, including Provider Status, MTM, Compounding, Biosimilars, and Reimbursement
• To advance pharmacy initiatives, active engagement from pharmacy stakeholders, particularly those in the field, is essential
Answer to Assessment Question #1

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

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Questions?

Michael Spira  
APhA Senior Lobbyist  
mspira@aphanet.org

Jillanne Schulte, JD  
APhA Director, Regulatory Affairs  
jschulte@aphanet.org