

Massachusetts, and South Carolina, 1989–1991. *MMWR* 1992; 41:1–4.

5. Centers for Disease Control and Prevention. Foodborne Outbreak of *Cryptosporidiosis*–Spokane, Washington, 1997. *MMWR* 1998; 47:27.

Dated: September 23, 2002.

Joseph R. Carter,

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

[FR Doc. 02–24579 Filed 9–26–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Vaccine Information Materials for Pneumococcal Conjugate, Diphtheria, Tetanus, acellular Pertussis and Hepatitis B Vaccines

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. On March 6, 2001, CDC published a notice in the **Federal Register** (66 FR 13540) seeking public comments on proposed new vaccine information materials for pneumococcal conjugate vaccine, and revised vaccine information materials for diphtheria, tetanus, acellular pertussis (DTaP/DT) vaccines and hepatitis B vaccine. Following review of the comments submitted and consultation as required under the law, CDC has finalized these vaccine information materials. The final materials are contained in this notice.

DATES: Beginning no later than December 15, 2002, each health care provider who administers any vaccine that contains pneumococcal conjugate vaccine shall, prior to administration of each dose, provide a copy of the pneumococcal conjugate vaccine information materials contained in this notice to the parent or legal representative of any child to whom such provider intends to administer the vaccine.

Beginning as soon as practicable, each health care provider who administers any vaccine that contains diphtheria, tetanus, acellular pertussis or hepatitis B vaccine shall, prior to administration of each dose of the vaccine, provide a

copy of the relevant vaccine information materials contained in this notice 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 hepatitis B 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. Since June 1, 1999, health care providers are also required to provide copies of vaccine information materials for the following vaccines that were added to the National Vaccine Injury Compensation Program: hepatitis B, haemophilus influenzae type b (Hib), and varicella (chickenpox) vaccines.

Pneumococcal Conjugate Vaccine Information Materials

Following the addition of pneumococcal conjugate vaccine to the National Vaccine Injury Compensation Program, CDC, as required under 42 U.S.C. 300aa–26, proposed vaccine information materials covering that vaccine which were published in a **Federal Register** notice on March 6, 2001 (66 FR 13540). With publication of this notice, as of December 15, 2002, health care providers will also be required to provide copies of pneumococcal conjugate vaccine information materials

Revised Vaccine Information Materials for Diphtheria, Tetanus, acellular Pertussis (DTaP/DT) Vaccines and Hepatitis B Vaccine

Proposed revised vaccine information materials for diphtheria, tetanus, acellular pertussis (DTaP/DT) vaccines and hepatitis B vaccine were also published in the March 6, 2001 **Federal Register** notice.

New/Revised Vaccine Information Materials

The new/revised vaccine information materials were drafted in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, the American Academy of Pediatrics, American Pharmaceutical Association, Association of American Indian Physicians, Every Child by Two, Immunization Action Coalition, Immunization, Education and Action Committee, Infectious Diseases Society of America, National Association for Pediatric Nurse Associates and Practitioners and the National Vaccine Advisory Committee. Also, CDC provided copies of the draft materials to other organizations and sought their consultation; however, those organizations did not provide comments.

Following consultation and review of comments submitted, these vaccine information materials have been finalized and are contained in this notice. They are entitled “Pneumococcal Conjugate Vaccine: What You Need to Know,” “Diphtheria,

Tetanus & Pertussis Vaccines: What You Need to Know,” and “Hepatitis B Vaccine: What You Need to Know.” CDC has also revised the Instructions for the Use of Vaccine Information Statements.

Instructions for use of the vaccine information materials and copies of the materials can be found on the CDC website at: <http://www.cdc.gov/nip/publications/VIS/>. In addition, single camera-ready copies 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).

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Pneumococcal Conjugate Vaccine: What You Need to Know

1. Why get vaccinated?

Infection with *Streptococcus pneumoniae* bacteria can cause serious illness and death. Invasive pneumococcal disease is responsible for about 200 deaths each year among children under 5 years old. It is the leading cause of bacterial meningitis in the United States. (Meningitis is an infection of the covering of the brain).

Each year pneumococcal infection causes severe disease in children under five years old. Before a vaccine was available, pneumococcal infection each year caused:

- Over 700 cases of meningitis
- 13,000 blood infections, and
- About 5 million ear infections

It can also lead to other health

problems, including:

- Pneumonia,
- Deafness,
- Brain damage.

Children under 2 years old are at highest risk for serious disease. Pneumococcus bacteria are spread from person to person through close contact.

Pneumococcal infections can be hard to treat because the bacteria have become resistant to some of the drugs that have been used to treat them. This makes prevention of pneumococcal infections even more important.

Pneumococcal conjugate vaccine can help prevent serious pneumococcal disease, such as meningitis and blood infections. It can also prevent some ear infections. But ear infections have many causes, and pneumococcal vaccine is effective against only some of them.

2. Pneumococcal conjugate vaccine

Pneumococcal conjugate vaccine is approved for infants and toddlers. Children who are vaccinated when they are infants will be protected when they are at greatest risk for serious disease.

Some older children and adults may get a different vaccine called pneumococcal polysaccharide vaccine. There is a separate Vaccine Information Statement for people getting this vaccine.

3. Who should get the vaccine and when?

- Children under 2 years of age:
 - 2 months
 - 4 months
 - 6 months
 - 12–15 months

Children who weren't vaccinated at these ages can still get the vaccine. The number of doses needed depends on the child's age. Ask your health care provider for details.

- Children between 2 and 5 years of age:

Pneumococcal conjugate vaccine is also recommended for children between 2 and 5 years old who have not already gotten the vaccine and are at high risk of serious pneumococcal disease.

This includes children who:

- Have sickle cell disease,
- Have a damaged spleen or no spleen,
- Have HIV/AIDS,
- Have other diseases that affect the immune system, such as diabetes, cancer, or liver disease, or who
- Take medications that affect the immune system, such as chemotherapy or steroids, or
- Have chronic heart or lung disease.

The vaccine should be considered for all other children under age 5 years, especially those at higher risk of serious pneumococcal disease. This includes children who:

- Are under 3 years of age,
- Are of Alaska Native, American Indian or African American descent, or
- Attend group day care.

The number of doses needed depends on the child's age. Ask your health care provider for more details.

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

4. Some children should not get pneumococcal conjugate vaccine or should wait.

Children should not get pneumococcal conjugate vaccine if they had a severe (life-threatening) allergic reaction to a previous dose of this vaccine, or have a severe allergy to a vaccine component. Tell your health-care provider if your child has ever had a severe reaction to any vaccine, or has any severe allergies.

Children with minor illnesses, such as a cold, may be vaccinated. But children

who are moderately or severely ill should usually wait until they recover before getting the vaccine.

5. What are the risks from pneumococcal conjugate vaccine?

In studies (nearly 60,000 doses), pneumococcal conjugate vaccine was associated with only mild reactions:

- Up to about 1 infant out of 4 had redness, tenderness, or swelling where the shot was given.
- Up to 1 out of 3 had a fever of over 100.4°F, and up to about 1 in 50 had a higher fever (over 102.2°F).
- Some children also became fussy or drowsy, or had a loss of appetite.

So far, no moderate or severe reactions have been associated with this vaccine. However, a vaccine, like any medicine, could cause serious problems, such as a severe allergic reaction. The risk of this vaccine causing serious harm, or death, is extremely small.

6. What if there is a moderate or severe reaction? What should I look for?

Look for any unusual condition, such as a serious allergic reaction, high fever, or unusual behavior.

Serious allergic reactions are extremely rare with any vaccine. If one were to occur, it would most likely be within a few minutes to a few hours after the shot. Signs can include:

- Difficulty breathing
- Hoarseness or wheezing
- Hives
- Paleness
- Weakness
- A fast heart beat
- Dizziness
- Swelling of the throat

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 health care provider 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>.

7. The 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 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 their Web site at <http://www.hrsa.gov/bhpr/vicp>.

8. How can I learn more?

• Ask your health care provider. 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, Pneumococcal Conjugate Vaccine, (9/30/02), 42 U.S.C. 300aa-26.

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Diphtheria, Tetanus & Pertussis Vaccines: What You Need to Know

1. Why get vaccinated?

Diphtheria, tetanus, and pertussis are serious diseases caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts or wounds.

Diphtheria causes a thick covering in the back of the throat.

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

Tetanus (Lockjaw) causes painful tightening of the muscles, usually all over the body.

• It can lead to "locking" of the jaw so the victim cannot open his mouth or swallow. Tetanus leads to death in about 3 out of 10 cases.

Pertussis (Whooping Cough) causes coughing spells so bad that it is hard for infants to eat, drink, or breathe. These spells can last for weeks.

• It can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death.

Diphtheria, tetanus, and pertussis vaccine (DTaP) can prevent these diseases. Most children who are vaccinated with DTaP will be protected throughout childhood. Many more children would get these diseases if we stopped vaccinating.

DTaP is a safer version of an older vaccine called DTP. DTP is no longer used in the United States.

2. Who should get DTaP vaccine and when?

Children should get 5 doses of DTaP vaccine, one dose at each of the following ages:

—2 months

—4 months

—6 months

—15–18 months

—4–6 years

DTaP may be given at the same time as other vaccines.

3. Some children should not get DTaP vaccine or should wait

• Any child who has had a life-threatening allergic reaction after a dose of DTaP should not get any more doses.

• Any child who suffered a brain or nervous system disease within 7 days after a dose of DTaP should not get any more doses.

• Talk with your doctor if your child:

—had a seizure or collapsed after a previous dose of DTaP,

—cried non-stop for 3 hours or more after a previous dose of DTaP,

—had a high fever (over 105°F) after a previous dose of DTaP.

• Children who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting DTaP vaccine.

Ask your health care provider for more information. Children who should not get the pertussis part of the vaccine can get a vaccine called DT, which doesn't contain pertussis.

4. Older children and adults

DTaP should not be given to anyone 7 years of age or older. Pertussis can still strike older children, adolescents, and adults, but the pertussis vaccine is currently licensed only for children under 7.

Adolescents and adults still need protection from tetanus and diphtheria. A booster shot called Td is recommended at 11–12 years of age. It should be repeated every 10 years. There is a separate Vaccine Information Statement for Td vaccine.

5. What are the risks from DTaP vaccine?

Getting diphtheria, tetanus, or pertussis disease is much riskier than getting DTaP vaccine.

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

Mild Problems (Common)

• Fever (up to about 1 child in 4)
• Redness or swelling where the shot was given (up to about 1 child in 4)
• Soreness or tenderness where the shot was given (up to about 1 child in 4)

These problems occur more often after the 4th and 5th doses of the DTaP series than after earlier doses.

Another mild problem is swelling of the arm or leg in which the shot was given, after the 4th or 5th dose (up to about 1 child in 30).

Other mild problems include:

• Fussiness (up to about 1 child in 3)
• Tiredness or poor appetite (up to about 1 child in 10)

• Vomiting (up to about 1 child in 50)

These problems generally occur 1–3 days after the shot.

Moderate Problems (Uncommon)

• Seizure (jerking or staring) (about 1 child out of 14,000)

• Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)

• High fever, over 105°F (about 1 child out of 16,000)

Severe Problems (Very Rare)

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

• Several other severe problems have been reported after DTaP vaccine. These include:

—Long-term seizures, coma, or lowered consciousness

—Permanent brain damage.

These are so rare it is hard to tell if they are caused by the vaccine.

Controlling fever is especially important for children who have had seizures, for any reason. It is also important if another family member has had seizures.

You can reduce fever and pain by giving your child an aspirin-free pain reliever when the shot is given, and for the next 24 hours, following the package instructions.

6. 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. If a high fever or seizure occurs, it is usually within 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.

7. 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 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/bhpr/vicp>.

8. How can I learn more?

- Ask your health care provider. 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, DTaP/DT, (7/30/01), 42 U.S.C. 300aa-26.

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Hepatitis B Vaccine: What You Need to Know

1. Why get vaccinated?

Hepatitis B is a serious disease.

The hepatitis B virus can cause short-term (acute) illness that leads to:

- Loss of appetite
- Diarrhea and vomiting
- Tiredness
- Jaundice (yellow skin or eyes)
- Pain in muscles, joints, and

stomach

It can also cause long-term (chronic) illness that leads to:

- Liver damage (cirrhosis)
- Liver cancer
- Death

About 1.25 million people in the U.S. have chronic hepatitis B virus infection. If you are infected as a young child, you are much more likely to develop chronic illness.

Each year it is estimated that:

- 200,000 people, mostly young adults, get infected with hepatitis B virus
- More than 11,000 people have to stay in the hospital because of hepatitis B
- 4,000 to 5,000 people die from chronic hepatitis B

Hepatitis B vaccine can prevent hepatitis B. It is the first anti-cancer vaccine because it can prevent a form of liver cancer.

2. How is hepatitis B virus spread?

Hepatitis B virus is spread through contact with the blood and body fluids of an infected person.

A person can get infected in several ways, such as:

- During birth when the virus passes from an infected mother to her baby
- By having sex with an infected person
- By injecting illegal drugs
- By being stuck with a used needle on the job
- By sharing personal items, such as a razor or toothbrush with an infected person

People can get hepatitis B infection without knowing how they got it. About 1/3 of hepatitis B cases in the United States have an unknown source.

3. Who should get hepatitis B vaccine and when?

(1) Everyone 18 years of age and younger

(2) Adults over 18 who are at risk

Adults at risk for hepatitis B infection include people who have more than one sex partner, men who have sex with other men, injection drug users, health care workers, and others who might be exposed to infected blood or body fluids.

If you are not sure whether you are at risk, ask your doctor or nurse.

People should get 3 doses of hepatitis B vaccine according to the following schedule. If you miss a dose or get behind schedule, get the next dose as soon as you can. There is no need to start over.

HEPATITIS B VACCINATION SCHEDULE

	Who?		
	Infant whose mother is infected with hepatitis B virus	Infant whose mother is not infected with hepatitis B virus	Older child, adolescent, or adult
When:			
First Dose	Within 12 hours of birth	Birth-2 months of age	Any time.
Second Dose	1-2 months of age	1-4 months of age (At least 1 month first after dose).	1-2 months after first dose.
Third Dose	6 months of age	6-18 months of age	4-6 months after first dose.

—The second dose must be given at least 1 month after the first dose.

—The third dose must be given at least 2 months after the second dose and at least 4 months after the first.

—The third dose should not be given to infants younger than 6 months of age.

Adolescents 11 to 15 years of age may need only two doses of hepatitis B vaccine, separated by 4-6 months. Ask your health care provider for details.

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

4. Some people should not get hepatitis B vaccine or should wait

People should not get hepatitis B vaccine if they have ever had a life-threatening allergic reaction to baker's

yeast (the kind used for making bread) or to a previous dose of hepatitis B vaccine.

People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting hepatitis B vaccine.

Ask your doctor or nurse for more information.

5. What are the risks from hepatitis B vaccine?

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

Getting hepatitis B vaccine is much safer than getting hepatitis B disease.

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

Mild Problems

- Soreness where the shot was given, lasting a day or two (up to 1 out of 11 children and adolescents, and about 1 out of 4 adults)
- Mild to moderate fever (up to 1 out of 14 children and adolescents and 1 out of 100 adults)

Severe Problems

- Serious allergic reaction (very rare)

6. What if there is a moderate or severe reaction?

What should I look for?

Any unusual condition, such as a serious allergic reaction, 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. If such a reaction were to occur, it would be within a few minutes to a few hours 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.

7. 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 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/bhpr/vicp>.

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's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
—Call 1-800-232-2522 or 1-888-443-7232 (English)
—Call 1-800-232-0233 (Español)
—Visit the National Immunization Program's Web site at <http://www.cdc.gov/nip> or CDC's Hepatitis Branch Web site at <http://www.cdc.gov/ncidod/diseases/hepatitis>

U.S. Department of Health & Human Services, Centers for Disease Control

and Prevention, National Immunization Program.

Vaccine Information Statement, Hepatitis B, (7/11/01), 42 U.S.C. 300aa-26.

Dated: September 23, 2002.

Joseph R. Carter,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifiers: CMS-10073, CMS-1557, CMS-1500, CMS-1490U, CMS-1490S CMS-1450J]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Survey of Rural Medicare Providers Regarding Provider Education Needs; *Form No.:* CMS-10073 (OMB# 0938-NEW); *Use:* The Division of Provider Education and Training, Centers for Medicare and Medicaid Services (CMS), is requesting Office of Management and Budget (OMB) approval to conduct a survey of the provider education needs of rural Medicare providers. CMS has contracted The Lewin Group to develop and field

the survey instrument, analyze and synthesize the information collected, and present findings and recommendations to help CMS better understand the provider education needs of rural providers. The study will also provide an assessment of the specific and unique education challenges faced by rural Medicare providers and the success of current education methods in meeting those challenges; *Frequency:* Other: One-time; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,832; *Total Annual Responses:* 1,832; *Total Annual Hours:* 608.

(2) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Survey Report Form Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1-493.2001; *Form No.:* CMS-1557 (OMB# 0938-0544); *Use:* CLIA requires the Department of Health and Human Services (DHHS) to establish certification requirements for any laboratory that performs tests on human specimens, and to certify through the issuance of a certificate that those laboratories meet the requirements established by DHHS. The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA. In order for the State survey agency to report to CMS its findings on facility compliance with the individual standards on which CMS determines compliance, the surveyor completes the Survey Report Form. The Survey Worksheet provides space to document the surveyor's notes; *Frequency:* Biennially; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 26,500; *Total Annual Responses:* 13,250; *Total Annual Hours:* 6,625.

(3) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Flexibility in Payment Methods for Hospitals, Nursing Facilities, and Intermediate Care Facilities for the Mentally Retarded and Supporting Regulations in 42 CFR 447.254; *Form No.:* CMS-R-252 (OMB# 0938-0784); *Use:* Section 4711 of BBA 1997 replaced the Boren requirements with Section 1902(a)(13)(A), which requires States to use a public process for determining institutional payment rates and publish proposed and final rates, underlying methodologies and