#### Purpose

To provide a policy for Alabama vaccine providers planning and conducting school-located immunization clinics with VFC vaccine targeting school-aged children enrolled in elementary, middle, and high schools.

#### Glossary

ACIP- Advisory Committee for Immunization Practices ADPH – Alabama Department of Public Health ALSDE – Alabama State Department of Education CDC – Centers for Disease Control and Prevention DDL – Digital data logger SBVC – School-based vaccine clinics ILAC – International Laboratory Accreditation Cooperation ImmPRINT – Immunization Provider Repository with Internet Technology registry MRA – Mutual Recognition Arrangement NCVIA - National Childhood Vaccine Injury Act VFC – Vaccines for Children program VIS – Vaccine Information Statements

### 2018 SJR 113 School-based Vaccination Program Resolution

In March 2018, the Alabama State Legislature passed Resolution SJR113 urging ALDSE and ADPH to encourage all schools to participate in a school-based vaccination program or SBVC. These SBVC are to ensure more students are up-to-date on vaccines to reduce the cost, time, staff, supplies, and resources needed to respond to an outbreak. The SBVC attributes include:

- 1. The clinics are run by healthcare providers
- 2. Must offer both VFC and non VFC vaccine
- 3. Providers are responsible for insurance & consent
- 4. No cost to family and school
- 5. Must administer ACIP recommended vaccine
- 6. No child refused
- 7. Doses must be in registry (ImmPRINT)

The Alabama American Academy of Pediatrics and the Alabama American Academy of Family Physicians are requesting all SBVC providers to distribute information regarding the importance of teen well child visits. This information stresses adolescent children should have a medical home for continuity of care. Please see the enclosed Teen Well Visit flyer to be distributed with each SBVC consent packet distributed through students to the parents. To order the fliers, please contact AAP at (334) 954-2543.

### Procedure

1. VFC providers who meet the requirements outlined herein shall be authorized by the Alabama Department of Public Health to administer VFC vaccine at school-based clinics.

- 2. An emergency plan must be in place in the event of anaphylaxis or symptoms of immediate hypersensitivity following administration of the vaccine(s). Prior to the clinic, all school vaccine providers attending the clinic shall be familiar with the emergency procedures for anaphylaxis and the administration of epinephrine and diphenhydramine (Benadryl).
- 3. VFC providers must follow the VFC program requirements as outlined in the VFC provider profile that is signed each year.
- 4. Within 30 days or less of the scheduled SBVC, the parent/guardian shall be given the current VIS for the vaccine(s) to be administered. The NCVIA requires that patients (or their parent or legal representative) be given, or shown, a copy of the appropriate VISs prior to receipt of any vaccine listed on the routine childhood immunization schedule.
- 5. Within 30 days or less of the scheduled SBVC, the parent/guardian shall be sent a consent form for their child to receive vaccine(s). By use of the provider consent form, the school vaccine provider shall obtain a vaccine history in ImmPRINT to determine the number of vaccines appropriate for each child.
- It is strongly encouraged all SCVC providers also distribute AAP/AAFP's Well Visit Flyer in the initial packet sent to parents. To order the fliers, please contact AAP at (334) 954-2543.
- 7. VFC providers must look into ImmPRINT to determine what ACIP recommended vaccine to administer for each student. All ACIP vaccine(s) should be offered to VFC children served during the clinic.
- 8. Providers should follow all contraindications/precautions listed on the VIS for each vaccine offered.
- 9. The SBVC provider's consent form shall include the following:
  - a) The vaccine recipient's name, address, telephone number, date of birth, and name of his/her primary healthcare provider.
  - b) List all ACIP vaccines from which parents/guardians can select.
  - c) The signature of the parent/guardian indicating consent for the vaccine administration and allowing parents to decide which vaccine their child will receive.
  - d) VFC eligibility status no VFC-eligible child may be turned away due to their eligibility status or the parent/guardian's inability to pay.
  - e) Insurance category including space for name of insurance carrier and policy number.
  - f) The name of the vaccine, dosage, manufacturer, lot number, site of injection, and expiration date.
  - g) The signature of the provider administering the vaccine(s).
  - h) The date of the administration of the vaccine(s).
- 10. A copy of each individual consent form shall be retained by the provider for a minimum of ten years.

11. All vaccines administered during a school-based immunization clinic must be entered into ImmPRINT within 72 hours.

### **Storage and Handling of Vaccines**

- 1. All VFC vaccine doses ordered and purchased through CDC's federal vaccine purchase contracts will be distributed via CDC's centralized distributor. VFC vaccine will only be sent to VFC providers, not to depots for further distribution.
- 2. VFC providers must be an active VFC provider's office and must have an individual who is responsible for proper vaccine storage and handling on site.
- 3. Vaccine should be moved and handled as infrequently as possible. A location in closest proximity (i.e., same county) to the school will reduce the risk of compromising the cold chain.
- 4. If stored at an off-site facility, vaccine must be stored at an enrolled and active VFC provider office within the same county where the mass/SBVC clinics are being held.
- 5. The VFC provider will be responsible for maintaining the vaccine and performing all VFC requirements, including proper storage and handling procedures.
- 6. If vaccines must be transported to an off-site facility, the amount of vaccines transported should be limited to the amount needed for that workday to avoid potential loss of vaccines. Vaccines should be:
  - a. Attended at all times during transport.
  - b. Not placed in the trunk of the vehicle.
  - c. Delivered directly to the facility.
  - d. Promptly unpacked and placed into appropriate storage units upon arrival unless transported in CDC recommended portable refrigerator units.
  - e. Returned to the VFC provider's office for storage at the end of the clinic day.
- All neglected VFC vaccine is subject to the VFC Replacement Policy published in April 1, 2018, <u>http://www.alabamapublichealth.gov/immunization/assets/AL\_VFC\_Replacement\_Policy.pdf</u>.

# **Packing Vaccines for Transport**

- 1. CDC recommends transport with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls may be used if it can maintain the recommended temperature range (between 36° and 46°F [2° and 8°C]).
- 2. The packing of vaccines for transport consists of 6 layers (coolant, barrier, thermometer/vaccine, barrier, coolant, and barrier).
- 3. Packing instructions include:
  - a. Place a layer (at least 2 inches) of "conditioned" coolant packs in the transport container first. Coolant packs that are frozen must be "conditioned" by leaving them at room

temperature for 1 to 2 hours until the edges have defrosted and the packs look like they have been "sweating." Frozen coolant packs that are not "conditioned" can freeze vaccine.

- b. Place an insulating barrier on top of the coolant packs (e.g., bubble wrap or Styrofoam pellets).
- c. Place a digital data logger (with current calibration certificate) with a biosafe glycolencased thermometer probe on top of the barrier next to the vaccines.
- d. Stack the vaccines on top of the barrier and thermometer, ensuring that the vaccines do not touch the coolant packs.
- e. Place another insulating barrier layer on top of the vaccines.
- f. Place another layer of "conditioned" coolant packs on top of the insulating barrier layer, ensuring there is no direct contact between the coolant packs and the vaccines.
- g. Place a final insulating barrier layer (at least 2 inches) on top of the coolant packs along with an inventory list of the vaccines in the container.
- 4. If transport is necessary on a regular basis, the provider should use a portable refrigerator or freezer for transport, especially if over 8 hours and if the vaccine is stored in these units during the off-site clinic.
- **5.** Regardless of container used, the vaccine must be monitored at all times by an unexpired calibrated DDL that provides continuous monitoring information and can be downloaded for review.

# **Monitoring Temperatures at Off-Site Facilities**

- 1. Vaccines should be placed in an appropriate storage unit(s) at the recommended temperature range(s) immediately upon arrival at the school.
- 2. Place a DDL in each storage unit(s) with the vaccine.
- 3. Vaccine must be kept in a transport container(s) during an off-site clinic:
  - a. The container(s) should remain closed as much as possible.
  - b. Only the amount of vaccine needed at one time should be removed for preparation and administration.
  - c. The temperature(s) inside the container(s) should be read and documented at least hourly.
- 4. The DDL shall provide continuous data monitoring information in an active display and be placed on the outside of the unit door to allow for reading temperatures without opening the unit door. The DDL should have:
  - a. Biosafe glycol-encased thermometer probe placed as close as possible to the vaccines.
  - b. Capability to download the file for review.

- c. Detachable probe which facilitates downloading temperature data without removing the probe from the storage unit, which will simplify daily use and minimize operator cause of temperature variability.
- d. Certificate of Traceability and Calibration Testing.
- e. Audible alarm for out-of-range temperatures.
- f. Current temperature display, as well as minimum and maximum temperatures.
- a. Reset button.
- b. Low battery indicator.
- c. Accuracy of  $+/-1^{\circ}F(0.5^{\circ}C)$ .
- d. Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full.
- e. User programmable logging interval (or reading rate).

# For additional information, please refer to:

- The Alabama VFC Provider Profile, <u>http://www.alabamapublichealth.gov/immunization/assets/Alabama%20Provider%20Agreement\_201</u> <u>8.pdf</u>
- CDC's Vaccine Storage and Handling Toolkit, https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf