

## Evaluation and Quality Assurance

- How should the HRA standards be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?

**Procedure:** Interested persons may present data, information, or views orally or in writing, on topics listed in this **Federal Register** notice. Written submissions for the public comment period may be made to the contact person on or before January 18, 2011. Oral presentations from the public will be scheduled during 30-minute public comment periods at the end of each half day of proceedings, *i.e.*, from 11:30 a.m. to 12 noon and 4:30 p.m. to 5 p.m. on Tuesday, February 1, 2011 and Wednesday, February 2, 2011. Those individuals interested in making formal oral comments should notify the contact person and submit a brief statement of the general nature of the comments they wish to present and the names and addresses of proposed participants on or before January 11, 2011. Each commenter will be limited to 3–5 minutes. The CDC is not responsible for providing access to electrical outlets.

Individuals who have not submitted comments ahead of time will have the opportunity to sign up to comment during registration on the day of the forum. However, if time does not allow for all interested parties to comment, individuals who have submitted their comments ahead of time will be given preference. If the number of participants requesting to comment is greater than can be reasonably accommodated, the CDC may conduct a lottery to determine the speakers for the scheduled open public comment sessions. The contact person will notify interested persons regarding their request to comment by January 18, 2011.

Public forum participants not receiving an opportunity to comment during the open public comment period may submit their comments to OPTH mailbox at: <http://www.cdc.gov/policy>. CDC will make all comments it receives available to the public without change, including personal information you may provide, which includes the name of the person submitting the comment or signing the comment on behalf of an organization, business, or any such entity. If anyone does not wish to have this information published, then that information should not be included when submitting the comment.

Dated: December 21, 2010.

**Tanja Popovic,**

*Deputy Associate Director for Science,  
Centers for Disease Control and Prevention.*

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**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Proposed Consolidated Vaccine Information Materials for Multiple Infant Vaccines

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. 300aa–26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. CDC seeks written comment on a proposed new vaccine information statement that consolidates the six vaccine information statements for the following childhood vaccines: DTaP, *Haemophilus influenzae* type b, inactivated polio vaccine, pneumococcal conjugate vaccine, hepatitis B, and rotavirus. This consolidated Vaccine Information Statement is available to be used by vaccination providers as an alternative to providing the six individual Vaccine Information Statements for the same vaccines.

**DATES:** Written comments are invited and must be received on or before February 28, 2011.

**ADDRESSES:** Written comments should be addressed to Jennifer Hamborsky, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop E–52, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

**FOR FURTHER INFORMATION CONTACT:** Skip Wolfe, National Center for Immunization and Respiratory Diseases, Mailstop E–52, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–8809.

**SUPPLEMENTARY INFORMATION:** The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660), as amended by section 708 of Public Law 103–183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa–26, requires the Secretary of Health and Human Services to

develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, hepatitis A, meningococcal conjugate and polysaccharide, rotavirus, human papillomavirus (HPV), and trivalent influenza vaccines have subsequently been added to the National Vaccine Injury Compensation Program. Use of the Vaccine Information Statements applicable to all of these vaccines, except meningococcal, rotavirus and HPV, is also required. (Interim versions of Vaccine Information Statements for meningococcal, rotavirus and HPV vaccines are available for discretionary use pending completion of the statutory process for finalizing VISs applicable to those vaccines.) Instructions for use of the vaccine information materials and copies of the materials can be found on

the CDC Web site at: <http://www.cdc.gov/vaccines/pubs/vis>.

### Proposed Consolidated Vaccine Information Materials

With six vaccines recommended for infants from birth through 6 months of age—all covered by the National Vaccine Injury Compensation Program—CDC, as required under 42 U.S.C. 300aa–26, developed Vaccine Information Statements for each of those vaccines. In addition, CDC published, in 2008, an alternative consolidated Vaccine Information Statement covering those six vaccines in one document, which providers can choose to use instead of the existing individual Vaccine Information Statements for the same vaccines. The attached document is an update of this consolidated Vaccine Information Statement.

### Development of Vaccine Information Materials

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

In addition, we invite written comment on the proposed vaccine information materials that follow, entitled “Your Baby’s First Vaccines: What You Need to Know.” Comments submitted will be considered in finalizing these materials.

\* \* \* \* \*

### Proposed Multi-Vaccine Vaccine Information Statement:

Your Baby’s First Vaccines: What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See <http://www.immunize.org/vis> Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>

Babies get six vaccines between birth and 6 months of age, with at least one “booster” dose given later.

These vaccines protect your baby from 8 serious diseases. Your baby will get these vaccines today:

☐ DTaP ☐ Polio ☐ Hib  
☐ Rotavirus ☐ Hepatitis B  
☐ PCV13

(Provider: Check appropriate boxes.)

Ask your doctor about “combination vaccines,” which can reduce the number of shots your baby needs by combining several vaccines in one shot. These combination vaccines are as safe and effective as these vaccines given separately.

### About This Vaccine Information Statement

Please read this Vaccine Information Statement (VIS) before your baby gets his or her immunizations, and take it home with you afterward. Ask your doctor, nurse, or other healthcare professional if you have any questions.

This VIS tells you about the benefits and risks of these 6 vaccines. It also contains information about reporting an adverse reaction and about the National Vaccine Injury Compensation Program, and how to get more information about vaccines and vaccine-preventable diseases. (Individual VISs are also available for these six vaccines.)

### How Vaccines Work

Most medicines are designed to treat diseases. Vaccines are designed to prevent diseases, by producing immunity. A child who is immune to a disease will not get sick from it.

*Immunity from Disease:* Before vaccines, a child had to get sick to get immunity. When a child gets sick with a disease, like measles or whooping cough, her immune system produces protective “antibodies,” which keep her from getting the same disease again. But getting sick the first time is unpleasant, and it can be dangerous or even fatal.

*Immunity from Vaccines:* Vaccines are made with the same bacteria or viruses that cause disease, but they have been weakened or killed to make them safe. A child’s immune system responds to a vaccine by producing antibodies, just the same as it would if the child were infected with the actual disease. This means he will develop immunity in the same way \* \* \* but without having to get sick first.

### Vaccine benefits: Why get vaccinated?

Your baby’s first vaccines protect him from 8 serious diseases, caused by viruses and bacteria. These diseases have injured and killed millions of children (and adults) over the years. Polio killed more than 1,000 people a year, and paralyzed tens of thousands more in the early 1950s. Hib disease was once the leading cause of bacterial meningitis in children under 5 years of age. About 15,000 people a year died from diphtheria before there was a vaccine. Most children have at least one rotavirus infection before their 5th birthday.

These diseases might be uncommon today, but if we stopped vaccinating they would come back. This has happened in the past, and even today disease rates go up when vaccination rates go down. For example in 2010 California had more pertussis cases than in any year since 1947.

### 8 Diseases Prevented by Childhood Vaccines

#### 1. Diphtheria

You can get it from contact with an infected person.

Signs and symptoms include a thick covering in the back of the throat that can make it hard to breathe.

It can lead to breathing problems, heart failure, and death.

#### 2. Tetanus (Lockjaw)

You can get it from a cut or wound. It does not spread from person to person.

Signs and symptoms include painful tightening of the muscles, usually all over the body.

It can lead to stiffness of the jaw that prevents swallowing or even opening the mouth. Of every 5 people who get tetanus, 1 dies.

#### 3. Pertussis (Whooping Cough)

You can get it from contact with an infected person.

Signs and symptoms include violent coughing spells that can make it hard for an infant to eat, drink, or breathe. These spells can last for weeks.

It can lead to pneumonia, seizures, brain damage, and death.

#### 4. Hib (Haemophilus influenzae type b)

You can get it from contact with an infected person.

Signs and symptoms. There may not be any signs or symptoms in mild cases.

It can lead to meningitis (infection of the brain and spinal cord coverings); pneumonia; infections of the blood, joints, bones, and covering of the heart; brain damage; deafness; and death.

#### 5. Hepatitis B

You can get it from blood or body fluids of an infected person. Babies can get it at birth if the mother is infected, or through a cut or wound.

Signs and symptoms include tiredness, diarrhea and vomiting, jaundice (yellow skin or eyes), and pain in muscles, joints and stomach.

It can lead to liver damage, liver cancer, and death.

#### 6. Polio

You can get it from close contact with an infected person. It enters the body through the mouth.

Signs and symptoms can include cold-like illness, or there may be no signs or symptoms at all.

It can lead to paralysis (can’t move an arm or leg), or death (by paralyzing the breathing muscles).

**7. Pneumococcal Disease**

You can get it from contact with an infected person.

Signs and symptoms include fever, chills, cough, and chest pain.

It can lead to meningitis (infection of the brain and spinal cord coverings),

blood infections, ear infections, pneumonia, deafness, brain damage, and death.

**8. Rotavirus**

You can get it from contact with other children who are infected.

Signs and symptoms include diarrhea (sometimes severe), vomiting and fever.

It can lead to dehydration, hospitalization (up to about 70,000 a year), and death.

**Routine Baby Vaccines**

Vaccine	Number of doses	Recommended ages	Other information
DTaP (diphtheria, tetanus, and pertussis)	5 .....	2 months, 4 months, 6 months, 15–18 months, 4–6 years.	Some children should not get pertussis vaccine. These children should get a vaccine called DT.
Hepatitis B .....	3 .....	Birth, 1–2 months, 6–18 months .....	A child might receive a 4th dose if “combination” vaccines are used.
Polio .....	4 .....	2 months, 4 months, 6–18 months, 4–6 years.	A child might receive a 5th dose if “combination” vaccines are used.
Hib (Haemophilus influenzae type b)	3 or 4 .....	2 months, 4 months, (6 months), 12–15 months.	There are 2 types of Hib vaccine. With one type the 6-month dose is not needed.
PCV13 (pneumococcal) .....	4 .....	2 months, 4 months, 6 months, 12–15 months.	Older children with certain chronic diseases may also need this vaccine.
Rotavirus .....	2 or 3 .....	2 months, 4 months, (6 months) .....	Rotavirus vaccine is given as drops that are swallowed. There are 2 types of rotavirus vaccine. With one type the 6-month dose is not needed. A virus called porcine circovirus is present in both vaccines. There is no evidence that it is a safety risk. For information ask your doctor or visit <a href="http://www.cdc.gov/vpd-vac/rotavirus">http://www.cdc.gov/vpd-vac/rotavirus</a> .

An annual dose of flu vaccine is also recommended for children 6 months of age and older.

**Precautions**

Most babies can get all of these vaccines. But some babies should not get certain vaccines because of allergies or other health conditions. Your doctor can advise you.

If your child ever had a serious reaction, such as a life-threatening allergic reaction, after a dose of vaccine, she should not get another dose of that vaccine. *Tell your doctor if your child has any severe allergies.* (Serious reactions to vaccines and severe allergies are rare.)

If your child ever had any of these reactions after a dose of DTaP vaccine:

- A brain or nervous system disease within 7 days,
- Non-stop crying for 3 hours or more,
- A seizure or collapse,
- A fever of over 105 °F.

Talk to your doctor before getting DTaP vaccine.

If your child has:

- A life-threatening allergy to the antibiotics neomycin, streptomycin, or polymyxin B,
- Talk to your doctor before getting Polio vaccine.

If your child has:

- A life-threatening allergy to yeast,
- Talk to your doctor before getting Hepatitis B or PCV13 vaccine.

If your child has:

- SCID (Severe Combined Immunodeficiency),

- A weakened immune system for any other reason,
  - Ongoing digestive problems,
  - Recently gotten a blood transfusion or other blood product,
  - Ever had intussusception (an uncommon type of bowel obstruction),
- Talk to your doctor before getting Rotavirus vaccine.

If your child has:

- Ever had a severe reaction after any vaccine containing diphtheria toxoid (such as DTaP),
- Talk to your doctor before getting PCV13 or DTaP vaccine.

If your child is sick on the day her vaccinations are scheduled, your doctor might want to reschedule them after she recovers. A child with a mild cold or low fever can usually be vaccinated the same day, but for a more serious illness it might be better to wait.

**Risks**

Vaccines can cause side effects, like any medicine. The risk of a serious reaction, such as a severe allergic reaction, or death, is extremely low.

*Mild Reactions:* Most vaccine reactions are mild “local” reactions: Tenderness, redness, or swelling where the shot was given; or a mild fever. These affect about 1 child in 4. They appear soon after the shot is given and go away within a day or two.

*Other Reactions:* Severe allergic reactions to a substance in a vaccine happen very rarely—less than once in a

million shots. They generally occur within minutes or hours after the vaccination. Individual vaccines have been associated with other mild problems, or with moderate or serious problems:

**DTaP Vaccine**

*Mild Problems:* Fussiness (up to 1 child in 3); tiredness or poor appetite (up to 1 child in 10); vomiting (up to 1 child in 50); swelling of the entire arm or leg for 1–7 days (up to 1 child in 30)—usually after the 4th or 5th dose.

*Moderate Problems:* Seizure (1 child in 14,000); non-stop crying for 3 hours or longer (up to 1 child in 1,000); fever over 105 °F (1 child in 16,000).

*Serious problems:* Long term seizures, coma, lowered consciousness, and permanent brain damage have been reported. These are so rare it is hard to tell if they are caused by the vaccine.

**Polio Vaccine/Hepatitis B Vaccine/Hib Vaccine**

These vaccines have not been associated with mild problems other than local reactions. These vaccines have not been associated with problems other than mild local reactions.

**Pneumococcal Vaccine**

*Mild Problems:* During studies of the vaccine, some children became fussy or drowsy or lost their appetite.

**Rotavirus Vaccine**

*Mild Problems:* Children who get rotavirus vaccine are slightly more

likely than other children to be irritable or to have mild, temporary diarrhea or vomiting. This happens within the first week after getting a dose of the vaccine.

**Serious Problems:** Some studies have shown a small increase in cases of intussusception during the week after the first dose. Intussusception is a type of bowel blockage that is treated in a hospital. In some cases surgery might be required. The estimated risk is 1 case per 100,000 infants.

#### What if my child has a severe reaction?

#### What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe 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 the doctor what happened, the date and time it happened, and when the vaccination was given.

Ask your doctor 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 <http://www.vaers.hhs.gov>, or by calling 1-800-822-7967. *VAERS does not provide medical advice.*

#### The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

People who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382, or visiting the VICP Web site at <http://www.hrsa.gov/vaccinecompensation>.

#### For More Information

- Ask your doctor. 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) or

—Visit CDC's Web site at <http://www.cdc.gov/vaccines>.

Department of Health and Human Services

Centers for Disease Control and Prevention

Vaccine Information Statement (00/00/0000) (Proposed)

42 U.S.C. 300aa-26

Dated: December 21, 2010.

**Tanja Popovic,**

*Deputy Associate Director for Science,  
Centers for Disease Control and Prevention (CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), (last amended at 75 FR 14176-14178, dated March 24, 2010) is amended to change the title of the Office of Executive Operations and Regulatory Affairs to the Office of Strategic Operations and Regulatory Affairs, to reflect the establishment of a new Federal Coordinated Health Care Office and to update the organization for CMS, as follows:

(1) Under Part F, CMS, FC. 10 Organizations, change the title of the Office of Executive Operations and Regulatory Affairs (FCF) to the Office of Strategic Operations and Regulatory Affairs (FCF).

(2) Under Part F, CMS, FC. 10 Organizations, insert the following new Office after the Center for Medicare and Medicaid Innovation (FCP): "Federal Coordinated Health Care Office (FCQ)."

(3) Under Part F, CMS, FC. 20 Functions, change the title of the Office of Executive Operations and Regulatory Affairs (FCF) to the Office of Strategic Operations and Regulatory Affairs (FCF).

(4) Under Part F, CMS, FC. 20 Functions, insert the following after the description of the Center for Medicare and Medicaid Innovation (FCP):

#### Federal Coordinated Health Care Office (FCQ)

- Manages the implementation and operation of the Federal Coordinated Health Care Office mandated in section 2602 of the Affordable Care Act, ensuring more effective integration of benefits under Medicare and Medicaid for individuals eligible for both programs and improving coordination between the Federal Government and States in the delivery of benefits for such individuals.

- Monitors and reports on annual total expenditures, health outcomes and

access to benefits for all dual eligible individuals, including subsets of the population.

- Coordinates with the Center for Medicare and Medicaid Innovation to provide technical assistance and programmatic guidance related to the testing of various delivery system, payment, service and/or technology models to improve care coordination, reduce costs, and improve the beneficiary experience for individuals dually eligible for Medicare and Medicaid.

- Performs policy and program analysis of Federal and State statutes, policies, rules and regulations impacting the dual eligible population.

- Makes recommendations on eliminating administrative and regulatory barriers between the Medicare and Medicaid programs.

- Develops tools, resources and educational materials to increase dual eligibles' understanding of and satisfaction with coverage under the Medicare and Medicaid programs.

- Provides technical assistance to States, health plans, physicians and other relevant entities of individuals with education and tools necessary for developing integrated programs for dual eligible beneficiaries.

- Consults with the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment Advisory Commission with respect to policies relating to the enrollment in and provision of benefits to dual eligible beneficiaries under Medicare and Medicaid.

- Studies the provision of drug coverage for new full benefit dual eligible individuals.

- Develops policy and program recommendations to eliminate cost shifting between the Medicare and Medicaid program and among related health care providers.

- Develops annual report containing recommendations for legislation that would improve care coordination and benefits for dual eligible individuals.

**Authority:** 44 U.S.C. 3101.

Dated: December 7, 2010.

**Kathleen Sebelius,**  
*Secretary.*

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