Medication Shortage

A. Definitions:

1. ***Alternate Concentration*** – same medication, different concentration, while volume may change, the delivered dose remains unchanged, dilution may be required (*Epinephrine 1: 10,000 replaced using Epi 1: 1,000 with a 10mL diluent)*
2. ***Alternate Supplied Volume –*** same medication, same concentration, standard volume is unavailable, the delivered dose and volume remain the same *(Epi 1: 1,000, typically supplied in a 1mL vial replaced with Epi 1: 1,000 in a 10mL multi-dose vial due to shortage of the smaller vials)*
3. ***Alternate Supply/Type –*** same medication, standard supply type is unavailable (preloads vs. vials), dosing remains unchanged *(diphenhydramine 50mg/5mL preload is unavailable, replaced with diphenhydramine 50mg/5mL in a vial)*
4. ***Alternate Form*** – same medication, different route such that identical dosing does not yield the same systemic concentration or effect *(ondansetron 4mg vial unavailable, replaced with ondansetron 4mg ODT, option to repeat x 1 added to allow approximation of equivalent dosing)*
5. ***Alternate Medications*** – medication other than the standard approved medication which accomplishes an acceptably similar effect as the medication it replaces *(fentanyl 100mcg approved to replace morphine 10mg, dosing adjusted to obtain therapeutic equivalency)*
6. ***Missing Medication*** – standard medication which is unavailable *(amyl nitrite not available, acceptable alternative of Cyanokit is excessive in cost and size: alternate means to access treatment established – MEDDRUN)*
7. ***Outsourced medications – Repackaged by a 340B or 503 B medications in the same concentration and volume that have at least a 90 day expiration date.***

B. Criteria:

1. Participating pharmacies be it at the individual MCA or at a wider regional level, shall establish and maintain a listing of the standard medications and supplies contained in drug bags or boxes supplied to life support agencies for the purposes of treating patients.
2. Each participating pharmacy shall maintain a dated listing of alternative medications which are approved as substitutes or replacements for medications which are in shortage.
3. Due to the frequency of medication shortages and the need for alternative dosing or medication substitutions, each MCA shall develop and enact a medication cross-check procedure, to which EMS personnel will be held accountable as a means to avoid medication errors
4. Both the standard list and the alternate list (may be combined into a single document) shall be made readily available to system participants
5. The participating pharmacy shall enact policies/procedures which guide each of the following:
   A. Recognition of medication shortages and a means to report them

B. Pharmacy involvement in the investigation and designation of acceptable alternatives when shortages are identified
C. An organized process by which participant pharmacies will enact the replacement or substitution
D. A documented means of visually identifying when an alternative medication or dosing has been placed into an EMS drug bag or box, or when a medication is missing
    a. ***Alternate medications*** will be indicated by the placement of a sticker, tag or label on the outside of the bag or box; on the compartment where the alternate medication is located (if applicable) such that one inspecting the bag or box could easily recognize that the medication was included and what the missing medication it is intended to replace was. (Stickers GREEN or WHITE with GREEN)
    b. ***Missing medications*** will be signified by the placement of a sticker, tag or label on the outside of the bag or box, on the compartment where the missing medication would be located (if applicable) such that one inspecting the bag or box could easily recognize that the medication was missing and what the potential alternate medication was. (Stickers YELLOW or WHITE with YELLOW)
E. A method for dissemination of information related to changes made to the participating pharmacy drug bags or boxes with a means of accounting for receipt of the notifications at the agency/pharmacy levels

C. Selection of Alternative Medications:

1. Alternative concentrations, alternative supply/type and alternative supplied volume may be approved at the MCA/participating pharmacy level without a change to protocol provided that the standard and approved alternate medications are documented in the required lists, by effective date or date range.
2. Alternate form and alternate medications may be enacted as an emergency protocol according to statute and state approval, in the event of imminent shortage.
3. Non-standard medications, or those with no precedence of EMS use within Michigan must be submitted as new protocol submissions. The state may allow for expedited review in the event of imminent shortage of the medication being replaced.
4. If a missing medication will not be replaced, or an acceptable alternative is not found, a protocol or process should be developed or presented which addresses the potential inability to meet the existing protocol established standard of care.

D. Process:

1. A brightly colored ALTERNATE DOSE sticker/tag MUST be attached to the outside of the drug bag, box or narcotics box that lists the effected medication, the concentration of the substituted medication, the expiration date of the medication and the pharmacy name/date.
2. A brightly colored – MISSING MEDICATION sticker/tag must be placed on bags/boxes when a protocol medication is not available to stock in that bag/box.

3. A dosing/instruction card may be required to be included in the bag/box depending on the change.
4. Pharmacies experiencing shortages must provide notification of the need to utilize alternate dosing to the MCA , and receive MCA approval, prior to any change being implemented.
5. Drug bags, boxes or narcotics boxes with alternate dose medications/missing medications should have the medication replaced and the sticker/tag removed by pharmacy as soon as possible when the proper medication or concentration of medication is available.
6. Any additional equipment, which is needed to deliver the medication, must be included with the alternate dose.
7. EMS Agencies receiving notice of the utilization of alternate dosing, alternate medications or missing medications due to shortage must post the changes and ensure that all providers that may have cause to use the medications are made aware of the changes and are educated on proper use, risk and dosing of any new or replacement medication prior to their first potential exposure to the alternate dose or medication.
8. Any Special Instruction for a particular shortage will be communicated to all effected pharmacies and EMS services.