Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/ohrms/dockets* approximately 30 days after the meeting.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX: 301–594–6777 *Erik.Mettler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 4, 2007 (72 FR 56769), FDA announced that it would hold a public meeting regarding BTC availability of certain human drugs. BTC availability could make certain drugs available behind the counter at the pharmacy without a prescription and require the intervention of a pharmacist before dispensing.

Some groups have asserted that pharmacist interaction with the consumer could ensure safe and effective use of a drug product that otherwise might require a prescription. Because pharmacists have the training and knowledge to provide certain interventions, they may be able to ensure that patients meet the conditions for use and educate patients on appropriate use of the drug product. These groups have suggested that the availability of certain drugs BTC could increase patient access to medications that may be underutilized, particularly by patients without health insurance, because these medications otherwise would be available only with a prescription.

The **Federal Register** notice stated that interested persons would be able to submit comments to the Division of Dockets Management and that the public docket would remain open for 30 days following the meeting. Our intent was to state that the docket would remain open until December 17, 2007 (30 days after the meeting, which occurred on November 14, 2007). However, the notice also instructed persons to register if they wished to attend or participate in the meeting; the instructions stated that registration would occur on a first-come, first-serve basis, but then mistakenly declared that written or electronic comments would be accepted ''until November 28, 2007'' (72 FR 56769).

II. Comments

This notice clarifies that we will accept comments to the public docket until December 17, 2007.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: November 20, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–23026 Filed 11–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

The Health Resources and Services Administration is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

Pursuant to section 100.2 of the VICP's implementing regulations (42 CFR Part 100), the Secretary announces that the revised average cost of a health insurance policy under the VICP is $380.04 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the Secretary to the United States Court of Federal Claims. Such notice was delivered to the Court on October 17, 2007.

Dated: November 19, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–23090 Filed 11–26–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HIV/AIDS Bureau; Ryan White HIV/AIDS Program Core Medical Services Waiver Application Requirements

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of opportunity to provide written comments.

SUMMARY: This notice solicits comments on the HRSA proposed uniform waiver standards for Ryan White HIV/AIDS Program grantees requesting a core medical services waiver for Fiscal Year 2008 and beyond. Title XXVI of the Public Health Service Act (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Ryan White HIV/AIDS Program) requires that grantees expend 75 percent of Parts A, B, and C funds on core medical services, including antiretroviral drugs, for individuals with HIV/AIDS identified and eligible under the legislation, effective Fiscal Year (FY) 2007. HRSA has issued guidance for obtaining a waiver for FY 2007 and seeks to issue waiver requirements for grantees under Parts A, B, and C of Title XXVI of the PHS Act for FY 2008 and future years.

DATES: Written comments must be received no later than 30 days after date of publication in the **Federal Register**.

ADDRESSES: Written comments should be sent to HRSA, HAB, Division of Science and Policy, *Attention:* LCDR Gettie A. Butts, 5600 Fishers Lane, Room 7–18, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: *LCDR Gettie A. Butts, at: GButts@hrsa.gov* or by writing to the address above.

SUPPLEMENTARY INFORMATION: The statute, Title XXVI of the Public Health Service Act (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006, imposes two criteria for waiver eligibility: (1) No waiting lists for AIDS Drug Assistance Program (ADAP) services; and (2) core medical services availability within the relevant service area to all individuals with HIV/AIDS identified and eligible under Title XXVI of the PHS Act. See sections 2604(c)(2), 2612(b)(2), and 2651(c)(2) of the PHS Act. The Health Resources and Services Administration (HRSA) HIV/AIDS Bureau has issued interim waiver eligibility guidance for FY 2007 to provide immediate implementation of these waiver provisions. The FY 2007 guidance

required that grantees provide written certification stating that all Ryan White-funded core medical services are available in the service area and that no ADAP waiting list exists. Given the need for immediate implementation, the guidance offered an expeditious process by which grantees could apply for a waiver for FY 2007. HRSA now provides notice of its proposal for a more permanent process by which such waivers will be granted beginning in FY 2008 and seeks public comment on its proposal.

Beginning in FY 2008, HRSA will utilize new standards for granting waivers of the core medical services requirement for Ryan White HIV/AIDS Programs. These standards meet the intent of the Ryan White HIV/AIDS Treatment Modernization Act of 2006 to increase access to core medical services, including antiretroviral drugs, for persons with HIV/AIDS and to ensure that grantees receiving waivers demonstrate the availability of such services for individuals with HIV/AIDS identified and eligible under Title XXVI of the PHS Act. The purposes of this notice are: (1) To establish requirements for core medical services waiver eligibility for grantees under Parts A, B, and C of Title XXVI of the PHS Act; and (2) to establish a process for waiver request submission, review and notification. The core medical services waiver uniform standard and waiver request process proposed in this notice will apply to Ryan White HIV/AIDS Program grant awards under Parts A, B, and C of Title XXVI of the PHS Act.

Proposed Uniform Standard for Waiver of Core Medical Services Requirements for Grantees Under Parts A, B, and C

Grantees must submit a waiver request with the annual grant application containing the following certifications and documentation which will be utilized by HRSA in determining whether to grant a waiver. The waiver must be signed by the chief elected official or the fiscally responsible agent, and include:

1. Certification from the Part B state grantee that there are no current or anticipated ADAP services waiting lists in the state for the year in which such waiver request is made. This certification must also specify that there are no waiting lists for a particular core class of antiretroviral therapeutics established by the Secretary, e.g., fusion inhibitors;

2. Certification that all core medical services listed in the statute (Part A section 2604(c)(3), Part B section 2612(b)(3), and Part C section 2651(c)(3)), regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available within 30 days for all identified and eligible individuals with HIV/AIDS in the service area;

3. Evidence that a public process was conducted to seek public input on availability of core medical services;

4. Evidence that receipt of the core medical services waiver is consistent with the grantee's Ryan White HIV/AIDS Program application (e.g., ''Description of Priority Setting and Resource Allocation Processes'' and ''Unmet Need Estimate and Assessment'' sections of the application for Parts A, ''Needs Assessment and Unmet Need'' section of the application under Part B, and ''Description of the Local HIV Service Delivery System,'' and ''Current and Projected Sources of Funding'' sections of the application under Part C).

Types of Documentation and Evidence

Grantees must provide evidence that all of the core medical services listed in the statute, regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available to all individuals with HIV/AIDS identified and eligible under Title XXVI of the PHS Act in the service area within 30 days. Such documentation may include one or more of the following types of information for the service area for the prior fiscal year: HIV/AIDS care and treatment services inventories including funding sources, HIV/AIDS met and unmet need assessments, HIV/AIDS client/patient service utilization data, planning council core medical services priority setting and funding allocations documents, and letters from Medicaid and other state and local HIV/AIDS entitlement and benefits programs including private insurers. Information provided by grantees must show specific verifiable evidence that all listed core medical services are available and are being utilized to meet the needs of persons with HIV/AIDS who are identified and eligible for Ryan White HIV/AIDS Program services without further infusion of Ryan White HIV/AIDS Program dollars. Such documentation must also describe which specific core medical services are available, from whom, and through what funding source.

Grantees must have evidence of a public process for the dissemination of information and must seek input from affected communities related to the availability of core medical services and the decision to request a waiver. This public process may be the same one utilized for obtaining input on community needs as part of the comprehensive planning process. In addition, grantees must describe in narrative form the following:

1. Local/state underlying issues that influenced the grantee's decision to request a waiver and how the submitted documentation supports the assertion that such services are available and accessible to all individuals with HIV/AIDS identified and eligible under Title XXVI in the service area.

2. How the approval of a waiver will impact the grantee's ability to address unmet need for HIV/AIDS services and perform outreach to HIV-positive individuals not currently in care.

3. The consistency of the waiver request with the grantee's grant application, including proposed service priorities and funding allocations.

Waiver Review and Notification Process

As indicated, grantees must submit a waiver request with their annual grant application. No waiver requests will be accepted at any other time (other than with the annual grant application). Application guidance documents will be amended to include this requirement. HRSA/HAB will review requests for waiver of the core medical services requirement and will notify grantees of waiver approval no later than the date of issuance of Notice of Grant Award. Core medical services waivers will be effective for a one-year period consistent with the grant award period.

The Paperwork Reduction Act of 1995

This activity is subject to Office of Management and Budget review and approval under the Paperwork Reduction Act of 1995.

Dated: November 16, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–22982 Filed 11–26–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2007–29114]

Delaware River and Bay Oil Spill Advisory Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Notice of committee establishment and request for applications.

SUMMARY: The Secretary of Homeland Security is establishing the Delaware River and Bay Oil Spill Advisory