Supporting Statement

Factor Replacement Product Data Sheet for Health Resources and Services Administration Funded Hemophilia Treatment Centers Having Factor Replacement Product Sales Programs

A. Justification

1. Circumstances of Information Collection

This is a request for Office of Management and Budget (OMB) approval of an annual reporting form to be submitted by the grantees funded by the Health Resources and Services Administration (HRSA) of the Maternal and Child Health Bureau's (MCHB) National Hemophilia Program (NHP) and their Hemophilia Treatment Center (HTC) affiliates having a 340B Factor Replacement Product (FRP) Program. The HTCs sell FRPs to their patients.

HRSA/MCHB's NHP began in the 1970s and is funded through Section 501(a)(2) of the Social Security Act, the Maternal and Child Health Federal Set-Aside Program: Special Projects of Regional and National Significance (SPRANS) (42 U.S.C. 701(a))2)). The purpose of this program is to provide comprehensive diagnostic and treatment services to persons with hemophilia and other congenital bleeding disorders throughout the United States, Puerto Rico, U.S. Virgin Islands, and the Pacific Basin. To achieve this purpose, the MCHB NHP is comprised of 12 regional project grantees that contract with HTCs within their designated region resulting in a network of 130 HTCs. HTCs are a part of a larger organization such as a children's hospital or a university medical center. A list of the 12 regions and the geographical area covered by each is attached.

With the advent of the Drug Pricing Program established by Section 340B of the Public Health Service Act enacted on November 4, 1992, HRSA-funded HTCs became eligible to purchase drugs (including FRPs) at a discounted price. Since that time, there has been a continuous increase in the number of HRSA funded HTCs choosing to participate in this program so that currently there are approximately 70 HTCs participating. Program income generated by the sale of FRPs is used in addition to funds from other sources to pay for patient services and program activities.

The Office of Inspector General (OIG) conducted a review of six HTCs having 340B FRP sales programs; the report on their findings and recommendations was released June 17, 2003. This report along with the HRSA response to the report is attached. On page 5 of this report, under "Inadequate Program Monitoring," the OIG states "Our review showed that MCHB did not have sufficient controls over the grantees that subcontract with HTCs to ensure program funds are used for their intended purposes and to further program objectives."

The regulatory authority for monitoring program income as well as the responsibility of grantees to monitor the program income generated by the sub-awardees is discussed in a May 23, 2003 communication sent to the MCHB Hemophilia Project Grantees (attached). This communication established the requirement that grantees report program income using the long form of the Financial Status Report (FSR) standard form 269 (OMB Approval No. 0348-0039, Circulars A-102 and A-110). In addition, in July 2005 HRSA/MCHB produced the *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act*.

The MCHB has now drafted a "FRP Data Sheet for HRSA Funded HTCs Having FRP Sales Programs" to help ensure appropriate 340B program implementation. It is for this data sheet and accompanying instructions that we are currently requesting OMB approval.

2. Purpose and Use of Information

The data sheet is to be completed annually by each HTC having a FRP sales program. The most important purpose of this data collection is to achieve the monitoring needed to assess HTCs' FRP program operations, including the use of program income. The data sheet includes program income based on calculated revenue and costs and a description of the use of program income to assess if the program income is being used to further program objectives. Additionally, the data will be used to assess the efficiency of each FRP program by evaluating its costs of operation. Finally, the data will allow an evaluation of the financial needs of HTCs having FRP programs and HTCs not having FRP programs so that appropriate adjustments in the distribution of HRSA/MCHB grant funds can be made.

Regarding specific items on the data sheet:

The **Reporting Period** is to be the same as the most recently completed grant budget period. A FSR is required for this period and most of the information contained on the data sheet is needed for the accurate completion of the FSR.

Patient Data provides basic information regarding the number of patients choosing to buy their FRPs from the HTC and allows us to see how this number changes over time. The patient data have a breakout regarding Medicaid patients to assess the use of a "Medicaid Carve Out." (It has been determined that an HTC can choose to sell FRPs to Medicaid patients that it has purchased at a non-340B price.) Collecting these Medicaid data allows for an evaluation as to the extent of this practice and its financial implications. Also, we need to make sure that FRP programs report program income from the sale of FRPs and from the "Medicaid Carve Out," if they have both.

Balance at start of reporting period is collected because it is not likely that the exact amount of income generated during the budget period will be spent during the same exact time period and because a FRP sales program may need to have some funds on hand to meet unexpected expenses.

FRP revenue is the first item of information needed to begin to calculate net program income.

FRP operating costs are subtracted from FRP revenue to calculate FRP Net Program Income. The main cost for a FRP sales program is the cost of FRPs. The other main cost is either the cost of pharmacy staff for a FRP sales program that has its own pharmacy or the cost of contractual services for FRP Sales Programs that contract for pharmacy services.

The main expected use of FRP Net Program Income is to pay the salaries of HTC staff serving patients.

Another possible use of FRP Net Income is to apply it to indirect costs as these have been determined as a part of establishing a negotiated indirect cost rate.

Balance at End of Reporting Period: This is the balance at the start of the reporting period plus program income generated during the reporting period minus program income expended during the reporting period.

3. Use of Improved Information Technology

As a part of the grantee's grant application submission, each individual HTC Report is to be submitted electronically through HRSA's Electronic Handbook (EHB) using the established HRSA electronic grant application submission requirements.

4. Efforts to Identify Duplication

Aggregated net program income is reported on the required annual FSR. In order to produce an accurate FSR, grantees require revenue and cost information which is similar to the information that would be submitted on the proposed HRSA Data Sheet. This significantly and substantially reduces the reporting burden for the Data Sheet leaving only a relatively small additional reporting burden. However, the FSR contains no information on use of program income, revenue or costs, or information regarding the individual HTC Factor Sales Programs. This additional data would allow an evaluation of these individual HTC Factor Sales Programs.

5. Involvement of Small Entities

None

6. Consequences If Information Collected Less Frequently

This information is to be collected once a year in order to satisfy the OIG's recommended action and to address the OIG's findings. If this information is not collected annually, HRSA/MCHB will not have the necessary information to assess whether program income is

being calculated appropriately and is being used for the maximum feasible benefit of HTC patients and the National Hemophilia Program.

7. Consistency with the Guidelines in 5 CFR 1320.5(d) (2)

This project is consistent with the guidelines in 5 CFR 1320.5(d) (2)

8. Consultation Outside the Agency

The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on February 6, 2007 (Volume 72, Number 24, pages 5444-5445). Comments were received from five organizations. These comments and HRSA's responses are attached.

Consultation has occurred with representatives of all twelve HRSA/MCHB Hemophilia Regional Project Grantees during telephone conference calls and at grantee meetings and also with a representative of The Hemophilia Alliance, Inc. (see attached list) A number of changes to previous drafts of the proposed HRSA Data Sheet and Instructions have been made as a result of these consultations ensuring that the information requested is reasonable, the request is clearly stated in coherent, unambiguous language, and the information is collected in the least burdensome way possible. The consultations have resulted in the data collection instrument being written using plain, coherent, and unambiguous terminology and being understandable to those who are to respond.

9. Remuneration of Respondents

None

10. Assurance of Confidentiality

No personally identifiable information will be collected.

11. Questions of a Sensitive Nature

None

12. Estimates of Annualized Hour Burden

The estimated annual response burden is as follows:

Form name: Factor Replacement Product Data Sheet for HRSA Funded Hemophilia Treatment Centers Having FRP Sales Programs

Form	Number of Respondents	Average Number of Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
Factor Replacement Product (FRP) Data Sheet	68	1/year	68	30	2040

The estimated respondent reporting burden is based on estimates received from several of the Hemophilia Regional Project Grantees.

Using an estimated hourly rate of $25 and estimated total burden hours of 2040, the estimated annualized cost to the respondents is $750 per respondent and $51,000 in total.

13. Estimates of Annualized Cost Burden to Respondents

There are no capital and startup costs for the respondents. Almost all of the information is needed for the submission of the required FSR (standard form 269).

14. Estimates of Annualized Cost to the Government

The cost for a GS-14 at 4% time is estimated to be approximately $4,500.

15. Changes in Burden

This is a new project.

16. Time Schedule, Publication and Analysis Plans

There are no publication plans.

The data that relates to this report will be submitted on the requested data sheet as a part of the next grant application due in December 2007.

17. Exemption for Display of Expiration Date

No exemption is requested.

18. Certifications

No exceptions are requested.