

Dated: October 11, 2000.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10017]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing
Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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.

Type of Information Collection Request: New; *Title of Information Collection:* Follow-Up of Medicare+Choice Disenrollees Receiving Fee-for-Service Inpatient Hospital Care; *Form No.:* HCFA-10017 (OMB# 0938-NEW); *Use:* This study will survey Medicare beneficiaries who had a fee-for-service hospital stay after choosing to leave a Medicare+Choice health plan. The purpose is to gather information about their reasons for disenrolling and to explore the link between the decision to disenroll and their subsequent fee-for-service care; *Frequency:* On occasion; *Affected Public:* Individuals or households; *Number of Respondents:* 600; *Total Annual Responses:* 600; *Total Annual Hours:* 650.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regspdract95.htm>, or E-mail your

request, including your address, phone number, OMB number, and HCFA 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 HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Date: October 24, 2000.

John P. Burke, III,

Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-0209 and HCFA-R-0245]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing
Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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:* Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set

(OASIS) Data as Part of the Conditions of Participation for Home Health Agencies and Supporting Regulations in 42 CFR 484.11 and 484.20; *Form No.:* HCFA-R-0209 (OMB# 0938-0761); *Use:* The information collection requirements contained in the regulations state that HHAs must report data from the OASIS data set as a condition of participation for HHAs. Specifically, they provide guidelines for HHAs for the electronic transmission of the OASIS data set as well as responsibilities of the State agency or OASIS contractor in collecting and transmitting this information to HCFA. These requirements are necessary to establish a prospective payment system for HHAs and to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs; *Frequency:* As determined by HHA and monthly; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local, or Tribal Government; *Number of Respondents:* 7,500; *Total Annual Responses:* 7,500; *Total Annual Hours:* 911,313.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare and Medicaid Programs: Use of Outcome and Assessment Information Set (OASIS) as Part of the Conditions of Participation for Home Health Agencies and Supporting Regulations in 42 CFR 484.55; *Form No.:* HCFA-R-0245 (OMB# 0938-0760); *Use:* These information collection requirements are part of the existing conditions of participation that home health agencies (HHAs) must meet to participate in the Medicare program. Specifically, each patient must receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, the regulation requires that, as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, when evaluating adult, non-maternity patients. These changes are an integral part of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care; *Frequency:* Upon patient assessment; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local, or Tribal Government; *Number of Respondents:* 7,500; *Total Annual Responses:* 7,500; *Total Annual Hours:* 885,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA'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 HCFA 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 HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Date: October 24, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-0232]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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.

Type of Information Collection Request: Extension; *Title of Information Collection:* Supporting Statement for Medicare Program Integrity Program Organizational Conflict of Interest Disclosure Certificate and Supporting Regulations in 42 CFR 421.310 and 421.312; *Form No.:* HCFA-R-0232 (OMB# 0938-0723); *Use:* This information is used to assess whether contractors who perform, or who seek to perform, Medicare Integrity Program functions, such as medical review, fraud review or cost audits, have organizational conflicts of interest and whether any conflicts have been resolved. The entities providing the information will be organizations that have been awarded, or seek award of, a Medicare Integrity Program contract; *Frequency:* On occasion; *Affected Public:* Businesses or other for profit; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 2,400.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA'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 HCFA 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 HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: October 24, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program ("the Program"), as required by section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005, (202) 219-9657. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 8A-46, Rockville, MD 20857; (301) 443-6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated her responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested after the time periods specified in the Table, but only