The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: August 1, 2003.

Laura M. Tarantino,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 03–21396 Filed 8–20–03; 8:45 am]

BILLING CODE 4160–01–S

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)—Revision

Section 602 of Pub. L. 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.

In response to the statutory mandate of section 340B(a)(5)(C) to develop audit guidelines and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Pharmacy Affairs Branch (PAB) 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 PAB 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 PAB 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 PAB has developed an informal 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 PAB, 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 PAB. 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, but two disputes have reached the level where a committee review may be 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	No. 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	0	0
DISPUTE RESOLUTION					
Mediation Request	2	4	8	10	80
Rebuttal	2	1	2	16	32
TOTAL	8	1.8	14	9.2	129

[1] Prepared by the manufacturer

Recordkeeping requirement	No. of record-keepers	Hours of rec-ordkeeping	Total burden
Dispute records	10	15	5

The total burden is 134 hours.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Allison Eydt, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503 Fax Number 202–395–6974.

Dated: August 15, 2003.

Jon L. Nelson,

Associate Administrator for Management and Program Support.

[FR Doc. 03–21399 Filed 8–20–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting; Cancellation

In notice FR Doc. 03–20249, on page 47344 in the **Federal Register** of August 8, 2003, the meeting scheduled for September 7–9, 2003, is canceled.

Authority: Public Law 92–463.

Dated: August 15, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–21397 Filed 8–20–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Reauthorization Workgroup

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of public meetings and opportunity to provide written comments.

SUMMARY: On May 15, 2003, the Centers for Disease Control and Prevention (CDC)/Health Resources and Services Administration (HRSA) Advisory Committee on HIV and STD Prevention and Treatment established the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Reauthorization Workgroup. The workgroup is seeking public input about future HIV/AIDS care program directions including issues related to the third reauthorization of the Ryan White CARE Act. The CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment will subsequently submit a set of formal recommendations relating to future program directions and reauthorization issues to the HRSA Administrator.

DATES: Three public meetings will be held on September 12, 2003, September 25, 2003, and October 3, 2003, from 9:30 a.m. to 3:30 p.m. To be assured of consideration for this public session, written comments should be postmarked no later than 12 days prior to each meeting.

ADDRESSES: The September 12, 2003, public meeting will be held at the Marriott Wardman Park Hotel, 2660 Woodley Road, NW., Washington, DC, telephone (202) 328–2000; the September 25, 2003, public meeting will be held at the Miami Airport Marriott, 1201 NW., LeJeune Road, Miami, Florida, telephone (305) 649–5000; and the October 3, 2003, public meeting will be held at the Hyatt Regency Los Angeles, 711 South Hope Street, Los Angeles, California, telephone (213) 683–1234. Written comments should be sent to the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment, c/o HRSA HIV/AIDS Bureau, Office of Policy and Program Development, Attention: Regina Tosca, Parklawn Building, Room 7–18, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Shelley Gordon, Office of Policy and Program Development, HIV/AIDS Bureau, Health Resources and Services Administration, (301) 443–5400, fax (301) 443–3323, or e-mail *SGordon@HRSA.gov.*

SUPPLEMENTARY INFORMATION: The meetings will be open to the public, limited only by the space available. The meeting rooms will accommodate approximately 80 people. The purpose of the meetings is to obtain public input into future program directions and issues related to the reauthorization of the Ryan White CARE Act of 1990, as amended by the Ryan White CARE Act Amendment of 1996 and 2000 (Pub. L. 104–146 and Pub. L. 106–345). Written comments should be limited to no more than 10 single-spaced pages (or 20 double-spaced, excluding addendum or supplemental materials) and should contain the name, address, telephone and fax numbers, and any organizational affiliation of the persons requesting to provide a written statement. All requests for making oral comments will be honored at the meetings on September 12, September 25, and October 3. Depending on the number of requests to present oral comments, it may be necessary to limit the length of time for each presenter. We are particularly interested in comments which address the following questions:

1. Is the CARE Act structured to best provide Federal Emergency Assistance for HIV treatment and care services?

2. What in the CARE Act works for you and what does not?

3. Does the CARE Act provide adequate resources to respond to your needs or those of your community?

4. Does the CARE Act local planning process (*e.g.,* needs assessment, priority setting, and allocation processes) ensure a fair and appropriate opportunity to determine the HIV care and support service needs of your community?

5. What are the most significant HIV service gaps in your community? How can the CARE Act help fill them?

6. What are the most significant barriers to access to services? How can the CARE Act help overcome them?

7. How can the CARE Act respond more fully to the current and changing needs of people living with HIV?

8. What is the single most important thing you would change in the CARE Act and why?

Authority: Pub. L. 92–463 (5 U.S.C., App. 2); 42 U.S.C. 217a, sec. 222 of the Public Health Service Act.

Dated: August 14, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–21398 Filed 8–20–03; 8:45 am]

BILLING CODE 4165–15–P