2016 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 and pharmacy technicians should be able to:
  1. Identify new federal legislative activity that will affect the practice of pharmacy.
  2. Describe new federal regulations and activities that will affect the practice of pharmacy.
  3. List new additions to the CMS Medicare Part D Call Letter of primary importance to pharmacists.
  4. Discuss the current congressional composition of both the House and Senate.

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 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 & Regulatory Update

#### Legislative
- Congressional Composition
- Provider Status
- Prescription Drug Abuse
- Preferred Network Status
- PBM Transparency/MAC Pricing
- Infusion Therapy
- MTM
- 21st Century Cures

#### Regulatory
- Environmental Protection Agency
- FDA
- DQSA (drug quality and security)
- Health Care Reform
- CMS
- MTM
- HRSA
- Non-discrimination
- Medical Marijuana

### Congressional Composition
- House of Representatives
  - 246 Republicans
  - 188 Democrats
  - 1 vacancy
- Senate
  - 54 Republicans
  - 44 Democrats
  - 2 Independents
### Senate

**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)
House

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

Senate 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 Kevin Brady (R-TX)
  - Ranking Member Sander Levin (D-MI)

2016 Congressional Agenda
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
  • Medicine spending was $374 billion in 2014 (IMS)
• 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 2014, 4.3 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) Now 38 Organizations

- APHA
- AACP
- ASCP
- ASHP
- FMI
- IACP
- NCPA
- NACDS
- NASPA
- Rite Aid
- Walgreens

Patient Access to Pharmacists’ Care Coalition (PAPCC)
- Albertson’s
- Amerisource Bergen
- Association of Clinicians for the Underserved
- BI-LO Pharmacy
- Cardinal Health
- CVS Health
- Fred’s Pharmacy
- Fruth Pharmacy
- Healthcare Distribution Management Association
- Healthcare Leadership Council
- Hematology/Oncology Pharmacy Association
Patient Access to Pharmacists’ Care Coalition (PAPCC)

• Kroger
• League of United Latin American Citizens
• McKesson
• National Center for Farmworker Health
• National Consumers League
• National Patient Advocate Foundation
• National Pharmaceutical Association
• National Rural Health Association

Patient Access to Pharmacists’ Care Coalition (PAPCC)

• Omnicell
• Pediatric Pharmacy Advocacy Group
• 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
- 284 cosponsors May 3
- Senators Chuck Grassley (R-IA), Sherrod Brown (D-OH), Robert Casey (D-PA), and Mark Kirk (R-IL) introduced on January 29, 2015
- 44 cosponsors May 3

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

- 128 Democrats and 156 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)
Provider Status Legislation

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

Provider Status Legislation

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

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

Path to Provider Status

• **Federal Sector**
  - Social Security, Medicare Part B & D, CMMI, ACO
  - Federal Regulations (CMS, AHRQ, HRSA)
• **State**
  - Medicaid
  - Health Insurance Exchanges, state health plans
  - Existing provider status and collaborative practice
• **Private Payer**
  - Accountable Care Organizations (ACOs)
  - Private or Employer-based Insurers
  - Medical Homes
http://pharmacistscare.org/

Patient Access to Pharmacists’ Care Coalition
Expanding Patient Access to Pharmacists’ Services

PREScription DRUG ABUSE
Prescription Drug Abuse – Congressional Activity

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

Prescription Drug Abuse – Congressional Activity

- Numerous bills in House and Senate addressing prescription drug abuse, misuse and treatment; areas addressed include:
  - Increasing access to buprenorphine by easing requirements to prescribe and dispense the drug
  - Establishing an inter-agency tasking force to develop best practices for pain management and pain medication prescribing
  - Expand access to opioid overdose reversal drugs, such as naloxone
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)
• Passed House 4/21/2015
• S. 483 is a bipartisan bill reintroduced by Senators Orrin Hatch (R-UT) and Sheldon Whitehouse (D-RI)
• Passed Senate 3/17/2016
• Obama signed 4/19/2016 PL 114-145

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
  • Notify 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

Prescription Drug Abuse – Industry Recommendations

- Advancing team-based care by encouraging pharmacist inclusion to improve care management and outcomes
- Improving communication and access to information by standardizing and integrating real-time prescription drug monitoring programs (PDMPs)
- Encouraging the development, dissemination, and incentivizing of naloxone-related education to patients and caregivers as well as to all members of the health care team
Prescription Drug Abuse – Industry Recommendations

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

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
Prescription Drug Abuse – CDC Guidelines

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

Industry Comments

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

- Among the 12 recommendations in the guideline, three principles are key to improving patient care:
  - Nonopioid therapy is preferred for chronic pain outside of active cancer, palliative, and end-of-life care.
  - When opioids are used, the lowest possible effective dosage should be prescribed to reduce risks of opioid use disorder and overdose.
  - Providers should always exercise caution when prescribing opioids and monitor all patients closely.

Role for Pharmacists (A3)

- Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy (recommendation category: A, evidence type: 3).
  - Advise patients about serious adverse effects of opioids, including potentially fatal respiratory depression and development of a potentially serious lifelong opioid use disorder that can cause distress and inability to fulfill major role obligations.
  - Advise patients about common effects of opioids, such as constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids. To prevent constipation associated with opioid use, advise patients to increase hydration and fiber intake and to maintain or increase physical activity. Stool softeners or laxatives might be needed.
  - Discuss effects that opioids might have on ability to safely operate a vehicle, particularly when opioids are initiated, when dosages are increased, or when other central nervous system depressants, such as benzodiazepines or alcohol, are used concurrently.
  - Discuss increased risks for opioid use disorder, respiratory depression, and death at higher dosages, along with the importance of taking only the amount of opioids prescribed, i.e., not taking more opioids or taking them more often.
  - Review increased risks for respiratory depression when opioids are taken with benzodiazepines, other sedatives, alcohol, illicit drugs such as heroin, or other opioids.

http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
Role for Pharmacists (A4)

• Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present (recommendation category: A, evidence type: 4).

• Patients with Sleep-Disordered Breathing, Including Sleep Apnea
• Pregnant Women
• Patients with Renal or Hepatic Insufficiency
• Patients Aged ≥65 Years
• Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present

http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

Prescription Drug Abuse – White House

• **October 21:** The White House convened stakeholders in Charleston, West Virginia where the President announced new public and private efforts
  – APhA committed to developing an Opioid Use, Abuse, and Misuse Resource Center
  – President’s Memorandum to Federal Departments and Agencies directs prescriber training and improving access to treatment

• **February 2:** President Obama proposes $1.1 billion in new funding to address prescription drug abuse and heroin use epidemic
  – $920 million of the $1.1 billion will be used to support cooperative agreements with States to expand access to medication-assisted treatment for opioid use disorders
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)
- 95 Cosponsors May 3: 57 R 38 D

Preferred Network Access

- S. 1190, Ensuring Seniors Access to Local Pharmacies Act
- Introduced May 5, 2015 by Sen. Shelly Moore Capito (R-WV), Joe Machin (D-WV), Tom Cotton (R-AR), Sherrod Brown (D-OH)
- 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)
- 10 Cosponsors: 7 R and 3 D
Preferred Network Access

- Coalition letter of support to House Leadership in 3/2015
  - 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

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
• 41 Cosponsors: 35R and 6D
• 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

Infusion Therapy

- Medicare Home Infusion Site of Care Act H.R.605/S.275
  - Introduced in the House by Reps. Engel (D-NY) and Tiberi (R-OH)
  - 60 Cosponsors-36D and 24R
  - Introduced in the Senate by Sens. Isakson (R-GA) and Warner (D-VA)
  - 23 Cosponsors-13D, 9R and 1I
  - 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
  - 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, 2015
- Improve access to MTM under Medicare Part D
- 15 Cosponsors-11D and 4R

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)
21st Century Cares

- Industry 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

Legislative & Regulatory Update

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ENvironmental Protection Agency

EPA Proposed Rule – Hazardous Waste Pharmaceuticals

- On September 25, 2015, EPA formally released the proposed rule “Management Standards for Hazardous Waste Pharmaceuticals”
  - Unifies requirements for health care facilities, which includes pharmacies, that generate more than 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
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

Industry Comments:
- Pharmaceutical definition: Recommend that EPA exempt dietary supplements and pharmaceuticals with a radioactive component
- Hazardous Waste Pharmaceutical: Recommend development of a hazardous waste pharmaceutical list and reconsider counting potentially creditable pharmaceuticals as waste
- Residue: Requested EPA clarify exemptions
- Sewering ban: Recommended exempting run-off from cleaning
- Additional requests:
  - Harmonize regulations with other federal agencies and their regulations; such as DQSA/ DSCSA and DEA (e.g., disposal options for controlled substances)
  - Increase education and awareness initiatives before the rule is effective
FDA UPDATES
Adapted from Ilisa Bernstein’s March, 2016 presentation at APhA with permission

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 Biosimilars

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Biological Patent Expiration

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</table>

Biosimilar User Fee Act (BUFA)

- As of January 21, 2016, 59 proposed biosimilar products were in the Biosimilar Product Development Program (BPD) to 18 different reference products.

- Since program inception and as of December 31, 2015, five companies have publicly announced submission of eight 351(k) BLAs to FDA for proposed products.

- The BPD Program was created as a part of BsUFA to provide a mechanism and structure for the collection of development-phase user fees to support FDA's biosimilar review program activities.

FDA – Naming Biosimilars

FDA released a draft guidance on biosimilars naming on August 28, 2015, with comments due October 27, 2015.

- FDA proposed that reference products and their biosimilars share a nonproprietary name (the “core name”), but that each product have a unique suffix.
  - Core name + suffix = FDA “Proper Name”

<table>
<thead>
<tr>
<th>Proprietary or “brand” name</th>
<th>FDA “Proper Name”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neupogen</td>
<td>Filgrastim-jcwp</td>
</tr>
<tr>
<td>Zarfico</td>
<td>Filgrastim-bfim</td>
</tr>
</tbody>
</table>
FDA – Naming Biosimilars

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

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

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

<table>
<thead>
<tr>
<th>Current Name</th>
<th>Proposed Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>rastim</td>
<td></td>
</tr>
<tr>
<td>filgrastim</td>
<td>filgrastim-jcwp</td>
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<tr>
<td>o-filgra</td>
<td>filgrastim-vk</td>
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<td>pegfilgrastim</td>
<td>pegfilgrastim-ljfd</td>
</tr>
<tr>
<td>infliximab</td>
<td>infliximab-hjmt</td>
</tr>
</tbody>
</table>
Anticipated FDA Policy

- **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

Industry Comments - Biosimilars

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

Purple will be the new orange for biosimilar makers

By Matt Samuels
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 biosimilar products.

Actually, the Purple Book is two listings. One references 10 of biologics approved by the FDA’s drug center, and the other lists 29 biologic products, including vaccines, approved by the biologic center. The lists will be updated periodically as new biologics and follow-ons are approved.

Each listing includes the biologic license application (BLA) number, sponsor 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

Novel Drug Report - 2015

- In 2015, the Center for Drug Evaluation and Research (CDER) approved 45 novel drugs
- Approvals were significantly more than the average of 28 approved during the previous nine years
- 64% of CDER’s novel drug approvals were approved in the United States first - before any other country

Notable new products - 2015

Expedited Development and Review

pathways

- Fast Track 31%
- Priority Review 53%
- Breakthrough 22%
- Accelerated Approval 13%
Generic Drugs

- Generic drugs represent 88% of all prescriptions dispensed in the U.S.*
- Generic drugs are responsible for $254 billion in health system savings in 2014**
- Use of generic drugs is increasing domestically and internationally**

  * Dr. Woodcock’s Testimony on January 28, 2016
  ** GPhA

Generic Drug User Fee Act (GDUFA)

- Ten-month review cycle for 90% in year 5
- Review goals began on October 1, 2014 for newly filed applications
- Risk-adjusted, biennial surveillance inspections
- Parity of foreign and domestic inspection frequency in year 5
- 1ST generics create competition & drive down costs
- FDA expedites the review of potential first generics because they are public health priorities
- If a generic drug application can mitigate a drug shortage, its review is expedited
ANDA Submissions

- Since FY2012 FDA received more ANDA submissions than expected
- Projected 750 - received 1473 in FY2014

ANDA Approvals/Tentative Approvals

- Graph showing number of approvals and tentative approvals over time.
Drug Quality and Security Act (DQSA)

Title I: The Compounding Quality Act

Title II: Drug Supply Chain Security Act

Product Tracing

Wholesaler Distributor and 3rd Party Licensing and Standards

Drug Supply Chain Security Act (DSCSA)

• Signed into law November 27, 2013
• Two parts:
  • Compounding Quality Act (CQA)
  • Drug Supply Chain Security Act (DSCSA) or “Track and Trace”
Compounding Quality Act – Drug Quality and Security 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 503A

- 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)
Section 503B

- Describes conditions under which certain human drug products compounded at a facility registered as an outsourcing facility are entitled to exemptions from certain 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 Current Good Manufacturing Practice (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
Inspections

• Since enactment of the DQSA, FDA has:
  • Conducted over 230 inspections of compounders including approximately 60 inspections of compounders registered as outsourcing facilities
  • Approximately 80 of these inspections have been for-cause, generally based on reports of serious adverse events or product quality issues such as drug contamination

Inspections and Resulting Actions

• Since enactment of the DQSA, FDA has:
  • Overseen over 85 recalls by compounders, and requested numerous compounders to cease operations
  • Issued over 75 warning letters; one addressed violations identified at four facilities
  • Issued 20 letters referring findings from inspections of pharmacies that compounded their drugs in accordance with the conditions of section 503A to the state
  • Obtained 3 civil consent decrees of permanent injunction
  • Sought several criminal prosecutions
Guidance issued since DQSA

• Draft and Final Guidances:
  – 503A
  – Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act (April 2016)
  – Clarifies limited quantity: As long as provider stays within the 30 day supply limit, the FDA will not question whether the product was compound-based on the expectation that the compounder would receive a prescription from a specific patient or prescriber.

Guidance issued since DQSA

• Draft and Final Guidances:
  – Outsourcing Facility Fees
  – Registration of Outsourcing Facilities
  – Guidance For Entities Considering Whether to Register as Outsourcing Facilities
  – Adverse Event Reporting for Outsourcing Facilities
Guidance issued since DQSA

- Draft Guidances:
  - Interim CGMPs for Outsourcing Facilities
  - Draft and Revised Draft Product Reporting Guidance for Outsourcing Facilities
  - Repackaging Non-biologics
  - Mixing, Diluting, and Repackaging Biologics
  - Interim Policies on Compounding Using Bulk Drug Substances Under Sections 503A and 503B (two separate draft guidances)
  - Animal drug compounding from bulk drug substances

DQSA: Compounding Regulation & Guidance

- The Memorandum of Understanding between FDA and states regarding interstate distribution of compounded products (MOU) drafted
DQSA: Compounding Regulation & Guidance

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

DQSA Implementation

- During Congressional deliberations and in its 503A Guidance document, FDA stated that it would take a “risk-based” approach to enforcement
  - Many organization’s thought 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
Other Compounding Activities

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

www.fda.gov/KnowYourSource
Drug Supply Chain Security Act

- Traceability: establishes national system for tracing pharmaceutical products through the supply chain
- Licensing: sets national licensing standards for wholesaler distributors and third party logistics companies (3PLs)
- Preemption: immediately preempts all state laws/regs for pedigree requirements AND state laws on wholesale/3PL licensure

Drug Supply Chain Security Act

- 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
DSCSA Major Provisions

- Product tracing (by 2015 lot-level, by 2023 package-level)
- Product verification
  - Quarantine and investigation (steps for 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)
- Penalties

National Uniform Policy

DCSCA Pharmacist Requirements

- Pharmacists will need to be able to
  - Scan 2D barcodes
  - Retain records
  - Implement a policy regarding suspect/illegitimate product identification and quarantine
  - Exchange transaction information (must include product identifier at the package level) and transaction statements in an interoperable electronic manner.
# Scope of the Law

**Product**
- What's covered:
  - Prescription drug in liquid form for administration to a patient (e.g., injection, instillation, suppository, transdermal, topical, or inhalation products before reconstitution)
- What's not covered:
  - Intranasal administration
  - Ophthalmic instillation
  - Intraocular injection
  - Intravenous injection

**Transaction**
- Transaction of product where a change of ownership occurs.
- Exemptions:
  - Intercompany distribution to affiliates
  - Distribution among hospitals & HCEs under common control
  - Public health emergencies
  - Dispensing drugs to patients
  - Product sample distribution
  - Distribution of minimal quantities (undefined) by a licensed retail pharmacy to a licensed practitioner for office use

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# DSCSA

- Transaction
- Transfer of product where a change of ownership occurs
- Exemptions:
  - Intercompany distributions between affiliates
  - Distribution among hospitals & HCEs under common control
  - Public health emergencies
  - Dispensing drugs to patients
  - Product sample distribution
  - Distribution of minimal quantities (undefined) by a licensed retail pharmacy to a licensed practitioner for office use
Definitions

• **Dispenser**: a retail pharmacy, hospital pharmacy, group of chain pharmacies under common ownership and control that do not act as wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor

Definitions-Wholesale Distributor

• A person (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider or repackager) engaged in wholesale distribution (as defined in the DSCSA and FD&C Act)
• *Wholesale distribution* is distribution of an Rx product to an entity/person other than the patient
Definitions - Manufacturer

• A person who holds application or license, or if no approved application or license, person who manufactures product
• A co-licensed partner
• An affiliate

Definitions: 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
Tracing

- Beginning 1/1/2015, manufacturers, wholesaler drug distributors, repackagers, and many dispensers (was to begin 7/1/2015; effective 3/1/2016) 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.

*Note: Lot number, transaction date and shipment date are not required for sale of direct purchase products*

**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.

Product Tracing

- As a general rule, each seller must
  - provide the TI, TH and TS to the subsequent owner for each transaction, and
  - store for six years the TI, TH and TS it provides for each transaction
- As a general rule, each buyer must
  - store for six years the TI, TH and TS it receives for each transaction
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 within 2 business days
  - 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

- 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.
- 2019: Wholesale distributors must only accept returns that contain the required product identifier before redistributing returned products.
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

Critical Dates for Dispensers

- **January 1, 2015**
  - Only purchase from authorized trading partners
  - Systems to comply with requirements for dealing with suspect and illegitimate products (building on current systems)
- **July 1, 2015—Enforceable March 1, 2016**
  - Receive and store TI/TH/TS
  - 6 year record retention
  - May use third party agreement to hold data under written agreement
Critical Dates for Dispensers

- **November 27, 2019**
  - Change to requirements for saleable returns

- **November 27, 2020**
  - Product identifier
  - Change to requirements for investigating suspect and illegitimate products
    - Sampling method

- **November 27, 2023**
  - No TH
  - TI includes product identifier
  - Changes to requirements for investigation of suspect and illegitimate products

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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
FDA Request for Information

- On April 15, 2016, the FDA issued an RFI; comments are due by May 16, 2016
  - The Food and Drug Administration (FDA) is soliciting information regarding issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, and identifying system attributes that are necessary to implement the requirements established under the Drug Supply Chain Security Act (DSCSA). The information gathered from public comments will assist with the design and development of the pilot project(s) that FDA establishes under the DSCSA.
  - The request for information is intended to provide interested persons an opportunity to submit comments relating to FDA's implementation of the DSCSA. We are particularly interested in comments regarding past or present pilot projects related to enhancing the safety and security of the pharmaceutical distribution supply chain. Stakeholders that may be interested in responding to this request for information include: Manufacturers, repackagers, wholesale distributors, dispensers, State and Federal authorities, solution providers, standards organizations, and other interested persons. FDA is particularly interested in learning about the practices, processes, and systems that supply chain stakeholders have used or considered using in such pilot projects.

https://www.regulations.gov/#!documentDetail;D=FDA-2016-N-1114-0001

DQSA – Track and Trace

- **October 2015**: FDA releases wholesaler and third-party logistics provider (3PL) facility licensure data to the public
- **October 29, 2015**: FDA delays enforcement from the already extended November 1, 2015 deadline to March 1, 2016 requiring a pharmacy to:
  - Not accept ownership of a product, unless the previous owner provides Transaction History (TH), Transaction Information (TI), and a Transaction Statement (TS) (i.e., product 3Ts)
  - Capture and maintain such information, history, and statements for 6 years after the transaction
  - Enforcement delay did not extend to products transferred from pharmacy to pharmacy – meaning that 3Ts must be included
    - Exception: 3Ts are not required for a specific patient need
- **February 2016**: FDA issues a request for comments and notice of a public workshop (April 5-6, 2016) regarding proposed pilot project(s)

HEALTH CARE REFORM
Health Care Reform

• *King v. Burwell*: Second challenge to Affordable Care Act (ACA)
  – Decided June 25, 2015; Subsidies upheld for plans purchased from federal exchange/marketplace
  – Case revolved around the question of whether subsidies are available to individuals who purchase coverage from the federal exchange/marketplace

Health Care Reform

• Move to Value-Based Payment Models (i.e., ACOs, PCMHs)
  • January 26, 2015
  • 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
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
CMS – Annual Part D Change Process

Part D Proposed Rule (CMS proposes technical changes to Part D)

Part D Call Letter (plans use to structure bids that must be submitted to CMS)

Draft Call Letter released for comments

Part D Final Rule

Final Call Letter published

CMS Draft Call Letter – CY 2017

• CMS published the draft Call Letter on February 19, 2016
• Comments were due March 4, 2016
• CY 2017 Call Letter does not propose major revisions to Part D plan requirements and patient benefits, but does propose minor changes on issues that are of interest to pharmacists and technicians, including:
  – Coverage determination timelines
  – Formulary tier labeling and composition
  – Point-of-Sale edit rules
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
- 2017 No action based upon monitoring
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
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)
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)
  - CMS comment opportunities (e.g., the Call Letter)
  - CMMI Enhanced MTM Model Test

CMMI Enhanced MTM Model Test

- CMMI Model Test for Innovation
  - Announced in late September 2015 and scheduled to begin January 1, 2017
- Model Test participation is limited to stand-alone, individual- market prescription drug plans in certain geographic areas: 11 States
  - Intended to provide flexibility in MTM; targeting and interventions
  - Participating plans receive a per member/per month payment (varies by model tested) for all enrollees
  - 5 year initial program period, with option to extend performance- based payments for an additional 2 years
CMS Hospital Discharge Proposed Rule

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

CMS Hospital Discharge Proposed Rule

- On January 4, 2016, NCPA and APhA submitted joint comments
  - **Medication Reconciliation**: Agreed it should be a standard element of discharge planning in hospitals and critical access hospitals
  - Suggested that in order to provide meaningful, high-quality medication reconciliation services, pharmacists should be actively engaged in the discharge planning process and in medication management processes generally
  - **Burden Estimates for Medication Reconciliation**: Encouraged CMS to revisit its burden estimates for medication reconciliation to ensure the estimates reflect services that will actually improve patient safety
ACA Benefit and Payment Parameters – CY 2017

- On November 21, 2015, CMS released its annual proposed rule to amend and update its policies for the Affordable Care Act marketplaces for 2017 and beyond
- New policies of particular interest to pharmacists include:
  - Development of network adequacy standards for marketplace plans
  - Solicitation of comment on six standardized plan options
- Industry Comments:
  - **Network Adequacy Standards**: Urged CMS to develop and adopt robust network adequacy standards that expand patient access by integrating pharmacists’ patient care services
  - **Transparency/Reporting Requirements**: Encouraged the incorporation of transparency and reporting requirements for network access and benefits/coverage information
  - Better information is necessary for patients to have accurate information and metrics about qualified health plans’ benefits (e.g. actual access and copays)

CMS “AMP” Rule

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

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

Highlights of the CMS “AMP” Rule

- **AAC-Based Reimbursement:** State Medicaid fee-for-service pharmacy reimbursement must be based on AAC
  - Must be, in aggregate, the lower of AAC + "sufficient professional dispensing fee" or the pharmacy’s usual and customary charges to the public
- **Professional Dispensing Fees:** CMS instructed states to consider pharmacy costs when setting the professional dispensing fee
  - CMS included a robust list of costs related to the pharmacist’s time as well as pharmacy overhead for necessary equipment and facilities
HHS Proposed Non-discrimination rule

• On September 8, 2015, HHS released a proposed rule regarding nondiscrimination in certain health care programs and activities
• The proposed rule is a result of Section 1557 of the Affordable Care Act which prohibits discrimination on the basis of race, color, national origin, sex (including gender identity), age, or disability in certain health care programs and activities.
• In general, the regulation applies to any health entity, program or activity receiving Federal financial assistance
  → Medicaid, Medicare Part D and other government programs make pharmacies subject to the regulation

HHS Proposed Non-discrimination rule highlights

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

- Clarifies that individuals can seek legal remedies, such as a court order to end such discrimination and/or damages, for discrimination under the section of the Affordable Care Act which prohibits discrimination on the ground of race, color, national origin, sex (including gender identity), age or disability.
- HHS expects that the cost of compliance with the proposed rule will be minimal, although there may be major impacts in the areas of voluntary training and enforcement where increased caseloads pose incremental costs on covered entities.
- Training employees on the new requirements is voluntary but HHS expects that facilities will provide one-time training to employees once the rule is finalized.

HRSA – 340B Draft Guidance

- August 28, 2015: HRSA released the long-awaited draft 340B “mega-guidance”
- Draft guidance addresses most aspects of the program, including:
  - Definition of “patient”;
  - Covered entity eligibility;
  - Duplicate discounts; and
  - Contract pharmacy compliance
- Final Rule publication scheduled for September 2016
Oversight and Scrutiny

- HHS Office of the Inspector General outlined action items in its CY 2016 Investigative Plan that directly relate to pharmacy practice
- In 2016, HHS plans to:
  - Analyze drug-related hospitalizations of Medicare beneficiaries to identify the role of beneficiaries' pharmacies and prescribers
  - Conduct a drug traceability test to gauge the efficacy of Drug Supply Chain and Security Act (“DSCSA”) requirements currently in effect
  - Evaluate states’ Medicaid Drug Utilization Review (“DUR”) programs for clinical misuse or possible fraud
  - Review Medicare and Medicaid payment policies and trends for specialty drugs

Patient Medication Information

- Regulation in development to require all prescription drugs have a single Patient Medication Information (PMI) document - Draft rule is still in development
- Article published July 10, 2015, “Influence of patient medication information format on comprehension and application of medication information”
Medical Marijuana

- Legalization of marijuana for medicinal and/or recreational purposes has been taking place at the state level
- DEA studying reclassification
Bottom line…

• Keep looking ahead…

…stay flexible

As things can change quickly…
CPE Instructions

Logon to www.GoToCEI.org Click on My Profile.
Locate the activity title you wish to complete within your Profile and click on Exam.
Complete the Exam and Evaluation as prompted; click SUBMIT to send your information to CPE Monitor.

• CPE Codes:
  • (Pharmacists)
  • (Technicians)
• Once your credit has been claimed, the activity will move to your Completed Activities.

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 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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