

- The history and current status of the documentation guidelines.
- Our technical assessment of the June 1999 proposed AMA recommendations.
- Other proposals for revising the guidelines.
- The proposed study.
- The role of organized medicine and practicing physicians in commenting on the guidelines and the study.
- A proposed time line for eventual implementation of new documentation guidelines.
- New efforts to improve responsiveness and service to physicians.

Registration

If you wish to attend the meeting, you must register in advance by sending a fax to the attention of Ms. Martha Dixon, Office of Professional Relations, at (202) 401-7438 by the date listed in the **DATES** section of this notice. Your fax must include your name, organization, address, telephone number, and fax number. Our receipt of your fax will constitute confirmation of your registration. If space at the meeting is no longer available when your fax is received, you will be notified by phone that you are on an attendance waiting list. If space should subsequently become available, individuals on the waiting list will be notified in turn. Written materials will be provided at the time of the meeting.

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 1, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Privacy Act of 1974; System of Records

AGENCY: Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA).

ACTION: Notice To Delete Three Systems of Records.

SUMMARY: The Health Care Financing Administration is deleting three systems of records from its inventory subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

EFFECTIVE DATE: The deletions will be effective on June 6, 2000.

ADDRESSES: The public should address comments to: Director, Division of Data Liaison and Distribution, HCFA, Room N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. The telephone number is (410) 786-3673. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.-3 p.m., eastern time zone.

SUPPLEMENTARY INFORMATION: The "Medicare Enrollment Records Statistics (MERS)," System No. 09-70-0006, was established to study the characteristics of persons enrolled in the Medicare program and establish the basis for Medicare services utilization rates. The "Health Insurance Enrollment Statistics (HIES), General Enrollment Period," System No. 09-70-0007 was established to contact persons eligible for Part B benefits who had refused or withdrawn coverage of these benefits, for purposes of re-enrollment for Part B coverage and to evaluate results of such contacts. The "Medicare Beneficiary Correspondence Files (MBC)," System No. 09-70-0509 was established to maintain and track correspondence in a HCFA component that no longer exist. All of these systems are being deleted from HCFA's inventory because they are no longer used. Retention and destruction of the data contained in these systems has been in accordance with the retention and disposal schedules listed in the system notice.

Deletions

No. 09-70-0006 "Medicare Enrollment Records Statistics (MERS)," HHS/HCFA/BDMS;

No. 09-70-0007 "Health Insurance Enrollment Statistics (HIES), General Enrollment Period," HHS/HCFA/BDMS.

No. 09-70-0509 "Medicare Beneficiary Correspondence Files (MBC)," HHS/HCFA/BPO;

Dated: May 26, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00-14071 Filed 6-5-00; 8:45 am]

BILLING CODE 4120-03-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden 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.

Proposed Project: Drug Pricing Program Reporting Requirements (OMB No. 0915-0176)

Extension—Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate.

Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) has developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audits of covered entities.

Audit guidelines: A manufacturer will be permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer must notify the covered entity in writing when it believes the covered entity has violated these provisions of section 340B. If the problem cannot be resolved, the

manufacturer must then submit an audit work plan describing the audit and evidence in support of the reasonable cause standard to the HRSA OPA for review. The office will review the documentation to determine if reasonable cause exists. Once the audit is completed, the manufacturer will submit copies of the audit report to the HRSA OPA for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General.

Dispute resolution guidelines: Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA OPA has developed a dispute resolution process which can be used if an entity or manufacturer is believed to be in violation of section 340B. Prior to filing a request for resolution of a

dispute with the HRSA OPA, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute to the HRSA OPA. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

To date, there have been no requests for audits, and no disputes have reached the level where a committee review was needed. As a result, the estimates of annualized hour burden for audits and disputes have been reduced to the level shown in the table below.

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours/ response	Total burden hours
Audits:					
Audit Notification of Entity ¹	2	1	2	4	8
Audit Workplan ¹	1	1	1	8	8
Audit Report ¹	1	1	1	1	1
Entity Response	0	0	0	16	0
Dispute Resolution:					
Mediation Request	5	1	5	8	40
Rebuttal	2	1	2	16	32
Total	9	1.2	11	8.1	89

¹ Prepared by the manufacturer

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total burden
Dispute records	10	.5	5

The total burden is 94 hours.

Send comments to Susan G. Queen, HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: June 1, 2000.

James J. Corrigan,

Associate Administrator for Management and Program Support.

[FR Doc. 00-14215 Filed 6-5-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), as enacted by Public Law (Pub. L.) 99-660 and as subsequently amended, and advises the Secretary of Health and

Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

FOR FURTHER INFORMATION CONTACT: Ms. Shelia Tibbs, Principal Staff Liaison, Policy Analysis Branch, Division of Vaccine Injury Compensation, at (301) 443-4036.

DATES: Nominations are to be submitted by July 6, 2000.

ADDRESSES: All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, HRSA, Parklawn Building, Room 8A-46, 5600 Fishers Lane, Rockville, Maryland 20857.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, viz., the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and section 2119 of the Act, 42 U.S.C. 300aa-19, as added by Public Law 99-