Overview of ASHP Opioid Efforts

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My educational background includes B.S.Pharm, Pharm.D., MHA, and a 2 year research fellowship. I have been a pharmacist since 1996. I am currently the Director of Medication Safety and Quality at ASHP. My current professional interests are IV and oral liquid standardization, naloxone usage and safety, Enfit connector and syringe design, opioid use/abuse, and antimicrobial resistance.

My expertise includes being a PICU pharmacy specialist, pharmacy clinical coordinator, medication safety chair/leader, and senior project manager overseeing large clinical, operational, and technology initiatives. I am LEAN certified and act as a LEAN coach at ASHP and previously at the University of Michigan.

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The Director of State Grassroots Advocacy and Political Action for ASHP. In this position, he works with state affiliates on state-level legislation and promotes ASHP’s grassroots mobilization efforts and its political action committee, ASHP-PAC. He received his bachelor’s degree from The American University, where he majored in political science and law in society. Prior to ASHP, Mr. Gentile spent ten years at the National Association of Home Builders (NAHB) working in various positions within the government affairs department. He worked with state and local government affairs issues, federal relations, grassroots mobilization and BUILD-PAC (NAHB’s political action committee).
To Ask a Question and Collapse Control Panel

Expand or Collapse

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Overview of ASHP

Opioid Efforts

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Outline

- Facts and background
- Problem
- Needs
- ASHP efforts
- Resources
Facts and Background

More than 40 people die every day from overdoses involving prescription opioids.\(^1\)

Since 1999, there have been over 165,000 deaths from overdose related to prescription opioids.\(^1\)

4.3 million Americans engaged in non-medical use of prescription opioids in the last month.\(^2\)

https://www.cdc.gov/drugoverdose/data/index.html
Facts and Background

- Since 2000, the rate of overdose deaths involving opioids—Fentanyl, Percocet, Vicodin, and others—has increased by 200 percent, according to the Centers for Disease Control and Prevention (CDC).
- And in 2014 alone, nearly 30,000 people died from a drug overdose involving some type of opioid, including prescription pain relievers and heroin—more than in any previous year on record.
Problem

249M prescriptions for opioid pain medication were written by healthcare providers in 2013.

Enough prescriptions were written for every American adult to have a bottle of pills.

Nearly 2M Americans, aged 12 or older, either abused or were dependent on prescription opioids in 2014.
Problem

- How do we assure the patients who need opioids get them?
- How do we prevent diversion, misuse, abuse?
Problem

- Historically opioids have been the mainstay of therapy for both acute and chronic pain
- Lack of reasonable pain control expectations and/or conversations with patients
  - Same patients will never be a zero
- Quantities prescribed
  - Need more guidance for minor procedures
- Not enough take back efforts
  - Infrequent, cumbersome, lack of pharmacist involvement
  - Pharmacists dispense medications, why can’t they take them back?
Problem

• **One size fits all patient approach**
  – Pain management needs to be more targeted
  – Opioid naïve
  – Genomics
    • The concept of “I took one pill and fell in love”

• **Medical professions not recognizing and treating dependency and addiction accordingly**

• **Prescription drug abuse becomes expensive and turns into heroin abuse**
Virginia declares opioid emergency, makes antidote available to all

Virginia’s health commissioner on Monday 11/21 declared opioid addiction to be a public health emergency and issued a standing prescription for any resident to get the drug Naloxone, which is used to treat overdoses.
Needs

• **More pain experts**
  – Education may become mandatory
  – Need for interprofessional teams, including psychiatry/ology
  – Tailored pain plans

• **Understanding the needs for each patient**
  – Vulnerable patients (pediatric, geriatric)
  – Disease states with needs for high dosing (sickle cell, oncology)

• **Advocacy on national, state, local levels**

• **Patient voice**
  – Partial fills or refill concepts
More needs

• **Understanding abuse is a disease state**
• **Need for substance abuse experts**
  – Medication experts
  – Interprofessional teams
• **Availability of naloxone**
  – Who’s at risk, how do we know?
  – Education for patients, families, etc
  – What does rescue look like
  – Emphasis to call 911
  – Involvement of community pharmacies
• **Interoperable, real-time PDMP process**
Prescription Drug Monitoring Programs
Prescription Drug Monitoring Programs

• CDC: “State-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs to patients”

• Enables multiple parties (including pharmacists, prescribers, and others) to access patient controlled substance prescription records when appropriate
  – Patient name/demographics, prescriber, dispenser, payment method, drug name/strength/quantity, amount of drug supplied, and refills remaining

• Decreases drug abuse and diversion
PDMP Prevalence

Status of Prescription Drug Monitoring Programs (PDMPs)

* Click on state abbreviation to view PDMP contacts *

- Operational PDMPs (50)
- Enacted PDMP legislation, but program not yet operational (1)
- No PDMP (1)

Research is current as of August 28, 2015
## State Agencies Operating PDMP

<table>
<thead>
<tr>
<th>Type of Agency</th>
<th>Number of PDMPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boards of Pharmacy</td>
<td>21</td>
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<tr>
<td>Departments of Health</td>
<td>16</td>
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<tr>
<td>Law Enforcement</td>
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<td>Health Information Exchange</td>
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<tr>
<td>Professional Licensing</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
</tr>
</tbody>
</table>
NCPDP Proposed Recommendations

• **Standardization**
  – Adopt a consistent method of reporting and retrieving PDMP data
  – Promote interoperability

• **Real-time updates through a national data repository**
  – Utilize NCPDP’s Telecommunication Standard: Support real-time data input and validation at the point of care to a national data repository
  – Utilize NCPDP’s SCRIPT Standard: Pharmacist/Prescribers receive real-time PDMP data without disruption of workflow

• **Develop a nationally adopted clinical risk score**
  – Assist clinicians with prescribing and dispensing
Future Goals and Optimized Use of PDMP

- Pharmacists inputting controlled substance prescription data immediately into the PDMP database
- Require clinicians to use a PDMP prior to prescribing or dispensing controlled substance medications
- Secure and efficient exchange of standardized PDMP data between states
- Proactive reporting
- Real-time access to all relevant PDMP data by pharmacists and prescribers involved in the patient’s care
- Easily integrated into the workflow
National Methods

- **CDC**
  - Research
  - Data
  - PDMP
  - Chronic pain guidelines

- **Surgeon General**
  - Turn the tide (take the pledge)
  - Facing Addiction in America (https://addiction.surgeongeneral.gov/)

- **White House**
  - Focus on prevention and treatment
ASHP Opioid Efforts

• **Federal level**
  – White House workgroup
  – CDC
  – FDA
  – NABP
  – Various national stakeholder groups
  – NCPDP

• **State level**
  – PDMP’s
  – Advocacy around various bills, laws, etc
ASHP Opioid Efforts

- **Internal**
  - Taskforce
  - Councils (policies, guidelines, etc)
    - Policies in draft form for partial fills and excess quantity prescribing
    - Gap analysis of all policies, guidelines, etc
  - SAG’s
    - Clinical specialists (ED, critical care, OR, etc)
    - Ambulatory care (Pain and Palliative Care)
    - Informatics
ASHP Opioid Efforts con’t

• **Education**
  - MCM 2016
  - Webinar series

• **Focus on diversion**
  – Council on Pharmacy Management
  – Led by David Chen
On 10/28 ASHP published the first set of national guidelines designed to help healthcare organizations devise and implement strategies to prevent the diversion of controlled substances. The guidelines include a framework for creating a collaborative, comprehensive controlled substances diversion prevention program (CSDPP) to protect patients, employees, organizations, and the community.

See more at:

Diversion Guidelines

- Core elements of program
- Legal and regulatory requirements
- Organization oversight and accountability
- Human resource management
- Automation and technology
- Monitoring and surveillance
- Investigation and reporting of suspicious diversion
- Chain of custody
- Storage and security
- Internal pharmacy controls
- Prescribing and administration
- Returns, waste, disposal
- Special considerations
What Can You Do?

• Start somewhere
• Know what is happening in your area
• Education, advocacy
• Leadership support
• Support and team with providers
Opioid Abuse is an Epidemic

• The death rate from prescription opioid overdose quadrupled between 2000 and 2014

• The cost of opioid abuse is $700 billion annually

• Insurers' payments for opioid abuse grew 1,375 percent between 2011 and 2015

• Pharmacists can play a major role in ending the opioid abuse epidemic
ASHP’s Efforts to Address Opioid Abuse

• **ASHP’s Efforts on Opioid Abuse**
  • Developed a comprehensive guideline on controlled substance diversion prevention best practices
  
• Working with FDA, CDC, NGA and NABP to:
  ❖ Improve interprofessional educational materials and access to opioids
  ❖ Encourage abuse and tamper-deterrent formulations
  ❖ Revise prescribing guidelines to limit use of opioids to treat chronic pain
Comprehensive Addiction and Recovery Act of 2016 (CARA)

- Signed into law July 201
- Includes pharmacists on a Federal “best practices” task force
- Focuses on education and treatment over criminal prosecution
- Includes provision allowing for partial fill of Schedule II narcotics
- Lock-in provisions under Medicare Parts C & D
- May not have the necessary funding to execute
State Opioid Abuse Legislation

- 46 states have laws that address access to Naloxone
- 49 states have Prescription Drug Monitoring Programs (PDMP)
  - Most of the PDMPs are not interoperable
- Some legislation is moving with restricted supply prescriptions (7 day supply)
State Opioid Abuse Legislation Continued

• Massachusetts passed a comprehensive law on opioid abuse in March 2016.

  – Has 7 day supply for all first time prescriptions and minors
  – Requires physicians to check PDMP every time they prescribe an addictive opioid
  – Allows patients to request physicians to prescribe less than normal amount and pharmacies to provide less than the full amount
State Opioid Abuse Legislation Continued

- **Maine passed legislation in late spring.**
  - New acute scripts 7 day prescriptions and ongoing chronic scripts for 30 day
  - New scripts capped at 100 morphine milligram equivalents
  - Allows prescriptions to be higher than cap for a documented medical necessity
  - Dispensers will check PDMP before dispensing for opioid prescription and will notify program and physician and withhold medication if they have reason to believe script fraudulent or duplicative
  - Hospital carve out on PDMP checking
  - 3 hours of opioid education within current CME required hours for prescribers
  - Opioid prescriptions need to be made electronically or the prescriber has to apply for a waiver and have a plan in place to electronic prescribe
State Opioid Abuse Legislation Continued

- Maine passed a naloxone access bill in early April
- Governor Paul LePage vetoed it in late April
- ASHP along with the Maine affiliate and other pharmacy groups sent letters to legislature to override the veto
- The veto was overridden by a wide margin on April 29, 2016
Best Practices in Opioid Legislation

• Open a dialogue with other pharmacy groups and other health care organizations

• Work with state legislators who are passionate about this issue

• Find common themes and agree on basic principles
  – PDMP Access
  – 7-day supply on opioids and other C2s
  – Other pain management avenues

• Regularly meet with decision makers (build relationships)

• Be a resource to decision makers (testify, write letters, make phone calls, attend town halls, and setup meetings)
Questions?