Addressing legal barriers to naloxone access

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Overview of legal environment

- Prescribing naloxone to own patient is fully consistent with state and federal law
- Risk of liability no higher than with any other medications, and likely lower than some
- Many states have passed laws increasing access and reducing liability risk
- However, prescription requirement remains significant barrier
Naloxone prescribing

- Generally applicable law and regulation require that any prescription be issued:
  - In good faith
  - In the usual course of professional practice
  - For a legitimate medical purpose

- Naloxone prescription issued to own patient meets all three criteria
Shortcomings of traditional system

- Traditional prescription regime fails many of those most at risk
  - Expense of health care visits and naloxone, particularly for uninsured/underinsured
  - Stigma, fear of losing access to opioid medication
  - Difficulty in getting/keeping appointments
  - Lack of provider knowledge/comfort with naloxone prescribing and dispensing
  - Liability concerns
State response

In absence of federal action, states have modified law to increase access to naloxone

- Permit prescriptions to third parties
- Permit prescription and dispensing by standing or protocol order
- Provide civil and professional immunity to prescribers, dispensers, and administrators
- Permit lay dispensing and administration
- Provide protections for Good Samaritans who report overdose
- Expand first responder scope of practice to include naloxone
State response

- Third party prescribing/dispensing
  - Permits the prescription and dispensing of naloxone to a person other than the person at risk of overdose
  - 38 states permit as of June 22, 2015

- Prescribing by standing or protocol order
  - Permits the dispensing of naloxone to persons who meet specified criteria, instead of named individual
  - 28 states permit as of June 22, 2015
State response

- **Reduced liability for prescribers, dispensers, administrators**
  - No evidence that naloxone prescription or dispensing is any more risky than other medications, but concern may alter behavior
    - 34 states provide immunity to prescribers or dispensers as of June 22, 2015
    - 30 states provide immunity to administrators as of June 22, 2015

- **Good Samaritan provisions**
  - Provide limited criminal immunity to witness who summons aid in event of overdose emergency, as well as victim
    - Becoming more comprehensive – probation, parole
    - Important to educate and inform
  - 30 states provide as of June 22, 2015
State response

- Add naloxone administration to first responder scope of practice
  - In most states, naloxone administration was confined to paramedics
  - States are rapidly permitting EMTs, law enforcement, and firefighters to administer naloxone
  - Variety of mechanisms being used, including specific law, general law, regulation, and existing authority

- Explicitly permit lay distribution
  - Practice is widespread, but explicit authorization is not
  - Important for individuals who are separated from traditional care system
States with naloxone access and drug overdose Good Sam laws

States with drug overdose Good Sam laws only

States with naloxone access laws only
Shortcomings of state action

- These changes are welcome, but inadequate

- Most continue to require prescriber, pharmacist, or both
  - Many at-risk people do not access medical system
  - Community distribution is both feasible and cost-effective

- State-level change is time-consuming, imperfect, and often confusing

- States are laboratories of democracy, and over 80% permit naloxone to be accessed outside of the traditional prescriber/patient relationship
Number of states with naloxone access laws

![Graph showing the number of states with naloxone access laws from 2010 to 2015. The graph includes two categories: Good Sam and Naloxone.]

- **2010**: 0 states
- **2011**: 5 states
- **2012**: 10 states
- **2013**: 15 states
- **2014**: 20 states
- **2015**: 30 states

*Legend:*
- **Good Sam**
- **Naloxone**
Federal action welcome but insufficient

- FDA has been proactive in speedily approving auto-injector and expediting review of nasal formulations

- NIDA has provided millions of dollars for development of intranasal product

- These advances are welcome, but high cost of new formulations places them out of reach of many uninsured, underinsured, and community distribution programs
Move naloxone OTC

- Process can be initiated via citizen petition, manufacturer request, or Commissioner action
  - Consumer behavior, safety, and efficacy must be shown, but a great deal of data already exists
    - Efficacy beyond dispute
    - No known contraindications; very good safety profile
    - No negative effects if given when not indicated
    - Tens of thousands of lay reversals
  - Label would need to be consistent with lay administration
    - Has already been created for auto-injector
  - Insurance coverage concern, but coordinated federal action can address
Other agencies

- **CDC**
  - Fund education, evaluation, and access

- **DEA**
  - Require providers to obtain education in evidence-based opioid prescribing and naloxone co-prescribing as condition of granting DEA #

- **NIH**
  - Provide funding for naloxone purchase
    - Must not be limited to first responders
  - Provide funding for evaluations to determine best practices
  - Provide funding for easy-to-use formulations, require that they be OTC or provided to CBOs at no or minimal cost

- **ONDCP**
  - Encourage passage of and education on comprehensive Good Samaritan laws
**Congressional action**

- **Possibilities are essentially limitless**
  - Require FDA to conduct review, and provide funding for necessary studies
  - Require drug or formulation be made OTC
  - Explicitly permit community distribution
  - Require Medicaid, Medicare, Exchange plans to cover naloxone – even if OTC
  - Provide sufficient funding to provide naloxone to those who cannot afford to pay
  - Remove criminal barriers to calling for assistance
  - Reform punitive drug laws
  - Provide funding for evidence-based drug treatment
Conclusion

- Overdose is a medical emergency

- Rise in overdose deaths has been described as an “epidemic” by CDC, FDA, HHS, ONDCP, WHO, etc.

- Laws and policies that make it easier for lay people to access naloxone, administer naloxone, and summon emergency assistance in the event of overdose save lives and resources

- States are doing what they can, but robust action by federal government is necessary and overdue

- Inaction is literally costing lives
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