TO:   All Users of State Supplied Vaccines  
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SUBJECT: Availability of New Vaccine Products and Hib Vaccine Supply Status 

The primary purpose of this communication is to notify you on the licensure and availability of 
two new vaccines: a combination tetanus, diphtheria, acellular pertussis and inactivated polio 
vaccine (DTaP/IPV) for children 4-6 years of age and a second live, oral rotavirus vaccine 
(Rotarix) for infants and children 6-24 weeks of age, as well as the status of the current Hib 
vaccine supply.

**DTaP/IPV Combination Vaccine**
On June 24, 2008 the Food and Drug Administration (FDA) approved a DTaP/IPV combination 
vaccine for use at 4-6 years of age. The vaccine is manufactured by Glaxo SmithKline under the 
brand name Kinrix (CPT Code 90696). **Beginning October 1st providers can begin to order 
Kinrix for the 4-6 year old booster dose of DTaP and Polio.** The vaccine is available for all 
patients, including those with private insurance. Kinrix comes packaged in a box of 5 pre-filled 
syringes that must be refrigerated between 35-46 degrees. For those providers who do not want 
to use Kinrix, the Immunization Program will continue to offer separate DTaP and Polio 
vaccines.

**New Rotavirus vaccine Product and Schedule**
On April 3, 2008 the FDA approved a second live, oral rotavirus vaccine manufactured by Glaxo 
SmithKline under the brand name Rotarix (CPT Code 90681). Rotarix is licensed for the 
prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9) in 
infants and children 6-24 weeks of age. Rotarix is a two dose series with dose number one 
administered no earlier than 6 weeks of age and dose two given no later than 24 weeks of age. 
The minimum spacing between doses is 4 weeks.

The Immunization Program currently provides Rotateq vaccine given as a 3 dose series at 2, 4, 
and 6 months of age. The combination of fewer doses in the series for the new Rotarix vaccine 
plus overall cost savings will result in a change of the brand of Rotavirus vaccine supplied by the 
state. **Effective October 1, 2008, we will begin to offer Rotarix vaccine in place of Rotateq 
for VFC-eligible children.** Rotarix comes packaged in a box of ten with each box containing 
lyophilized vaccine, pre-filled oral applicators, and diluent for reconstituting the vaccine. Only 
the lyophilized vaccine needs to be kept refrigerated between 35-46 degrees; the diluent can be 
stored at room temperature. The complete package insert for Rotarix can be found at: 
http://www.fda.gov/CbER/label/rotarixLB.pdf. We will continue to offer Rotateq vaccine
1 What is rotavirus?

Rotavirus is a virus that causes severe diarrhea, mostly in babies and young children. It is often accompanied by vomiting and fever.

Rotavirus is not the only cause of severe diarrhea, but it is one of the most serious. Before rotavirus vaccine was used, rotavirus was responsible for:

• more than 400,000 doctor visits,
• more than 200,000 emergency room visits,
• 55,000 to 70,000 hospitalizations, and
• 20-60 deaths in the United States each year.

Almost all children in the U.S. are infected with rotavirus before their 5th birthday.

Children are most likely to get rotavirus diarrhea between November and May, depending on the part of the country.

Your baby can become infected by being around other children who have rotavirus diarrhea.

2 Rotavirus vaccine

Better hygiene and sanitation have not reduced rotavirus diarrhea very much in the United States. The best way to protect your baby is with rotavirus vaccine.

Rotavirus vaccine is an oral (swallowed) vaccine, not a shot.

Rotavirus vaccine will not prevent diarrhea or vomiting caused by other germs, but it is very good at preventing diarrhea and vomiting caused by rotavirus. Most babies who get the vaccine will not get rotavirus diarrhea at all, and almost all of them will be protected from severe rotavirus diarrhea.

Babies who get the vaccine are also much less likely to be hospitalized or to see a doctor because of rotavirus diarrhea.

3 Who should get rotavirus vaccine and when?

There are two brands of rotavirus vaccine. A baby should get either 2 or 3 doses, depending on which brand is used.

The doses are recommended at these ages:

 First Dose:  2 months of age
 Second Dose:  4 months of age
 Third Dose:   6 months of age (if needed)

The first dose may be given as early as 6 weeks of age, and should be given by age 14 weeks 6 days. The last dose should be given by 8 months of age.

Rotavirus vaccine may be given at the same time as other childhood vaccines.

Babies who get the vaccine may be fed normally afterward.

4 Some babies should not get rotavirus vaccine or should wait

• A baby who has had a severe (life-threatening) allergic reaction to a dose of rotavirus vaccine should not get another dose. A baby who has a severe (life threatening) allergy to any component of rotavirus vaccine should not get the vaccine. Tell your doctor if your baby has any severe allergies that you know of, including a severe allergy to latex.

• Babies who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover. This includes babies who have moderate or severe diarrhea or vomiting. Ask your doctor or nurse. Babies with mild illnesses should usually get the vaccine.
5 What are the risks from rotavirus vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of any vaccine causing serious harm, or death, is extremely small.

Most babies who get rotavirus vaccine do not have any problems with it.

Mild problems

Babies may be slightly more likely to be irritable, or to have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine than babies who did not get the vaccine.

Rotavirus vaccine does not appear to cause any serious side effects.

If rare reactions occur with any new product, they may not be identified until thousands, or millions, of people have used it. Like all vaccines, rotavirus vaccine will continue to be monitored for unusual or severe problems.

6 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

A federal program has been created to help people who may have been harmed by a vaccine.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO)
  - Visit CDC’s National Immunization Program website at: www.cdc.gov/vaccines
through the end of 2008 in order to allow providers to complete the series for any child who started with Rotateq.

In the next few weeks you will be receiving a supply of new Vaccine Order Forms (VOFs) that include space for these 2 new vaccines. Once you receive the new VOFs, please discard any old versions you have in stock. When reporting doses administered data for Rotavirus, you can combine any doses administered for both Rotateq and Rotarix in the space provided—you do not need to separate out the data by vaccine.

**Update on Hib Vaccine Supply**

CDC expects the Hib shortage to ease with the reintroduction of Merck Hib vaccine in the last quarter of 2008. For the time being we have sufficient inventory of ActHiB to support provider vaccine orders of the current 3 dose series and will do our best to accommodate your request but may need at times to modify orders based on provider usage and inventory. We will continue to monitor inventory levels on a month to month basis. We will not be offering the DTaP/IPV/Hib (Pentacel) combination vaccine product at this time. As a reminder providers should continue to defer the booster dose of Hib for healthy children 12-15 months of age.

**New Vaccine Information Statement**

Enclosed please find a camera-ready copy of the new Vaccine Information Statement (VIS) for Rotavirus. The VIS statements are also available electronically through the CDC website at [http://www.cdc.gov/vaccines/pubs/vis/default.htm](http://www.cdc.gov/vaccines/pubs/vis/default.htm). There is no VIS revision planned for the new DTaP/IPV combination vaccine; continue to use the current VIS for DTaP and Polio vaccines. Also enclosed is an updated Vaccine Eligibility Criteria with a list of all vaccines currently provided by the Immunization Program.

As always, if you have any questions please call the State Immunization Program at (860) 509-7929.