

Reminder: Pharmaceutical Grade Refrigerators are Required for All Vaccine Storage Units (Primary and Secondary)

The *Guidelines for Compliance with Federal and State Vaccine Administration Requirements* state that the Massachusetts Department of Public Health (MDPH) requires all pediatric practices (any site that administers at least some vaccine to those <19 years of age, excluding flu only sites) to have pharmaceutical grade refrigerators for all refrigerated vaccine storage units in their facility. Stand-alone freezers that are not pharmaceutical grade will be acceptable as long as they maintain the proper storage temperature.

Although there is no specific description of a pharmaceutical grade refrigerator, some of the characteristics include:

- ✎ Internal overhead fans to disperse air throughout the unit, eliminating pockets of cold air
- ✎ Adjustable wire shelves to allow better air flow
- ✎ Electronic digital thermostat
- ✎ Micro processor
- ✎ Evaporator coil
- ✎ No storage bins, or shelves on door
- ✎ Typically, pharmaceutical grade refrigerators have a narrow operating range (varying by less than 2°C)

Listed below are a sample of manufacturers and distributors that you may wish to consider for safe vaccine storage in your practice. Please note that MDPH cannot endorse or recommend specific products or brands.

- Aegis www.aegisfridge.com
- American Biotech Supply www.americanbiotechsupply.com
- Fisher Scientific (Isotemp) www.fishersci.com
- Helmer www.helmerinc.com
- Migali Scientific Refrigeration www.migaliscientific.com
- Tempure www.tempurescientific.com

MDPH has determined that most standard domestic combination refrigerator/freezer units are inappropriate for vaccine storage. In addition, many stand-alone refrigerators that are not pharmacy grade lack the necessary features for the safe storage of vaccines. As a result, MDPH is requiring the use of pharmaceutical grade refrigerators for **all** refrigerated vaccine storage units. Providers identified to be storing any vaccine in non-pharmaceutical grade refrigerators will receive follow-up contacts to ensure that all storage units are in compliance. In addition, as part of the MDPH Restitution Policy, providers may be held financially responsible for vaccine loss due to negligence. This could be significantly more than the cost of a pharmaceutical grade refrigerator.

Exposing vaccines to freezing temperatures is the most common risk to the potency of refrigerated vaccines. It is impossible to visually determine if a vaccine has been exposed to a freezing temperature. If this vaccine were administered, it may not prevent the disease. MDPH wants to ensure this never happens. With the use of continuous temperature monitoring digital data loggers and the appropriate storage equipment, we can all be more confident with vaccine potency and efficacy.

If you have questions, please contact the Vaccine Management Unit at 617-983-6828.