

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](mailto: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.*

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**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