Legislative and Regulatory Update 2018

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CPE Information and Disclosures

Michael Baxter declares 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.
CPE Information

- Target Audience: Pharmacists and Pharmacist Technicians
- ACPE#: 0202-0000-18-235-L03-P/T
- Activity Type: Knowledge-based
Learning Objectives

1. Recognize recent federal legislative activity impacting the practice of pharmacy.

2. Describe new federal regulations and activities related to the practice of pharmacy.

3. State the current efforts at the federal level to reimburse pharmacists for their services.
Self-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.
2. Which of the following requirements of ‘Track and Trace’ has not yet been implemented?

A. Pharmacies must only accept medications that contain a “2D barcode”.

B. Procedures must be in place by pharmacies to identify suspect or illegitimate products.

C. Pharmacies must verify all trading partners are legitimate.

D. All medications received by a pharmacy must be accompanied by their product tracing information.
Today’s Update

- Provider Status
- Drug Pricing
- Compounding/ Track and Trace
- Pain Management and Opioid Abuse and Misuse
What is ‘Provider Status’?

- Increasing patient access to and coverage of pharmacists’ patient care services
- For decades, pharmacists have been one of the few health care professionals that lack recognition as health care providers in federal law - nearly all other health care professional services are rightfully covered under Medicare laws, including services provided by chiropractors, midwives, and dieticians, but not services provided by pharmacists
- Since 2014, APhA and its members are calling on Congress to pass a bill that would amend section 1861(s)(2) of the Social Security Act to enable Medicare beneficiaries to access pharmacist-provided services under Medicare Part B (H.R 592/ S. 109)
- Under the legislation, these services would be reimbursable under Medicare Part B if provided to patients in medically underserved communities and if the services are consistent with state scope of practice laws
Federal Provider Status – Update

- The Pharmacy and Medically Underserved Areas Enhancement Act
  - Senate – S. 109 – 54 supporters, House – H.R. 592 – 296 supporters
- APhA led efforts to include opioid-specific pharmacists’ services language in the opioid bill(s) currently under review by Congress
- Potential cost of the bill/ Congressional Budget Office (CBO) score is a barrier
- Next steps are unclear due to potential change in party control of House and Senate and new bill leaders
- APhA is committed to advancing legislation to allow patient access to pharmacists’ services
Drug Pricing

Congress Actions

- House PBM investigation and 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
- Efforts to increase the amount of generic drugs on the market are also viewed as a measure to improve competition and drive down costs (i.e., CREATEES Act, Fair Access to Safe and Timely Generics Act)
- Bipartisan amendment to require disclosure of prescription drug prices in television ads eventually removed from federal funding bill
- Passed legislation banning PBM “Gag Clauses”
Drug Pricing

Administration Actions

- POTUS signs law prohibiting “Gag Clauses” for Part D, MA, Fully Insured (Exchange/Obamacare and small group) plans and employer (large group) plans
- CMS PBM “Gag Clause” prohibition letter to Part D plans
- Part D Rule Request for Information (RFI)/ Trump Drug Pricing “Blueprint” RFI – Including rebates / pharmacy price concessions (including DIR fees) at the Point-of-Sale (POS)
- OIG Proposed Rule to remove safe harbor protection for drug rebates paid to insurance plans and PBMs
- FDA Drug Importation Working Group established to make recommendations for drugs that are off-patent or off-exclusivity and produced by one manufacturer (single-source)
Drug Pricing

► APhA House of Delegates (HOD) Policy
  - APhA strongly supports patient access to affordable and cost effective medications
  - APhA supports a “transparent pricing” framework which would eliminate hidden discounts, free goods and other subtle economic devices throughout the supply chain

► APhA has been linking drug pricing to provider status/ pharmacists’ service—the most expensive drugs are those not taken or not taken correctly
  - The issue of drug pricing is broader than just the actual price of medication
  - Medication management and patient education is an important part of controlling costs, especially as medications become more expensive and complex
Drug Importation

➤ Bills/ amendments 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
  ➢ Scope of prescription drug products eligible for importation

➤ Bills often do not address oversight, the Drug Supply Chain Security Act (DSCSA) (or provide very broad exemptions to DSCSA), or coverage

➤ APhA has submitted comment letters in opposition to importation proposals
DQSA: Compounding

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”
DQSA: Compounding

FDA

► 2018 Compounding Policy Priorities Plan (Compounded drugs pursuant to valid patient-specific prescriptions)
  ➢ New Draft MOU (If # of Compounded Rx is < 50% in any Month) (9/7)
  ➢ “503B Light”- 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
  ➢ Insanitary Conditions at Compounding Facilities (Revised Draft Guidance) (9/25)

► FDA intends to announce a plan soon to improve the information available about compounded topical pain creams, with the intention to “…help inform reimbursors' and the medical community's decisions about these products”

► Pharmacy Compounding Advisory Committee (PCAC) meetings on bulk substances list—forthcoming Bulk Drug Substances guidances (503A-Draft), (503B-final)
DQSA: Compounding

**OIG**
- August 10 report identifies 547 pharmacies and 124 prescribers with questionable billing patterns (one California pharmacy billed $7.2 million for compounded drugs in 2016, compared to $60,000 the prior year)

**CMS**
- Response to the OIG report - “It is important to note that pharmacies that specialize in compounded drugs may have billing patterns that differ from traditional pharmacies and may not be indicative of fraud”
- August 10 memorandum instructing Part D plans to incorporate training on fraud schemes into ongoing training programs and encourage Part D plans to continue efforts to ensure medical necessity of Part D compounds through the use of utilization management tools and when considering exception requests
DQSA: Compounding

USP

- Revisions to USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
  - Comments Submitted: July 31 - Final Chapter Becomes Official on December 1, 2019

- Revisions to USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
  - Comments Due: November 30 - Final Chapter Becomes Official on December 1, 2019

- New USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging
  - Comments Due: November 30 - Final Chapter Becomes Official on December 1, 2019

- USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings
  - Final Chapter Becomes Official on December 1, 2019
Drug Supply Chain and Security Act (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 (TBD)
- Establish and evaluate pilot projects on enhancing supply chain safety/security (initial steps underway, TBD)
- 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: Recent Activity

- February 2018: FDA hosts last of three mandated public meetings regarding enhanced drug distribution security under DSCSA
- March 2018:
  - Standardization of Data and Documentation Practices for Product Tracing (Draft Guidance)
  - Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act (Draft Guidance)
- May 2018:
  - FDA offers free continuing education course (45 minutes) for pharmacists to help explain DSCSA requirements
  - Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug and Cosmetic Act (Draft Guidance)
- September 2018:
  - Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier (Final Guidance)
  - Product Identifier Requirements under the Drug Supply Chain Security Act (Final Guidance)
  - Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers (Draft Guidance)
- Anticipated: Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs

DSCSA: Current Concerns for Dispensers

- Barcode issues
  - Linear barcode confusion
  - Need standards for 2D bar codes (e.g. placement, size)
- Access to medications
- Inclusion of variable pharmacies in pilot projects
- Need additional education for pharmacists as generally smaller entities than other trading supply chain stakeholders
- Pharmacy-to-pharmacy transfers
- FDA indicated it will grant enforcement discretion to manufacturers unable to meet November 2017 product identifier requirement, but there is no cascading effect for other supply chain members’ deadlines
- Federal wholesale distributors and third party logistics provider licensure clarification / regulations needed
- Scope creep
- Cost of implementation, including unintended consequences of fewer trading partner options
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 and regulatory issue.

Ongoing issue areas:
- Pharmacists’ role in pain management and the opioid epidemic
- Access
- Prescription Drug Monitoring Programs (PDMPs)
- Disposal
- Pharmacists’ corresponding responsibility
- Packaging
- Guideline and best practices development

APhA has provided comment letters and direct feedback to Members of Congress on several areas of concern, including the above issues.
# Opioid Legislative Package (as of 9/28)

<table>
<thead>
<tr>
<th>Topic</th>
<th>Included?</th>
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<tbody>
<tr>
<td>Mandatory e-prescribing (Medicare)</td>
<td>✔️</td>
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<tr>
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<tr>
<td>Medicare drug management program (“lock-in”)</td>
<td>✔️</td>
</tr>
<tr>
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<td>✗</td>
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<tr>
<td>Medicaid drug utilization review</td>
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<tr>
<td>Telehealth / Telemedicine (e.g., DEA regulations for special registration)</td>
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<tr>
<td>Medicare (Welcome to Medicare package, initial physical exam, and annual wellness visit)</td>
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<tr>
<td>FDA Prescribing Guidelines</td>
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<tr>
<td>FDA Packaging and Disposal (REMS)</td>
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<tr>
<td>Mental health records/ history of SUD (Jessie’s Law)</td>
<td>✔️</td>
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<td>Pharmacists’ corresponding responsibility resources and materials</td>
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<tr>
<td>Drug Disposal Grants (DEA)</td>
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<tr>
<td>Prescription Drug Monitoring Program enhancements</td>
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</tr>
<tr>
<td>• Medicaid providers required to note experiences in record systems</td>
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<tr>
<td>• Medicaid providers to check PDMP before prescribing schedule II CS</td>
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<td>• “Qualified prescription drug monitoring program”</td>
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<tr>
<td>Suspicious orders</td>
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<tr>
<td>Pharmacy controlled substance delivery of MAT injection/implantation</td>
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<td>medications</td>
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<tr>
<td>Best practice development (multiple topics)</td>
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<tr>
<td>Expand MTM Part D eligibility</td>
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<td>Expand DATA waiver eligibility to pharmacists</td>
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Ongoing Government Activity

- HHS
  - 5-point opioid strategy
  - Pain Management Best Practices Interagency Task Force
- FDA
  - Opioid Action Plan
  - REMS
  - MAT indications
- SAMHSA
  - DATA waiver program management
  - Grants
- CDC
  - Prescribing guidelines
  - Surveillance
- Surgeon General
  - Naloxone and Opioid Overdose Advisory
  - Spotlight on Opioids and Digital Postcard
- Veterans Affairs (VA)/ Department of Defense (DOD)
  - Clinical Practice Guideline for Opioid Therapy for Chronic Pain (Version, 3.0, February 2017)
- DEA
  - Opioid production quotas
  - Suspicious orders
  - E-prescribing
  - Disposal
  - Telehealth
- AHRQ
- ONC

WHAT CAN YOU DO TO PREVENT OPIOID MISUSE?

TALK ABOUT IT.
Opioids can be addictive and dangerous. We all should have a conversation about preventing drug misuse and overdose.

BE SAFE.
Only take opioid medications as prescribed. Always store in a secure place. Dispose of unused medication properly.

UNDERSTAND PAIN.
Treatments other than opioids are effective in managing pain and may have less risk for harm. Talk with your healthcare provider about an individualized plan that is right for your pain.

KNOW ADDICTION.
Addiction is a chronic disease that changes the brain and alters decision-making. With the right treatment and supports, people do recover. There is hope.

BE PREPARED.
Many opioid overdose deaths occur at home. Having naloxone, an opioid overdose reversing drug, could mean saving a life. Know where to get it and how to use it.
Part B & D Opioid-Related Activity

- Drug management programs (pharmacy lock-ins)
  - Currently voluntary with final regulations released 2018

- Edits
  - Opioid care coordination edit (at 90 MME) pharmacist is to contact prescriber to verify legitimacy of prescription and document contact with prescriber before dispensing
  - Optional high MME hard edit (200 MME or more and may include prescriber/pharmacy counts)
  - Duplicate long-acting opioid therapy soft edit
  - Concurrent opioid-benzodiazepine soft edit
  - 7-day supply hard edit on initial opioid prescription fills (acute pain)
Part B & D Opioid-Related Activity

- Physician Fee Schedule (Proposed Rule)
  - Request for feedback specific to bundled payments for Substance Use Disorder (SUD)
  - E-prescribing objective includes new (quality measures)
Questions

For APhA Comment Letters to Congress and Agencies go to: http://www.pharmacist.com/apha-advocacy-issues

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

   Answer: C. Pharmacists’ services will be covered when provided to Medicare beneficiaries in medically underserved communities

2. Which of the following requirements of ‘Track and Trace’ has not yet been implemented?

   Answer: A. Pharmacies must only accept medications that contain a “2D barcode”