Minnesota Emergency Medical Services Regulatory Board

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M E M O R A N D U M

Date: September 6, 2016

To: Ambulance Services and Medical Directors

From: Emergency Medical Service Regulatory Board

Re: Alternative to the Auto Injector for Administration of Epinephrine – BLS Ambulance Services

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Background:

The Minnesota Emergency Medical Services Regulatory Board (EMSRB) is very understanding of the current cost issues facing Basic Life Support (BLS) ambulance services with purchasing epinephrine auto-injectors for administration of life-saving medication to anaphylaxis (allergic reaction) patients.

By way of background, BLS ambulance services may seek a variance to carry and administer certain drugs, including premeasured subcutaneous epinephrine, under Minnesota Rule part 4690.8300, subpart 7 (if certain requirements are met by the licensee). The rule provides in relevant part:

> ***Variance for certain drugs.*** *The board shall grant a variance to a basic ambulance service licensee to carry and to administer… premeasured subcutaneous epinephrine….*

Nearly all BLS services in Minnesota possess a variance for premeasured subcutaneous epinephrine. In general, the interpretation of "*administer. . . premeasured subcutaneous epinephrine*" has been the use of an auto-injector, which by default has been and continues to be the EpiPen®. Due to significant cost increases for the Epi-Pen®, the EMSRB has been asked to clarify administration of a *"premeasured subcutaneous epinephrine"* dose to allow for alternatives to using the auto-injector.

Clarifications from the EMSRB:

In a letter to ambulance services and medical directors dated May 27, 2014, the EMSRB Medical Direction Standing Advisory Committee (MDSAC) provided the following clarification.

> *"The law does not allow EMT's to draw up a medication dose. They could draw up epinephrine into a syringe and give the medication if it were a single dose vial of medication. That would be similar to the glucagon kit where they draw up the saline, inject it into a vial of medication and then give that "premeasured" dose. The purpose of the premeasured dose is to eliminate a higher or lower dose of a medication being given in error. A single dose vial or a glucagon kit or EpiPen® has only one possible dose to give. No overdose potential.*
>
> *It should be noted that use of pharmacy pre-filled syringes is allowable as long as the syringes are obtained through a licensed pharmacy and have appropriate labeling with drug name, dose, expiration date and proper storage of the medication filled syringes is maintained."*

At its board meeting on March 17, 2016, the EMSRB passed the following motion:

> *"Dr. Burnett [Dr. Aaron Burnett, State Medical Director] moved to clarify the definition of premeasured medication to include a commercial premeasured auto-injector, unit dose vial, **or volume limited syringe** to allow a maximum dose of medication to treat the condition consistent with the service medical director guidelines." (emphasis added)*

Dr. Burnett further clarified the definition of a premeasured medication:

> *"The individual service medical director is the one who has final authority to approve the type of device used based on the interpretation of "premeasured" from the full board. Basically the syringe has to have the same volume as the volume indicated in the patient care guidelines for administration of epi. This is typically 0.3mg of 1:1000=0.3mL. Again, as different services may have a different epi dose the syringe needed has to be individualized to the individual service patient care guidelines. The length of the needle that is used etc., is at the discretion of the service medical director. If the service is not finding a device which fits their needs in a 0.3mL volume they could reach out to a syringe manufacturer and see if they would make them a device that would fit their needs."*

What this means for BLS ambulance services with a variance to carry and administer premeasured subcutaneous epinephrine:

- It is the Medical Director's call if the BLS ambulance service must continue to use:
  - an auto-injector (i.e., EpiPen®); or
  - a syringe with the same volume indicated in the patient care guidelines.

- If the Medical Director allows for the use of a syringe with the same volume indicated in the patient care guidelines:
  - The length of the syringe needle is at the discretion of the Medical Director.

- Please note that drawing up medication from its original container (e.g., vial) and using it at a later date on an unidentified patient is not allowed and is a violation of law.[1]

If you have any questions, please do not hesitate to contact EMSRB staff.

[1] Under Minn. Stat. § 151.01, subd.14, the drawing up of medication from its original container and using it at a later date on an unnamed patient constitutes "manufacturing" which only can be done by a pharmacy licensed by the Board of Pharmacy.