2015 Federal Pharmacy Law Update

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Disclosure

- Marsha K. Millonig reports no actual or potential conflicts of interest associated with this presentation
Learning Objectives

- Upon successful completion of this activity, pharmacists should be able to:
  - Describe new federal legislative activity that will impact pharmacy practice
  - Explain new federal regulatory activity that will impact pharmacy practice
  - List new additions to the CMS Medicare Part D Call Letter of primary importance to pharmacists
  - Identify stakeholders that are working on achieving Pharmacist Provider Status
Self-Assessment Question 1

- Which of the following legislative bills are currently introduced in Congress to achieve pharmacist provider status?
  1. H.R. 592
  2. H.R. 4190
  3. S. 314
  4. S. 540
  5. Both 1 & 3
Self-Assessment Question 2

• What section of Medicare are legislative efforts directed at to achieve pharmacist provider status?
  1. Medicare Part A
  2. Medicare Part B
  3. Medicare Part C
  4. Medicare Part D
Self-Assessment Question 3

- Which statement about the 2016 CMS Call Letter issued on 4-5-2015 is true?
  1. CMS plans to terminate contracts with plans that have not achieved a 3-star rating for 2 consecutive years
  2. CMS will add a Comprehensive Medication Review (CMR) completion rate star measure for Part D
  3. CMS will pay a 5% Quality Bonus Payment (QBP) to plans achieving a star-rating of 3.5 or more
  4. CMS will adopt a more stringent control of blood pressure quality indicator based on the new JNC 8 Guidelines
Self-Assessment Question 4

Which organization is working to achieve pharmacist provider status through Federal legislation?

1. CMS
2. Provider Status Pharmacy Association
3. Patient Care Services Coalition
4. Patient Access to Pharmacists’ Care Coalition
Legislative Update

- Preferred Network Access
- PBM Transparency/MAC Pricing
- Provider Status
- Sustainable Growth Rate
- Infusion Therapy
- Medication Therapy Management
- 21st Century Cures
- Access to Pain Medication
Congressional Composition

- House of Representatives
  - 244 Republicans
  - 188 Democrats
  - 3 vacancies

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

- 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

- 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

• Speaker of the House – John Boehner (OH)
• 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 Committees

- 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)
House Committees

- 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)
Preferred Network Access

- H.R. 793, Ensuring Seniors Access to Local Pharmacies Act
- Reps. Morgan Griffith (R-VA) and Peter Welch (D- VT)
- Would amend the Social Security Act to ensure that Medicare patients have equal access to community pharmacies in medically underserved areas as network pharmacies under Medicare prescription drug coverage
- Mirrors the approach of H.R. 592 (i.e. Provider Status)
- Mirrors old H.R. 4577, 80 co-sponsors in 2014
Preferred Network Access

- Coalition letter of support to House Leadership in March
  - Alliance for Retired Americans
  - Center for Medicare Advocacy
  - Families USA
  - HealthHIV
  - Justice in Aging
  - LeadingAge
  - Medicare Rights Center
  - National Consumers League
  - National Grange
  - National Rural Health Association
  - The AIDS Institute
  - US Pain Foundation
March 11, 2015

The Honorable Fred Upton
Energy and Commerce Committee
Washington, DC 20515

The Honorable Frank Pallone
Energy and Commerce Committee
Washington, DC 20515

The Honorable Paul Ryan
Ways and Means Committee
Washington, DC 20515

The Honorable Sander Levin
House Ways and Means Committee
Washington, DC 20515

Re: Supporting HR 793

Dear Chairman Upton, Ranking Member Pallone, Chairman Ryan and Ranking Member Levin:

We write to voice our support for H.R 793, the Ensuring Seniors Access to Local Pharmacies Act, sponsored by Representatives Morgan Griffith (R-Va.) and Peter Welch (D-Vt.). This legislation would benefit seniors and people with disabilities in medically underserved areas by giving them more convenient access to discounted or “preferred” cost-sharing in Medicare Part D prescription drug plans (PDPs). It is identical to H.R. 4577 in the 113th Congress which garnered 80 co-sponsors, Republicans and Democrats alike.

Many patients require additional pharmacy choices

The proliferation of “preferred pharmacy” PDPs has been accompanied by a wave of confusion and uncertainty among Part D beneficiaries and their caregivers. Distinctions between “preferred” and “network” pharmacies are not easily understood and may not be properly disclosed or communicated by PDP sponsors.

Furthermore, a recent study by the Centers for Medicare and Medicaid Services (CMS) found that more than half of these Medicare Part D drug plans (54 percent) failed to meet the government’s threshold for reasonable access to pharmacies in urban areas (in this case those authorized to offer “preferred” copay discounts). CMS said that the findings reinforced its concerns surrounding access to “preferred” pharmacy discounts.

Additionally in many rural communities, beneficiaries may be forced to travel 20 miles or more to access a “preferred” pharmacy or pay higher co-pays.

Fresh evidence of beneficiary confusion

Moreover, in early 2015 there was great confusion among those enrolled in Aetna/Coventry drug plans. Specifically, larger pharmacy networks were advertised on Medicare plan finder and on Aetna’s own website during the open enrollment period than was actually the case. This caused
Key Points

• Proliferation of networks:
  • Confusion
  • Uncertainty

• CMS study found 54% failed to meet threshold for reasonable access in urban areas

• Rural areas some beneficiaries are driving more than 20 miles to network & experiencing higher co-pays

• 25 Montana patients sent 85 miles away to North Dakota
PBM Transparency/MAC Pricing

- The MAC Transparency Act of 2015 was introduced by Representatives Doug Collins (R-GA-09) and Dave Loebsack (D-IA-02) on January 9th, 2015
- Generics are 80% of dispensed drugs but pricing a mystery to most
- Lack of transparency by PBMs
- Contracts non-negotiable and do not disclose generic drug reimbursement
MAC Transparency Act of 2015

- Increase transparency of generic drug payment rates in Medicare Part D, the Federal Employees Health Benefits program (FEHB), and TRICARE pharmacy programs, by requiring PBMs to:
  - Provide pricing updates once every 7 days
  - Disclose sources used to update MAC prices
  - Notify pharmacies of any changes in individual drug prices in advance of the use of such prices for claims
  - Establish an appeals process to resolve disputes when drug prices are less than the acquisition cost of a drug
MAC Transparency Act of 2015

- Expands the definition of a drug pricing standard.
  - Definition specifically includes MAC as a pricing standard
- Protects Patient Privacy & Choice
  - Prohibits PBM from transmitting personally identifiable utilization or claims data to a PBM-owned pharmacy, unless the patient has voluntarily elected to fill their prescription at such pharmacy
  - Prohibits PBM from requiring that a beneficiary use a retail or mail order pharmacy if has ownership interest
NCPA Member Survey March 2015

• In the past six months, 49% of the respondents had experienced 51 to more than 100 instances of large upswings in acquisition costs for generic drugs.

• On reimbursement rates, 62% said it took three months or more for PBMs to update prices and 11% said they never saw an update.

• On appeals protesting underpayments, 57% said the appeal was rejected by the PBM and 26% said they received no response at all.
Provider Status

- 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

- Nearly 70% of Americans are on at least one prescription drug, and more than 50% take two.
- In 2011, there were nearly 4 billion prescriptions filled at US outpatient pharmacies – an average of more than 12 prescriptions/person.
- Almost 50% of people prescribed medications for chronic diseases do not take their medications correctly.
Provider Status Coalition

• A broad coalition of pharmacy organizations and stakeholders are united
  • 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)

• APhA
• AACP
• ASCP
• ASHP
• FMI
• IACP
• NCPA
• NACDS
• NASPA
• Rite Aid
• Walgreens
Patient Access to Pharmacists’ Care Coalition (PAPCC)

- Albertson's
- Amerisource Bergen
- BI-LO Pharmacy
- Cardinal Health
- CVS Health
- Fred's Pharmacy
- Fruth Pharmacy
- Healthcare Leadership Council
- Hematology/Oncology Pharmacy Association
Patient Access to Pharmacists’ Care Coalition (PAPCC)

• Kroger
• National Center for Farmworker Health
• Omnicell
• Safeway Inc.
• SuperValu Pharmacies
• Target
• Thrifty White Pharmacy
• WalMart
• Winn-Dixie
Pharmacy and Medically Underserved Areas Enhancement Act

- H.R. 592/S. 314
- Representatives Brett Guthrie (R-KY), G.K. Butterfield (D-NC), Todd Young (R-IN), and Ron Kind (D-WI) introduced on January 28, 2015
  - 78 cosponsors April 1
- Senators Chuck Grassley (R-IA), Sherrod Brown (D-OH), Robert Casey (D-PA), and Mark Kirk (R-IL) introduced on January 29, 2015
  - 10 cosponsors April 1
Pharmacy and Medically Underserved Areas Enhancement Act

- Amends section 1861 of the Social Security Act to recognize pharmacists’ services within Medicare Part B
H.R.592/S. 314

- Pharmacist-provided services would be reimbursable under Medicare Part B only if they are provided in areas of the country that HRSA defines as medically underserved areas (MUAs), medically underserved populations (MUPs), or health professional shortage areas (HPSAs).
- Does not expand services beyond each State’s already existing scope of practice.
- Consistent with precedent established by the Nurse Practitioners (NPs) and Physicians’ Assistants (PAs) provider status efforts; pharmacist services would be reimbursed at 85% of the physician fee schedule.
H.R.592

- In the 113th Congress, this popular and bipartisan legislation (then H.R. 4190) gathered 123 cosponsors
- 68 Democrats and 55 Republicans
- Pharmacists greater role in healthcare
- Enabling them to greater utilize education & expertise
- Lack of recognition limits patient access
- Small, independent pharmacies often serve the medically underserved areas
Scope

- 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

- March 18 the Senate Budget committee included S. 314 language in the Chairman’s Mark – recommendation by the committee chair – Senator Enzi (R-WY)
- Impact of the language
  - Shows the message is resonating
  - Demonstrates Senate support so influences undecided Senators
  - Provision does not require funding – both positive and negative
  - The Senate budget will not be signed into law
Hill Feedback

- 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)
Patient Access to Pharmacists’ Care Coalition

Expanding Patient Access to Pharmacists’ Services
Sustainable Growth Rate

- The sustainable growth rate (SGR) was enacted in 1997 as part of the “Balanced Budget Act” to control physician spending.
- Since 2003 Congress has repeatedly implemented a temporary “doc fix,” costing almost $150 billion to prevent substantial Medicare reimbursement rate cuts, which could result in fewer physicians being able to serve Medicare patients.
Sustainable Growth Rate

- The current SGR expired on March 31, 2015 so a solution or another patch was needed.
- Bipartisan House Speaker Boehner & Minority Leader Pelosi.
- House passed new legislation repealing and replacing SGR on Thursday, March 26 more than 300 votes.
- Senate passed legislation April 14 with a 92-8 vote.
- Averts a 21.2% cut in payments that would have kicked in.
- Sets up a two-track payment system pushing physicians away from the traditional fee-for-service reimbursement.
Sustainable Growth Rate

• Considered watershed event breaking 15-year logjam
• “Most important legislation” since health care reform says writer Paul Demko
• 2-year extension of the Children’s Health Insurance Program
• $7.2 billion for community health centers
• 2019: doctors with 25% of patients in value-based payment models will be eligible for 5% bonus payment through 2024
• After 2024: 0.75% payment bumps: 3 times the level of increase of FFS track
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
- Not in the home: most desirable, convenient, and cost effective
Medicare Home Infusion Site of Care Act

- H.R. 605/S.275
- 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
Medication Therapy Management

- Senators Pat Roberts (R-KS), Jeanne Shaheen (D-NH), Mark Kirk (R-IL) and Sherrod Brown (D-OH)
- S. 776, March 18
- Improve access to MTM under Medicare Part D
Medication Therapy Management Empowerment Act of 2015

• Allows beneficiaries with a single chronic condition to be eligible for MTM services
• Limited to diabetes, cardiovascular disease, COPD and high cholesterol.
• Currently MTM is limited to those who have two or more chronic conditions.
21st Century Cures

- 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
- January 27 introduced by HECC
21st Century Cures

- Streamline clinical trials
- Include patient perspective
- Better access and sharing of data
- New drugs and devices
- Improvement of scientific research
- Lay the ground work for the next iteration of the Prescription Drug User Fee Act (PDUFA)
Ensuring Patient Access and Effective Drug Enforcement Act of 2015

- H.R. 471/S.483
- H.R. 471 is a bipartisan bill reintroduced by Representatives Tom Marino (R-PA-10), Marsha Blackburn (R-TN-7), Peter Welch (D-VT-At Large) and Judy Chu (D-CA-27)
- S. 483 is a bipartisan bill reintroduced by Senators Orrin Hatch (R-UT) and Sheldon Whitehouse (D-RI)
Ensuring Patient Access and Effective Drug Enforcement Act of 2015

- Prevents prescription drug abuse and diversion
- Ensures patient access to necessary medications
- Creates a more collaborative partnership between drug manufacturers, wholesalers, pharmacies, and federal enforcement and oversight agencies.
Ensuring Patient Access and Effective Drug Enforcement Act of 2015

- Pharmacies may submit corrective action plan prior to license revocation/suspension
- Order to show cause must:
  - Contain statement of basis for denial, law citations
  - Direct registrant to appear before attorney general no less than 30 days after order receipt
  - Notifies of opportunity to submit correction action plan
Ensuring Patient Access and Effective Drug Enforcement Act of 2015

- dHHS report to Congress on effects of law enforcement activities on patient medication access
  - Obstacles to legitimate patient access to controlled substances
  - Issues with diversion of controlled substances
  - Collaboration benefits patients and prevents diversion
- Feedback & recommendations by pharmacists
Regulatory Update

- Drug Quality & Security Act
- FDA Compounding
- FDA Biosimilars
- FDA Prescription Labeling
- FDA Pregnancy & Lactation Labeling
- Medical Marijuana
- Health Care Reform
- CMS
- Drug Abuse/Diversion
Drug Quality and Security Act

• Signed into law November 27, 2013
• Two parts:
  • Drug Supply Chain Security Act (DSCSA) or “Track and Trace”
  • Compounding Quality Act (CQA)
    • Establishes Outsourcing Facilities
Beware of Rogue Wholesale Drug Distributors

Wholesale drug distributors are a link between manufacturers and health care professionals. Their role is to ensure prescription medications are delivered safely and efficiently to thousands of health care practitioners and pharmacies nationwide every day.

While the U.S. health care supply chain is one of the most secure and sophisticated in the world, there is a growing network of rogue wholesale drug distributors selling potentially unsafe drugs in the U.S. market.

Reduce the Chance of a Potentially Unsafe Drug Reaching Your Patients

In order to protect your patients from unsafe or ineffective drugs, FDA urges health care professionals to verify that their suppliers are licensed by the state. Drugs from rogue wholesale drug distributors may harm your patients and expose them to unknown risks or side effects. FDA advises health care providers to know the source for prescription drugs.

www.fda.gov/KnowYourSource
Drug Quality and Security Act (DQSA)

Title I: The Compounding Quality Act

Product Tracing

Title II: Drug Supply Chain Security Act (DSCSA)

Wholesale Distributor and 3PL Licensing and Standards
Drug Supply Chain Security Act

- Establishes national system for tracing pharmaceutical products through the supply chain
- Sets national licensing standards for wholesaler distributors and third party logistics companies (3PLs)
- Why?
  - 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
Drug Supply Chain Security Act: Timeline

- Product tracing (by 2015 lot-level, by 2023 package-level)
- Product verification
- Quarantine and investigation--detection and response
- Notification, Recordkeeping
- Product identification (applied to product beginning 2017)
- Wholesale distributor and Third-party logistics provider standards for licensure
- Enhanced system (electronic, interoperable system to trace products at the package-level by 2023)
- National uniform policy
DSCSA: Product Scope

- Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)

- What’s not covered:
  - Blood or blood components intended for transfusion
  - Radioactive drugs or biologics
  - Imaging drugs
  - Certain IV products
  - Medical gas
  - Homeopathic drugs
  - Lawfully compounded drugs
DSCSA

• Transaction
• Transfer of product where a change of ownership occurs
• Exemptions:
  • Intercompany distributions
  • Distribution among hospitals under common control
  • Public health emergencies
  • Dispensed pursuant to a prescription
  • Product sample distribution
DSCSA: Transaction Exemptions

- Blood and blood components for transfusion
- Minimal quantities by a licensed pharmacy to a licensed practitioner
- Charitable organizations
- Distributions pursuant to a merger or sale
- Certain combination products
- Certain medical kits
- Certain IV products
Tracing

- Beginning 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (beginning 7/1/2015) in the drug supply chain will provide information about a drug and who handled it each time it is sold in the U.S. market.

- This transaction documentation consists of:
  - Transaction information (TI) which include lot number of product (except for certain wholesale drug distributor transactions)
  - Transaction history (TH)
  - Transaction statement (TS)
Transaction Information (TI)

- Proprietary or established name or names of the product;
- Strength and dosage form of the product;
- National Drug Code number of the product;
- Container size;
- Number of containers;
- Lot number of the product;
- Date of the transaction;
- Date of the shipment, if more than 24 hours after the date of the transaction; and
- Business name and address of the person from whom and to whom ownership is being transferred.
Transaction History (TH)

- A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.
Transaction Statement (TS) Entity is:

- Is authorized as required under DSCSA;
- Received the product from a person that is authorized as required under DSCSA;
- Received transaction information and a transaction statement from the prior owner of the product, as required under the law;
- Did not knowingly ship a suspect or illegitimate product;
- Had systems and processes in place to comply with verification requirements under the law;
- Did not knowingly provide false transaction information; and
- Did not knowingly alter the transaction history.
Authorized Trading Partners

- Manufacturers and Repackagers: valid registration with FDA
- Wholesale distributors: valid State or Federal license and compliance with reporting requirements; considered authorized before federal licensing regulations effective if possesses "valid license under State law"
- Third-party logistic providers: valid State or Federal license and compliance with reporting requirements; considered authorized before federal licensing regulations effective, unless FDA makes certain findings and gives notice
- Dispensers: valid State license
Verification: 1/1/2015

• Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) shall establish systems and processes to be able to comply with the verification requirements
  • Must be able to respond to verification requests from Secretary about suspect product
  • Quarantine and investigate suspect product to determine if illegitimate product (includes validating applicable TI and TH)
  • Notify trading partners and FDA of illegitimate product (within 24 hours of determination)
  • Respond to notifications of illegitimate product
  • Recordkeeping
Verification

• Verification requirements change once product is serialized. Starting in:
  • 2017 for Manufacturers
  • 2018 for Repackagers
  • 2019 for Wholesale distributors
  • 2020 for Dispensers
Pharmacy Provisions: 7/1/2015

- Not accept ownership of a product, unless the previous owner provides Transaction History (TH), Transaction Information (TI), and a Transaction Statement (TS).
- Provide the subsequent owner with TH, TI, and TS for the product,
  - Except in pharmacy to pharmacy sales to fulfill a specific patient need
  - Specific patient need: Prescription for an identified patient
- Capture TH, TI, and TS, to investigate a suspect product, and maintain such information, history, and statements for 6 years after the transaction.
Drug Product Transfer

- Clarification on transfer between pharmacies expected soon
- FDA intends to issue guidance clarifying what form and manner pharmacies must provide the TH, TI, and a TS for the transferred product
Role of Wholesaler

• A dispenser may have a third party (including a wholesale distributor) maintain the TI, TH, TS required to be captured and stored by pharmacies.
• Wholesalers are not “required” by law to do this on behalf of pharmacies.
• A written “agreement” between a pharmacy owner and applicable wholesaler(s). Wholesalers may establish and maintain a web portal based-system in which dispensers may access the relevant information about his/her transactions.
• Agreements should provide for 6-year storage.
Returns

• For saleable returns, a dispenser may return product to the trading partner they purchased the product from without providing the requisite information.

• For non-saleable returns, a dispenser may return product to the manufacturer or repackager, to the wholesale distributor from whom the product was purchased, to a returns processor, or to a person acting on their behalf without providing the requisite information.
Serialization: Product ID

- 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
FDA Must:

- Conduct a technology and software assessment on the feasibility of small pharmacies to conduct tracing at the package level by 2020
- Establish pilot projects in coordination with stakeholders to explore and evaluate methods to enhance the safety and security of the supply chain by 2020
- Develop regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level by 2021
- Publish final guidance: standards for interoperable data exchange enhancing secure tracing of product at the package level by 2022
Are you ready for the Drug Supply Chain Security Act?

[Updated 12/23/2014] FDA issued guidance to inform industry that we do not intend to take action against manufacturers, wholesale distributors, or repackagers who do not, prior to May 1, 2015, provide or capture the product tracing information required by sections 582(b)(1), (c)(1), and (e)(1) of the FD&C Act. This action is to minimize possible disruptions in the distribution of prescription drugs in the United States.

✔ Become familiar with the law

There are new requirements under the Drug Supply Chain Security Act (DSCSA) for manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers (trading partners). Some requirements began in November 2014 and several key requirements begin at various stages in 2015. The new requirements, development of standards, and the system for product tracing will continue to be phased in over the next nine years. FDA will continue working with trading partners and other stakeholders to effectively implement the new requirements.

✔ Work with your trading partners to ensure they are familiar with the law

It is important that all trading partners understand their responsibilities and work together to help facilitate efficient distribution and availability of drug products in the United States.
Compounding

- FDC Act Section 503(A)
- Describes conditions under which certain compounded human drug products are entitled to exemptions from three sections of the FDCA requiring:
  - FDA approval prior to marketing (section 505)
  - Compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); and
  - Labeling with adequate directions for use (section 502(f)(1))
- Pharmacies that qualify for the exemptions are primarily regulated by the states, although some Federal requirements still apply (e.g. no insanitary conditions)
Compounding Quality Act

- Removes certain provisions from section 503A related to solicitation of prescriptions and advertising and promotion that were found to be unconstitutional by the U.S. Supreme Court in 2002
- Clarifies that section 503A is applicable to compounders nationwide
- Adds new section 503B: “Outsourcing Facilities”
Section 503(B) FDC Act

- Describes conditions under which certain human drug products compounded at a facility registered as an outsourcing facility are entitled to exemptions from sections of the FDCA, including those requiring:
  - FDA approval prior to marketing (section 505); and
  - Labeling with adequate directions for use (section 502(f)(1))
- Outsourcing facilities are not exempt from CGMP requirements and will be inspected by FDA according to a risk-based schedule
Outsourcing Facilities

• Defined as one that:
  • Is engaged in the compounding of sterile drugs
  • Has elected to register as an outsourcing facility
  • Complies with all of the requirements in section 503B

• In addition, an outsourcing facility:
  • Is not required to be a licensed pharmacy, but compounding must be by or under the direct supervision of a licensed pharmacist
  • May or may not obtain prescriptions for identified individual patients
FDA has published final guidance for:
  • 503A compounding (July 2014)
  • 503B outsourcing facility registration (November 2014)
  • 503B outsourcing fees (November 2014)

Draft Guidances and the MOU have been published for comment:
  • Comments on guidance documents are 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
Status

• Issued draft MOU under 503(A)
• Comments on the MOU are due June 13, 2015
• Issued proposed rule describing additions and modifications to the Withdrawn or Removed List (503A and 503B)
• Solicited nominations for 503A and 503B bulks lists and for drugs that are difficult to compound under sections 503A and 503B
• Announced membership of Pharmacy Compounding Advisory Committee and held first meeting covering drugs proposed for withdrawn or removed list and 503A bulks list
Actions since Enactment

• Conducted approximately 130 inspections of compounders including approximately 40 inspections of compounders registered as outsourcing facilities

• Approximately 45 of the 130 inspections of compounding facilities since enactment of the DQSA have been for-cause, generally based on reports of serious adverse events or product quality issues such as drug contamination
Actions since Enactment

• Overseen recalls by over 20 compounders
• Issued over 30 warning letters
• Issued 9 State referral letters from inspections of pharmacies that compounded their drugs in accordance with the conditions of section 503A to the state
• Obtained 2 consent decrees
• Obtained 3 criminal prosecutions, including one guilty plea and 2 indictments
FDA Biosimilars

• The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was passed as part of health reform (Affordable Care Act) that President Obama signed into law on March 23, 2010.

• Act creates an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product.
Biologic:

- U.S. Code of Federal Regulations:
  - “Any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.”
- Derived from living sources
- Various cultures of bacteria or viruses
- Manufactured in living cells
- More similar a therapeutic protein is to human, the less likelihood for immunogenicity
- Differences in manufacturing may lead to real consequences
Biosimilar:

• The biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components

• There are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product

• Is “similar” to the reference product with demonstrated similarity in physicochemical characteristics, efficacy, and safety based on data from analytical studies, animal studies, and clinical study or studies
Biosimilars are not Generics

• A generic is an identical copy of a chemical drug that has gone off patent
• Biosimilars are not identical to the reference product because of differences in manufacturing processes
• Assessing biosimilarity is much more complex than the assessment of “bioequivalence” for small-molecule generic drugs
FDA Draft Guidance

- Safety and efficacy of the biologic has been demonstrated by the innovator
- Sponsor of biosimilar requires evidence that the biosimilar is not significantly different than original
  - Smaller-scale direct comparisons vs replicating clinical trials
- Should not expect differences in safety and efficacy when approved
FDA Actions

- Oncologic Drug Advisory Committee meeting, the Committee unanimously recommended approval of Sandoz’s biosimilar, Zarxio on January 7
- FDA approved Zarxio March 6
- Not designated as interchangeable
- Sandoz has not announced pricing yet
- FDA has stated that it will release naming guidance shortly
## FDA Biosimilars

<table>
<thead>
<tr>
<th>Biosimilar Applicant</th>
<th>Reference Drug</th>
<th>Nonproprietary name</th>
<th>Proposed Biosimilar Name</th>
<th>Placeholder Name</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandoz</td>
<td>Amgen’s Neupogen</td>
<td>Filgrastim</td>
<td>Zarxio</td>
<td>Filgrastim-sndz</td>
<td>Approved on March 6, 2015</td>
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<tr>
<td>Celltrion</td>
<td>Jannssen’s Remicade</td>
<td>infliximab</td>
<td>Remsima</td>
<td>TBD</td>
<td>Application Pending</td>
</tr>
<tr>
<td>Apotex</td>
<td>Amgen’s Neulasta</td>
<td>pegfilgrastim</td>
<td>ApoBiologix</td>
<td>TBD</td>
<td>Application Pending</td>
</tr>
</tbody>
</table>
## Biological Patent Expiration

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Potential Biosimilar Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filgrastim</td>
<td>Neupogen</td>
<td>2014</td>
</tr>
<tr>
<td>Epoetin alpha</td>
<td>Epogen/Procrit</td>
<td>2014</td>
</tr>
<tr>
<td>Insulin glargine</td>
<td>Lantus</td>
<td>2015</td>
</tr>
<tr>
<td>Pegfilgrastim</td>
<td>Neulasta</td>
<td>2015</td>
</tr>
<tr>
<td>Palivizumab</td>
<td>Synagis</td>
<td>2015</td>
</tr>
<tr>
<td>Rituximab</td>
<td>Rituxan</td>
<td>2016</td>
</tr>
<tr>
<td>Cetuximab</td>
<td>Erbitux</td>
<td>2016</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>Humira</td>
<td>2016</td>
</tr>
<tr>
<td>Infliximab</td>
<td>Remicade</td>
<td>2018</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>Herceptin</td>
<td>2019</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>Avastin</td>
<td>2019</td>
</tr>
<tr>
<td>Darbepoetin</td>
<td>Aranesp</td>
<td>2024</td>
</tr>
<tr>
<td>Etanercept</td>
<td>Enbrel</td>
<td>2026</td>
</tr>
</tbody>
</table>

State Activity

- State legislation to clarify pharmacist authority to substitute
  - Criteria for substitution: FDA interchangeability designation
  - Dispense as written (DAW)
  - Health systems to have own therapeutic interchange process?
  - Patient/prescriber notification/communication
  - Record keeping
State Activity

• While FDA continues implementing Biologics Price Competition and Innovation, states are considering proposals to restrict substitution of biologic medications.

• Supporters of state proposals believe the ultimate decision on substitution should be left to the patient’s prescribing physician.

• Opponents believe state proposals are restrictive/inconsistent with forthcoming national standards, and will increase the cost of healthcare unnecessarily.

State Legislation Related to Biologics and Biosimilar Substitution - 2014

State Legislation

- Prescriber preference
- Patient choice: notification of patient/prescriber if substitution occurs
- Labeling
- Recordkeeping (years required vary by state)
- Pricing (not more than product originally prescribed)
- List of substitutable products (State Board of Pharmacy)
Purple will be the new orange for biosimilar makers

By Mali Serebrov
Washington Editor

Shaking up the color wheel, the FDA released what it's calling the Purple Book — a listing of biologics that may serve as reference products for biosimilars and interchangeables.

Actually, the Purple Book is two listings. One references 104 biologics approved by the FDA’s drug center, and the other lists 276 biologic products, including vaccines, approved by the biologics center. The lists will be updated periodically as new biologics and follow-ons are approved.

Each listing includes the biologic license application (BLA) number, nonproprietary product name, brand name, date of licensure, date of first licensure and expiration date of reference drug and pediatric exclusivity. (Since orphan drug exclusivity is available elsewhere, the FDA said it would not be included in the listing.) The Purple Book also indicates whether a product has been withdrawn.
Prepare Yourself

• Familiarize yourself with applicable laws
• Some laws are being adopted with sunset clauses and may expire in whole or in part before applications/determinations occur
• Closely follow your State Board of Pharmacy’s guidance
• Pharmacy/healthcare organizations are a good resource for updates
Practice Implications

- Pharmacists will need to lead evaluation of biosimilars for formulary inclusion
- Range of indications
- Therapeutic equivalence
- Process for therapeutic interchange within health systems
- Information systems to enable pharmacovigilance
Electronic Rx Labeling

- New regulation to require all prescription drugs to have a single Patient Medication Information (PMI) document
- Standardized in content and format
- Providing prescription medication information
- Accurate and balanced form
- Delivered in a consistent and easily understood format
Electronic Rx Labeling

• A public workshop was held on July 1, 2014 to explore:
  • lessons learned from health literacy researchers engaged in PMI projects
  • the role of stakeholders who regularly interface with patient medication information in moving the initiative forward. Additional information is available online at, http://www.brookings.edu/events/2014/07/01-patient-medication-information-prescription-phrma-fda.
Patient Medication Information

• RTI published the results from the qualitative portion of the PMI study (75 FR 78252) on October 14, 2014, in an article entitled, “Preferences for Patient Medication Information: What Do Patients Want?”

• The article is available online at, http://www.tandfonline.com/doi/full/10.1080/10810730.2014.946114
Prescription Labeling

• Purpose is to further ensure that the most current prescribing information is publicly accessible
• Would require electronic distribution of the prescribing information intended for health care professionals
• 24-7 toll-free number available to request paper copies of prescribing information
Electronic Package Insert

- On December 18th 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:
  - Manufactures must submit the most up-to-date label to an FDA controlled electronic repository.
  - Health care professionals who wish to consult the PI must access the FDA’s website to view the material.
  - Pharmacists and patients who request the PI in paper form can print it.
Electronic Package Insert

- FDA requests specific comments on alternative schema:
- To deliver paper PI to health care professionals upon request
- To maintain easy access to manufacturers instructions for use for pharmacists
FDA Pregnancy & Lactation Labeling

- FDA published a proposed rule in May of 2008, replacing the current risk classification system (the use of letters A, B, C, D, and X).
- On December 4, 2014, FDA finalized the rule requiring manufacturers to provide a more comprehensive summary of the risks and a discussion of the data supporting the summary.
Pregnancy and Lactation Labeling Final Rule

[12/3/14] The FDA published the Content and Format of Labeling for Human Prescription Drug and Biological Products, Requirements for Pregnancy and Lactation Labeling, referred to as the "Pregnancy and Lactation Labeling Rule" (PLLRR or final rule).

The PLLRR requires changes to the content and format for information presented in prescription drug labeling in the Physician Labeling Rule (PLR) format to assist healthcare providers in assessing benefit versus risk and in subsequent counseling of pregnant women and nursing mothers who need to take medication, thus allowing them to make informed and educated decisions for themselves and their children. The PLLRR removes pregnancy letter categories – A, B, C, D, and X. The PLLRR also requires the label to be updated when information becomes outdated.

Below is a comparison of the current prescription drug labeling with the new PLLRR labeling requirements.

The Pregnancy subsection (8.1) includes information for a pregnancy exposure registry for the drug when one is available. Pregnancy exposure registries collect and maintain data on the effects of approved drugs that are prescribed to and used by pregnant women. Information about the existence of any pregnancy registries in drugs

THE COLLABORATIVE EDUCATION INSTITUTE
Medical Marijuana

- June 2014: FDA announced it is in the process of conducting eight-factor analysis
- Previously performed eight-factor test in ’01 and ’06
- Currently a Schedule I controlled substance
- Legalization of marijuana for medicinal and/or recreational purposes has been taking place at the state level
Medical Marijuana

These states have medical marijuana laws enacted. Modern research suggests that cannabis is a valuable aid in the treatment of a wide range of clinical applications. These include pain relief, nausea, spasticity, glaucoma, and movement disorders. Marijuana is also a powerful appetite stimulant and emerging research suggests that marijuana's medicinal properties may protect the body against some types of malignant tumors, and are neuroprotective. Select a state to get detailed information.

Information for each state

Alabama CBD-Specific Marijuana Law

Alaska Medical Marijuana Law

Arizona Medical Marijuana Law

Health Care Reform

• King v. Burwell: Second challenge to Affordable Care Act (ACA)
• Oral arguments on March 4, 2015, with a decision expected in late spring
• Case revolves around the question of whether subsidies are available to individuals who purchase coverage from the federal marketplace
• If the Court sides with the plaintiffs, the ACA will stand, but it’s possible that individuals purchasing insurance from the federal marketplace will lose access to subsidies
Health Care Reform

- Move to Value-Based Payment Models (i.e., ACOs, PCMHs)
- January 26th
- CMS announced that its goal is to transition 90% of Medicare fee-for-service payments to value-based models by 2018
- 30% of FFS/traditional to ACOs by 2016 (50% increase from current levels) and 50% by 2018
- 20% payments currently under alternative payment models
Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value

In a meeting with nearly two dozen leaders representing consumers, insurers, providers, and business leaders, Health and Human Services Secretary Sylvia M. Burwell today announced measurable goals and a timeline to move the Medicare program, and the health care system at large, toward paying providers based on the quality, rather than the quantity of care they give patients.

HHS has set a goal of tying 30 percent of traditional, or fee-for-service, Medicare payments to quality or value through alternative payment models, such as Accountable Care Organizations (ACOs) or bundled payment arrangements by the end of 2016, and tying 50 percent of payments to these models by the end of 2018. HHS also set a goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and 90 percent by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs. This is the first time in the history of the Medicare program that HHS has set explicit goals for alternative payment models and value-based payments.

To make these goals scalable beyond Medicare, Secretary Burwell also announced the creation of a Health Care Payment Learning and Action Network. Through the Learning and Action Network, HHS will work with private payers, employers, consumers, providers, states and state Medicaid programs, and other partners to expand alternative payment models into their programs. HHS will intensify its work with states and private payers to support adoption of alternative payments models through their own aligned work, sometimes even exceeding the goals set for Medicare. The Network will hold its first meeting in March 2015, and more details will be announced in the near future.

"Whether you are a patient, a provider, a business, a health plan, or a taxpayer, it is in our common interest to build a health care system that delivers better care, spends health care dollars more wisely and results in healthier people. Today's announcement is about improving the quality of care we receive when we are sick, while at the same time spending our health care dollars more wisely," Secretary Burwell said. "We believe these goals can drive transformative change, help us manage and track progress, and create accountability for measurable
Results

• Medicare savings of $417 million from ACOs
• Reduction in readmissions saving 50,000 lives and $12 billion in spending
• 2010-2013
• Private insurers note they plan to transition up to 75% of their business to value-based payment by 2020
• Health Care Transformation Task Force Members
• Led by former CMS Innovation Center chief Richard Gilfillan
CMS

- MTM
- Annual Part D Changes
  - Part D proposed rule 2014
  - Part D final rule for 2015
  - Part D final rule for 2016
- Call letter
MTM: Expansion Efforts 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 Requests for Information)
MTM Expansion

- 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
- Organizations continue to advocate for standardization, lowering thresholds and improved targeting
Part D Final Rule 2015

- For a Medicare prescription to be considered valid, the prescriber must be enrolled in Medicare.
- GAO Report that indicated widespread prescribing of pain medication by inappropriate providers, eg massage therapists and veterinarians.
- CMS did not list the providers that must be enrolled—instead, eligibility is dictated in large part by state scope of practice laws.
- Changes go into effect on 12/1/2015, with CMS requesting the providers submit Medicare applications by 6/1/2015.
- Following a joint letter from APhA and other groups, on February 19, 2015, CMS clarified that pharmacists should not attempt to enroll in or opt-out of Medicare and that CMS is aware of the issue and is looking for options to address it.
Part D Final Rule 2016

• 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
• Focused on efficiency and program requirements
Part D Final Rule 2016

- Encouraging the use of efficient LTC dispensing techniques and clarifying that payments for these techniques do not require prorated dispensing fees
- Reinforcing requirements for the implementation of Quality Improvement Projects (QIPS) and Chronic Care Improvement Programs (CCIPs) annually
- 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
Part D Final Rule 2016

• Requiring plans to provide annual notice of changes to CMS and to enrollees at least 15 days prior to the election period

• 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

• Establishing that legal presence or U.S. citizenship is a prerequisite for enrollment in cost, Medicare Advantage, and Part D plans
CMS 2016 Call Letter

- CMS draft 2016 draft Call Letter was published on February 20, 2015, comment due March 6, 2015, Final April 6, 2015

- Quality
- Preferred Networks
- Drug Tier Labeling
- Value-Based Payment Models
- Maximum Allow Cost (MAC) Data
- Mail Order and Auto-Ship Policy Changes
CMS 2016 Call Letter

• Preferred Networks

• Proposes plans provide beneficiaries with more information about actual rates of access to pharmacies offering preferred cost sharing

• CMS noted that it would continue to monitor beneficiary access to preferred cost sharing and would follow up with “outlier” plans
CMS Call Letter: Pricing

• Requires 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
CMS 2016 Call Letter

- Incident-to Billing Changes for Certain 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
CMS 2016 Call Letter

• Star Ratings
• Risk Assessments
• Changes to Networks
CMS 2016 Call Letter

- More stringent in-home visit assessments to avoid revenue activities
- Eliminating predetermined 4-star thresholds and adjusting dual eligible calculations
- New star measures: MTM Comprehensive Medication Review Completion Rate
- Additional measures:
  - Breast cancer screening
  - Call center foreign language interpreter
  - Benefit access and performance problems.
Star Measures

- Part C
  - Controlling Blood Pressure
  - Plan Makes Timely Decisions about Appeals
  - Plan All-Cause Readmissions
  - Osteoporosis Management in Women who had a Fracture

- Part C & D
  - Complaints about the Health/Drug Plan (CTM)
  - Improvement Measures
  - CAHPS CMS is making minor modifications to permit imprecisely measured low-reliability contracts to receive 5 stars or 1 star, if evidence warrants such a designation.
Star Measures

- Part D
- Appeals Auto-forward and Upheld measures
- Medication Adherence (for Diabetes Medications and Hypertension (RAS antagonists)) and Diabetes Treatment
- Medication Adherence (Diabetes Medications, Hypertension (RAS antagonists), and for Cholesterol (Statins))
- Obsolete National Drug Codes (NDCs)
Measure Retirement

- NCQA retired the following measures from HEDIS 2015 so they will no longer be included in the Star Ratings:
  - Cardiovascular Care: Cholesterol Screening
  - Diabetes Care: Cholesterol Screening
  - Diabetes Care: Cholesterol Controlled
Low-Performing Plans

• CMS to terminate those contracts failed in 3 consecutive years to achieve a three-star rating for Part C or D (i.e., the 2014, 2015, or 2016 sets of ratings).

• Non-renewal notices from CMS in February 2016 with an effective date of December 31 2016.

• In March 2016, CMS will issue notices to beneficiaries enrolled in non-renewed contracts that they must select a new plan during the 2016 open enrollment period.

• CMS will not calculate 2017 Star Ratings for non-renewed contracts, so there will not be another opportunity to show improvement.
Quality Bonus Payments

Table II-2 Percentage Add-on to Applicable Percentage for Quality Bonus Payments

<table>
<thead>
<tr>
<th>Star Rating</th>
<th>2016 QBP Percentage*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 3 stars</td>
<td>0%</td>
</tr>
<tr>
<td>3 stars</td>
<td>0%</td>
</tr>
<tr>
<td>3.5 stars</td>
<td>0%</td>
</tr>
<tr>
<td>4 stars</td>
<td>5%</td>
</tr>
<tr>
<td>4.5 stars</td>
<td>5%</td>
</tr>
<tr>
<td>5 stars</td>
<td>5%</td>
</tr>
</tbody>
</table>

*The QBP percentage is a percentage point increase to the applicable percentage for a county in a qualifying plan’s service area.
Drug Abuse/Diversion

- Ensuring Patient Access and Effective Drug Enforcement Act of 2015
- H.R. 471/S.483
- H.R. 471 is a bipartisan bill reintroduced by Representatives Tom Marino (R-PA-10), Marsha Blackburn (R-TN-7), Peter Welch (D-VT-At Large) and Judy Chu (D-CA-27)
- S. 483 is a bipartisan bill reintroduced by Senators Orrin Hatch (R-UT) and Sheldon Whitehouse (D-RI)
Drug Abuse

• In 2013, DEA announced an $80 million settlement to resolve the charges that pharmacy chain failed to control the sales of opioid pain relievers. DEA continues to actively pursue pharmacies

• April 2013: NABP convened a stakeholder group (pharmacy and medical associations/organizations, wholesalers and pharmaceutical companies)

• NABP report on “Warning Signs for Pharmacists” and “Challenges and Suggestions for Prescribing and Dispensing Controlled Substances”
Drug Abuse

- February 27, 2014: DEA published a proposed rule to reschedule hydrocodone products to C-II
- August 22, 2014: DEA published the final rule
- DEA noted that it received over 600 comments on the rule of which a “small majority” endorsed the change
- Prescriptions with refills issued before October 6, 2014 are able to be dispensed so long as the dispensing occurs before April 8, 2015
- Most chains did a hard stop, did your pharmacy?
Implementation

- 18 states have publically supported DEA’s accommodation made in the final rule and also allow refills on prescriptions written before October 6 to be filled after the implementation date
- Two states implemented a modified refill allowance
- Seven states have specified that they will not permit refills after the date of federal rescheduling
- Many pharmacies did not honor refills after the implementation date due to pharmacy software limitations and conflicting federal and state controlled substance laws
- Some pharmacies experienced drug shortages due to the relatively short timeframe given to manufacturers to make the necessary FDA label changes
Tramadol

- January 3, 2014: DEA published a proposed rule placing tramadol into schedule IV
- July 2, 2014: DEA published the final rule
- DEA noted that it received 27 comments on the rule, with a majority of stakeholders endorsing the change
- Effective August 18, 2014, tramadol prescriptions may be filled up to six months after the date prescribed, and may be refilled up to five times within six months from the date the prescription was written
Abuse Deterrent Opioids

- FDA hosted a public meeting on abuse-deterrent formulations October 2014
- DEA supports FDA’s vision of a future where all opioids are formulated with abuse-deterrent technology
- Transition to all opioids with abuse-deterrent technology may:
  - Increase patient out-of-pocket costs
  - Limit ability to individualize doses and dosage forms (i.e. compounding)
Take-Back Rule

- DEA published the final rule on the take-back and disposal of controlled substances in 9/2015
- Regulation provides expanded options for discarding unused, unwanted or expired controlled substances
  - Mail-Back Programs
  - Pharmacy-Maintained Collection Receptacles
- Expands participation in take back events; previously only law enforcement-sponsored events allowed
- Subject to state laws
Take-Back Rule

- Pharmacies (retail, hospital/clinics), manufactures, distributors among those who may be an “authorized collector” by modifying their registration with DEA
- Concerns about program requirements
  - Receptacles to be accessible to the public AND also in an area where controlled substances are stored and where an employee is present
  - Receptacles to be for disposal of legal non-controlled and controlled prescription drugs from patients
Bottom line...

- Keep looking ahead...

...stay flexible
As things can change quickly...
Are You Up to the Challenge?

• Just remember...when you think all is lost the future remains!
  • Robert Goddard

• It’s not whether you get knocked down. It’s whether you get up again.
  • Vince Lombardi

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Self-Assessment Question 1

- Which of the following legislative bills are currently introduced in Congress to achieve pharmacist provider status?
  1. H.R. 592
  2. H.R. 4190
  3. S. 314
  4. S. 540
  5. Both 1 & 3
Self-Assessment Question 2

• What section of Medicare are legislative efforts directed at to achieve pharmacist provider status?
  1. Medicare Part A
  2. Medicare Part B
  3. Medicare Part C
  4. Medicare Part D
Self-Assessment Question 3

Which statement about the 2016 CMS Call Letter issued on 4-5-2015 is true?

1. CMS plans to terminate contracts with plans that have not achieved a 3-star rating for 2 consecutive years
2. CMS will add a Comprehensive Medication Review (CMR) completion rate star measure for Part D
3. CMS will pay a 5% Quality Bonus Payment (QBP) to plans achieving a star-rating of 3.5 or more
4. CMS will adopt a more stringent control of blood pressure quality indicator based on the new JNC 8 Guidelines
Self-Assessment Question 4

- Which organization is working to achieve pharmacist provider status through Federal legislation?
  1. CMS
  2. Provider Status Pharmacy Association
  3. Patient Care Services Coalition
  4. Patient Access to Pharmacists’ Care Coalition
Thanks for Having Me!

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