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Date: June 29, 2009
To: Vaccines for Children (VFC) Providers
From: Immunization Program
RE: Reinstatement of Hib Booster Dose

Background of the Hib Vaccine Shortage

On December 13, 2007, certain lots of *Haemophilus influenzae* type b (Hib) vaccine marketed as PedvaxHIB (monovalent Hib vaccine) and Comvax (Hib-HepB vaccine), and manufactured by Merck & Co., Inc., were recalled voluntarily, and the company temporarily suspended production of these vaccines. To conserve the limited supply of Hib-containing vaccines, CDC, in consultation with the Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), and the American Academy of Pediatrics (AAP), on December 18, 2007, recommended that vaccination providers temporarily defer the routine Hib vaccine booster dose administered to most healthy children at age 12 through 15 months.

Production of Merck Hib vaccine products is still suspended. However, two other Hib-containing vaccines manufactured by Sanofi Pasteur have been available for use in the United States during this shortage: monovalent Hib vaccine (ActHIB) and DTaP-IPV/Hib (Pentacel). Beginning in July 2009, the manufacturer of these two vaccines will increase the number of doses of these two products available for use in the United States, which will result in the supply being sufficient to reinstate the Hib vaccine booster dose.

Recommendations: Reinstatement of Hib Booster Dose

Effective immediately, CDC, in consultation with ACIP, AAFP, and AAP, is recommending reinstatement of the booster dose of Hib vaccine for children aged 12 through 15 months who have completed the primary 3-dose series.

- Infants should continue to receive the primary Hib vaccine series at ages 2, 4 and 6 months.
- Children aged 12 through 15 months should receive the booster dose on time.
- Older children for whom the booster dose was deferred should receive their Hib booster dose at the next routinely scheduled visit or medical encounter.
- Although supply is sufficient to reinstate the booster dose and begin catch-up vaccination, supply is not yet ample enough to support a mass notification process to contact all children with deferred Hib booster doses.

Use of Combination Vaccines

During the Hib shortage, children received protection from certain vaccine preventable diseases in their primary vaccination series through various permutations of available combination vaccines (e.g., DTaP-IPV/Hib [Pentacel] and DTaP-IPV-HepB [Pediarix]) and monovalent vaccines (e.g., ActHib, HepB, and IPV). Therefore, a mismatch might exist between patient vaccination needs and the available stock of different vaccine formulations (e.g., combination products versus single-antigen vaccines) in local provider offices.

This situation presents a challenge for providers to administer vaccines to ensure appropriate coverage while minimizing extra doses of unneeded vaccine. For example, if a provider is using DTaP-IPV/Hib (Pentacel) vaccine to protect infants against Hib disease, the provider should ensure that adequate stock of monovalent HepB vaccine is available to complete the HepB vaccine series.

Children who need the Hib booster and who already have received 4 doses of DTaP should receive monovalent Hib vaccine (ActHIB) as their Hib booster dose. However, if DTaP-IPV/Hib is the only Hib-containing vaccine available, this combination product can be used to complete the series of Hib vaccination, even if the child already has received all the necessary doses of DTaP and IPV.

The Immunization Program will continue to receive allocations from CDC for all Hib containing vaccine and anticipates the majority of the state's additional Hib allocation will be as Pentacel. The Program will continue to monitor and contact providers regarding vaccine orders to assure there is Hib containing vaccine available for all VFC Providers.

The Immunization Program appreciates your assistance in working through this situation. Providers who have questions regarding the Hib vaccine supply and reinstatement of the booster dose should contact the Immunization Program at 1-800-831-6293.