

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

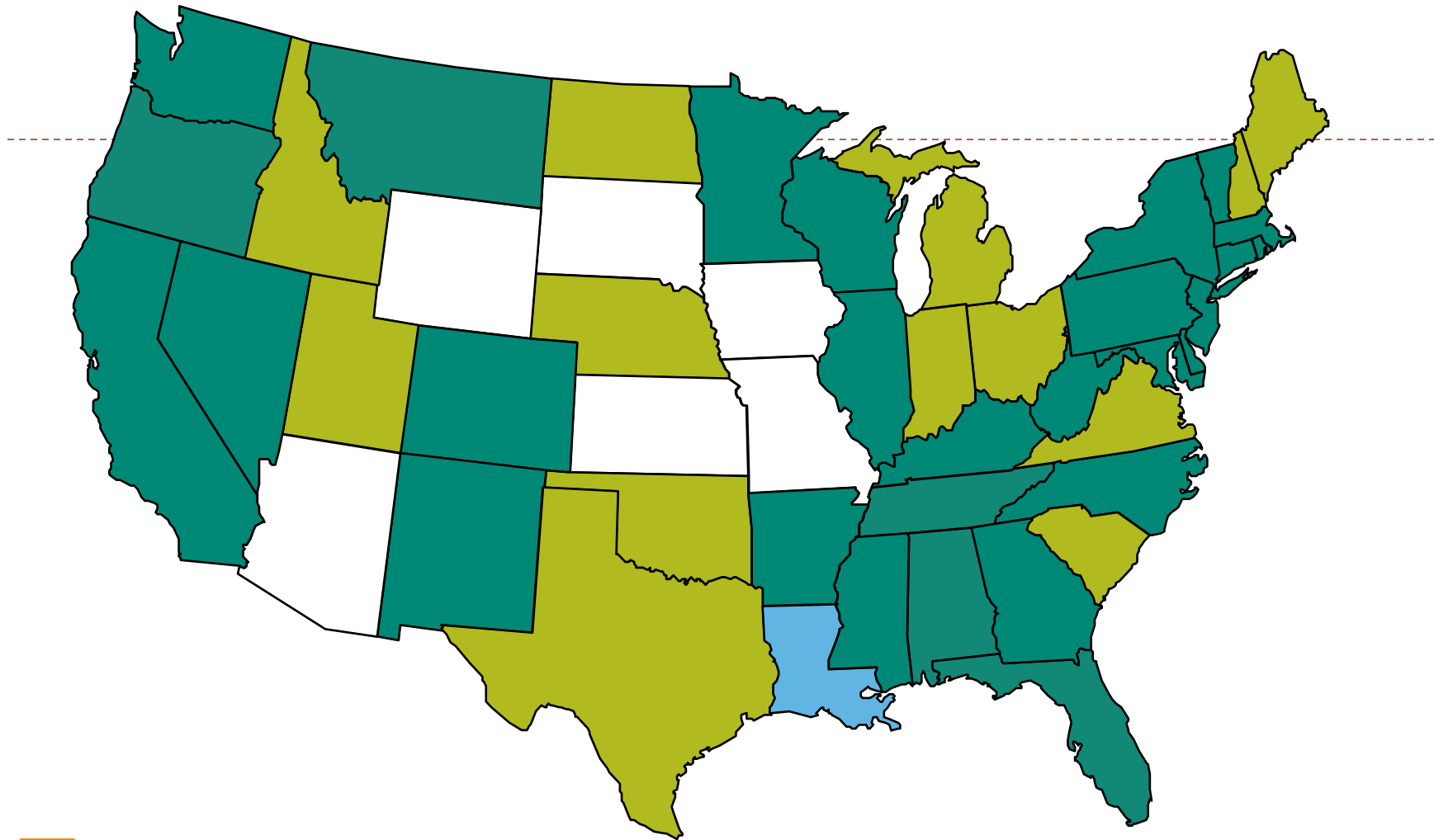
- ▶ **Reduced liability for prescribers, dispensers, administrators**
 - ▶ No evidence that naloxone prescription or dispensing is any more risky than other medications, but concern may alter behavior
 - ▶ 34 states provide immunity to prescribers or dispensers as of June 22, 2015
 - ▶ 30 states provide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



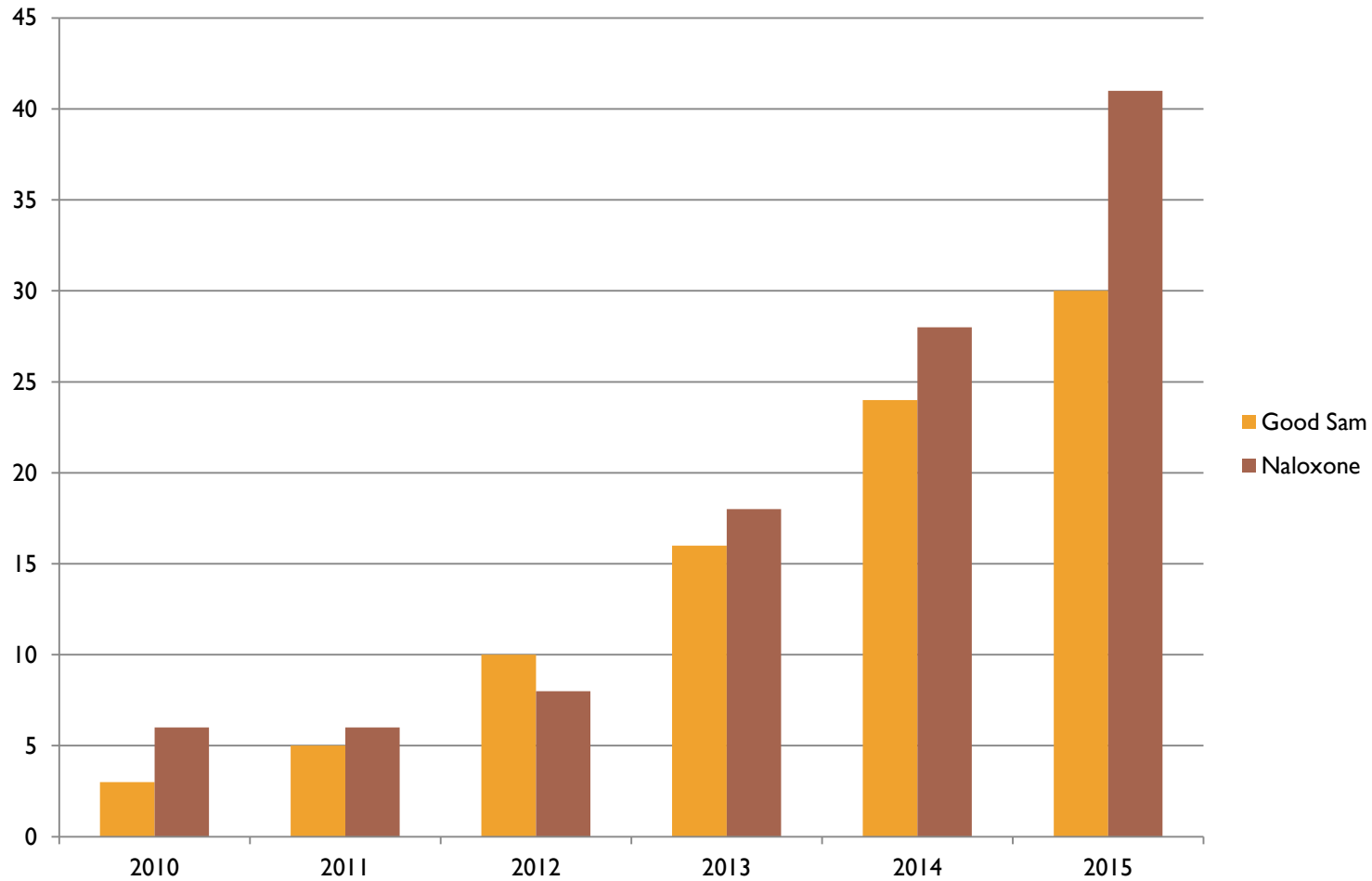


-  States with naloxone access and drug overdose Good Sam laws
-  States with drug overdose Good Sam laws only
-  States with naloxone access laws only

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
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Number of states with nlx access laws



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



FDA

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
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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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