

**Attachment 1 List of SUDs Known To Be Reprocessed or Considered for Reprocessing—Continued**

|     | Medical Specialty | Device Type                                    | Regulation Number                                        | Class | Product Code                        | Risk <sup>A</sup> | Critical/Semicritical/Non-critical | Premarket Exempt |
|-----|-------------------|------------------------------------------------|----------------------------------------------------------|-------|-------------------------------------|-------------------|------------------------------------|------------------|
| 226 | Surgery           | Surgical Cutting Accessories                   | 878.4800,<br>874.4420                                    | I     | GDZ, GDX,<br>GES,<br>KBQ,<br>KAS    | 2                 | C                                  | Y                |
| 227 | Surgery           | Electrosurgical Electrodes/<br>Handles/Pencils | 876.4300<br>878.4400                                     | II    | HAM, GEI,<br>FAS                    | 2                 | C                                  | N                |
| 228 | Surgery           | Scissor Tips                                   | 878.4800,<br>884.4520,<br>874.4420                       | I     | LRW, HDK,<br>HDJ,<br>JZB,<br>KBD    | 2                 | C                                  | Y                |
| 229 | Surgery           | Laser Fiber Delivery Systems                   | 878.4810<br>874.4500<br>886.4390<br>884.4550<br>886.4690 | II    | GEX EWG<br>LLW<br>HQF<br>HHR<br>HQB | 1                 | C                                  | N                |

<sup>A</sup>Risk categorization may be either:

1 = low risk according to RPS

2 = moderate risk according to RPS

3 = high risk according to RPS

3\* = high risk due to neurological use

See section II of this document, "FDA's Implementation of New Section 510(o) of the Act" for methodology and criteria used to identify the risk.

Dated: September 22, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## **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 at (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 through the use of automated collection techniques or other forms of information technology.

#### **Proposed Project: Maternal and Child Health Services Title V Block Grant Program—Guidance and Forms for the Title V Application/Annual Report, OMB No.0915-0172: Revision**

The Health Resources and Services Administration (HRSA) proposes to revise the *Maternal and Child Health Services Title V Block Grant Program—Guidance and Forms for the Application/Annual Report*. The guidance is used annually by the 50 States and 9 jurisdictions in making application for Block Grants under Title V of the Social Security Act, and in preparing the required annual report. The proposed revisions follow and build on extensive consultation received from a workgroup convened to provide suggestions to improve the guidance and forms. The proposed revisions are editorial and technical revisions based on the experience of the states and jurisdictions in using the guidance and forms since 2003.

Two new performance measures were developed (obesity in children aged 2 to

5 years; and smoking in the last trimester of pregnancy) and two existing performance measures were either removed entirely (low birth weight) or incorporated into an existing health status capacity indicator (eligible children receiving services under Medicaid). This will result in no net increase in the number of performance measures. In addition, the directions in the guidance for the Health Systems Capacity Indicators (HSCI) were expanded to enhance clarification. This proposed change will make it easier for the states to report on these indicators.

The existing electronic system used by the states to submit their Block Grant Application and Annual Report has also been enhanced. First, using the electronic system, the narrative from the prior year's submission is available online in the system so that the applicant need only edit those sections that have changed. This reduces burden by avoiding duplicating material. For national performance measures 2-6, the data obtained from the National Survey of Children with Special Health Care Needs are pre-populated which eliminates the need to retrieve and enter data from this survey, unless the states choose to use another data source. Also, notes from the prior year's submission are available to the states allowing for more efficient updating through edits rather than recreating them. Data are entered once (in a data entry field on a given form), and where those data are referenced elsewhere, the value is

copied and displayed. The electronic system includes an automatic character counter that tells the user how many characters the states have left. This eliminates the need to independently track entries against the Maternal and Child Health Bureau's limits for each section and ensures compliance. The electronic system includes forms status checker and data alerts, which conduct automated checks on data validity, data

consistency, and application completeness, as well as value tolerance checks. This facilitates application review and eliminates much of previously required data cleaning activity. Also, this allows the user to obtain an immediate update at any point in time on the completeness and compliance of the application, reducing the need to conduct a review of the application. Data are saved directly to

the HRSA server so that no manual transmission is required. Finally, the automatic commitment of data to the HRSA server eliminates the need for version control or data migration.

The estimated average annual burden per year is as follows for the Annual Report and Application without the Needs Assessment:

| Type of respondent  | Number of respondents | Responses per respondent | Burden hours per response | Total burden hours |
|---------------------|-----------------------|--------------------------|---------------------------|--------------------|
| States .....        | 50                    | 1                        | 297                       | 14,868             |
| Jurisdictions ..... | 9                     | 1                        | 120                       | 1,077              |
| Total .....         | .....                 | .....                    | 59                        | 15,945             |

Burden in the 3 Year Reporting Cycle for the Annual Report and Application with Needs Assessment is:

| Needs assessment                            | Number of respondents | Burden hours per responses | Responses per respondent | Total burden hours |
|---------------------------------------------|-----------------------|----------------------------|--------------------------|--------------------|
| States/Jurisdictions .....                  | 59                    | 378.5                      | 1                        | 22,303             |
| Total Average Burden for 3 year cycle ..... | .....                 | .....                      | .....                    | 18,064             |

Send comments to Susan G. Queen, PhD., HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of notice.

Dated: September 23, 2005.

**Tina M. Cheatham,**

*Director, Division of Policy Review and Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Ricky Ray Hemophilia Relief Fund Program Administrative Close-Out

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** This Notice announces the administrative close-out of the Ricky Ray Hemophilia Relief Fund Program (the Program). All business concerning petitions and related payment documentation associated with the Program will conclude on October 31, 2005.

As of that date, the Program will cease to accept or process any additional documentation submitted by individuals (or their representatives) relating to the eligibility or payment of petitions still pending. Remaining funds will be returned to the United States Treasury, and the Program will archive all outstanding documentation at the Washington National Records Center in Suitland, Maryland, in accordance with the requirements of the National Archives and Records Administration.

**DATES:** Effective Date: October 31, 2005.

**ADDRESSES:** Ricky Ray Hemophilia Relief Fund Program, Healthcare Systems Bureau, Health Resources and Services Administration, U.S. Department of Health and Human Services, 5600 Fishers Lane, Room 11C-06, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** Paul T. Clark, Director, Ricky Ray Hemophilia Relief Fund Program, 5600 Fishers Lane, Room 11C-06, Rockville, MD 20857; (301) 443-2330.

**SUPPLEMENTARY INFORMATION:** The Program implemented the Ricky Ray Hemophilia Relief Fund Act of 1998 (the Act), Pub. Law 105-369. The Act established a Trust Fund to provide compassionate payments to individuals with blood-clotting disorders, such as hemophilia, who were treated with antihemophilic factor between July 1,

1982 and December 31, 1987, and contracted human immunodeficiency virus (HIV), as well as to certain persons who contracted HIV from these individuals. In the event individuals eligible for payment were deceased, the Act also provided for payments to certain survivors of these individuals.

Under section 101(d) of the Act, the Trust Fund terminated on November 12, 2003. The Act requires all remaining funds to be deposited in the miscellaneous receipts account in the Treasury of the United States.

The Program has made compassionate payments totaling in excess of \$559 million to more than 7,171 eligible individuals and survivors.

Dated: September 22, 2005.

**Dennis P. Williams,**

*Deputy Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Meetings: Organ Transplantation Advisory Committee

**AGENCY:** Health Resources and Services Administration, HHS.