

Reminder: Pharmaceutical Grade Refrigerators are Required for Primary Vaccine Storage Units in 2016

In the January 2015 *Guidelines for Compliance with Federal and State Vaccine Administration Requirements* document, it indicated that beginning in 2016 the Massachusetts Department of Public Health (MDPH) will require all pediatric practices (any site that administers at least some vaccine to those <19 years of age) to have pharmaceutical grade refrigerators for their primary vaccine storage unit 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 cold air throughout the unit, eliminating cold pockets of air
- Adjustable wire shelves to allow better air flow
- No storage bins, or shelves on door
- Typically, pharmaceutical grade refrigerators have a narrow operating range (less than 2 Celsius degrees or 3 Fahrenheit degrees)

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, through a grant funded by the Centers for Disease Control and Prevention (CDC), 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 the primary vaccine storage unit. Providers who do not transition to these refrigerators will be recorded as not meeting MDPH Immunization Program requirements during VFC provider site visits beginning next year. These sites will then be required to receive follow-up contacts to ensure an appropriate storage unit is obtained. 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 to be 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.