

October 27, 2012

Re: Drug Shortages and Give Life a Chance Law

Greetings Medical Directors,

As you all know there have been shortages of many drugs in the Pharmaceutical Industry. In the last few years many of the medications we use in EMS are not always available. This is not just a problem in Minnesota, but nationally and it is not going to improve but may get worse. There are ongoing discussions with Pharmaceutical Companies, the FDA, ACEP, and many other medical organizations to identify the source of these issues, make policy to adapt to these shortages and ultimately find a solution. Until then we will continue to have intermittent shortages of medications with often very little notice.

Many other states are having significantly more problems with the shortages than Minnesota. These states have the drugs that an ambulance, ALS or BLS, carry listed in law. Oregon has developed a process whereby the Ambulance Service may receive permission to use an alternate drug or an expired medication. The FDA was asked for their opinion and has been silent in an official capacity. They did however respond to an email to another state medical director stating that "an expired medication is considered adulterated" and not to be used. A copy of this email as well as other information cited in this letter is attached.

The EMSRB has received a number of questions regarding the use of expired medications when that medication is not available due to a shortage. The MDSAC met in September to discuss this issue. Pam Biladeau and I have had discussions with the Attorney General's office and Cody Wiberg the Director of the Minnesota Board of Pharmacy, as well as other interested parties. There is definite opposition to using expired medications from some venues. The FDA has set the expiration dates and defines expired medications as adulterated and not to be used. That will not change in the near future. Minnesota has numerous laws regarding the expiration date that would need to be changed. There are also many medico-legal implications in the use of expired medications and their efficacy in the case of a bad outcome. Was it the expired medication or the disease process? Also, there is not always data on how long the medication is expired and its effect on the efficacy. There was an article in the "The Medical Letter, On Drugs and Therapeutics" that indicated many medications have a much longer shelf life at satisfactory efficacy. Storage of the medications is also a factor: multi-dose vial now open or single use package intact, stored at the appropriate temperature, etc.

We have a unique situation in Minnesota in the autonomy of our Medical Directors. The State does not set out policy, protocols or dictate the medication that is on an ambulance except for minimum equipment. The Medical Director has the authority to change medications in reaction to the shortages at a moment's notice. The MDSAC was presented the research and information accompanying this letter. The following was recommended to the EMSRB and accepted:

The Minnesota EMSRB has the following statement regarding the use of expired medication:

1. The EMSRB supports the National efforts to find a broad resolution to the problem of medication shortages.
2. The EMSRB encourages the local Medical Director to prepare and adopt protocols in anticipation of shortages of medication.

*"To provide leadership which optimizes the quality of emergency medical care for the people of Minnesota -- in collaboration with our communities -- through policy development, regulation, system design, education, and medical direction"*

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3. The EMSRB recognizes the final decision will rest with the local EMS Medical Director as established by Minnesota State Statute after weighing the risks and benefits to patients.

After presenting the MDSAC recommendation to the EMSRB at the next Board meeting it was decided that: the EMSRB Specialists will continue with assessment of medications and regulation as established and concerns will be directed to the CRP regarding expired drugs.

I have attached a list of resources to assist in decision making. Feel free to contact me through the EMSRB if you have questions or information ([melody.nagy@state.mn.us](mailto:melody.nagy@state.mn.us), 651-201-2802).

There has also been some new legislation regarding newborns. When a Mother decides to leave her newborn the ambulance is now considered a safe place along with the hospital and the police. Below I have included some information on that legislation and in this letter a copy of a flyer that can be used for education and information. It can also be found on the EMSRB website.

Dr. Mari Thomas, MD  
Chair MDSAC

Enclosures: Federal Drug Administration, e-mail March 30, 2012  
Federal Drug Administration, Title 21, Subchapter V

Resources:

1. National Association of State EMS Officials [www.nasemso.org](http://www.nasemso.org)
2. American College of Emergency Physicians [www.acep.org](http://www.acep.org)
3. 2011 Minnesota Statutes 151.35 <https://www.revisor.mn.gov/statutes/?id=151.35&format=pdf>
4. The Medical Letter, On Drugs and Therapeutics. Volume 51 (Issue 1327/1328), December 14/28, 2009, Published by The Medical Letter, Inc., New Rochelle, NY, [www.medicalletter.org](http://www.medicalletter.org).
5. Title 21 Food and Drugs, Subchapter V--Drugs and Devices, Part A, Statute 351 Adulterated drugs and devices, <http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapV-partA-sec351.pdf>, 10/24/2012.
6. Safe newborn legislation Minnesota State Statutes section 145.902 <https://www.revisor.mn.gov/statutes/?id=145.902>, 10/27/12.