**The Recommendation of the National EMS Advisory Council (NEMSAC)
in response to:
National Highway Traffic Safety Administration's (NHTSA) questions regarding Naloxone and National EMS Scope of Practice Model that were submitted to NEMSAC on March 10, 2016**

This response is to the NHTSA's inquiry of the NEMSAC, which reads in pertinent part as follows:

> *Should NHTSA immediately revise the National EMS Scope of Practice Model to add the administration of narcotic antagonists to the Emergency Medical Responder (EMR) and Emergency Medical Technician (EMT) scopes of practice?*
>
> *If so, what supporting materials would States need to implement a change in their scopes of practice?*

The NEMSAC supports the need for the National EMS Scope of Practice Model (SOPM) to be modified to include the administration of narcotic antagonists at all levels of providers; however, this revision should occur during the next SOPM update. An established process to emergently revise and distribute the SOPM does not currently exist. Were this process in place, the NEMSAC would recommend the immediate amendment of the SOPM to include the administration of narcotic antagonists at all levels of providers within appropriate clinical parameters and necessary practitioner education.

Without an established urgent update process, the NEMSAC recommends the review of the expansion of the SOPM to include naloxone administration by EMRs and EMTs as one of the priorities during the next SOPM update. The rationale for this recommendation is two-pronged.

First, and most importantly, the SOPM was designed as minimum standards for provider practice at each EMS level. There is nothing in the SOPM that prevents states from choosing to expand provider practice and incorporate naloxone administration at any provider level at any time. It should be noted that a number of states have already done so.

Second, there is no existing process to emergently revise and distribute the SOPM in an expeditious, yet still thoughtful, evidence-supported manner that would lead to rapid adoption and implementation of any amendments, including naloxone administration, at the state level. Ultimately, the states retain the authority and responsibility for the determination of the provider scope of practice within their jurisdictions and must make changes they deem necessary and appropriate using their individual state's processes.

Based on the current structure and framework, the NEMSAC offers these additional recommendations:

1. The NHTSA's Office of EMS should provide guidance to the upcoming Scope of Practice Model update to specifically address the issue of naloxone administration at all levels of EMS providers.

2. The NHTSA's Office of EMS and FICEMS should fund the creation of an evidence-based guideline regarding naloxone administration for both medical and nonmedical (i.e. police, firefighter, layperson) responders that addresses naloxone administration by medical personnel, first responders with a duty to act, and laypersons. Specific areas that should be incorporated include, but are not limited to:

    a. Enumeration of specific risks and benefits of immediate versus deferred naloxone administration
    b. Specific clinical effects, side effects, and adverse reactions in patients following the administration of naloxone potential hazards to the rescuer
    c. Avenues to mitigate adverse consequences and hazards to the patient and to the rescuer
    d. Critical airway management interventions
    e. Supportive options for the patient if naloxone is unavailable or ineffective
    f. Linkage to preventive, educational, and rehabilitation resources

    The referenced Substance Abuse and Mental Health Services Administration (SAMHSA) and Emergency Nurses Association (ENA) toolkits address many of these items and could potentially be utilized or adopted for this purpose.

3. The NHTSA's Office of EMS should develop a defined process for the identification of significant gaps in patient care or essential psychomotor skills for EMS providers. To accompany this gap identification process, NHTSA's Office of EMS should develop a designated pathway through which future evidence-based urgent or emergent amendments can be made to the Scope of Practice Model and other similar programs prior to a planned revision cycle.

4. A committee of EMS stakeholders and the appropriate subject matter experts should review this new process after it is developed, address periodic SOPM change requests, and provide timely response from the NEMSAC and other partners in the future.

5. The NEMSAC and the FICEMS should create and issue a consensus statement to be broadly distributed to EMS and related emergency responder stakeholder groups (including law enforcement) to clarify the details of the NEMSAC's position on the issue of naloxone administration.

6. The FICEMS should consider recommending that the FDA prioritize prescription to over-the-counter dispensing in the future development of naloxone products.

7. The NHTSA and the FICEMS should fund quality research to evaluate the impact of naloxone administration by medical and nonmedical responders on individual patient populations and the public as a whole.

DISCUSSION:

The National EMS Advisory Council strongly supports broad access to naloxone administration for both medical and nonmedical responders as a temporizing measure while the country grapples with the complex issues surrounding prescription and illicit opioid addiction and intentional and inadvertent overdose.

While naloxone provides rapid reversal of opioid-induced respiratory arrest, it does not in any way address the complicated underlying issues of accidental or intentional misuse, abuse, and addiction associated with narcotics. Furthermore, use of naloxone does not address the treatment of addiction at the individual or population level. As a result, it is critical that naloxone administration be paired with robust public health initiatives and emergency medical care linkages to community support, rehabilitation options, and long-term follow-up for these patients. The widespread provision and increased access to naloxone for the immediate reversal of opioids without engagement of the patient into a definitive and effective process or mechanism to treat the underlying opioid misuse, abuse, and addiction is not in the public's best interest long-term.

In addition, currently, there is no research that demonstrates a long-term benefit or change in short- or long-term morbidity and mortality of any given subgroup of patients or to the general public to whom naloxone has been administered. While the administration of naloxone may stem the immediate mortality of an individual or sector of a community, the root cause will persist unimpeded without a comprehensive treatment plan for the accidental or intentional misuse, abuse, and dependence related to narcotics. It is essential that research validate the impact of this intervention on long-term outcomes including morbidity, mortality, and recidivism. The current recommendation for widespread naloxone administration is considered an expert consensus based on observational studies, but has yet to be supported by scientific/quality evidence-based data or research.

Due to the urgent state-level need for action and implementation, the NEMSAC emphatically encourages states to promptly and carefully examine the issues surrounding narcotic overdose and death in their jurisdiction. As the vast majority of state EMS offices have already done for their EMS systems, states should strongly

consider the prompt amendment of their respective state statutes and/or regulations to facilitate the systematic promotion of broad naloxone access and administration and the implementation of measures to prevent and treat opioid misuse, abuse and addiction within all sectors of the healthcare system and the general public.

LITERATURE REVIEW

1. Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality, Am Journal of Public Health, March 2009, Vol 99, No 3, pp 402-402.
2. Saved by the Nose: Bystander-Administered Intranasal Naloxone Hydrochloride for Opioid Reversal, Am Journal of Public Health, May 2009, Vol 99, No 5, pp 788-791.
3. Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis, BMJ 2013;346:f174 doi: 10.1136/bmj.f174 (Published 31 January 2013).
4. Community-Based Opioid Overdose Prevention Programs Providing Naloxone – United State 2010, MMWR Weekly, February 17, 2012, Vol 61, No 6, pp 101-105.
5. Overdose: A Major Cause of Preventable Death in Central and Eastern Europe in Central Asia: Recommendations and overview of the situation in Latvia, Kyrgyzstan, Romania, Russia and Tajikistan, Philip Coffin for the Harm Reduction Knowledge Hub for Europe and Central Asia, Eurasian Harm Reduction Network (EHRN) August 2008.
6. Reducing Opioid Overdose through Education and Naloxone Distribution, APHA Policy Statement LB-12-02 – Preventing Overdose Through Education and Naloxone Distribution, 2016.
7. Substance Abuse and Mental Health Services Administration's (SAMHSA) Opioid Overdose Prevention Toolkit. Web search on July 26, 2016: http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2016/SMA16-4742 .
8. Emergency Nurses Association (ENA) Emergency Department Safety Naloxone Education Toolkit. http://www.ena.org/. 2016.