Committee of Ten Thousand

Advocates for Persons with HCV-HIV/AIDS

236 Massachusetts Ave., NE Suite 609 • Washington, DC 20002
(800) 488-COTT • (202) 543-0988 • www.cottl.org • cott-dc@earthlink.net

April 6, 2007

Re: Federal Register Notice February 6, 2007: Reporting form for the MCHB HTCs with 340b Programs (p. 5444)

Ms. Susan G. Queen, Ph.D.
HRSA Reports Clearance
Officer Room 10-33
Parklawn Building 5600
Fishers Lane Rockville,
MD 20857

Dear Ms. Queen:

The Committee of Ten Thousand (COTT) is pleased to have this opportunity to comment on the above-referenced notice. COTT is one of the three national hemophilia community organizations, representing specifically those in our community infected with HIV and the hepatitis C viruses through tainted factor concentrates. Thus our member community, having three conditions each of which is potentially fatal and more dangerous in concert, is very attuned to sources of health care.

The management of high-cost clotting factor concentrates by hemophilia service grantees should be performed in not only a cost-effective manner but one which respects the serious threat that the costs of this disease pose to family stability. As an example, the federal grantees of the MCHB hemophilia program which are enrolled in the HRSA OPA 340b Medicaid pricing program should pass on to their clients the substantial savings they realize, in order to reduce to the extent possible billings to insurers, thus prolonging the period of time their clients can remain covered before reaching their lifetime maximums.

MCHB Response:

MCHB is in agreement that the management of high-cost clotting factor concentrates by hemophilia service grantees should be performed in not only a cost-effective manner but one which respects the serious threat that the costs of this disease pose to family stability. However, passing some or all of the savings realized from Hemophilia Treatment Center (HTC) 340B Factor Replacement Product Sales Programs on to clients is not a HRSA/MCHB Hemophilia Program requirement. The existing statute [Section 602 of the Veterans Health Care Act of 1992 (Public Law 102-585) codified as Section 340B of the Public Health Service Act of 1992] does not place a limitation on the price at which

covered entities can sell covered drugs to their patients.

The history of HRSA oversight of the HTC program in general and the 340b segment of it in particular has been inadequate. Projects routinely draw support from three different sources (MCHB, OPA, and CDC) which do not seem to have or execute annual oversight coordination plans. The Office of Inspector General reports of 1999 and 2003, occasioned by others similarly concerned with program integrity, showed substantial room for management improvements, in one case documenting likely misuse of federal funds in almost 20% of the grantees studied.

MCHB Response:

HRSA/MCHB acknowledges the need for oversight to insure that income generated by 340B Factor Replacement Product Sales Programs is not misused and believes the proposed data collection will provide needed oversight.

This comment does not address any specific item in the proposed data collection. However, HRSA/MCHB believes the proposed data collection will provide needed oversight.

Moreover many of these 340b HTCs have banded together to petition factor manufacturers to sell to them at prices even lower than those mandated through the 340b program. While no manufacturers have agreed to do so, COTT wonders whether this focus on profit margin is really part of the mission of the federal grant program to which they owe their existence. (We have noted that the group lacked aggregate data on costs, revenues and expenses such as are under discussion here. Not only were there no grantor requirements for same, but the entities failed to see the market importance thereof, or, apparently, its value in sound internal management.)

MCHB Response:

HRSA has not made participation in the 340B program mandatory for HRSA grantees. HTCs are free to participate if they wish to do so and are also free to attempt to negotiate prices below the 340B price.

COTT was particularly concerned to learn that, following the most recent OIG report's release, a reporting system developed by HRSA for these programs was resoundingly criticized by the grant funds recipients, primarily as being unnecessary. The proposal was withdrawn.

MCHB Response:

HRSA/MCHB understands that HRSA/MCHB funded HTCs currently do not object to the proposed data collection.

MCHB acknowledges the COTT concerns that the previous proposal for a reporting system was criticized, resulting in modifications in order to improve clarity, ease of use, and increased likelihood of response. The reporting system proposal was not withdrawn but rather HRSA/MCHB worked to modify it to improve the previous. MCHB regards this data collection as necessary to provide appropriate oversight.

This comment does not address any specific item in the proposed data collection; however, HRSA/MCHB believes HRSA/MCHB Hemophilia Grantees and HTCs currently do not object to the proposed data collection.

COTT is deeply concerned that reporting requirements, which appear reasonable and necessary given the size of the revenue streams, associated with the sale of factor concentrates, are opposed by the grantees in the most strident terms, and delayed repeatedly by MCHB/HRSA.

MCHB Response:

HRSA/MCHB agrees that the proposed reporting requirements are reasonable and necessary and believes that HRSA/MCHB Grantees and HTCs currently do not object to the proposed data collection. The reporting system proposal was not withdrawn but rather HRSA/MCHB worked to modify the previous form for clarity, ease of use, and greater response.

These centers see some 12,000 patients in our community, who consume roughly $80,000 worth of factor annually per person. Four thousand of them, with severe hemophilia, use triple that of others. Over one billion dollars flows through this program yearly, from factor sales alone. These are numbers that demand federal fiscal oversight. Imposition thereof should not be left to a vote by the grantees. At these numbers, we wonder whether the negative votes were cast less out of a desire to minimize workload than to cover widespread abuses.

MCHB Response:

HRSA/MCHB agrees that federal fiscal oversight is necessary. There is no voting process that has been involved in determining either the data items to be collected or the implementation of the data collection.

HRSA/MCHB agrees that federal fiscal oversight is necessary and should not be left to a voting process. MCHB feels strongly that this data collection is necessary as a part of federal oversight.

The small hemophilia community is constantly being bombarded by industry, because the profits to be made are so large. It is a travesty to see this greed-driven avarice in our own

centers, which were set up to protect us. Half of the HTCs, which do not sell factor, badly need help; perhaps one-third are in danger of going under. Yet these selling centers do not aid them, and HRSA does not 'sweep up' excess profits for redistribution, so that the program serves the entire hemophilia community as intended.

MCHB Response:

Program income that is generated by a HTC covered entity belongs to the HTC covered entity. HRSA does not have the authority to redistribute program income among HTCs.

To speak more directly to the Notice, drawing from its own wording, we feel that the proposed collection of information on Patient FRP program participation, FRP program review, FRP program costs, and use of FRP program net income is definitely necessary for the proper performance of the functions of the agency, and that having the information will have immense practical utility.

MCHB Response:

HRSA/MCHB acknowledges that COTT is in favor of the proposed data collection. HRSA/MCHB also feels strongly that this data collection is necessary.

We cannot comment on the accuracy of the agency's estimate of the burden of the proposed collection, except to say that, although 'burden' is the technically correct term for 'respondent time' anticipated in implementing a data collection activity, its use in such a short notice, wherein even the details of the financial reporting categories are not spelled out, almost seems to convey a foregone conclusion: that the responses would be quite burdensome (here meaning inappropriately heave workload demands), and any but a most highly developed argument on the data's utility in program management would fall before this overwhelming, overbearing reason ***not*** to collect data.

MCHB Response:

HRSA/MCHB does not believe that the proposed data collection requires inappropriately heavy workload demands on the part of respondents. The great majority of the effort for producing the proposed data collection has already been necessitated by the requirement that grantees submit a Financial Status Report (STANDARD FORM 269). MCHB believes that this data collection is necessary for federal oversight.

We wonder why these comments are only being solicited to be due AFTER the next round of grants starts – rather than having been built into its requirements, mere months earlier. We question MCHB's intent here. There clearly is no intent to see reporting Ms.

occur as part of the 2007 grant cycle. Furthermore, if there is no reporting as part of the 2007 cycle then we can realistically conclude that no relevant data will be collated and available until 2009. How are we as the consumers of HTC care to interpret this apparent inconsistency?

MCHB Response:

The intent of HRSA/MCHB is for data to be provided on the proposed data sheet as soon as reasonably feasible within the requirements of the Office of Management and Budget Clearance Process. The time period proposed for reporting is one that coincides with the reporting period for the required annual Financial Status Report in order to minimize reporting burden.

The intent of MCHB is for data to be provided on the proposed data sheet as soon as reasonably feasible within the requirements of the Office of Management and Budget Clearance Process. The reporting period will be annual based on the grant year.

As to ways to enhance the information to be collected: these grantees are small organizations within large multi-million dollar hospital operations. Calculation of HTC data such as this should be routine for the large Operations staff found in the facility. We would suggest no report should be accepted without a letter of audit accompanying it, prepared by an agent outside of the hospital or other parent organization's employ.

MCHB Response:

The proposed data collection includes a reporting period that coincides with the grantee budget period. Established grants policy and procedure requires the grantee to submit a Financial Status Report (FSR) including the amount of program income generated during this reporting period. The sum of the program income amounts indicated by the individual HTCs included under a grant that are provided as part of the proposed data collection should be equal to the amount of program income indicated on the FSR. HRSA/MCHB believes that this provides an adequate check regarding the correctness of the program income information to be reported in the proposed data collection.

On the final point, minimizing burden, COTT is more interested in seeing the 340B shoulder a little financial analysis burden for a change, rather than putting so much effort into profit seeking. They may be comfortable not putting their clients concerns first, but we're not.

MCHB Response:

HRSA/MCHB acknowledges the need for financial analysis and believes that the reporting burden pertaining to the proposed data collection is reasonable.

COTT finds the complete lack of serious oversight of the HTC 340B program unacceptable. We are dismayed at the apparent lack of concern on behalf of MCHB and some of the 340B centers regarding the efficient and responsible usage of taxpayer dollars. Only required reporting, complete in scopt [sic] and incorporated into agency planning, will restore stability to the program.

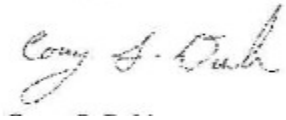
MCHB Response:

HRSA/MCHB acknowledges the COTT concern regarding oversight and reporting and believes the proposed data collection (if approved) will provide needed oversight of the 340B programs of HRSA/MCHB funded HTCs.

The information from the proposed data collection (if approved) will become an element incorporated into HRSA/MCHB planning.

Thank you for this opportunity to comment on the proposed data collection from 340B HTCs. We are happy to answer any questions you may have, or provide clarification of any of the points above.

Sincerely,



Corey S. Dubin
President