THE HEMOPHILIA ALLIANCE, INC.
Integrating Pharmacy with Comprehensive Care

April 6, 2007

Susan G. Queen, PhD.
HRSA Reports Clearance Officer
Health Resources Services Administration
Room 10-33 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

VIA USPS, CMRR

Re: **Agency Information Collection Activities: Proposed Collections Comment Request. Proposed Protect: Reporting Form for MCHB National Hemophilia Program Grantees and Hemophilia Treatment Center (HTC) Affiliates Having Factor Replacement Product (FRP) Programs (72 Fed. Reg. 24, 5444, February, 6, 2007)**

Dear Dr. Queen:

This letter serves as a response from the Hemophilia Alliance, Inc. to the February 6, 2007 Federal Register Notice (72 Fed. Reg. 24, 5444, 5445) requesting comments on a proposed data collection project of the Maternal and Child Health Bureau ("MCHB") of the Health Resources Services Administration ("HRSA"). The Hemophilia Alliance, Inc. (the "Alliance") is a 501(c)(6) organization representing fifty-six Hemophilia Treatment Centers ("HTC") who either have or are considering having a factor replacement product (FRP) program under Section 340B of the Public Health Service ("PHS") Act

You have invited comment on four areas:

(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 of other forms of information technology.

We will examine each area in turn.

General Comments

This proposed form is a resubmission of a form first submitted for comment in the September 21, 2004 Federal Register (69 Fed. Reg. 182, 56432). The Alliance submitted comments to that notice on November 17, 2004. Since that time MCHB has made changes to the proposed form and engaged in dialogue with HTCs regarding these changes. With these changes, the Alliance does not object to the form but we do have some suggestions as to how it can best serve the functions of HRSA/MCHB (the "agency"). These suggestions will be presented within the context of the areas in which you have invited comment.

MCHB Response:

MCHB acknowledges that the Hemophilia Alliance, Inc. does not object to the proposed data collection form but does have some suggestions as to how it can best serve the functions of HRSA/MCHB (the "agency").

Comments

(a) Is the Proposed Collection of Information Necessary for the Proper Performance of the Functions of the Agency, Including Whether the Information will have Practical Utility?

The Alliance recognizes that collection of the proposed data can have practical utility and support the proper functioning of the agency. However, if the data is not utilized appropriately this could be problematic and we are particularly concerned with how the data will be interpreted by the agency.

MCHB Response:

MCHB agrees that collection of the proposed data can have practical utility and can support the proper functioning of HRSA/MCHB.

MCHB also agrees that if the data are not utilized appropriately this could be problematic. For this reason, any request for release of information will be forwarded to the HRSA Freedom of Information Officer. MCHB will cooperate with the HRSA FOA officer regarding release of information.

(i) The Varied Structure of HTCs Will Make Data Interpretation Difficult

The Alliance is concerned that the agency will seek to compare data provided by the HTCs and draw erroneous conclusions regarding cost appropriateness and/or cost efficiency. We suggest that such comparisons be avoided given that the reporting HTCs will have very different operating structures. Some HTCs exist within larger institutions such as hospitals, hospital systems, health science centers and universities while others are free standing clinics. Even HTCs imbedded within large institutions vary. Some are well established, large centers while others only come together on clinic days when they share clinic space with

other pediatric and/or adult programs. Such variation makes cost comparisons difficult, if not impossible.

MCHB Response:

HRSA/MCHB will review individual HTC data and will also compare data provided by the HTCs being careful not to draw erroneous conclusions regarding cost appropriateness and/or cost efficiency taking into account the different HTC operating structures.

We are also concerned how the data will be used to determine, "cost efficiency". "Efficiency" can be viewed in a number of ways but essentially, efficiency ratios in a business context are used to determine how well an entity is utilizes its assets. In terms of revenue and expenses, efficiency is usually determined by how much *an* entity has to spend to generate each dollar of revenue. When these efficiency ratios are determined for a particular entity, for them *to* have meaning, they must be compared with other similarly situated entities. As previously stated, comparing results between reporting HTCs will be problematic given the differences between the HTCs.

To avoid this problem, we encourage the agency to examine data individually and to raise any concerns with the reporting HTC. HTCs should not be evaluated for "efficiency" (at least not through this data form) but rather reviewed to determine, (i) how much program income was generated, (ii) how that income was used and (iii) whether the stated uses were allowable. We believe that this is precisely why the form was developed, as a response to increase oversight over how much program income HTCs generate and how it is being used. By monitoring these three items, the agency will be fulfilling its goal of increased monitoring and the data being collected will have the greatest practical utility.

MCHB Response:

MCHB is interested in assessing the reasonableness of HTC FRP Sales Program operating costs and believes that comparing these costs among HTCs can be useful in this regard. MCHB also believes that raising concerns with the reporting grantees and/or HTCs is useful in making such assessments.

(b) Is the Agency's Estimate of the Burden of the Proposed Collection of Information Accurate?

While the Alliance recognizes the importance of collecting the information requested, we believe the agency has underestimated the total burden hours which will be needed to complete the form. The agency appears to assume that there will only be one person responding per entity. It is true that only one form will be submitted by each HTC but we estimate that a minimum of three persons will be involved in responding to the form. We see three distinct steps in the process of completing the form.

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Step 1: A member of the HTC staff will receive the form and will complete the patient data section.

Step 2: The form will be sent to the appropriate financial personnel within the HTC's institution. This person will complete the financial section with collaboration from the pharmacy staff.

Step 3: Once the form is complete, the HTC staff, the financial staff and the pharmacy staff will need to review the form for accuracy and to ensure that all parties understand and agree with the data to be submitted.

Estimate of burden hours:

Step 2 will be the most time consuming step and will take approximately 80 hours to complete. Step 1 will take approximately 16 hours *and step 3* approximately 8 hours. Therefore we see the burden estimate *as follows:*

No. of Respondents	Responses per Respondent	Total Responses	Hours Per Response	Total Burden Hours
68	1	68	104	7,072

MCHB Response:

MCHB does not believe that HRSA/MCHB has underestimated the total burden hours needed to complete the form. The data for the proposed data collection are to be reported for the same time period for which each grantee is required to submit a Financial Status Report (FSR). This FSR is to include the total amount of program income generated by HTC Factor Replacement Product Sales Programs that are included under the grant. All of the information referred to as Step 2 is required in order for the grantee to submit an accurate FSR. (The financial information for each of the individual HTCs must be determined and then added together to calculate the program income amount required by the FSR.) The burden hours necessary for completion of the FSR are not burden hours that are assignable to the proposed data collection. Regarding the estimate by The Hemophilia Alliance, Inc. when the hours per response for (Step 2) are subtracted from total hours per response (104-80), the number of hours per response becomes 24 compared to the MCHB estimate of 30 hours per response. The MCHB estimate or 30 hours per response is based on estimates received from several of the Hemophilia Grantees.

(c) Wavs to Enhance the Quality, Utility and Clarity of the Information to be Collected.

We see the form needing the following minor enhancements:

- The line items requested on the form should be numbered and the instructions would then correspond to a particular line number.

- Under the 7ª' paragraph in the instructions, which begins, "From the revenue items on the form...", the last sentence should be modified to read, "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." By adding the word, "its" and the commas, the instruction would emphasize the earlier sentence that, "sales to non-HTC patients should not be included in this report."

MCHB Response:

MCHB has adopted these suggestions and has revised the proposed data collection form and instructions accordingly in the interest of increased clarity of the information to be collected.

(d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques of other forms of information technology.

(i) The Reporting Period Should be a Twelve Month Period chosen at the Discretion of the Reporting HTC

Since the majority of the form is requiring financial data, the Alliance believes that it would be least burdensome if respondents were able to retrieve the required information from their most recent audited financial statements. By allowing this data to be reported on the respondent's fiscal year, they would be providing information *which* would be consistent with their institution's records. This will be very important to HTCs especially if they are ever called upon to verify the numbers they have submitted.

If respondents must submit data for a period other than their fiscal year, then this will mean having to compile data from different fiscal years which increases the risk for error and makes the process more difficult.

MCHB Response*:*

MCHB appreciates the concern about accurate completion of the FSR, but believes that the most appropriate time period to be applied to this proposed data collection is the grant budget period. A Financial Status Report (Standard Form 269) FSR is required for this budget period and the accurate completion of this FSR requires the generation of the great majority of the information required by the proposed data collection.

(ii) The Financial Data Being Sought Should be Classified as Confidential Business Information

HTCs with FRPs operate in a competitive environment and the data being sought is confidential. As such, any data collected must be treated as, "confidential business information" (CBI) as that term is used in Exemption 4 to the Freedom of Information Act

(FOIA). Exemption 4 states that the FOIA protects, "trade secrets and commercial or financial information from a person (that is) privileged or confidential".[1]

As stated, Exemption 4 covers two categories of information contained federal agency records: (1) trade secrets and (2) CBI. To be protected from a FOIA request, CBI must be (a) commercial or financial, and (b) obtained from a person, and (c) privileged or confidentiaL[2]

The data to be submitted on the proposed form is "financial" and be submitted by a "person". "Person" is defined in the FOIA to include many entities including private and public corporations 3 We also believe that the data being collected is "confidential" as this term is viewed by the FOIA.

The courts have set different standards to determine if financial information is confidential based on whether the information was required by the government or voluntarily submitted.

Under the "required submission" standard, the financial matter, "is "confidential" *for* purposes of the exemption if disclosure of the information is likely to have either of the *following effects: (1) to* impair the Government's ability *to* obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained."[4] Information that is voluntarily submitted will be protected *from FOIA* disclosure if the information submitted would not normally be submitted to the public.[5]

The instructions for the proposed form state in the opening paragraph, "These instructions are for a ***mandatory*** *data* sheet..." (emphasis added). This would lead one to conclude that the data being submitted is required and not being submitted voluntarily. Using the required submission standard, the disclosure of this information would, to cause substantial harm to the competitive position of the HTCs. Courts have held that held that there has been competitive harm caused by submission of the same type of data which is being required. For example, disclosure of a company's actual costs and purchase activity have been found. to be included in the type of competitive injury which is sought to be avoided in Exemption 4.

Even if submission of the data was found to be voluntary, this data is not customarily (or ever) released to the public and would therefore still be protected from a FOIA request under

Exemption 4.

If there is a FOIA request for the data submitted *in* response to this form, the Alliance is of the view that the agency should inform the HTC(s) which submitted, the data as soon as this occurs. This would be consistent with Executive Order 12,600 (52 Fed Reg. 23781). This process allows the HTC to have time to raise its own independent objections to the request.

MCHB Response:

The comments regarding the belief that the financial data being sought by this proposed data collection should be classified as confidential business information are subject to Freedom of Information determination. HRSA/MCHB will not release information to the public regarding individual grantees including individual HTCs in the absence of such determination. Any request for these data will be forwarded to the HRSA Freedom of Information Officer. MCHB will cooperate with the HRSA Freedom of Information Officer in providing any needed program information. A description of the Freedom of Information Act (FOIA) including HRSA and MCHB contacts can be found at:

http://intranet.hrsa.gov/Communications/FOIA.asp

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[1]FOIA, 5 U.S.C. §552(b)(4) (2000).
[2]USDOJ, Freedom of Information Act Guide, Exemption 4. May 2004. http://www.usdoj.gov/oip/foi-act.htm Accessed 4/5/07.
[3]Id at FN40
[4]Op. Cit.
[5]*Id*.

Recommendations

The Alliance does not object to the form but does recommend minor changes for clarity.

(1) Do not use the data to attempt to compare HTCs with a view to determining efficiency between centers. Use the data for its intended purpose,.[sic] that is, monitor how much program income is generated, how this program income is spent and whether expenditures were allowable
(2) Make minor language changes to paragraph seven of the instructions and number the line items of the data form and corresponding instruction paragraph
(3) Allow the HTC to determine the reporting period so that the respondent can rely on its audited financial statements to *provide* the data
(4) View the data submitted as Confidential Business Information which means the data is protected from a FOIA request under Exemption 4 to the FOIA.

MCHB Response:

MCHB appreciates the concerns of the Hemophilia Alliance regarding the use of data and the reporting period. HRSA/MCHB acknowledges the recommendations of The Hemophilia Alliance, Inc. and has attempted to satisfactorily respond to these recommendations.

The Hemophilia Alliance appreciates MCHB's continuing efforts to ensure access to care for persons with bleeding disorders and recognizes that this proposal is an attempt to enhance that effort. We hope our comments are helpful and strongly urge HRSA and MCHB to give frill consideration to our requests. The Alliance is available to discuss our comments with you in more detail. Please direct questions or inquiries you may have to me at 410-465-3611 or by email at derek@hemoalliance.org

MCHB Response:

MCHB acknowledges the Hemophilia Alliance's appreciation of its continuing efforts to ensure access to care for persons with bleeding disorders and the recognition that the proposed data collection is an atempt to enhance that effort.

Sincerely,

Derek Robertson
General Counsel