April 30, 2014

RE: Policy 0014-4 Vaccine Management – Thermometers

Dear Texas Vaccines for Children Provider,

The Texas Vaccines for Children (TVFC) Program would like to remind all providers of the requirements and recommendations for thermometer use for monitoring TVFC vaccine supply.

2014 Requirement

Providers enrolled in the TVFC Program are required to have calibrated thermometers with valid and up-to-date certificates issued either by an International Laboratory Accreditation Cooperation (ILAC) laboratory or, if not ILAC accredited, the certificate must contain measurement results and a statement indicating that it meets International Organization for Standardization (ISO) 17025 standards.

All certificates must contain:
- model number
- serial number
- date of calibration
- measurement results that indicate unit passed the test and the documented uncertainty is within suitable limits (recommended uncertainty = +/-1°F(0.5°C)

Providers are required to have thermometers that meet the criteria in all refrigerator and freezer compartments used for TVFC vaccine storage.

2014 Recommendations

The TVFC Program recommends the use of a digital thermometer with a biosafe glycol-encased probe that measures liquid temperature. Studies by the National Institutes of Standards and Technology (NIST) conducted in 2009 showed that compared to temperature monitors that measure ambient air temperature, a glycol-encased probe more accurately reflects the temperature of the vaccine vial and does not register extraneous air temperature fluctuations that do not impact vaccine temperature.

In addition to the use of a digital thermometer with a biosafe glycol-encased probe, the recommended temperature monitor should also be placed on the outside of the unit door to allow for reading temperatures without opening the unit door.
TVFC recommends that all enrolled providers have at least one back-up thermometer with a current certificate of calibration on hand (not stored in unit alongside current thermometer) for use when a thermometer in a storage unit unexpectedly stops working or when the thermometer needs to be sent for re-calibration. Please note: beginning January 1, 2015 this will become a TVFC Program requirement.

The use of a continuous temperature monitoring system provides more accurate and comprehensive monitoring of temperature excursions to which vaccines may be exposed. If a digital data logger is used, it must have the following capabilities:

- Detachable probe (kept in the glycol-filled bottle)
- Alarm for out-of-range temperatures
- Current temperature, as well as minimum and maximum temperatures
- Reset Button
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4000 readings (device will not rewrite over old data and stops recording when memory is full)
- User-programmable logging interval (or reading rate)

Thank you for your continued support of the TVFC Program. For any questions, please contact the appropriate Health Service Region below.

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Sincerely,

Saroj Rai, PhD
Immunization Branch Manager