HRSA Responses to OMB Questions on the Hemophilia ICR

1. Did the OIG review the FRP data sheet? Did OIG indicate that it was adequate?

The OIG has not reviewed the FRP data sheet. Upon the completion of the final report from OIG in 2003, HRSA followed the report recommendations to develop program guidelines and to increase the areas of monitoring. The FRP data sheet was developed as a result. HRSA informed OIG that the data sheet was under development and the OIG commented that: "Periodic preparation and reporting to HRSA of this information should provide a valuable tool for monitoring HTC activities with respect to program income to ensure maximum profits benefit hemophilia patients." OIG did not request a copy of the form or a list of potential data points for its review and comment.

2. Please elaborate in more detail the relationship between FSR standard form 269 and this FRP data sheet. For each of the problems identified by the OIG, please provide a crosswalk of which element in which form will provide the information to HRSA to address the problem. Here's what a sample cross-walk might look like (the information is hypothetical). To the extent that there is any overlap between the information collected on FSR standard form 269 and the FRP data sheet, these overlaps should be noted.

The HRSA/MCHB Hemophilia Program consists of 12 Regional Project Grants. Each Regional Project Grantee contracts with a number of organizations (affiliates) within its' Region to operate Hemophilia Treatment Centers (HTC). Most of the grantees and many of the affiliates have FRP Sales Programs. Each HTC having a FRP Sales Program is to submit the FRP data sheet to the pertinent Regional Hemophilia Project Grantee for review and to be sent on to HRSA/MCHB. The FSR standard form 269 contains the aggregate amount of net program income for all of the FRP Sales Programs of the HTCs within a region. (This amount should be equal to the sum of all of the individual net program income amounts indicated on the individual HTC FRP Sales Program data sheets for the HTCs within that region having FRP Sales Programs).

The FSR standard form 269 does not directly relate to the concerns expressed by the OIG because these are directed toward the individual HTC FRP Sales Programs. The data elements in the FSR request total gross program outlays and the recipient's share of net outlays, but the form does not provide the needed information on 340B FRP patients, 340B FRP sales, and FRP program operating costs. Therefore, we have not included the FSR standard form 269 as a part of the crosswalk as the data elements on the standard form will not collect information that addresses the detailed areas of concern.

We have outlined the data elements on the FSR data sheet that directly relate to the OIG concerns and have provided some additional narrative following the table:

OIG concern	Form	Data element
Inappropriate Medicaid Billing Practices (page 6)	FSR data sheet	#4, 5, 6, 7, 12, and 15
Inflated pharmacy costs (page 5)	FRP data sheet	#16, 17, and 18
Inappropriate corporate overhead	FRP data sheet	#22

(indirect costs, page 6)		
Inappropriate use of program income (pages 3 and 6)	FRP data sheet	#10-18, #21-23
Efficiency regarding pharmacy costs (pages 7-8)	FRP data sheet	#7, 16, 17, 18, 22

OIG Concern-Inappropriate Medicaid Billing Practices: In conjunction with information on the HRSA Office of Pharmacy Affairs Web Site regarding the status of the HTCs' use or non-use of the Medicaid Carve-out provision, these data items provide the information needed to ascertain if Medicaid billing is appropriate. Under a provision of the 340B program, HTCs having a 340B FRP Sales Program may choose to either buy FRPs for their Medicaid patients at a discounted 340B price or at a non-340B price. This choice determines how Medicaid is to be billed.

OIG Concern-Inappropriate Use of Program Income (pages 3-6 of OIG report): this includesing ensuring program funds are used for their intended purposes and to further program objectives. The FRP data sheet elements 10-18 indicate items necessary to calculate net program income and items 21-23 indicate uses of net program income.

OIG Concern-Efficiency Regarding Pharmacy Costs (pages 7-8 of OIG report):. tThe FRP data sheet items 16, 17, 18, and 22 provide information regarding pharmacy costs and item 7 provides the number of patients receiving FRPs, allowing for an assessment of pharmacy cost per patient.

3. It is unclear how the data reported on the FRP data sheet will provide information on how program income is used. The data sheet seems to simply ask HTCs to state the amount of income, rather than uses. Please clarify.

Items 21-23 address uses of net program income. It is expected that the predominant use of net program income will be to pay salaries and fringe benefits for HTC staff that serve patients (item 21). The amount listed for this item is compared with the HTC staffing lists required as a part of the pertinent grant application to verify that the amount indicated is appropriate. Also, net program income can be spent to pay for appropriate indirect costs (item 22) and additional items that vary and need to be identified under other HTC costs (item 23) can be paid for by using net program income.

4. How will sub-grantees be monitored?

Each sub-grantee (affiliate) having a HTC FRP sales program will complete a FRP data sheet. These affiliates are included in our total number of respondents.

5. If the FSR standard form 269 does not collect information on "use of program income, revenue or costs, or information regarding the individual HTC Factor Sales Programs" (page 3), what is the utility of collecting information with the FSR standard form 269?

The FSR standard form 269 provides added useful information regarding the financial picture of each HRSA/MCHB Hemophilia Regional Grant Program by calculating a total aggregate amount for net program income for the entire Region and the amount of this income that has been disbursed. Since the numbers for the FSR should be based on the numbers in the individual FRP Sales Program reports, very little additional burden is required to complete this report. Also, from the point of view that the FSR standard form 269 is already an OMB-approved required report for the HRSA/MCHB Hemophilia Grantees, little additional burden is required for completion of the individual HTC FRP Sales Program Reports. A letter initiating the requirement for HRSA/MCHB Hemophilia Grantees to begin submitting the FSR standard form 269 is attached.

6. Please explain in more detail how the data will be used to assess the efficiency of each FRP program.

The main item of interest regarding efficiency is pharmacy cost per patient. We are interested in noticing how this cost varies among HTC FRP Sales Programs and asking the grantees for more information regarding the reasons for the programs that have the highest cost per patient calculations.

a. What are the numerator and denominator in the efficiency equation (e.g. costs per output/outcome)? Where will the data for the numerator and denominator come from (i.e., which #s on the data sheet)?

The numerator is the total of the items that make up pharmacy cost (items 16, 17, 18, and 22) and the denominator is the total number of patients (item 7).

b. What kind of stratification will be used to take account of structural variations in HTCs?

The main item of stratification is type of pharmacy operation (in-house or contract pharmacy). Contract pharmacies generally have higher costs than do in-house pharmacies, but costs vary considerably within each category.

c. Will the results of this analysis of efficiency be reported publicly?

We do not currently have any plan to publicly report the results of any analysis of efficiency. If we were to report this type of analysis publicly, we would not identify individual HTCs or grantees just as the OIG did not make these identifications on page 8 of their report.