Estimated Annual Costs to the Federal Government

The total cost to the government for activities directly related to this collection is $432,451.000.

Request for Comments

In accordance with the above cited legislation, comments on the AHRQ information collection proposal are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of the AHRQ, including whether the information will have practical utility; (b) the accuracy of the AHRQ's estimate of the burden (including hours and costs) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: February 27, 2003.

Carolyn M. Clancy,

Director

[FR Doc. 03–5298 Filed 3–5–03; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP): Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee on Childhood Lead Poisoning Prevention.

Time and Date: 8:30 a.m.–5:30 p.m., March 18, 2003.

Place: Hilton—Crystal City at National Airport, 2399 Jefferson Davis Highway, Arlington, VA 22202, telephone 703/418–6800.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 55 people.

Purpose: The Committee shall provide advice and guidance to the Secretary; the Assistant Secretary for Health; and the Director, CDC, regarding new scientific knowledge and technological developments and their practical implications for childhood lead poisoning prevention efforts. The Committee shall also review and report regularly on childhood lead poisoning prevention practices and recommend improvements in national childhood lead poisoning prevention efforts.

Matters to be Discussed: Agenda items include: Updates on Primary Prevention issues, Medicaid Targeted Screening, Review of Evidence for Effects at Blood Lead Levels <10 μg/dL issues, Screening of Immigrant/Adopted Children, and Study of Relationship of Environmental Tobacco Smoke and Blood Lead Levels.

Agenda items are subject to change as priorities dictate.

Opportunities will be provided during the meeting for oral comments. Depending on the time available and the number of requests, it may be necessary to limit the time of each presenter.

Contact Person for More Information: Crystal M. Gresham, Program Analyst, Lead Poisoning Prevention Branch, Division of Emergency and Environmental Health Services, NCEH, CDC, 1600 Clifton Road, NE., M/S F–30, Atlanta, Georgia 30333, telephone 770/488–7490, fax 770/488–4178.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 28, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–5247 Filed 3–5–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Revised Vaccine Information Materials for Measles, Mumps and Rubella Vaccines; Revised Instructions for Use of Vaccine Information Statements

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

ACTION: Notice.

SUMMARY: Under the National Childhood Vaccine Injury Act (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. Since the recommended interval between receiving rubella-containing vaccine and becoming pregnant has been amended from 3 months to 4 weeks, the vaccine information materials covering measles, mumps and rubella vaccine needed to be revised. On October 10, 2002, CDC published a notice in the **Federal Register** (67 FR 63106) seeking public comments on the proposed revised vaccine information materials for measles, mumps and rubella vaccines. The 60 day comment period ended on December 9, 2002. Following review of the comments submitted and consultation as required under the law, CDC has finalized these vaccine information materials. The final materials, and revised instructions for their use and for use of materials for other covered vaccines, are contained in this notice.

DATES: Beginning as soon as practicable, each health care provider who administers any vaccine that contains measles, mumps or rubella vaccine shall, prior to administration of each dose of the vaccine, provide a copy of the vaccine information materials contained in this notice, dated January 15, 2003, to the parent or legal representative of any child to whom such provider intends to administer the vaccine and to any adult to whom such provider intends to administer the vaccine, in lieu of providing earlier versions of these materials.

FOR FURTHER INFORMATION CONTACT: Walter A. Orenstein, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E–05, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–8200.

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 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, also known as Vaccine Information Statements (VIS), prior to administration of any of these vaccines. As new vaccines have been added to the National Vaccine Injury Compensation Program, materials for those vaccines have also been developed. Since June 1, 1999, health care providers are required to provide copies of vaccine information materials for the following vaccines: hepatitis B, haemophilus influenzae type b (Hib), and varicella (chickenpox) vaccines. And, effective December 15, 2002, use of vaccine information materials for pneumococcal conjugate vaccine was mandated.

Revised Vaccine Information Materials for Measles, Mumps & Rubella (MMR) Vaccines

The Advisory Committee on Immunization Practices revised its recommendations for administration of rubella-containing vaccines to change the recommended interval between receiving MMR vaccine and becoming pregnant from 3 months to 4 weeks (''Revised ACIP Recommendations for Avoiding Pregnancy After Receiving a Rubella-Containing Vaccine'' MMWR 50/49, Dec 14, 2001). Interim vaccine information materials reflecting this change were posted on the CDC Web site on June 13, 2002. We proposed slightly different language to further clarify this recommendation when the proposed revised MMR vaccine information materials were published for public comment in the **Federal Register** on October 10, 2002 (67 FR 63106).

Following consultation and review of comments submitted, these vaccine information materials have been finalized and are contained in this notice. They are entitled ''Measles, Mumps & Rubella Vaccines: What You Need to Know,'' and are dated January 15, 2003. CDC has also revised the Instructions for the Use of Vaccine Information Statements. The revised instructions, dated January 15, 2003, are included in this notice. These instructions and copies of the materials for all covered vaccines can also be found on the CDC Web site at: *http://www.cdc.gov/nip/publications/VIS/*. In addition, single camera-ready copies of the materials, and the instructions for their use, are available from State health departments. A list of State health department contacts for obtaining copies of these materials is included in a December 17, 1999 **Federal Register** notice (64 FR 70914).

* * * * *

Instructions for the Use of Vaccine Information Statements

Required Use

1. Provide VIS When Vaccination Is Given

As required under the National Childhood Vaccine Injury Act (42 U.S.C. 300aa-26), all health care providers in the United States who administer any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), or pneumococcal conjugate vaccine shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

—To the parent or legal representative* of any child to whom the provider intends to administer such vaccine, or

—To any adult to whom the provider intends to administer such vaccine.

The materials shall be supplemented with visual presentations or oral explanations, as appropriate.

If there is not a single VIS for a combination vaccine (*e.g.*, hepatitis A/Hepatitis B), use the VISs for both component vaccines.

* ''Legal representative'' is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor.

2. Record Information for Each VIS Provided

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided indicating:

(1) The edition date of the materials, and

(2) The date these materials were provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. 300aa–25 that all health care providers administering these vaccines must record in the patient's permanent medical record or in a permanent office log:

(3) The name, address and title of the individual who administers the vaccine,

(4) The date of administration, and

(5) The vaccine manufacturer and lot number of the vaccine used.

Additional Recommended Use

Health care providers may also want to give parents copies of all vaccine information materials prior to the first immunization visit, such as at the first well baby visit.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirements to provide the vaccine information materials supplement any applicable State laws.

Availability of Copies

Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are also available on the Centers for Disease Control and Prevention's Web site at *http://www.cdc.gov/nip/publications/VIS.* Copies are available in English and in other languages.

Current Editions of VISs

Diphtheria, Tetanus, Pertussis (DTaP/DT): 7/30/01
Tetanus Diphtheria (Td): 6/10/94
Measles, Mumps, Rubella (MMR): 1/15/03
Hepatitis B: 7/11/01
Polio: 1/1/00
Haemophilus influenzae type b: 12/16/98
Varicella (chickenpox): 12/16/98
Pneumococcal conjugate: 9/30/02
Reference 42 U.S.C. 300aa–26
1/15/03

* * * * *

Measles, Mumps & Rubella Vaccines: What You Need to Know

1. Why Get Vaccinated?

Measles, mumps, and rubella are serious diseases.

Measles

• Measles virus causes rash, cough, runny nose, eye irritation, and fever.
• It can lead to ear infection, pneumonia, seizures (jerking and staring), brain damage, and death.

Mumps

• Mumps virus causes fever, headache, and swollen glands.
• It can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries, and, rarely, death.

Rubella (German Measles)

• Rubella virus causes rash, mild fever, and arthritis (mostly in women).
• If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

You or your child could catch these diseases by being around someone who has them. They spread from person to person through the air.

Measles, mumps, and rubella (MMR) vaccine can prevent these diseases.

Most children who get their MMR shots will not get these diseases. Many more children would get them if we stopped vaccinating.

2. Who Should Get MMR Vaccine and When?

Children should get 2 doses of MMR vaccine:

—The first at 12–15 months of age.
—And the second at 4–6 years of age.

These are the recommended ages. But children can get the second dose at any age, as long as it is at least 28 days after the first dose.

Some adults should also get MMR vaccine:

Generally, anyone 18 years of age or older, who was born after 1956, should get at least one dose of MMR vaccine, unless they can show that they have had either the vaccines or the diseases.

Ask your doctor or nurse for more information.

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

3. Some People Should Not Get MMR Vaccine or Should Wait

• People should not get MMR vaccine who have ever had a life-threatening allergic reaction to gelatin, the antibiotic neomycin, or a previous dose of MMR vaccine.
• People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting MMR vaccine.
• Pregnant women should wait to get MMR vaccine until after they have given birth. Women should avoid getting pregnant for 4 weeks after getting MMR vaccine.
• Some people should check with their doctor about whether they should get MMR vaccine, including anyone who:

—Has HIV/AIDS, or another disease that affects the immune system.
—Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer.
—Has any kind of cancer.
—Is taking cancer treatment with x-rays or drugs.
—Has ever had a low platelet count (a blood disorder).

• People who recently had a transfusion or were given other blood products should ask their doctor when they may get MMR vaccine.

Ask your doctor or nurse for more information.

4. What Are the Risks From MMR Vaccine?

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

Getting MMR vaccine is much safer than getting any of these three diseases.

Most people who get MMR vaccine do not have any problems with it.

Mild Problems

Fever (up to 1 person out of 6).

Mild rash (about 1 person out of 20).

Swelling of glands in the cheeks or neck (rare).

If these problems occur, it is usually within 7–12 days after the shot. They occur less often after the second dose.

Moderate Problems

Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses).

Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4).

Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses).

Severe Problems (Very Rare).

Serious allergic reaction (less than 1 out of a million doses).

Several other severe problems have been known to occur after a child gets MMR vaccine.

But this happens so rarely, experts cannot be sure whether they are caused by the vaccine or not. These include:

—Deafness.
—Long-term seizures, coma, or lowered consciousness.
—Permanent brain damage.

5. What if There Is a Moderate or Severe Reaction?

What Should I Look For?

Any unusual conditions, such as a serious allergic reaction, high fever or behavior changes. Signs of a serious allergic reaction include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness within a few minutes to a few hours after the shot. A high fever or seizure, if it occurs, would happen 1 or 2 weeks after the shot.

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 file a Vaccine Adverse Event Reporting System (VAERS) form. Or call VAERS yourself at 1–800–822–7967 or visit their Web site at *http://www.vaers.org.*

6. The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help you pay for the care of those who have been harmed. For details about the National Vaccine Injury Compensation Program, call 1–800–338–2382 or visit the program's Web site at *http://www.hrsa.gov/osp/vicp.*

7. 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's immunization program.

Contact the Centers for Disease Control and Prevention (CDC):

—Call 1–800–232–2522 (English).
—Call 1–800–232–0233 (Español).
—Visit the National Immunization Program's Web site at *http://www.cdc.gov/nip.*

U.S. Department of Health & Human Services
Centers for Disease Control and Prevention
National Immunization Program
Vaccine Information Statement
MMR (1/15/03)
42 U.S.C. 300aa–26

* * * * *

Dated: February 28, 2003.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03–5248 Filed 3–5–03; 8:45 am]

BILLING CODE 4163–18–P