Model Universal Access to Naloxone Act - NASEMSO Medical Directors Council Comments (as of July 9, 2018)

SECTION V. CO-PRESCRIBING OF NALOXONE.
All prescribers within [state] shall co-prescribe naloxone whenever they prescribe a schedule II, III, or IV opioid to a patient. Where the prescriber has issued to the same patient a co-prescription for naloxone within the past 12 months, the prescriber may, but is not required to, issue an additional co-prescription for naloxone.

Comments: The majority of overdoses are not from prescription opioids. It is unnecessary to mandate co-prescribing of naloxone every time a patient is prescribed a schedule II, III, or IV opioid. For example, a patient who is prescribed a limited number of doses of an opioid pain medicine (e.g., 3-day supply) may not be a candidate, whereas a patient with a chronic condition and is using various types of pain meds may need the co-prescription. Required co-prescribing of naloxone could exacerbate naloxone shortages.

SECTION XI. PUBLIC EDUCATION PROGRAMS.
In conjunction with the issuance of a statewide standing order under this Act, the [state health department, single state authority on drugs and alcohol, and/or other appropriate party] shall:

(a) Promote the safe and effective use and administration of naloxone by all [state] residents, as set forth in this Act;
(b) Identify resources for and develop a public education program that trains all [state] residents about the need to carry naloxone, how to identify an overdose, the process for administering naloxone, and the necessity of immediately calling 911 upon encountering an overdose;
(c) Identify resources for and develop an educational program that trains all [state] law enforcement, probation, parole, and correctional officers on the importance of encouraging individuals to call 911 upon encountering an overdose, including utilizing discretion in arresting and charging such individuals for minor crimes and offenses so as to not deter 911 calls;
(d) Identify resources for and develop an educational program addressing the recommended procedures to limit first responders' potential exposure to the drug(s) involved in an underlying overdose;[1] and
(e) Establish or promote the development of community-focused organization naloxone access programs. At a minimum, such access program shall offer participants an approved training and education program as part of the program of naloxone distribution.

Comments: Knowing how to perform cardio pulmonary resuscitation (CPR) is as important as knowing how to administer naloxone to a patient who has stopped breathing. All naloxone education programs must include basic airway management and CPR training. If the overdose victim is in cardiac arrest, the naloxone will not be effective alone. Effective CPR can move the naloxone through the victim's body and help restore breathing.

SECTION XII. NEW OPIOID OVERDOSE REVERSAL DRUG.
In the event that the Food and Drug Administration (FDA) approves a new opioid overdose reversal drug, the provisions of this Act shall be applicable to such drug.

Comments: While naloxone has been in use for more than 40 years, and we know that it is non-addictive and has no known potential for abuse (other than use in conjunction with opiates), we cannot presume that will be the case with any future drug that comes on the market with opioid antagonist features.

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1 Recommended procedures should address both first responders and service animals working for first responders who may also come into contact with the drug(s) causing the overdose.

SECTION XIV. INSURANCE COVERAGE FOR NALOXONE.

(a) Every individual or group health-insurance contract, plan, or policy that provides prescription coverage that is delivered, issued for delivery, amended or renewed in [this state] on or after _____, including both state Medicaid programs and private health insurance plans, shall provide coverage for naloxone, as a nasal spray, an auto-injector, or both.

(b) The coverage provided under subsection (a) shall include both the naloxone product itself, any necessary administration supplies, and any reasonable pharmacy administration fees related to the dispensing of naloxone and provision of overdose prevention consultation. This coverage also must include refills for expired or utilized drugs.

(c) The coverage provided under this section shall not be subject to prior authorization.

(d) The coverage mandated by this section shall include naloxone that is intended for use on persons other than the insured.

Comments: it is recommended that state officials negotiate a cap on the cost of naloxone to first responder agencies (EMS, law enforcement, fire). This was done in Ohio when public naloxone laws were enacted.

SECTION XIII. CONSENTS.

(a) The attending physician in an emergency department, or the physician's designee, shall make reasonable efforts to obtain a signed patient consent to disclose information about the patient's opioid-related overdose to family members or other medical professionals involved in the patient's health care.

(b) If consent cannot practicably be provided because of the patient's incapacity or a serious and imminent threat to a patient's health or safety, the physician, or physician's designee, may disclose information about a patient's opioid-related overdose in compliance with applicable privacy and confidentiality laws and regulations.[1] Such laws include:

(1) the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191 (Aug. 21, 1996);

(2) 45 C.F.R. parts 160 and 164 (HIPAA Privacy and Security Rules);

(3) federal confidentiality law and regulations, 42 U.S.C. § 290dd-2, 42 C.F.R. Part 2; and

(4) any relevant state law related to the privacy, confidentiality, and disclosure of protected health information.

Comments: It would be preferable that the language require healthcare institutions and not individual physicians to have programs to reduce opioid death. To put this on the individual physician without the support of the institution where they work places the physician in an untenable situation.

SECTION XV. DATA COLLECTION AND EVALUATION.

(a) Notwithstanding any other law or regulation to the contrary, it is hereby directed that the [state prescription drug monitoring program] is authorized and required to collect certain information about the dispensing and administration of naloxone as provided for in this section.

(b) Collection of naloxone dispensing data.[2]

(1) Effective [date], all dispensers within [state] must submit naloxone dispensing information to the [state prescription drug monitoring program] as described further in this section.

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2 State health departments and agencies implementing statewide standing orders want naloxone dispensing information in order to determine the effectiveness of the standing order as well as to identify locations that lack pharmacies dispensing naloxone. For these purposes, the data does not need to be patient identifiable and should be aggregated by the geographic unit at the county level or below.

(2) The [state agency that regulates prescription drug monitoring programs] is directed to promulgate rules and regulations [by date] that will govern the methods and procedures for dispensers to submit this information.

(3) The information collected regarding dispensing of naloxone shall be for statistical, research, or educational purposes only. The rules and regulations developed pursuant to subdivision (b)(2) shall require the removal of patient, recipient, or prescriber information that could be used to identify individual patients or recipients of naloxone.

(c) Collection of naloxone administration data.[3]

(1) Effective [date], all agencies employing first responders within [state] must submit naloxone administration information to the [state prescription drug monitoring program] as described further in this section.

(2) In any case where a first responder encounters someone that he or she believes: (1) is undergoing, or has immediately prior experienced, an opioid-related drug overdose; or (2) died as a result of using a narcotic drug; the first responder's agency shall report to the [state prescription drug monitoring program] all of the following:

i. The name and date of birth of all of the following, if applicable:
   (A) The individual who experienced an opioid-related drug overdose;
   (B) The individual who died as a result of using a narcotic drug;
   (C) The individual for whom a prescription drug related to an event under (A) or (B) was prescribed;

ii. The name of the prescriber, the prescription number, and the name of the drug as it appears on the prescription order or prescription medicine container if a prescription medicine container was in the vicinity of the suspected drug overdose, or death.

(3) The [state agency that regulates prescription drug monitoring programs] is directed to promulgate rules and regulations [by date] that will govern the methods and procedures for agencies employing first responders to submit this information. The information collected shall be used by prescribers and dispensers on a need-to-know basis for purposes including improving patient health care by facilitating early identification of, and intervention with, patients who may be at risk for addiction, or who may be using, misusing, or diverting drugs for unlawful or otherwise unauthorized purposes.

(4) The collection and submission of this information to the [state prescription drug monitoring program] by agencies employing first responders does not afford such agencies any additional access to the [prescription drug monitoring program] information other than what is allowed pursuant to [state law laying out access rights to PMP information].

(d) The collection and submission of information by dispensers and agencies employing first responders to the [state prescription monitoring program] does not in any way change the protections afforded by this Act and [state Good Samaritan law(s)] to individuals suffering overdoses and individuals who call 911 or assist in the administration of naloxone.

(e) The [insert appropriate state health department/agency] shall evaluate the data collected pursuant to this section in conjunction with other applicable, available data, and annually report to [insert appropriate state policy bodies, e.g., governor's office, state legislature] all findings and recommendations relevant to the development and implementation of state policy regarding opioid-related overdoses, naloxone access and distribution, prescription drug abuse, addiction, and diversion, and evidence-based public health interventions.

Comments: While the need for data collection is appreciated, the requirement for first responder agencies to report details about all naloxone administrations and the patient is more difficult than it may

3 Healthcare professionals want naloxone administration data because it can be clinically relevant to decisions regarding a patient's care. In order to be useful, the data must be patient identifiable, and ideally, would be included in a tool that the practitioner uses as part of their clinical decision-making process. While a prescription monitoring program is one of several such tools, it presents the most established interface between law enforcement / first responders and healthcare professionals.

appear. Some of this information would be available from the patient care reports but not all first responder agencies may collect this level of detail.

Overall: Rather than proposing a law for all states to enact for universal access to naloxone, the same purpose could be accomplished by requesting the FDA to reclassify naloxone as an over-the-counter medication (especially given its 40 years of use with no adverse consequences). This might also have the benefit of significantly reducing the price of naloxone.