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TO: Vaccines for Children Providers

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SUBJECT: Digital Data Logger Requirement 2018

The Louisiana Immunization Program would like to inform you of the new Vaccines for Children (VFC) Program upcoming requirements related to proper vaccine storage and handling practices. The VFC Program now requires the use of digital data loggers to monitor temperatures in all refrigerators and freezers storing VFC vaccine. The use of digital data loggers is required as they provide more accurate and comprehensive documentation of storage unit temperatures. This requirement becomes effective January 1, 2018.

The CDC and Louisiana Immunization Program require that thermometers include the following characteristics:

- Continuous monitoring information and recording capabilities where the data can be routinely downloaded
- Provides current, minimum and maximum temperatures that are easily readable from the outside of the unit
- Digital thermometer with an external probe in a glycol-filled bottle
- Alarm for out-of-range temperatures
- Accuracy within +/-0.5°C (+/-1°F)
- Low battery indicator
- Memory storage for at least 4,000 readings-stops recording when memory is full

For accurate measurement, set the data logger to record temperatures every 30 minutes.

Thermometer calibration must be tested annually or according to the manufacturer’s recommendation and the certificate of calibration must be kept in an accessible location. At a minimum, the calibration certificate must include the:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument in tolerance)
- Recommended uncertainty of +/-0.5°C (+/-1°F) or less

Back-up thermometers must have the same features and set-up (i.e. probe in buffer such as glycol). The back-up device should have a different calibration testing schedule so that the back-up is available when the primary is set for testing.

Even though the data logger is recording, the temperature will still need to be checked and recorded by office staff twice daily, along with the maximum and minimum temperatures. This can prevent inadvertent loss of vaccine and the potential need for revaccination by assuring that any temperature excursions are identified quickly so that immediate corrective action can be taken. Data logger temperature should be downloaded and reviewed weekly, then stored for at least 3 years.

The Louisiana Immunization Program requires that providers contact the vaccine’s manufacturer any time there is a temperature excursion with a follow-up call to your Regional Immunization Consultant or the Immunization Program at 504-568-2600. Additional information about temperature excursion will be available by the summer/fall 2017.

Neither CDC nor the Louisiana Immunization Program endorses a particular digital data logger brand. Please refer to the Louisiana VFC Thermometer guide at https://linksweb.oph.dhh.louisiana.gov/linksweb/docs/vfc/2017%20Louisiana%20VFC%20Thermometer%20Guide.pdf

If you have any questions or concerns about this new requirement, please contact your Immunization Program Consultant or the Immunization program at 504-568-2600.