

Government Affairs Division

Baxter Healthcare Corporation
1501 K Street, N.W.
Suite 375
Washington, D.C. 20005
202.508.8200
Fax- 202 508.8201

Baxter

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

RE: Agency Information Collection Activities - Proposed Collection Comment Request

Dear Dr. Queen:

Baxter Healthcare Corporation appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA's) information collection proposal for hemophilia treatment centers participating in the agency's Public Health Service drug discount program, also known as the 340B program.

For more than 75 years, Baxter has assisted healthcare professionals and their patients with the treatment of complex medical conditions, including hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma, and other conditions. The company applies its expertise in biotechnology, medical devices, and pharmaceuticals to make a meaningful difference in patients' lives. As a leading manufacturer of clotting factor used to sustain the lives of persons with hemophilia, Baxter actively engages in providing these therapies to hemophilia treatment centers participating in the 340B program at the discount mandated by the Veterans Health Care Act of 1992.

Recently, HRSA issued a request for comments on a proposal to require hemophilia treatment centers that participate in the 340B program to begin reporting information on patient program participation, program revenue and costs, program net income, and use of program net income. Baxter supports this grant requirement and applauds the transparency and program accountability that such reporting will offer to HRSA as well as the consumers served by hemophilia treatment centers that participate in the 340B program.

MCHB Response:

MCHB acknowledges that Baxter Healthcare Corporation is in favor of the proposed data collection.

Baxter Healthcare Corporation applauds the transparency and program accountability that it believes the proposed data collection will provide to consumers served by hemophilia treatment centers that participate in the 340B program. This statement appears to be based on an assumption that data from this proposed data collection will be made public. This is an issue that is subject to Freedom of Information determination. HRSA/MCHB will not release information to the public regarding individual grantees including individual HTC's 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>

In particular, consumers who participate in the 340B program through their hemophilia treatment center have expressed an interest in gaining a greater understanding about the use of revenue earned by the centers who sell clotting factor, the amount of savings passed along to consumers in terms of access to lower cost therapy, and the practice of carving-out Medicaid consumers from the 340B program. The increased transparency provided by HRSA's reporting requirements will be an invaluable tool for consumers and for hemophilia treatment centers as they strive to educate consumers on the use of revenue earned by the entity. In addition, reporting of program revenue and income will provide greater accountability for HRSA and allow the agency the opportunity for improved oversight.

MCHB Response:

The transparency of the proposed data collection (making the data public) is subject to Freedom of Information determination.

We are in agreement that the reporting of program revenue and income will provide greater accountability for HRSA and allow the agency the opportunity for improved oversight.

One area in particular we would like to bring to HRSA's attention is the need for greater oversight of the program requirement to utilize income derived from 340B program sales to further the services provided by the hemophilia treatment centers. Many hemophilia treatment centers exist essentially as clinics within hospital systems. In some instances, revenue generated from the hemophilia treatment center's 340B program often is not retained at the center/clinic level, but rather flows upward to (sic) support general hospital operations and revenue. This practice detracts from the value of the 340B program for consumers served by the hemophilia treatment center programs and is in potential violation of program requirements and intent. Baxter encourages HRSA to

consider this issue as its capacity for program oversight increases with the income/revenue reporting requirement.

MCHB Response:

HRSA/MCHB acknowledges that there is a requirement to utilize income derived from 340B program sales to further the services provided by the hemophilia treatment centers [45CFR74.24(b)(1)]. Hemophilia Treatment Centers are to report how the program income from 340B program sales has been used as a part of the proposed data collection (proposed data collection items 22-24 and corresponding proposed data collection instructions). HRSA/MCHB plans to review the data from the proposed data collection based on the program income utilization requirement to evaluate the appropriateness of program income expenditures.

Baxter encourages HRSA to move forward with this grant requirement and urges HRSA to make the information provided by the hemophilia treatment centers publicly available to the consumers who are served by these programs. Baxter is not aware of any additional burden that would be incurred by the treatment centers in reporting this information to HRSA or to consumers.

MCHB Response:

HRSA acknowledges the encouragement to make data from the proposed data collection available to consumers who are served by these programs. The public release of such information is subject to Freedom of Information determination.

Thank you again for the opportunity to provide these comments. If you have any questions, please contact me at 847-948-4278 or at sarah_creviston@baxter.com

Sincerely,

Sarah Creviston
Vice President
Government Affairs and Public Policy