Your Annual Legislative and Regulatory Update

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Target Audience: Pharmacists and Pharmacy Technicians

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Activity Type: Knowledge-based
Alicia Kerry Mica, Michael Baxter and Jenna Ventresca: “...declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria”

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

1. Identify recent federal legislative activity impacting the practice of pharmacy
2. Describe new federal regulations and activities related to the practice of pharmacy
3. Explain the current efforts at the federal level to reimburse pharmacists for their services
Assessment Questions

1. Which of the following is correct with regard to the federal provider status legislation?
   A. Pharmacists will be able to provide services to Medicaid patients without any copay/cost-sharing
   B. Medicare Part B will cover any pharmacist-provided services
   C. Pharmacists’ services will be covered when provided to Medicare beneficiaries in medically underserved communities
   D. Only pharmacists’ services approved by the CMS Innovation Center will be covered
Assessment Questions

2. According to Drug Supply Chain Security Act (DSCSA) draft guidance, is a pharmacy required to obtain a wholesale distributor license for sales to another pharmacy if not for a specific patient need or otherwise exempt?

A. Yes
B. No
C. Depends on state law
D. Only if the transaction involves controlled substances
Assessment Questions

3. Which of these is true about drug pricing legislation?
   A. Congress passed legislation to allow the importation of prescription drugs from Canada but it has not been signed by the President yet
   B. A law enacted in 2017 allows HHS to negotiate Part D drug prices for the Medicare program
   C. 30 bills have been introduced in the 115th Congress that address drug pricing
   D. The President submitted a proposal to Congress that would allow the importation of prescription drugs from specific countries
Regulatory Update
Trump Administration — Executive Order to Reduce Regulation and Reorganize Government

• On February 24, 2017 the President issued an Executive Order (EO) forming federal agency task forces to target regulations for repeal, modification which eliminate or inhibit job creation; are outdated, unnecessary, or ineffective; impose costs that exceed benefits; are inconsistent or interfere with regulatory reform.

• On April 12, 2017 the White House ordered agencies to plan workforce reductions and develop sweeping agency reform plans.
Trump Administration — Executive Order 2 for 1

- On January 30, 2017 the White House issued an EO that whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a “new” “significant regulatory action,” ($100 million+) except for certain military, national security, or foreign affairs functions, it shall identify at least two existing regulations to be repealed.

- On February 5, 2017 the White House also issued interim guidance (Q&As) stating that a federal agency that cannot find its own savings to cover the costs of a new rule (2 for 1) - can ask the Office of Management and Budget (OMB) to find regulatory offsets from a different federal agency.
CMS Activity

APhA continues to urge CMS to better utilize pharmacists in its current and new programs and initiatives which aligns with its move toward value-based delivery and payment. Examples include:

- **Innovation and Team-based Care:** 2015 Medicare Access and CHIP Reauthorization Act (MACRA) law (Measuring 4 categories: Quality, Advancing Care Information (ACI)/ Health Information Technology (HIT), Improvement Activities (IA), Cost) - including the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Model (APMs); Accountable Care Organizations (ACOs), Enhanced Medication Therapy Management (MTM) Model, etc.
CMS Activity (cont.)

APhA continues to urge CMS to better utilize pharmacists in its current and new programs and initiatives which aligns with its move toward value-based delivery and payment. Examples include:

- **Reimbursement**: Examples include: MACRA, “Incident-to” services: Chronic Care Management (CCM), Transitional Care Management (TCM), preventive care, immunization(s), diabetes care (Diabetes Self Management Training (DSMT), Expanded Medicare Diabetes Prevention Program (MDPP)

- **Impact on Value and Quality**: CMS and private payor reimbursement continues to move toward quality. APhA continues to identify ways specific services and mechanisms pharmacists can improve quality. Examples include Part D regulation and physician fee schedule.
CMS Annual Activity

- **Part D Rule**: November-January – Draft; March/April – Final version
  - Mechanism for announcing significant policy changes to the Part D and Medicare Advantage (MA) prescription drug plans (MA-PDs)

- **Call Letter**: February – Draft; April – Final version
  - Sets forth changes in Medicare payment methodology for Part D/MA plans as well as benefit parameters for the defined standard benefit received by Part D plan beneficiaries—information used for plan sponsors to submit bids

- **Physician Fee Schedule (PFS) Rule**: September – Draft; November – Final version
  - Outlines payment requirements for physicians and other providers
Advocating to CMS

- 2015 MACRA Law: Metrics in the 2016/2018 final Quality Payment Program (QPP) rules specifically mention pharmacists (medication reconciliation post discharge, “integrating a pharmacist into the care team”). Pharmacists can also contribute to over 25% of the 271 current quality measures, including many improvement activity (IA) and advancing care information (ACI) measures - as practices and medications become more specialized, the role and the value of pharmacists will be critical.

- CY2018 Physician Fee Schedule (PFS): Pharmacist role in chronic care management (CCM), Medicare Diabetes Prevention Program (MDPP), Diabetes Self Management Training (DSMT)

- CY2019 Call Letter/Part D Rule: MA and Part D Star Ratings, hard/soft point-of-sale (POS) edits for opioids, improving drug utilization review (DUR) opioid overutilization policy, utilizing pharmacist care services from Other Payer Advanced APMs (commercial payers, etc.)
CMS Activity - MACRA

MACRA – Medicare Access and CHIP Reauthorization Act of 2015

- Eligible clinicians will choose one of two payment pathways: The Merit-Based Incentive Payment System (MIPS) or Advanced Alternative Payment Models (APMs)

CMS Activity - MACRA (cont.)

Clinicians Eligible to Participate in MIPS

Any affected clinicians are termed as "MIPS eligible clinicians" and will participate in MIPS.

**Note:** All Medicare Part B clinicians will report through MIPS during the first performance year.

<table>
<thead>
<tr>
<th>2019–2020</th>
<th>2021 and Beyond</th>
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- Physician
- Physician assistant
- Nurse practitioner
- Clinical nurse specialist
- Certified registered nurse anesthetist

- Physical or occupational therapists
- Clinical social workers
- Speech-language pathologists
- Audiologists
- Nurse midwives
- Clinical psychologists
- Dietitians/Nutritional professionals

*The statute provides flexibility to specify additional MIPS eligible clinicians in the 3rd and subsequent years.*

Any clinician who is not eligible for MIPS has the option to volunteer to report on applicable measures and activities under MIPS; however, these clinicians **will not receive a MIPS payment adjustment.**

The Bipartisan Budget Act, signed into law on February 9, 2018, included changes to MIPS. Makes further delays and CMS flexibility with regard to the weighting of cost in calculating providers’ performance (range between 10% - 30%) and

Trump Administration indicates desire to remove two categories (potentially IA, ACI) to make compliance easier; included in the Fiscal Year (FY) 2019 Budget for HHS
CMS Activity- Part D Proposed Rule

- Draft proposed regulation released in November 2018; first Part D regulation in three years
- APhA supported many of the provisions from CMS seeking to limit PBM efforts to restrict pharmacies’ access to Part D networks and potentially increase transparency that pharmacists and pharmacy groups have long sought
  - Any Willing Pharmacy (AWP): Revises definition of mail order pharmacy and retail pharmacy to allow patients to continue getting their prescription drugs from the same pharmacy
  - PBM Credentialing: PBMs may not require onerous pharmacy accreditation and credentialing requirements that go beyond state laws
  - Part D Plans’ Terms and Conditions: Mandates the timeline for when Part D standard terms and conditions are given to pharmacies (September 15 of each year for the succeeding benefit year; plans must respond within 2 days of a request)
  - Medication Therapy Management (MTM): Encourages plans to offer by clarifying that MTM counts as Quality Improvement Activities (QIA) under the Affordable Care Act’s Medical Loss Ratio (MLR) requirement
Included a request for Information (RFI): CMS requested feedback on potentially including rebates and pharmacy price concessions (direct and indirect remuneration (DIR)) at the point-of-sale and requiring savings to be passed from Part D plans/PBMs onto beneficiaries

- CMS acknowledges that rebates and pharmacy price concessions are not reflected in the negotiated price and the true price of a drug to the plan is not available at the point-of-sale (POS), making it difficult to identify cost-effective treatment.

- In the RFI, CMS states the rebates and price concessions to be included at POS will not include contingent amounts that could flow to network pharmacies and increase prices over the lowest reimbursement level (e.g., incentive fees).

- CMS estimates it would significantly reduce net beneficiary costs by $10.4 billion and give community pharmacies greater predictability regarding reimbursement rates.

- APhA anticipates rebates and pharmacy price concessions will remain an important issue in 2018 due to congressional and agency concerns with high drug prices, lack of transparency and anti-competitive policies.
FDA: Compounding - The Drug Quality and Security Act (DQSA)

Drug Quality and Security Act (DQSA)
Signed into law on November 27, 2013

Compounding Quality Act (CQA)
Establishes Outsourcing Facilities

Drug Supply Chain Security Act (DSCSA)
Also known as Track and Trace
FDA: Compounding Recent Activity

In 2016, APhA submitted comments on 6 FDA Draft Guidances and 1 Inspection “Notice” implementing the 2013 Drug, Quality and Security Act (DQSA), including:

- Final Guidance - Prescription Requirement Under Section 503A (prohibits office use under 503A)
- Draft Guidance - Hospital and Health System Compounding (allows compounding without a patient-specific prescription to a owned-facility within a 1-mile radius of its compounding pharmacy)
- Draft Guidance - Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A
In May 2017, FDA clarified it will not enforce compliance with USP <800> (Handling Hazardous Drugs) during inspections until USP completes a review of the chapter.

- In September 2017, USP announced that it will delay implementation of USP <800> until revised USP <797> (Sterile Compounding) is to become official (Target: by December 1, 2019) – timeline for comments posted in February 2018
  - <795> (Non-sterile Compounding): Able to provide written comments through the USP website from March 30, 2018 to July 31, 2018
  - <797> (Sterile Compounding): Able to provide written comments through the USP website from July 28, 2018 to November 30, 2018
FDA: Compounding Recent Activity (cont.)

- In 2017, continued congressional interest in clarifying the 2013 DQSA law (Congress added appropriations language on Memorandum of Understanding (MOU), office use, inspections and 66 bipartisan House members sent a letter to the new FDA Commissioner)

- For 2018, similar appropriations language was added by DQSA Coalition, of which APhA is a member, that calls on FDA to:
  - Rescind FDA’s final guidance prohibiting “office use” compounding and issue a stronger, proposed rule allowing for permissible “office-use” compounding as authorized by state law
  - Finalize a MOU for the states to consider which does not conflate “distribution” of compounded drug products across state lines with “dispensing” of compounded drug products to individual identified patients - would avoid incorrectly regulating activities not contemplated under the DQSA (i.e., dispensing to specific patients)
FDA: Compounding Concerns

Office Use and MOU

• In June/July 2017 listening sessions, FDA reconfirmed its position:
  – Its belief that its final 503A guidance prohibiting office use is aligned with congressional intent in DQSA and previously existing law (503A)
  – Plans to continue to include “dispense” in the definition of “distribute” in a new Memorandum of Understanding (MOU)
    • Affects prescriptions accounted for in “distribution” across state lines
• Pharmacy organization has continued to advocate that this above position ignores existing law, congressional intent in the DQSA and recent federal appropriations report language
FDA: Upcoming Compounding Regulatory Activity

- In January 2018, FDA released its “2018 Compounding Policy Priorities Plan” - includes a wide-ranging list of upcoming federal regulations from the Agency:
  - Revised Draft Guidance - Outsourcing Facilities (503B Light)
  - Final Guidance - Essentially Copies of FDA-approved Drugs (10% API, Significant Difference, Forthcoming Exemptions for Hospitals)
    - Similar Final Guidance - 503Bs
    - Final Guidance - Mixing, Diluting, or Repackaging Certain Biological Products
  - Bulk Substances (503A – Final Rule, 503B – Draft Guidance)
  - New Draft MOU (If # of Compounded RX is <50% in any Month)
  - Draft Guidance - Definition of Outsourcing Facilities (503B)
  - Final Guidance - Radiopharmaceuticals/Repacking Guidance for Outsourcing Facilities
  - Final Rule - Demonstratively Difficult to Compound List
FDA: Upcoming Compounding Reg Activity (cont.)

FDA’s announcement of forthcoming draft guidance - 503B Light (to encourage 503B registration):

- Revised draft outsourcing facility guidance will include a new risk-based approach where FDA will consider how CGMP requirements should be applied to compounders in light of the size and scope of an outsourcing facility's operations.

- At a January 2018 hearing before Congress, FDA Commissioner stated “…we estimated that it would cost a large manufacturer about a million dollars to become a 503B facility, a large pharmacy, and a medium-sized pharmacy, about $600,000.”

- All anecdotal examples provided to APhA indicates the cost at least $2 million for compounders under 503A to register as 503B outsourcing facilities (i.e., meet cGMP standards).

- On February 13, 2018, FDA Commissioner announced future plans for an Outsourcing Center for Excellence to “identify and propose solutions to market barriers to lower the cost for pharmacies to become outsourcing facilities.”
FDA: Compounding - The Drug Quality and Security Act (DQSA)

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Drug Supply Chain Security Act (DSCSA)
Also known as Track and Trace
DSCSA – Supply Chain Overview

Drug Supply Chain Security Act (DSCSA)

- Outlines the steps to build an electronic interoperable system to identify and trace certain prescription drugs as they are distributed in the United States

- Anticipated benefits:
  - Enhance FDA’s ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful
  - Improve detection and removal of potentially dangerous drugs from the U.S. supply chain
  - Harmonize licensure standards for wholesale distributors and third-party logistics providers

GTIN (01): 03453120000011
Expiry: 2031-12-21
Batch/Lot (10): XYZD7894
DSCSA Requirements

**Phase 1: Lot Level Traceability**
- Authorized trading partner verification (1/2015)
- Suspect/illegitimate product identification and notification (3/2016)
- Transaction data (1/2015 & 3/2016)

**Phase 2: Product Identifier (PI)**
- Re-packagers add PI to unit/case (11/2018)
- Wholesaler transactions with identified products (11/2019)
- Dispenser transactions with identified products (11/2020)

**Phase 3: Unit Level Traceability**
- Unit-level traceability for all supply chain stakeholders (11/2023)
- Track and exchange unit-level serialized data (11/2023)

**Additional Provisions for FDA:**
- Small pharmacy technology assessment on package-level tracing (2020)
- Establish and evaluate pilot projects on enhancing supply chain safety/security (2020) (initial steps underway)
- Regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level (2021)
- Final guidance on interoperable data exchange standards for secure package level product tracing (2022)
DSCSA Requirements (cont.)

General product tracing rules:
- Each seller must provide and store for 6 years the 3Ts to each subsequent owner for each transaction
- Each buyer must store for six years 3Ts received for each transaction
  - Note: Dispensers are exempt from trading 3Ts if transaction is to fulfill a specific patient need, however, FDA encourages sellers to document these transactions

General verification rules:
- Trading partners must have systems in place that enable them to quarantine suspect product and promptly conduct an investigation to determine whether the product is illegitimate
- Respond within 2 business days to government information requests
- Maintain for 6 years DSCSA specific suspect & illegitimate product records
- Only engage in transactions with a product identifier from verified trading partners
DSCSA Requirements (cont.)

General storing and accessing transaction data rules:

• Dispensers may use a third party (including wholesale distributor) to maintain transaction data
• Dispensers need to be able to access information to respond to government requests for information and other verification requests
• Note: FDA released draft guidances regarding DSCSA standards for the interoperable exchange of information and standardization of data and documentation practices for product tracing

Steps dispensers need or will need to take to comply:

• Confirm licensure status of wholesale distributors and other trading partners = verified trading partners
• Implement process related to suspect and illegitimate product identification, including quarantine procedures and notification requirements (FDA has outlined a process for trading partners to notify the agency of illegitimate products)
• Near future (2020?)- Only accept product with a product identifier; this may include verification at the unit-level
DSCSA – Implementation Concerns and Issues

- Implementation deadlines not met
- Variable levels of preparedness across industry
- Error rates
- Centralized vs. decentralized data repository
- Access to data and ownership
- Barcode issues
  - Early removal
  - Location of barcode
- Technology upgrades, software and hardware

- Scope creep
- Ability of small dispensers and other members of the supply chain to comply
- Preemption / State activity
- OIG recommendation: FDA provide technical assistance to wholesalers regarding direct purchase statements, exempt drugs and exchanging product tracing information for 340B contract pharmacies
DSCSA – What Should Dispensers be Doing?

- Monitor FDA guidance and rulemaking, especially as related to grandfathered products, licensure, and exceptions/exemptions to the law
- Monitor and engage with trading partners as their compliance decisions impact dispensers
- Identify compliance solutions (i.e., develop in-house solutions, rely on wholesale distributors and/or solutions providers)
  - Evaluate contracts with trading partners and solutions providers regarding data accessibility
  - Consider trading patterns’ compliance methods compatibility with selected compliance plan
- Consider participating in pilot projects
- Identify software and hardware upgrades needed for compliance
- Resources can be found on pharmacist.com
Upcoming FDA DSCSA-related Activity

FDA CDER 2018 Guidance Agenda (Released January 19, 2018)
- Definitions of Suspect Product and Illegitimate Product or Verification Obligations
- Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier (draft guidance released December 2017)
- Proposed Accreditation Program Under the DSCSA
- Proposed Licensing Program Under the DSCSA
- The Product Identifier for Human, Finished, Prescription Drugs: Question and Answers
- Standardization of Data and Documentation Practices for Product Tracing
- Verification Systems Under the DSCSA for Certain Prescription Drugs
- Waivers, Exceptions and Exemptions from the Requirements of Section 582 of the Federal Food, Drug and Cosmetic Act
Pain Management and Opioid Abuse, Misuse and Treatment - Federal Agency Activity

Department of Health and Human Services (HHS)

- Five point strategy:
  - Better addiction prevention, treatment and recovery services
  - Better data
  - Better pain management
  - Better targeting of overdose reversing drugs
  - Better research

- Announced creation of Pain Management Best Practices Inter-Agency Task Force which was authorized by CARA (August 2017)

- October 26, 2017: Acting Secretary Eric D. Hargan declares public health emergency regarding opioid crisis

- HHS Office for Civil Rights releases guidance clarifying when and how healthcare providers can share a patient’s health information with his or her family members, friends and legal representatives when that patient may be in crisis or incapacitated
Pain Management and Opioid Abuse, Misuse and Treatment – Federal Agency Activity

FDA
- Opioid Action Plan (released February 2016)
- Opioid Policy Steering Committee (formed May 2017)
- Mandatory education for prescribers in July 2017
  - Education blueprint modifications
- Generic abuse deterrent formulations: draft guidance released 2017
- REMS program expanded to include IR opioids
- Modifying labeling to clarify use of medication-assisted treatments for patients suffering from opioid use disorder

Centers for Medicare and Medicaid Services (CMS)
- Opioid Misuse Strategy (updated January 2017)
- Medicare “lock-in”: proposed regulations released via Part D proposed rule
- Call Letter
Pain Management and Opioid Abuse, Misuse and Treatment – Federal Agency Activity

National Institutes of Health (NIH)

- Opioid Initiative (public-private partnership) advancement areas:
  - New and innovative medications to treat opioid addiction and overdose prevention and reversal;
  - Safe, effective and non-addictive strategies to manage chronic pain; and
  - Neurobiology of chronic pain.

President’s Commission on Combating Drug Addiction and the Opioid Crisis

- Final report released November 2017
- Total of 56 recommendations regarding:
  - Federal funding and programs (3)
  - Opioid addiction prevention (2)
    - Prescribing guidelines, regulation, education (6)
    - PDMP enhancements (5)
    - Supply reduction and enforcement strategies (14)
  - Opioid addiction treatment, overdose reversal and recovery (21)
  - Research and development (5)
Pain Management and Opioid Abuse, Misuse and Treatment – Federal Agency Activity

Drug Enforcement Agency (DEA)
- Partial fills
- Disposal
- Electronic prescribing
  - Clarified unfilled electronically prescribed controlled substances (schedule II-V) may be transferred to another pharmacy
- Suspicious orders

Substance Abuse and Mental Health Services Administration (SAMHSA)
- DATA waivers
- 42 CFR Part 2

Centers for Disease Control and Prevention (CDC)
  - Clarified dosage thresholds in the guidelines are not meant to apply to opioid use disorder treatment

Office of National Coordinator for Health Information Technology (ONC)
- PDMPCconnect
- Clinical Decision Support
Pain Management and Opioid Abuse, Misuse and Treatment – Federal Agency Activity

CMS/ Medicare Part D: Drug Management Program (DMP)

- Authorized by the Comprehensive Addiction and Recovery Act of 2016 to lock-in an at-risk patient to a prescriber(s) and pharmacy(ies)
  - Some state Medicaid programs already had lock-ins
- The Proposed Rule codified practices associated with DUR, OMS and the DMP, clarifying a Part D sponsor may:
  - Implement a point-of-sale claim edit for frequently abused drugs that is specific to the beneficiary
  - Limit an at-risk beneficiary’s access to coverage for frequently abused drug for the beneficiary when obtained from the selected pharmacy or prescriber unless under certain circumstances
- Clarifies the DMP will be an extension of CMS’ Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS)
Pain Management and Opioid Abuse, Misuse and Treatment – Federal Agency Activity

CMS/ Medicare Part D: Drug Management Program (DMP) Key Components (proposed)

- Terms: at-risk beneficiary, potentially at-risk beneficiary, frequently abused drugs
- Exempted beneficiaries: those receiving hospice care; residents of long-term care facilities or another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy and those with a cancer diagnosis
- Requirements for part D plan sponsors:
  - Written policies and procedures
  - Case management, prescriber verification and agreement
  - Provide notice to beneficiaries
  - Must maintain “reasonable access”
  - Selection of prescriber and pharmacy is based on beneficiary preference
    - If the beneficiary does not make a selection, the sponsor may choose for the beneficiary
Pain Management and Opioid Abuse, Misuse and Treatment

Medicare Part D: Annual Draft Call Letter

- Enhancing the Overutilization Monitoring System (OMS) to identify high risk beneficiaries who use “potentiator” drugs (such as gabapentin and pregabalin) in combination with prescription opioids to ensure plans provide appropriate case management
  - Potentiators are drugs that when taken with an opioid increase the risk of an adverse event
  - OMS already flags concurrent benzodiazepine use by plan enrollees
- Expecting all sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy (which can only be overridden by the sponsor) at 90 morphine milligram equivalent (MME), with a 7 days supply allowance
- Implementing a supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME)
- Expecting all sponsors to implement soft POS safety edits (which can be overridden by a pharmacist) based on duplicative therapy of multiple long-acting opioids, and request feedback on concurrent prescription opioid and benzodiazepine soft edits
Homeopathic Products

- In December 2017, FDA proposed new, risk-based enforcement priorities for drug products labeled as homeopathic.
- Since 1988, FDA exercised enforcement discretion for drug products labeled as homeopathic which had been manufactured and distributed without FDA approval; the draft guidance marks a shift in this policy.
- FDA targeting unapproved drug products labeled as homeopathic that have the great potential to cause risk to patients.
  - 6 risk-based categories that FDA intends to focus enforcement authorities:
    - Products with reported safety concerns
    - Products that contain or claim to contain ingredient associated with potentially significant safety concerns
    - Products for routes of administration other than oral and topical
    - Product intended to be used for the prevention or treatment of serious and/or life-threatening diseases and conditions
    - Products for vulnerable populations
    - Products that do not meet standards of quality, strength or purity as required under law
Legislative Update
Overview of Congress
U.S. House of Representatives

435

193 Democrats

238 Republicans

As of January 12, 2018
House Leadership

Majority – Republicans
Speaker, Paul Ryan (WI)
Leader, Kevin McCarthy (CA)
Whip, Steve Scalise (LA)
Conference Chair, Cathy McMorris Rodgers (WA)
Conference Vice Chair, Doug Collins (GA)
NRCC Chairman, Steve Stivers (OH)

Minority – Democrats
Leader, Nancy Pelosi (CA)
Whip, Steny Hoyer (MD)
Assistant Leader, James Clyburn (SC)
Caucus Chairman, Joe Crowley (NY)
DCCC Chairman, Ben Ray Lujan (NM)
House Committees

Energy and Commerce
Chairman, Greg Walden (OR)
Ranking Democrat, Frank Pallone (NJ)
Health Subcommittee Chairman, Michael Burgess (TX)
Health Subcommittee Ranking Dem, Gene Green (TX)

Ways and Means
Chairman Kevin Brady (TX)
Ranking Democrat, Richard Neal (MA)
Health Subcommittee Chair, Peter Roskam (IL)
Health Subcommittee Ranking Member, Sander Levin (MI)
U.S. Senate

48 Democrats

51 Republicans

2 Independents
Senate Leadership

Majority - Republicans
Leader, Mitch McConnell (KY)
Assistant Leader, John Cornyn (TX)
Conference Chair, John Thune (SD)
Policy Committee Chairman, John Barrasso (WY)
NRSC, Cory Gardner (CO)

Minority – Democrats
Leader, Chuck Schumer (NY)
Whip, Dick Durbin (IL)
Assistant Leader, Patty Murray (WA)
DSCC, Chris Van Hollen (MD)
Senate Committees

Finance
Chairman, Orrin Hatch (UT)
Ranking Democrat, Ron Wyden (OR)

Health, Education, Labor and Pensions (HELP)
Chairman Lamar Alexander (TN)
Ranking Democrat, Patty Murray (WA)
Legislative Review
2017 Year in Review

- January - President Donald Trump Sworn Into Office
- April - Supreme Court Justice Neil Gorsuch confirmed by the U.S. Senate
- May - House Passed American Health Care Act
- July - Senate rejected proposal to repeal ACA
- September - Budget Reconciliation Resolution Expired – the vehicle Senate Republicans were using to move ACA repeal
  HHS Secretary Tom Price resigned
- December - Tax Reform Passed
  Short Term Government Funding Bill Passed

Laws Passed:

- ACA repeal/replace
- Medicaid reform
- Medicare “extenders” (Budget Agreement/CR)
- CHIP reauthorization (Budget Agreement/CR)
- FDA User Fee Acts (PDUFA, GDUFA, BsUFA)
- Drug pricing bills
- Tax Reform – includes repeal of ACA individual mandate
2018 Bipartisan Budget Act

- On February 9, 2018 the President signed into law legislation funding the government until March 23, 2018 that included a number of key health care policies
  - 4 additional years of reauthorized CHIP funding (10 total)
  - $6 billion to combat the opioid crisis and treatment of mental health issues
  - Additional $2 billion for NIH research
  - Accelerate the closing of the “doughnut hole” to 2019 in Medicare Part D drug coverage
  - Include biosimilars in the Medicare Part D coverage gap discount program
  - 2 years of funding for community health centers, teaching health centers and the National Health Service Corps student loan repayment and scholarship programs
  - Repeal of Medicare therapy caps
  - 2 year delay of the Medicaid Disproportionate Share Hospital (DSH) pay cuts and funding for other so-called Medicare extenders
2018 – Health Care Political Environment

- ACA will be the framework for any health care legislation debated
- Opioid Epidemic
- New Secretary of HHS: Alex Azar
- More active HHS
- March 23rd – Expiration of Current Continuing Resolution (CR) for Federal Government Funding
- Value-based Care
- 2018 Election
  - Health care will continue to play a role in elections
Potential Health Legislation 2018

- Omnibus Appropriations Package – Another CR to Fund the Government Past March 23rd
- Entitlement Reform (i.e. Medicaid)
- Drug Pricing
- 340B Program
- Opioids
- Individual Market Stabilization (ACA Cleanup Bill)
Drug Pricing

- 30 bills introduced in House and Senate to date; proposals include
  - Importation
  - Direct Federal government negotiation (Medicare Part D)
  - Fostering competition/ transparency
- Several currently introduced bills aim to address drug pricing, but at this time, these proposals are unlikely to pass this Congress
  - Importation is being touted as a drug pricing solution
  - Problems with PBMs are part of this discussion
- APhA connecting provider status and drug pricing – pharmacists ability to optimize the impact of medications
  - The most expensive medication is the one not taken, not appropriate or taken incorrectly
  - Need “transparent pricing” framework
Drug Importation

- Several bills introduced to authorize importation of drugs from foreign countries as a means to address drug pricing
- Bills tend to address the following areas:
  - Authorized importers (i.e. individuals, pharmacies, wholesale distributors)
  - Countries authorized for importation (i.e., Canada, members of the Organization for Economic Co-operation and Development, Australia, Israel, Japan, EU)
  - Foreign pharmacy certification requirements
  - Dispensing requirements
  - Definition of prescription drug as applied to importation
- Bills often do not address oversight, the Drug Supply Chain Security Act (DSCSA) (or provide very broad exemptions to DSCSA), or drug coverage
- APhA submitted comment letters to Capitol Hill and the President in opposition to importation proposals
Pain Management and Opioid Abuse

While Congress passed the Comprehensive Addiction and Recovery Act (CARA) in 2016, pain management and prescription drug abuse and treatment continue to be an important legislative issue.

- “CARA 2.0” momentum continues to build

Ongoing issue areas:
- Prescription Drug Monitoring Programs (PDMPs)
- Access to treatment, including naloxone and medication assisted treatment
- Limit on Fills
- Funding
- Disposal
- Education
- Partial Fills

APhA provided comment letters and direct feedback to members of Congress.
- Connecting this public health issue to the need for provider status
Recognition of Pharmacist Services – Provider Status
Pharmacist Provider Status Legislation

115th Congress – Reintroduction of the Pharmacy and Medically Underserved Areas Enhancement Act

• Senate – S. 109 – 51 supporters
  Senators Chuck Grassley (R-IA), Sherrod Brown (D-OH), Susan Collins (R-ME) and Robert Casey (D-PA) introduced S. 109 on January 12, 2017
  27 Original Co-sponsors

• House – H.R. 592 – 252 supporters
  Representatives Brett Guthrie (R-KY), G.K. Butterfield (D-NC), Tom Reed (R-NY), and Ron Kind (D-WI) introduced H.R. 592 on January 20, 2017
  126 Original Co-sponsors
Patient Access to Pharmacists’ Care Coalition

- Broad coalition of pharmacy organizations and stakeholders united in promoting patient access and coverage to pharmacists’ patient care services
- Efforts focused on regulatory and legislative action
- Coalition seeking provider status for pharmacists including advocacy for:
  - Consumer/patient access and coverage for pharmacists’ patient care services
  - Payers and policy makers to recognize pharmacists as health care providers who improve access, quality, and value of health care
  - Enhanced inclusion of pharmacists as members of patient health care teams
Patient Access to Pharmacists’ Care Coalition

www.PharmacistsCare.org
Patient Access to Pharmacists’ Care Coalition Activities

- Continual discussions with Congressional Committee staff and leadership
- Meetings with the administration
- Grassroots and Media Activities
  - Targeted Members during Congressional Recess
  - Vulnerable House Members
- Question for the Record for HHS Secretary Alex Azar
- Continue to build co-sponsor support
- Federal efforts are just one way for pharmacists to earn “provider status” recognition
  - Pharmacy-related associations and pharmacists’ progress in helping patients receive better coordinated care has been impressive at the state level
Legislation Considerations

- Dependent on possible vehicle / other health care legislation that is moving through Congress
- Cost of the legislation / Congressional Budget Office (CBO) Score
- After 4 years, involving 3 sessions of Congress, no opposition
- Support is bipartisan
  - Remarkable for health care legislation in a partisan Congress
APhA’s Provider Status Resources

Access to health care is a serious issue in Tennessee. 93 of 95 Tennessee counties include areas designated as “medically underserved”. Over 7,400 Pharmacists Licensed in Tennessee.

U.S. States with Counties Containing Medically Underserved Areas

LEGEND
- 0%-20% counties have medically underserved areas
- 21%-40% counties have medically underserved areas
- 41%-60% counties have medically underserved areas
- 61%-80% counties have medically underserved areas
- 81%-100% counties have medically underserved areas

Tennessee’s Pharmacists: Improving People’s Health

Meeting Patients’ Needs in Tennessee

- 6.5 Million people
- 71% of the population receive Medicaid
- 8,060 Pharmacists ready to help

Diabetes: A disease that can result in a lifetime of medical care and medical expenses. Pharmacists can diagnose and help patients manage the disease, and help improve health care and health outcomes.

Cardiovascular Disease (CVD): The leading cause of death and the leading cause of non-communicable disease (NCD) in several countries. Pharmacists can help prevent, manage, and control CVD.

Elderly care: Pharmacists can provide care coordination, medication adherence, and patient education to improve outcomes for older adults.

Medication adherence for the treatment of chronic conditions, especially when patients are taking multiple medications, is essential in the management of chronic diseases.
APhA Provider Status Activities

- Messaging, stories and profiles highlighting pharmacists’ services
- SHARE YOUR STORY!
- Identifying other health care providers supportive of pharmacists
- You don’t have to go to Washington DC to make a difference!!

www.pharmacistsprovidecare.com
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Michael Baxter, Director, Regulatory Affairs
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Questions
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1. Assessment Question

1. Which of the following is correct with regard to the federal provider status legislation?

A. Pharmacists will be able to provide services to Medicaid patients without any copay/cost-sharing
B. Medicare Part B will cover any pharmacist-provided services
C. Pharmacists’ services will be covered when provided to Medicare beneficiaries in medically underserved communities
D. Only pharmacists’ services approved by the CMS Innovation Center will be covered
2. Assessment Question

2. According to Drug Supply Chain Security Act (DSCSA) draft guidance, is a pharmacy required to obtain a wholesale distributor license for sales to another pharmacy if not for a specific patient need or otherwise exempt?
A. Yes
B. No
C. Depends on state law
D. Only if the transaction involves controlled substances
3. Assessment Question

3. Which of these is true about drug pricing legislation?
   A. Congress passed legislation to allow the importation of prescription drugs from Canada but it has not been signed by the President yet
   B. A law enacted in 2017 allows HHS to negotiate Part D drug prices for the Medicare program
   C. **30 bills have been introduced in the 115th Congress that address drug pricing**
   D. The President submitted a proposal to Congress that would allow the importation of prescription drugs from specific countries