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TO: California Vaccines for Children (VFC) Program Providers

FROM: Carol Glaser, M.P.V.M., M.D., M.P.H., Acting Chief *Carol A. Glaser, M.D.*
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SUBJECT: PENTACEL[®] (DTaP-IPV/Hib COMBINATION VACCINE) Again Available for
Ordering through the California Vaccines for Children (VFC) Program

SUMMARY

California's Vaccine for Children (VFC) Program providers may once again order Pentacel[®] (sanofi pasteur's pentavalent DTaP-IPV/Hib combination vaccine) through MYVFCVaccines. Given the limited availability of Pentacel[®] since April 2012 due to manufacturing delays, this document reviews the use of Pentacel[®] in the VFC program, dosing and schedule, and ordering guidelines.

COMPOSITION

Pentacel[®] (DTaP-IPV/Hib) includes diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV) components provided as a sterile liquid in a vial. This DTaP-IPV sterile liquid is used to reconstitute the lyophilized ActHIB[®] vaccine (vial) component to form the Pentacel[®] vaccine (DTaP-IPV/Hib).

RECOMMENDATIONS FOR VACCINE USE

Eligible Groups for Receipt of VFC Supplies of Pentacel[™]

VFC supplies of Pentacel[®] may be given to VFC-eligible infants and young children aged 6 weeks through 4 years.

Licensed Dosing Schedule

For routine immunization Pentacel[®] is recommended as a four-dose series administered intramuscularly at two months, four months, six months, and 15-18 months of age. The first dose may be given as early as six weeks of age.

Minimum ages and intervals:

- Dose 1: minimum age of six weeks.
- Dose 2: four weeks minimum interval from first dose.
- Dose 3: four weeks minimum interval from second dose.
- Dose 4: minimum age of 12 months (determined by DTaP and Hib components) and a minimum interval of six months after third dose (determined by DTaP component).

Reminder: The final dose of IPV is recommended at a minimum age of 4 years, regardless of the number of prior IPV doses.

Valid Doses: The schedule, minimum intervals, and minimum ages are determined by the individual components (DTaP, IPV, and Hib vaccines). If the minimum age and interval are met for some components, but not all, the components that have met both the minimum age and interval criteria may be counted and considered valid while components that have not met the minimum criteria will be considered invalid.

Administration

Instructions for reconstitution and administration of Pentacel[®] (see package insert for details):

- Thoroughly but gently shake the vial of DTaP-IPV component.
 - Withdraw the entire liquid content into a syringe
- Insert the syringe needle through the stopper of the vial of lyophilized ActHIB[®] vaccine component and inject the liquid into the vial.
- Shake vial thoroughly until a cloudy, uniform suspension results. Pentacel[®] vaccine is uniform, cloudy, and white to off-white (yellow tinge) suspension. If extraneous particulate matter or discoloration is seen, that dose of Pentacel[®] should not be administered.
- After reconstitution, immediately withdraw all of the reconstituted Pentacel[®] vaccine and administer intramuscularly.
- Pentacel[®] should be used immediately after reconstitution.

HOW SUPPLIED

The vaccine is provided in a five-dose package containing five vials of DTaP-IPV component to be used to reconstitute five single-dose vials of lyophilized ActHIB[®] vaccine component.

STORAGE AND HANDLING

Store at 2 to 8 °C (35 to 46 °F). **Do not freeze.**

It is important to carefully store the components together so that the DTaP-IPV vial (sanofi pasteur)[®] provided in the Pentacel[®] package is used to reconstitute the lyophilized ActHIB[®] component (vial). **Do not** use any other sterile liquid or DTaP-IPV vaccine to reconstitute the ActHIB[®] component supplied in the Pentacel[®] package.

Please make sure to record minimum and maximum temperatures twice daily, clearing the memory after each recording. If the minimum temperature is below 2 °C (35 °F) or the maximum temperature is above 8 °C (46 °F), please mark the vaccines with “Do Not Use” and contact the VFC Program’s Customer Service Center according to instructions outlined in the program’s temperature logs.

ORDERING

You may now order Pentacel[®] at MYVFCVaccines. Providers wishing to transition to Pentacel[®] may submit requests during their routine ordering cycle. New orders must be placed taking into consideration current vaccine supply. Supplemental vaccine requests for Pentacel[®] during this initial re-launch period will not be accepted.

In order to prevent vaccine wastage, providers must reduce their inventories of existing combination vaccines, and corresponding single-antigen doses of Hib, before placing a Pentacel[®] request.

Order approval for initial orders will be based on previous vaccine usage (Pediarix[®] [DTaP-IPV-HepB] or single-antigen vaccines) during the same timeframe as last year when applicable, or monthly average use if no annual order history is available. The number of doses on hand at the point of ordering will also be taken into consideration. If your practice is planning to transition to Pentacel[®], please consider these order approval guidelines.

In order to avoid confusion between the pentavalent combination vaccines (Pediarix[®] and Pentacel[®]), providers must choose to use only one combination vaccine within the practice. Once your practice has agreed to the re-introduction of Pentacel[®] and determined the best immunization schedule, orders for a different combination vaccine in subsequent vaccine requests will not be readily approved, and justification may be required.

Here are a few tips to follow when placing your Pentacel[®] request:

- Verify that the introduction of this product has been approved by your practice's medical director, or Physician-in-Chief.
- Practices using single-antigen vaccines (DTaP, IPV, Hib) should decrease orders for each single antigen (DTaP, IPV, and ActHIB[®]) by one dose for every dose of Pentacel[®] requested. Those previously using PedvaxHIB[®] or Comvax[®] should also adjust their orders as appropriate.
- Practices currently using other combination vaccines must carefully check current inventory for combination vaccines, Hib, DTaP, HepB, and IPV and develop a plan to deplete excess of inventory prior to placing a request for Pentacel[®]. It is the provider's responsibility to ensure all vaccines received from the VFC program are used prior to its expiration date or transferred to a VFC provider that may be able to use them.

Remember, managing on-hand inventory appropriately as this vaccine is introduced in your practice will be key in preventing unnecessary vaccine wastage, and decrease the risk of improper vaccination.

Please educate your entire office staff if you will be switching to Pentacel[®], as it will affect your vaccine ordering, storage, administration, and documentation.

If vaccine administration errors do occur, please report details of the error to <http://verp.ismp.org/>.

Billing Information for the administration of VFC Vaccine

Please refer to the VFC program's Pentacel[®] Fact Sheet for a listing of billing codes related to the administration of Pentacel[®] to VFC eligible children in your practice.

RESOURCES

For further information, please refer to the following resources:

- **Vaccine Information Statement (VIS) and fact sheet:** The multiple-vaccine VIS (11/16/12) for vaccines that are given between birth and the six months of age is currently being updated to reflect current ACIP recommendations. An updated edition should be available mid-2014. In the meantime, please use the separate VIS sheets for DTaP, IPV, and Hib when administering Pentacel®. These VIS sheets can be found at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>. Additional information on vaccines and vaccine-preventable diseases can be found at: <http://www.cdc.gov/vaccines/>.
- **Product Insert:** Refer to the product package insert for Pentacel® for additional vaccine information. This may be found at <http://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm172502.htm>
- **The VFC resolutions for DTaP, polio, and Hib-containing vaccines** have been updated and may be found at: <http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>.
- **CA VFC Program Pentacel® Fact Sheet** includes a quick consolidated summary of Pentacel® routine schedule, administration, storage and handling, billing codes, and additional helpful information: <http://eziz.org/assets/docs/IMM-1071.pdf>
- **ACIP and AAP recommendations:** Current ACIP recommendations may be found at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>. AAP vaccine recommendations and other information about vaccines are available to AAP members at <http://www2.aap.org/immunization/>.
- **General Recommendations on Immunization** (includes minimum ages and intervals): <http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>
- **Vaccine Injury Compensation Program (VICP):** Pentacel® is covered by the federal VICP. Information on the federal VICP and DTaP, polio, and Hib-containing vaccines may be found at: <http://www.hrsa.gov/vaccinecompensation>.

cc: Local Health Department Immunization Coordinators