

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

justifications. Hospital rates must take into account the situation of hospitals that serve a disproportionate number of low-income patients with special needs; *Frequency*: Once; *Affected Public*: State local, or tribal gov't; *Number of Respondents*: 54; *Total Annual Responses*: 108; *Total Annual Hours*: 27.

(4) *Type of Information Request*: Extension of a currently approved collection; *Title of Information Collection*: Medicare/Medicaid Health Insurance Common Claim Form, Instructions, and Supporting Regulations: 42 CFR 414.40, 424.32, 424.44; *Form Number*: CMS-1500, CMS-1490U, CMS-1490S (OMB #: 0938-0008); *Use*: This form is a standardized form for use in the Medicare/Medicaid programs to apply for reimbursement for covered services. Many private insurers also use this form. Use of this form reduces cost and administrative burdens associated with professional claims because only one format needs to be used and maintained. CMS does not require exclusive use of this form for Medicaid.; *Frequency*: On occasion; *Affected Public*: State, Local or Tribal Government, Business or other for-profit, Not-for-profit institutions; *Number of Respondents*: 1,216,702; *Total Annual Responses*: 740,215,135; *Total Annual Hours Requested*: 42,941,276.

(5) *Type of Information Request*: Extension of a currently approved collection; *Title of Information Collection*: Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5; *Form Number*: CMS-1450 (OMB #: 0938-0247); *Use*: This standardized form is used in the Medicare/Medicaid program to apply for reimbursement of covered services by all providers that accept Medicare/Medicaid assigned claims; *Frequency*: On occasion; *Affected Public*: Business or other for-profit, Not-for-profit institutions; *Number of Respondents*: 46,708; *Total Annual Responses*: 158,603,290; *Total Annual Hours Requested*: 1,666,208.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to

the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: September 19, 2002.

John P. Burke III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-R-137 and CMS-R-257]

Agency Information Collection Activities: Submission for OMB Review; 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*: Extension of a currently approved collection; *Title of Information Collection*: Internal Revenue Service/Social Security Administration / Health Care Financing Administration Data Match and Supporting Regulations in 42 CFR 411.20-411.206; *Form No.*: CMS-R-137; *Use*: Employers who are identified

through a match of IRS, SSA, and Medicare records will be contacted concerning group health plan coverage of identified individuals to ensure compliance with Medicare Secondary Payer provisions found at 42 U.S.C. 1395y(b). *Frequency*: Annually; *Affected Public*: Federal Government, Business or other for profit, Not for profit institutions, Farms, Federal Government and State, Local or Tribal Government; *Number of Respondents*: 327,947; *Total Annual Responses*: 327,947; *Total Annual Hours Requested*: 1,096,466.

(2) *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Medicare + Choice Disenrollment Form to original Medicare; *Form No.*: CMS-R-257 (OMB# 0938-0741); *Use*: Section 4001 of the Balanced Budget Act of 1997 amended the Social Security Act to add section 1851; including 1851(c)(1) which required the establishment of a procedure and form to make and change Medicare + Choice elections, which include disenrollment. In addition, BBA of 1997 also required information be provided to beneficiaries to make better informed choices. Certain information is needed from the beneficiary in order to process the disenrollment action as a change of election; *Frequency*: On occasion; *Affected Public*: Individuals or Households, Business or other for-profit, federal government, not-for-profit institutions; *Number of Respondents*: 50,000; *Total Annual Responses*: 50,000; *Total Annual Hours*: 3,300.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.hcfa.gov/regs/prdact95.htm>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 19, 2002.

John P. Burke III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

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