2018 Legislative Session
by
Jorgen Schlemeier

Disclosure and Conflict of Interest

Jorgen Schlemeier has no personal or financial conflicts of interest to disclose.

Pharmacist Objectives

At the completion of this activity, the participant will be able to:
1. Review the 2018 legislative session
2. Discuss the 2019 legislative session
3. Review the 2018 elections
Technician Objectives
At the completion of this activity, the participant will be able to:
1. Review the 2018 legislative session
2. Discuss the 2019 legislative session
3. Review the 2018 elections

2018 Legislative Update
- Opioids
- PBM's
- Medicaid
- Elections/Advocacy
- Questions

2018 Legislative Update
Opioids
- Number one reason for prison recidivism
- PDMPs
- Prescription limits
- Take back programs
- Treatment Programs
Substance use and mental health are key concerns of Missouri law enforcement officials

Law Enforcement and Dept of Corrections Believe Opioid and Substance Use #1 Concern

Top 4 challenges identified by law enforcement:
- 72% - opioid use
- 44% - mental illness
- 25% - repeat offenders
- 21% - domestic violence

Lack of access to quality community treatment contributes to the high number of people who are revoked to prison who have serious behavioral health conditions

- Nearly half of all revocations were for technical violations
- For females, 58% were revoked for technical violations
- Two-thirds of these revoked were enrolled in any community-based treatment while on supervision
- However, of those revoked for technical reasons, 24% had "moderate to severe" substance use disorder and 17% had "severe to nonsensical" mental health problems.

Between 2012 and 2016, opioid overdose deaths in Missouri increased 67 percent

<table>
<thead>
<tr>
<th>Year</th>
<th>Opioid Overdose Deaths</th>
</tr>
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<tbody>
<tr>
<td>2012</td>
<td>407</td>
</tr>
<tr>
<td>2013</td>
<td>413</td>
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<tr>
<td>2014</td>
<td>420</td>
</tr>
<tr>
<td>2015</td>
<td>432</td>
</tr>
<tr>
<td>2016</td>
<td>427</td>
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</tbody>
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Source: Missouri Department of Health and Senior Services, 2017.
A third of all people admitted to prison have been sentenced to prison for the purpose of getting treatment.

Opioid Legislation Continues to Seek Solution
- PDMP’s – mixed reviews – polarizing definitive statements
  - University of Texas Health Science Center at San Antonio
  - Northwestern
  - Pew Foundation
- Prescription limits
  - 7 day supply – certain exclusions for practitioners
  - Pharmacist exemption - A pharmacist or pharmacy shall not be subject to disciplinary action or other civil or criminal liability for dispensing or refusing to dispense medication in good faith pursuant to an otherwise valid prescription that exceeds the prescribing limits established by subsection 2 of this section.

Opioid Legislation Continues to Seek Solution
Cont...
- Mid level practitioners limitations
- State prior authorizations
  - Good if done well, bad if not
- State oversight of prescribing/dispensing habits
  - No good!
Opioid Legislation Continues to Seek Solution

- Take Back Programs
  - Pharmacies allowed to receive unused and destroy
- Treatment programs
  - Federal Funds pouring into the state
  - IAOATA – “Improved Access to Treatment for Opioid Addictions Program,” best practices guidelines
- Expanding roles of providers for treatment services
- Technology – apps – supplement treatment for adherence

2018 Legislative Update

PBM
- What is new in the PBM world
  - Competition
  - Acquisitions
  - Trump’s Tweets
  - Legislation

2018 Legislative Update

- Competition
  - Out of Country Purchasing
  - Amazon.com® et al
  - JP Morgan, Berkshire Hathaway
  - Insurers
• Competition
  • Amazon in the Pharmacy Business - acquisition of PillPack puts Amazon in the regulated pharmacy business.
  • PillPack has pharmacy licenses in all 50 states.
  • Amazon has entered the healthcare industry through its employee health cost endeavor with Berkshire Hathaway and J.P. Morgan.
  • Amazon entering medical supply products as well

• Competition
  Amazon is in talks with:
  - digital prescription platform Xealth and;
  - two hospital systems (at least)

launch a pilot that would have doctors prescribe products to patients before they're discharged, and then Amazon would send script directly from fulfillment center (aka mail order) - report from CNBC.

Prime members would be eligible for discounts.

Express Scripts Response to Amazon announcement:
“... Our scale and quality of care provides patients with access to a broader suite of products than other smaller pharmacies,” the north St. Louis County-based pharmacy benefit manager said.
(did they misunderstand the question? Is Amazon a “smaller pharmacy”?)
Market Reaction

“Still, investors were rattled. Walgreens’ shares fell 9.9 percent. Stock prices for other major players also dropped: CVS® Health fell 6.1 percent, while Express Scripts slipped 1.4 percent.”

-adding skepticism is major shareholder Carl Icahn’s recent opposition (since withdrawn) to acquisition. Reasoning is PBM current model is not sustainable.

2018 Legislative Update

- Acquisitions
  - $67.5 billion acquisition of insurer Aetna® Inc. by CVS® Health Inc., and
  - $54 billion takeover of PBM Express Scripts Holding Co. by insurer Cigna® Corp.

Trump’s Drug-Price Push Butts Into Two Megadeals

- A proposal seemingly targeting the PBM middlemen of the process may alter the math on more than $100 billion of M&A.
- What is the proposal??

Published in Bloomberg, July 19 2018
Trump’s Drug-Priced Push Butts Into Two Megadeals

- What does it do? We don’t know exactly but -
- Its long-winded but telling name
  “Removal Of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection”
- Suggests that it would be aimed at moving away from rebates and toward a system that would likely be less profitable for PBMs

Published in Bloomberg, July 19 2018

Market Reaction? Shares of companies involved in large insurer/PBM combinations plunged after the announcement.

- Note: more than 60 percent of CVS’s revenue comes from its PBM.

Published in Bloomberg, July 19 2018

2018 Legislative Update

- Legislation
  ◦ Scope of Practice
  ◦ Gag Clauses/Claw back - PBM
  ◦ DIR Fees - PBM
  ◦ Copay Caps - PBM
  ◦ Transparency - PBM
  ◦ Licensing under DOI - NCOIL
  ◦ Enforcement - NCOIL
  ◦ Network Adequacy - NCOIL
Legislative Update

- Revises Vaccination Protocol
  - Deletes 12 year old restriction on admin of vaccines
  - Allows 7 year old or CDC guidelines whichever is more
  - Requires entry into Show Me Vax in lieu of forwarding to PCP
    - Unless patient objects, then forward to PCP
  - BOHA and BOP file rules on Flu Vaccine restriction

Legislative Update

- Pharmacy Technician Legislation
- Sater
- Rizzo

Legislative Update – 2 line Script Pad

Pharmacist can choose select a less expensive generically equivalent or interchangeable biological product unless:
1. The patient requests a brand name drug or biological product; or
2. The prescribing practitioner indicates that substitution is prohibited or displays "brand medically necessary", "dispense as written", "do not substitute", "DAW", or words of similar import on the prescription.
PBM Bill - Gag Clauses

"A pharmacy or pharmacist shall have the right to provide to a covered person information regarding the amount of the covered person's cost share for a prescription drug, the covered person's cost of an alternative drug, and the covered person's cost of the drug without adjudicating the claim through the pharmacy benefits manager."

"Neither a pharmacy nor a pharmacist shall be prescribed by a pharmacy benefits manager from discussing any such information or from selling a more affordable alternative to the covered person."

Copayment Transparency

"No pharmacy benefits manager shall include a provision in a contract entered into or modified on or after Aug 28, 2018, with a pharmacy or pharmacist that requires a covered person to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:
1. The copayment amount as required under the health benefit plan; or
2. The amount an individual would pay for prescription if that individual paid with cash."

DIR Fees

"No pharmacy benefits manager shall, directly or indirectly, charge or hold a pharmacist or pharmacy responsible for any fee amount related to a claim that is not known at the time of the claim's adjudication, unless the amount is a result of improperly paid claims or charges for administering a health benefit plan."

-Only applicable to State Regulated Plans (ERISA)
-monitoring court cases in other states
Transparency

White House Council of Economic Advisers

Key Component
- Poke at the pharmacy benefit manager (PBM) industry, that calls out commonplace practices that have not only contributed to higher drug prices, but also restricts consumer choice in the marketplace.
- Transparency of their operation

Transparency IS HAPPENING!

“States across the country are struggling with this issue because there currently is no state or federal oversight of these pharmacy benefit managers.”

REPORT WILL STUDY
- How much does the state spend on PBMs?
- How do PBMs bill insurance companies for a drug?
- How PBMs determine reimbursement and are they consistent for different types of pharmacies?
- Do PBMs pass along savings from rebates and price cuts they get from drug manufacturers?
- Why is drug pricing information kept private when taxpayers are footing the bill?
- What the Department of Human Services is doing about contracts that involve PBMs?
- Are any Pennsylvania pharmacies subject to gag orders?
- How can Pennsylvania ensure transparency and fairness in pharmacy pricing for consumers?

Transparency IS HAPPENING!

National Council of Insurance Legislators

- Legislative organization comprised principally of legislators from around the nation
- Who serve on state insurance and financial institutions committees
- NCOIL writes Model Laws in insurance and financial services
- Serve as an educational forum for public policy makers and interested parties
“Up until now, the PBMs have been playing streetball and it is time for a referee”

Sen. Jason Rapert  
President ARKANSAS

Rep. Tom Oliverson  
Vice Chair Health  
TEXAS

Rep. Willie Dove  
KANSAS

Rep. Justin Hill  
MISSOURI

Rep. John Wiemann  
MISSOURI

Rep. Lewis Moore  
OKLAHOMA

Rep. Glen Mulready  
OKLAHOMA

State Regulators  

- Kentucky believes 40% Medicaid pharmacy spend went into the pockets of PBMs.
- Recently levied a fine

Health Plans/PBM’s

- want to include Drug Companies in model legislation
- There is much this Committee doesn’t know about PBMs and shouldn’t rush to action on recommending model legislation.

Health Plan/PBM cont...

- PBMs exist to work as a vendor for the health plan. The health plan makes all decisions, we just implement what the health plan decides.
- Stress ERISA Exemption
- Kentucky’s licensure act is working
- Florida legislation as a potential model bill for licensure
2018 Legislative Update

Medicaid
- Savings – all focused on savings
- Drug Utilization Boards
- Script limits
- Managed Care – own the “Alternative Solution” space
- Drug Reuse
- Formularies – Ohio/Mass – CMS - nope

Drug Utilization Review Board
- Use to delay specialty drugs
  - Set edits on them for certain people, others heavy prior authorize
  - The advisory council on rare diseases and personalized medicine
- Pay if the drugs work

Ohio Attorney General
- Today, I am putting (pharmacy benefit managers, known as) PBMs on notice that their conduct is being heavily scrutinized, and any action that can be taken and proven in court will be filed to protect Ohio taxpayers and the millions of Ohioans who rely on the pharmacy benefits provided,” DeWine said.
- The study said PBM fees should be in the range of 90 cents to $1.90 per prescription. CVS® Caremark billed the state about $5.60 per script; Optum charged $6.50 — three to six times higher.
2018 Legislative Update

Medicaid
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2018 Legislative Update

- Price Controls
  - Efficiencies of Scale – Independent to Amazon
  - Out of Country Purchasing
  - Make the patient healthier…??!! Pharmacists own this space.
    - What health care services does your state allow pharmacists to provide? Reimbursed? Hassle factor?
  - Technology
  - Trump’s Tweets

Study/Talk/Proposal of Out of Country Purchasing

1. Special committees
2. Legislation forecasted for 2019
3. Trump’s Talk/Tweet

- Direct to Customer?
- Direct to Pharmacy?
- Direct to Wholesaler?

“You see, the pharmacy world is much more complex than just delivering certain pills or certain packages,” Walgreens
**Pfizer® Bullied by Trump’s Tweet**

WASHINGTON — Pfizer, the giant multinational drug company, said on Tuesday that it would defer some price increases, after President Trump thrashed the company in a Twitter post.

“Pfizer & others should be ashamed that they have raised drug prices for no reason”

“Pfizer is rolling back price hikes, so American patients don’t pay more,” Mr. Trump tweeted. “We applaud Pfizer for this decision and hope other companies do the same. Great news for the American people!”

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**Impact of 2018 Elections on the 2019 Session**

- House and Senate will likely maintain their “super” majority
- Leadership will be determined after election and will likely change from the current makeup
- It is important for pharmacists to monitor the outcomes of the elections and maintain or establish a relationship with their elected officials

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**2019 Legislative Session**

- Medicaid Reform – **Biggest Issue facing Pharmacists**
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- New Director of MO HealthNet (Medicaid) to be announced in October –
  - The following 18 months will be critical to pharmacists’ ability to do business with Medicaid
  - Solutions to offer
  - Managed Care vs. Fee for Service
2019 Legislative Session

- Process for change
  - We are part of a Medicaid Provider Coalition
    - Mtg with Governor
  - Meeting with the new MO HealthNet Director
  - Meeting with key legislators who will have to approve the plan
  - Meeting with stakeholders in our own industry to ensure we have a united front as we move through this process.

2019 Legislative Session

Other Legislation

- Pharm Techs
- Behind the Counter products
- Out of Country Purchasing
- Scope

Advocacy

Advocacy — Best time to interact with your legislator is during the interim while they are home.

#1 – Be Ready – No A to Z in one step

- Direct
  - Mail, phone, in person
- Social Media
- Coalitions
- Media
  - Earned
  - Unearned
Learning Assessment:
Question 1
What is the top challenge identified by Law Enforcement and Dept of Corrections for recidivism?
A. Substance Use Disorder/Opioids
B. Mental Illness
C. Domestic Violence
Answer: A

Learning Assessment:
Question 2
What state’s Attorney General is most aggressively challenging the PBM’s?
A. Arkansas
B. Missouri
C. Washington
D. Ohio
Answer: D

Learning Assessment:
Question 3
What impact will the 2018 elections have on the 2019 Legislative Session?
A. Provider Status will be passed
B. Medicaid Reform will be addressed
C. PDMP will be reintroduced
D. The balance of the General Assembly will remain a Republican super majority
Answer: D
Any Questions?