

which deferment of the service obligation will be approved.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Deferment Request Forms .....	600	1	1	600
Letters of Intent and Request .....	100	1	1	100
Total .....	700		2	700

Send comments to Susan G. Queen, Ph.D., 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: August 15, 2000.

**James J. Corrigan,**

*Associate Administrator for Management and Program Support.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**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 audit 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 the 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 exist. 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
<b>Audits</b>					
Audit Notification of Entity <sup>1</sup> .....	2	1	2	4	8
Audit Workplan <sup>1</sup> .....	1	1	1	8	8
Audit Report <sup>1</sup> .....	1	1	1	1	1
Entity Response .....	0	0	0	0	0

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours/ response	Total burden hours
<b>Dispute Resolution</b>					
Mediation Request .....	5	1	5	8	40
Rebuttal .....	2	1	2	16	32
Total .....	9	1	9	37	89

<sup>1</sup> Prepared by the manufacturer.

Recordkeeping requirement	Number of record-keepers	Hours of record-keeping	Total burden
Dispute records .....	10	.5	5

The total burden is 94 hours.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: August 15, 2000.

**James J. Corrigan,**

*Associate Administrator for Management and Program Support.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of September 2000.

*Name:* Advisory Commission on Childhood Vaccines (ACCV).

*Date and Time:* September 6, 2000; 9:00 a.m.-5:00 p.m.

*Place:* Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

The full Commission will meet on Wednesday, September 6, from 9:00 a.m. to 5:00 p.m. Agenda items will include, but not be limited to: a presentation on Aluminum in Vaccines, a presentation on recent General Accounting Office Reports on the Vaccine Injury Compensation Program, a report on Vaccination and Autism, updates from the Department of Justice and the National Vaccine Program Office, and routine program reports.

Public comment will be permitted before lunch and at the end of the Commission

meeting on September 6, 2000. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Shelia Tibbs, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A-46, 5600 Fishers Lane, Rockville, MD 20857; Telephone (301) 443-6593. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file an advance request for a presentation, but desire to make an oral statement, may sign-up in Conference Rooms G and H on September 6, 2000. These persons will be allocated time as time permits.

Anyone requiring information regarding the Commission should contact Ms. Tibbs, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A-46, 5600 Fishers Lane, Rockville, Maryland 20857; Telephone (301) 443-6593.

Agenda items are subject to change as priorities dictate.

Dated: August 15, 2000.

**James J. Corrigan,**

*Associate Administrator for Management and Program Support.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Councils; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory bodies scheduled to meet jointly during the month of September 2000.

*Names:* Council on Graduate Medical Education (COGME) and National Advisory Council on Nurse Education and Practice (NACNEP).

*Date and Time:* September 13, 2000; 8:00 a.m.-6:00 p.m. September 14, 2000; 7:30 a.m.-11:30 a.m.

*Place:* Holiday Inn Capitol, 550 C Street, S.W., Washington, D.C. 20024.

The meeting is open to the public.

*Agenda:* At the joint Councils meeting, eight invited experts will address the effect of the relationships between physicians and nurses on patient safety; the impact of physician-nurse collaboration on systems established to protect patient safety; educational programs to ensure interdisciplinary collaboration to further patient safety; education to prepare students, practicing physicians, and nurses to apply new technologies to error prevention; and consumers' perspectives on physician-nurse collaboration and its effects on patient safety and communication with patients and their families. Members of the two Councils will then work together to develop recommendations on physician-nurse collaborative education and practice activities leading to enhanced safety in caring for their patients. The meeting presentations and recommendations will be published.

Anyone interested in obtaining rosters of COGME and NACNEP members or other relevant information should write or contact Elaine G. Cohen, MS, RN, Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9-35, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-1405.