

Health Resources and Services Administration (HRSA)
Maternal and Child Health Bureau (MCHB)

**Factor Replacement Product (FRP) Data Sheet
For HRSA Funded Hemophilia Treatment Centers (HTCs)
Having FRP Sales Programs**

Instructions and Definitions

These instructions are for a data sheet that provides a financial overview of the Factor Replacement Product (FRP) operations of HRSA-funded Hemophilia Treatment Centers (HTCs) that purchase FRP at prices mandated by section 340B of the Public Health Service Act and or purchase FRP outside of the 340B program. The data sheet is meant to provide a summary picture of the scope of the FRP program(s) operating during the most recent budget period including indicators of programmatic and financial benefits.

Each HTC having a FRP Program is to submit a data sheet to the applicable Hemophilia Regional Grantee for submission to the Project Officer at HRSA's Maternal and Child Health Bureau (MCHB) as a part of the Hemophilia Regional Grantee's annual application (either competitive or continuation). It is acceptable to identify a HTC either by name or by a designated letter (Item 1).

For "Reporting period" enter the starting and ending dates for your most recent completed grant budget period. Those dates should correspond to the dates on your most recent financial status report (Item 2).

The first section of the data sheet ("Patient Data") is for providing information on the patients served by the HTC's FRP program. The data are to be broken down between those receiving 340B priced FRP and those receiving non-340B FRP. Only those HTCs that have elected to carve out Medicaid from their FRP program should complete line 6, "Medicaid patients receiving NON-340B FRP from HTC. Forms cannot have numbers in both Medicaid lines unless the HTC changed the election within the reporting period (Items 3-7).

For purposes of this form, in counting the number of individuals, please define an individual as a "Medicaid patient" in a manner consistent with your reporting for your Medicaid or Medicare cost report. If no such definition exists, define a "Medicaid patient" as someone who qualified for Medicaid services for six months or more of the reporting year. Please ensure that you do not double count. That is, be careful not to include the same individual as a "Medicaid patient" as well as a non-Medicaid patient (Items 4-6).

For "Balance at start of reporting period" enter the amount of unspent funds from previous FRP collections as of the beginning of the reporting period (Item 9).

For the Revenue items on the form, the actual receipts from the sale of FRP and other

related products to HTC patients should be entered whether received by the HTC directly or by the parent organization. Sales to non-HTC patients should not be included in this report. Note: Provisions under the 340B program allow HTCs to purchase FRP at a non-340B price for their Medicaid patients if they so choose. This is referred to as the Medicaid Carve out. An HTC having a 340B program is not allowed to purchase factor for its patients, other than its Medicaid patients, at a non-340B price (Items 11 and 12).

For the Cost of FRP items on the form, the total amounts paid for FRP acquisitions based on pharmacy ordering and inventory records should be entered (Items 15 and 16).

For the cost of pharmacy staff (Item 17) enter an estimate of that part of the salaries and benefits for staff that operate or support the pharmacy that is attributable to the FRP program(s). This can include both staff that work in the pharmacy and staff at the HTC who work directly on the FRP program. If your pharmacy is not dedicated 100% to the distribution of FRP, then make sure you enter only that portion of a pharmacy staff member's salary and benefits that are attributable to the FRP program. Provide an estimate of the percentage of time the individual spends on the FRP program versus his/her other responsibilities. This is also important for HTC staff working on the FRP program. For example, if someone at your HTC is responsible for taking FRP orders but also has other responsibilities at the HTC, only the percentage of that person's salary and benefits which equates to the amount time spent taking orders should be reported in this line. NOTE: Staff supported 100% by the grant cannot simultaneously be included as a cost to the FRP program nor can an individual's effort be more than 100% between grant support and as a cost to the FRP program (Item 17).

For "Cost of contractual services," enter the amount of any contractual pharmacy services attributable to the FRP program(s) (Item 18).

For "Other direct costs," identify and enter any other direct costs attributable to FRP program operations, for example, equipment, supplies, shipping, insurance, etc. (Item 19).

"Total FRP Operating Costs" is the total amount for purchasing FRP plus the total for all of the other operating costs (Item 13).

"FRP Program net income" is the difference between FRP revenue received and FRP operating costs. This number is your program income generated by the FRP program (Item 20).

"Use of Program Income" is a breakdown of how available resources from the HTC FRP program are used. According to 45 CFR 74.24 (b) (1), program income must be used to further eligible project or program objectives." NOTE: Total Use of Program Income cannot exceed the total of the Balance at the start of the reporting period plus

FRP program income. Any amount above this total indicates that there was some other source of revenue that led to the expenditures (Item 21).

“HTC staff” refers to the total amount spent for salaries and benefits for HTC staff outside of the FRP operation that came from FRP income. This includes all medical, psychosocial, administrative, and support staff such as physicians, nurses, social workers, physical therapists, genetic counselors, program administrators, interpreters, and secretarial staff (Item 22).

“Indirect costs” should include both the indirect cost rate (% , percent) used to calculate the indirect cost and the dollar amount of the indirect costs. For “Indirect costs” in addition to providing the amount of program income expended, also provide the amount of FRP Sales Program direct costs this is being applied to, if any (Item 23).

“Other ” refers to any other types of expenditures for which FRP income has been used. Each of these types of expenditures is to be identified and the amount expended for each is to be provided on a separate list and attached to the Data Sheet. As noted above, all expenditures in this category must be to further eligible project or program objectives. Any cost incurred in these expenditures must be allowable under the Federal Cost Principles applicable to your institution (Item 24).

“Balance at end of reporting period” is calculated by adding program income generated during the reporting period to the Balance at the start of the reporting period and then subtracting program income expended during the reporting period. The Balance at the end of the reporting period cannot be less than zero (Item 25).