

Comments of the Hemophilia Alliance on
MCHB Performance Measures for Discretionary Grants

OMB No. 0915-0298

February 2, 2009

The Hemophilia Alliance is pleased to submit comments on the proposed revision of Maternal and Child Health Bureau (MCHB) Performance Measures for Discretionary Grants (OMB No. 0915-0298). The Hemophilia Alliance represents seventy-one (including eleven of twelve regional grantees) of the eighty-eight Hemophilia Treatment Centers (HTCs) that receive MCHB discretionary grants and participate in the discount pricing program under Section 340B of the Public Health Service Act (“the 340B drug pricing program”). The grants awarded to the HTCs are part of the Special Projects of Regional and National Significance (SPRANS). The HTCs serve an important and invaluable role as comprehensive care providers to individuals with bleeding disorders throughout the nation. These Centers provide multidisciplinary care for patients and their families, including: diagnosis, treatment, education, provision of concrete services, counseling and support. These services are supported in part by a grant awarded by the MCHB, a division of the Health Resources and Services Administration (HRSA) and are also supported in part by funding from the Center for Disease Control (CDC). The grants impose no non-federal cost share requirements, but the federal dollars do not completely support all costs of operating an HTC. The MCHB grant funds generally support, at least in part, the salaries of professionals providing comprehensive services through the HTCs. The federal government should only be able to obtain data regarding the expenditure of the federal dollars.

Specifically, you request comments on: (a) whether the proposed collection of information is necessary and has practical utility, (b) whether the burden estimate is accurate, (c) if there are ways to enhance the quality, utility, and clarity of the information requested, and (d) whether there are ways to minimize the burden of the collection. As set forth below, we believe that most of the information requested is not relevant to the HTC program purposes, the burden estimate of six (6) hours is grossly under-estimated. The information requested should be focused on the few questions relevant to Performance Measure No. 7 as it relates to the HTC program, and the information should only be provided once a year electronically via the HRSA EHB and eliminated completely from the grant application and reporting requirements.

HRSA suggested in the *Federal Register* notice that information gathered through the OMB No. 0915-0298 forms would be used as “part of the budgetary process, thus linking funding decisions with performance.” According to MCHB, HTCs are bound only by Performance Measure No. 7, which measures “the degree to which MCHB-supported programs ensure family participation in program and policy activities.” This information request is based upon HRSA’s need to comply with the Government Performance and Results Act (GPRA) in order to demonstrate the effectiveness of the grant program supported by federal appropriations, but we do not believe this sole criteria should be the basis for funding decisions regarding the HTC awards made by MCHB. This is only one purpose of the grant program.

The forms and their proposed revisions significantly increase the workload burden on HTC while producing almost no new information for MCUB relevant to the grant purposes or the basis for funding. Only the questions directly related to the purposes of the HTC grants should be imposed. The information is duplicative because the grantees submit this information in a variety of ways multiple times under their three year grant awards. As a result, the HTC grantees object to the use of Forms 1-7 and also question the applicability of some of the new and existing questions included in the Performance Measure No. 7 detail sheets. Furthermore, the estimate of six (6) burden hours to complete even a portion of these forms is grossly understated. We believe that the government and the HTCs are better served if the information requested were isolated to a few relevant questions to which the HTCs can respond to online once a year via HRSA EHB. All other information requests imposed by MCHB should be eliminated.

Information collected from HTCs through Forms 1-7 is unrelated to the performance measure No. 7 MCHB provided to HTC grantees.

There are currently six questions posed to the HTCs for Performance Measure No. 7 (*the Degree to which MCHB supported programs ensure family participation in program and policy activities*) which may be completed online via HRSA EHB. The revised scoring guidance for the detail sheets for Performance Measure No. 7 includes eight (8) pages of additional questions and calculations. MCHB additionally requires HTCs to complete Forms 1-7 as part of the application process each year. These forms request financial and demographic data that is entirely unrelated to the Performance Measure No. 7 supplied by MCHB. Furthermore, this information is being requested to assist the agency to determine the effectiveness of its funding, but the forms request information regarding other funding sources.

The information requested in Forms 1-7 is irrelevant to “family participation in program and policy activities.”¹ Forms 1 and 2 are strictly financial, Forms 3-6 are mostly demographics-related, and Form 7 is a Data Summary. Not one form asks a single question directly related to family participation, which MCHB identified to HTC grantees as their sole performance measure. Forms 1-7 do not collect any information related to the performance measure on which MCHB has suggested it will condition funding. If there are additional performance criteria being used to make funding determinations, these have not been made available to HTC grantees.

Of the six elements for Performance Measure No. 7, Element No. 5, in particular, is not relevant to the HTCs because they do not hire family members as paid staff or consultants. The other questions depend upon the structure of the HTC which may or may not have advisory committees or task forces and may or may not have federal dollars to reimburse family costs or provide training for family members. The costs of these activities are most likely not supported with federal dollars. The operation of each HTC varies greatly and using a standard form is not going to provide accurate data related to the use of federal funds. The relevance of these questions must be reassessed.

¹Performance Measure No. 7, Program Guidance for Fiscal Year 2009, Comprehensive Hemophilia Diagnostic and Treatment Centers, HRSA 5-H30-09-001 at p. 79.

MCHB Response:

The purpose of Forms 1-7 for the HRSA/MCHB Hemophilia Program is not specifically related to Performance Measure 7. The purpose of Forms 1-7 is to provide useful financial and demographic information.

MCHB has no basis to request information on non-federal funding sources.

Three of the OMB forms request financial data, including data on funding sources unrelated to the MCHB grant.² We object to reporting any non-federal sources of funding or program income generated by non-federal dollars. Specifically, we object to Line 4 of Form I: MCH Budget Details for FY____, Line 4 under Subheading II on Form 6: Maternal and Child Health Discretionary Grant Project Abstract for FY____, and Line 4 of Form 2: Project Funding Profile. We must request that MCHB excise from its forms any request for information related to non-federal funding sources. HTCs will provide only data for activities supported by the federal dollars they are provided by MCHB.

Funding derived from non-federal sources has no bearing on the performance of the HTC grantees in fulfilling their grant purposes as supported by the federal government, therefore, the government has no right to request this information. If this outside funding is not used for matching purposes, and it is not in this case, then the government has no legitimate basis for requesting financial information outside of the scope of the grant. The federal agency has no legal authority to inquire into the private sources of funds or other financial data that is not relevant to the expenditure of the federal dollars. If federal dollars are not supporting the activities detailed for Performance Measure No. 7, or any of the other forms 1-7, the information should not be requested. If the data is provided by the HTCs can not be attributed to the federally funded grant activity, then the results are not accurately reflecting the results of the federal investment for purposes of a GPRA measurement and assessment.

MCHB Response:

MCHB has a basis for requesting information on Other Project Funds including non-federal funding sources. These Other Project Funds are a part of the funds to be used to accomplish the HRSA/MCHB funded project. They, along with the federal dollars, indicate the amount of dollars available for the project. They also provide an indication of the extent to which HRSA/MCHB funding has been effective in influencing the generation of other dollars to be used for the project allowing scarce federal dollars to be used most efficiently. Regarding the HRSA/MCHB funded Hemophilia Program, most of the projects generate a considerable amount of program income through the sale of Factor Replacement Products used in the treatment of patients.

² See OMB No. 0915-0298, Form 1, Sec 4—Other Project Funds (Grantees are required to provide the balances for “local funds; State funds, Program Income (Clinical or Other), Applicant¹Grantee Funds (includes in-kind), and Other Funds (including private sector, e.g., Foundations).”

Information requested is duplicative and reporting it imposes unnecessary and unfair burdens on grantees.

Finally, we must disagree with MCHB's estimate of 6 burden hours per response. This is a gross underestimate. Each form will require far more than an hour to complete and much of the information required in these forms is not, as the MCHB suggests in the *Federal Register* notice, "based primarily on existing data." While completing the data request electronically via HRSA EHB for Performance Measure No. 7, is not too onerous, to provide the information in application packages, performance reports and financial reports under their grants is duplicative and burdensome. Within a three year grant award period, MCHB requires grantees to provide this data six to seven times within a three year grant award period which is excessive. The HTC Program Guidance for FY 2009 requires grantees to submit Forms 1-7 of the ten that are included under OMB No. 0915-0298. Additionally, the HTCs are subject to Performance Measure No. 7 and its corresponding form, which has been substantially expanded from a single detail sheet to include eight pages of scoring guidance. These forms collect information that are available in a number of other financial and progress reports submitted by the HTCs under their grants and is therefore duplicative.

The financial information sought in Forms 1 and 2 is budgetary and is already provided by the grantees on other grant forms. HTCs are required to provide detailed budgets when they submit their grant applications. Resubmitting this information on Forms 1 and 2 is duplicative and will likely result in errors and confusion for both grantees submitting the information and MCHB officials receiving it. Therefore, MCHB should not require HTC grantees to submit Forms 1 and 2.

For instance, it is unlikely that HTC grantees will have, as required by Form 3: Budget Details by Types of Individuals Served, details of expenditures on pregnant women, infants, children, CSHCN infants at their fingertips. Additionally, grantees will not have ready access to information required in Form 4: By Types of Services and Form 5: By Types of Insurance. While the HTCs serve infants, children and women, the budget cannot be broken down based upon the type of individuals served. Form 3 alone will require data-gathering that easily exceeds MCHB's estimate of six burden hours. Further, Forms 6 and 7 request information that can be obtained from the application. If all of this data is available in another place, as MCHB has suggested, it is unreasonable to burden grantees with the reproduction of cumulative and duplicative information.

MCHB also fails to consider that the HTC regional coordinators must compile all of the data from individual sub-awardees in order to fill out these forms. We estimate that the forms create an additional 20-80 burden hours per response depending on the region. HTC grantees must respond at application submission, twice each year, first in the Performance Report and then in the Final Year Performance Report, so these forms actually create, at minimum, an additional 120-160 burden hours per award. Considering that most of this information is not related to the Performance Measurement No. 7, we question what purpose it serves. MCHB must first be able to identify its needs for the data and how it relates to the GPRA performance measures. Second, it needs to limit its requests to relevant questions only and require the data preferably at the end of each award period, or at the most, only once annually.

MCHB Response:

We do not believe that HRSA/MCHB has underestimated the estimate of 6 burden hours per response. Nine grantees representing a broad range of grant categories were initially selected to pilot the common grant reporting measures. All grantees completed financial and demographic forms with grantees also completing performance measures and other data elements that were relevant to their program activities. The pilot grantees reported that the average time to complete the information was 6 hours. Program experience following OMB approval also found that the average hour burden was approximately 6 hours with individual grantees responding to only a limited number of performance measures that are specifically relevant to their programs. Five grantees participated in the January 2009 Subject Matter Expert Panel Meeting where proposed changes to the performance measures were discussed. In addition, several of the performance measures are cross-cutting throughout MCHB and are not unique to the HTC program; therefore, the collection of data on these measures is not an attempt to collect an excessive amount of information about MCHB's HTC grantees. Also, selected performance measures are required by OMB through its PART program.

MCHB needs to know the number and types of patients being served by the projects it funds as well as the types of services being provided. Projects are instructed to make estimates if actual numbers are not available thereby reducing reporting burden.

MCHB does not believe requesting information on Forms 1-7 is duplicative, but to the extent that this information is readily available reporting burden is minimal.

Information requests should relate to the Performance Criteria, be relevant to the Hemophilia Grants, and submitted electronically.

The HTCs are willing to work with MCHB to identify and clarify the questions that are relevant to the Hemophilia grant activities which are supported by federal dollars which is the purpose of GPRA performance measurements. They can submit the relevant information electronically preferably once a three-year award period or at least no more than once annually. There is no basis for the imposition of additional Forms 1-7 through the annual Program Guidance and this practice should be discontinued.

MCHB Response:

MCHB describes a number of project requirements and criteria in the Hemophilia Application Guidance. The information being requested in Forms 1-7 relates to the successful accomplishment of these items and is therefore relevant to the Hemophilia Grants. The information being requested is to be submitted electronically.

Thank you for the opportunity to provide comments and we look forward to your response. If you have any questions or need clarification, please contact me, Stacia Davis Le Blanc, by phone (202) 466-8960, or e-mail at sleblanc@feldesmantucker.com.