Legal and Policy Approaches to Reducing Prescription Drug Overdose

Presenters: Corey Davis and Kristi Weeks
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Legal and Policy Approaches to Reducing Prescription Drug Overdose

Our Presenters:

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Legal and Policy Approaches to Reducing Prescription Opioid Overdose

Corey Davis, JD, MSPH
Roadmap

» Overview
» Prescription Monitoring Programs
» Good Samaritan Laws
» Increased Naloxone Availability
» Parting Thoughts
Overview

» Non-medical use of prescription opioids by teens is increasing

» Most prescription drug deaths are from opioids

» Opioid overdose is typically reversible, which means that most opioid OD deaths are preventable
Overview

» A number of legal and policy approaches are being implemented in an attempt to reduce non-medical use and overdose

» Mix of ‘supply’ and ‘demand’ side interventions

» In the evidence continuum, most somewhere around the level of ‘good idea’
Prescription Monitoring Programs

» A previous webinar has covered PMPs in great detail, so I won’t re-hash the basics here
  - In general, if you know one state’s PMP, you know one state’s PMP

» But let’s touch briefly on some policy questions that are impacted by law
PMP Policy Questions

» What is the purpose of the PMP?

Most would say “Identifying possibly problematic use” – but to what end?

» To inform prescriber practice?
» To inform dispenser practice?
» To target individuals for substance misuse interventions?
» To target individuals for referrals to pain specialists?
» To target individuals for overdose prevention interventions?
» To target individuals for investigation/arrest?
‘Strong’ PMP Characteristics

» Monitor all drugs of misuse
» Unsolicited/proactive disclosure
» Disclosure of de-identified info for research/education
» Broad list of authorized users
» Required education and training for authorized users
» Standards and procedures for access
» Linkage to addiction treatment professionals
» Interstate sharing
» Strong and reasonable confidentiality protections
» Ongoing evaluation
‘Strong’ PMP Characteristics

» These characteristics have little empirical evidence supporting them, but they seem, in general, to make sense

» Are states following them?
States that Require Authorized Users to Undergo Training for Use of PMP

Authorized users with direct access to the PMP
Law enforcement officials only
Employees of the Cabinet for Health and Family Services only
Duly authorized representatives of: law enforcement, the attorney general’s office, licensing boards, Dept. of Health Drug Control Program, and Executive Office Of Health and Human Services personnel

Law enforcement officials in Vermont do not have access to the PMP, but must undergo training before being allowed access to PMP data provided to them by licensing boards.

This information was compiled using legal databases, state agency websites and direct communications with state PDMP representatives.
Many states require that persons requesting access to the state PMP database first register as an authorized user. This map and the accompanying memorandum is concerned with only those states that require all practitioners licensed in the state to also register to use the PMP database.

The Kentucky provision goes into effect in July 2012. The Tennessee provision goes into effect on January 1, 2013.

2 Maine’s statute requires all prescribers in six classes to register by March 1, 2014 if less than 90% of prescribers in each class have not registered to use the PMP by January 1, 2014.
Policy thoughts

» To be an effective public health tool, PMP information has to be readily available to practitioners

» To be an effective bridge to substance misuse treatment, information has to be readily available to substance use treatment professionals

» To be an effective surveillance tool, PMP must provide statistical data or make raw data available to outside researchers

» Where do the data go?
Law Enforcement Access to PMP Information

Probable cause, search warrant, subpoena, or other judicial process
Pursuant to an active investigation
May only receive information from professional licensing boards
Upon request from law enforcement officials

This information was compiled using legal databases, state agency websites and direct communications with state PDMP representatives.
States that Provide PMP Database Information to Mental Health/Substance Abuse Professionals

To substance abuse or mental health professionals

To substance abuse professionals for services to licensed health care professionals

To the chief pharmacist, the state opioid treatment authority or its designee, and the medical director of the department of mental health and substance abuse services

Please see the companion compilation of statutes and regulations on the NAMSDL website for more specific information.
States that Provide PMP Database Information to County Coroners and/or Medical Examiners

1 The Tennessee statute went into effect on May 10, 2012.

Please see the companion compilation of statutes and regulations on the NAMSDL website for more specific information.


This information was compiled using legal databases, state agency websites and direct communications with state PDMP representatives.
PMP Wrapup

» PMPs likely help identify outlying prescribers
» PMPs likely help identify patients w/ multiple prescribers
» Not great evidence that they have positive effects on biological outcomes (overdose)
» Not great evidence data is reaching the right people
OD Good Samaritan Laws

» Opioid OD is extremely common
  >60% of heroin users have witnessed OD

» It’s also typically reversible using a relatively cheap, safe drug called naloxone

» Unfortunately, often people who witness an overdose fail to summon aid out of fear that they will be arrested

Lots of anecdotal evidence, and now good empirical data that this is a serious problem
OD Good Sam Laws

» **Typical Good Sam laws provide *civil* protection**

But the people who aren’t calling 911 aren’t generally worried about getting sued - they’re worried about getting arrested. No reason to believe this isn’t as true for non-medical pill use as it is for heroin.

» **Enter the 911 Good Sam law**

Based on laws and policies designed to prevent alcohol OD, particularly among college students, as well as “Baby Moses” laws.
OD Good Sam Laws

» First law passed by New Mexico in 2007
» 8 drug-OD-specific laws enacted to date
» 1 in 2010 (WA), 2 in 2011 (NY, CT), 4 so far in 2012 (IL, CO, RI, FL)
» Legislation pending in many other states (NJ, PA)
Characteristics of Good Sam laws

» All provide immunity from prosecution for minor possession for Good Sam who requests help in good faith, as well as victim

Some also provide protection for crimes such as paraphernalia possession

» All require caller to have good faith belief OD is in progress

» 6 require courts to take Good Sam’s actions into account as mitigating factor for other crimes
Policy Questions

» Do Good Sam laws “work”?  
  • Existing data is positive: A survey of 355 opiate users found that once they became aware of Washington’s Good Samaritan law, 88% indicated that they were more likely to call 911 during future overdoses.
  • Anecdata extremely supportive

» What might best practices be?  
  • None mandate referral to drug treatment or other care – might this be a “good idea”?  
  • Need to be publicized and practiced “on the street”
Community Naloxone Provision

» Naloxone reliably reverses opioid OD
  • Prescription, but not controlled substance
  • No good evidence on necessity of followup

» However, many people do not have access to it
  Lots of reasons for this, but some of them are legal and most have a policy angle
Legal impediments

» Need someone with prescribing power

  In many states this includes PAs and NPs

» Can only be prescribed within bounds of ‘professional medical practice’

  • Typically requires examination, history, treatment plan, etc.
  • Cannot be prescribed to someone for whom it’s not indicated
    - Good ideas in general, but may impede access
Legal impediments

» **Concerns over criminal liability**
  
  • Some documented arrests for possession of prescription drug without prescription
  • Chilling effect

» **Concerns over civil liability**

  Burris et al. looked for but could not find any cases, but may have chilling effect
Legal changes

» Authorization of naloxone programs

• New Mexico authorized naloxone distribution programs in 2001; provided immunity to physicians and lay savers who administer naloxone to others
• Immunity available only to registered participants
• In 2005, New York passed substantially similar legislation
  California, Boston, Baltimore now have similar laws or regulations
• Legislation pending elsewhere
Legal changes

» *Specific removal of civil liability concerns*

• A few flavors: prescribers, providers, both
• Several states have now passed one or both, including: IL, WA, CA, NY
Parting thoughts

» Non-medical use is not an either/or

The line between medical and non-medical use is often blurry
Not all, and perhaps not most, non-medical use is ‘addiction’

» The importance of multi-disciplinary approaches

Project Lazarus, for example, has seen tremendous success –
but can it scale? Is it replicable?
Better provision of substance misuse treatment and integration
of tx into other initiatives would likely help
Parting thoughts

» What level of evidence is necessary for action?

   Should we move forward with ‘good idea’ programs?
   If we move forward with ‘good idea’ programs, do we have an obligation to rigorously evaluate them?

» Are there other promising legal interventions?

   Abuse-resistant formulations?
   Physician training?
   Pharmacy take-back?
   Pain management rules?
Parting thoughts

» Need for research
  Need for independent research from groups like PHLR
  Basic science: alternatives to opioids

» It’s complicated.
  Undertreatment of pain is real
  Many criminal justice approaches are not evidence-based; many are directly contraindicated from PH standpoint
  Addiction is a chronic recurring disease
  Comprehensive public health approaches are needed.
Thank you.

Opinions are my own and may not reflect those of NPHL or NHelP.
Chronic Pain Management Rulemaking in Washington
Children’s Safety Network Webinar
July 16, 2012

Kristi Weeks, Director, Office of Legal Services, Washington Department of Health
Purpose of the Rules

The 2010 Legislature passed ESHB 2876 in response to concerns about prescribing opioids for chronic noncancer pain management:

• Opioid prescribing overall is on the rise

• Opioid related deaths and overdoses are on the rise

• High profile regulatory actions
Requirements

Five boards and commissions must adopt pain management rules which include:

- Dosing criteria
- Exceptions
- Methods to enhance the availability of consultations
Requirements

• Guidance on tracking clinical progress
• Guidance on tracking the use of opioids
• Minimizing burden on practitioners and patients
Partners

The boards and commissions must consult with the:

- Agency Medical Director Group (AMDG)
- University of Washington
- Largest state professional association for each of the regulated professions
Exemptions

- Cancer related pain
- Palliative, hospice, or other end-of-life care
- Management of acute pain caused by an injury or a surgical procedure
- Mandatory consult with minimum training
- Repeated consultations for stable/ongoing course of treatment
Collaborative Workgroup

- Included members from each of the five boards and commissions
- Held five public workgroup meetings between June and October 2010
- Provided opportunities for stakeholder input
- Reached consensus for a single set of pattern rules
Final Rules

• Meet all the mandated elements

• Include guidance on “best practices”

• Encourage the use of the prescription monitoring program

• Effective for all boards and commissions July 1, 2011, except the Medical Commission (January 2, 2012)
Challenges

- Practitioners want autonomy when treating patients
- Practitioners and patients perceive interference with practitioner/patient relationship
- Practitioners fear disciplinary action for the slightest violation of the rules
- Patients fear they will lose access to medication
- Lack of pain management specialists
Legislative Follow-up

• Legislators heard concerns from practitioners, patients and professional associations
• Several informal meetings with individual Legislators
• Formal presentations:
  • House Health Care and Wellness Committee on April 6, 2011
  • Senate Health and Long-Term Care Committee on December 14, 2011
Next Steps

• The boards and commissions continue to work with the professional associations to provide education to practitioners

• The department is providing educational tools for practitioners and patients:
  • Informational brochures
  • Ongoing updates to the pain management webpage
Current Information Available

- Department of Health Pain Management web page:
  http://www.doh.wa.gov/hsga/Professions/PainManagement/
- Links to existing rules and ESHB 2876
- FAQs
- Patient brochure
- Practitioner resources
PUBLIC HEALTH
ALWAYS WORKING FOR A SAFER AND HEALTHIER WASHINGTON
Prescription Drug Overdose Prevention: State Level Legal Strategies

http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws/index.html
Thank you for joining us!

Please let us know if you are interested in working with CSN and a few states in a more interactive way to address the issue of neonatal abstinence or withdrawal syndrome.

Also, please let us know if you have ideas (either specific topics or speakers) for future webinars on Preventing Prescription Drug Abuse.

Contact for both: crodgers@edc.org

Please complete the evaluation of today’s session.