Maternal and Child Health Bureau

May 23, 2003

To: OFFICIALS OF THE HEMOPHILIA DIAGNOSTIC AND TREATMENT CENTER REGIONAL PROJECTS GRANTEE INSTITUTIONS

Subject: CLARIFICATION OF CURRENT REQUIREMENTS REGARDING PROGRAM INCOME

The Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA), is continuing its grant monitoring procedures concerning program income. We would like to take this opportunity to inform you and your affiliates of the reporting requirements and governing policies in reference to program income. As specified in 45 C.F.R. 74.2, program income is that "gross income earned by the [grant or subaward] recipient that is directly generated by a supported activity or earned as a result of the award." Costs incident to the generation of program income may be deducted from the gross income to determine the net program income, provided those costs have not been charged to the grant. 45 C.F.R. 74.24(f).

All Federal grants are subject to regulation under the "Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations." 45 C.F.R. Part 74. These same requirements are passed down from the grant recipient to the subawardee. 45 C.F.R. 74.5. A "subaward" means the "award of financial assistance…made under an award by a recipient to an eligible subrecipient or by a subrecipient to a lower tier subrecipient…even if the agreement is called a contract." 45 C.F.R. 74.2. Grant recipients are "responsible for managing and monitoring each project, program, subaward, function or activity supported by the award." 45 C.F.R. 74.51. Consequently, it is incumbent upon you to share this information with appropriate individuals/entities within your institution and affiliates.

Part 74 requires program income to be used in one or more of three ways: (1) added to funds committed to the project or program and used to further eligible project or program objectives; (2) used to finance the non–federal share of the program; or (3) deducted from the total program allowable costs. 45 C.F.R 74.24(b). As provided on the Notice of

Grant Award (Item #15), the MCHB requires the HTC grantees and their affiliate institutions to use the program income to "further eligible project and program objectives." Therefore, the program income is to be used for patient care, education, and supportive services necessary to provide comprehensive care to patients. This is consistent with the purpose of section 340B which is to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, at 12 (1992). Note that the grants awarding office may, on a case-by-case basis, allow a grantee to use the income for eligible costs of the project that might not be expressly allowable costs under the terms and conditions of the award. Such cases require prior written approval from the grants awarding office.

Many HTCs are Title V grantees, and are eligible to access section 340B drug ceiling prices as a result of receiving these grant awards. Section 340B(a)(4)(G) of the Public Health Service Act designates a "comprehensive hemophilia diagnostic treatment center receiving a grant under [Title V] section 501(a)(2) of the Social Security Act" as eligible for drug ceiling prices. Certain HTC grantees are participating in the 340B drug program and accessing such pricing. It is our understanding, that these centers are purchasing certain drugs at the ceiling prices and selling these drugs at a mark-up to their patients. Net income realized from the sale of 340B drugs purchased under the 340B program is considered to be program income**.** In addition, those grantees and affiliates that have factor programs that are non-participants in the 340B Program and those who have factor programs as a result of participation in the 340B Program must consider all sales of drugs, including Medicaid sales, as program income.

Program income from hemophilia treatment center (HTC) grant projects must be managed in accordance with the requirements of Part 74 and must be reported on the Financial Status Report (FSR) SF 269 (long form) within 90 days after the end of each budget period (form enclosed). It is the responsibility of the grantees to monitor the program income generated by the subawardees. To remind grantees of this reporting requirement, the Notice of Grant Award for the FY 2003 budget year (June 1, 2003 – May 31, 2004) will have a term of award pertaining to the accurate reporting of the net program income on the FSR form. Focusing on a prospective application, starting with FY 2003 grant funding cycle, the reporting of net program income on the FSR form is due in the HRSA Division of Grants Management Operations on August 31, 2004, 90 calendar days after the close of the budget period end date.

If you have any questions relating to this letter or if we can be of assistance, please contact Ms. Theda Duvall on 301-443-1440, e-mail tduvall@hrsa.gov or Mrs. Judith Hagopian on 301-443-5698, e-mail jhagopian@hrsa.gov.

Dorothy M. Kelley
Acting Chief, Grants Management Office
HRSA, Division of Grants Management Operations
Maternal and Child Health Bureau

Peter C. van Dyck, M.S., M.D., M.P.H.
Associate Administrator
Maternal and Child Health Bureau

Enclosure

cc: Kathy Lotfi, HHS, OGC
Nancy McGinnis, HRSA, OFPO
Dr. Merle McPherson, MCHB, DSCSHN
Michael A. Mucci, Jr., MCHB, OOM