June 28, 2018

Subject: HTC Financial Responsibilities Regarding MCHB Federal Subaward

To Whom It May Concern:

This letter provides guidance on a Hemophilia Treatment Center’s (HTC’s) financial responsibilities as a recipient of grant funds awarded through the Maternal Child Health Bureau’s (MCHB’s) Regional Hemophilia Network program. Specifically, this letter addresses the restrictions and requirements on the expenditure of income generated as a result of the grant, otherwise known as “program income.”

To carry out the Regional Hemophilia Network program, MCHB divides the country into eight regions and awards a grant to a single Hemophilia Network in each region (“Region”). The Region is considered the prime recipient of the grant. The Region then distributes the grant funds to other entities within its region through subawards or subgrants. In other words, the HTC is considered the subgrantee or subrecipient of the regional grantee.[[1]](#footnote-1) As a recipient of MCHB funds, an HTC is responsible for assuring compliance with the terms of its agreement with the prime recipient as well as the MCHB Regional Hemophilia Network program guidelines. The HTC is also subject to the Department of Health & Human Services’ (HHS’) grant administrative regulations and Federal cost principles at 45 CFR Part 75,[[2]](#footnote-2) MCHB grant project regulations at 42 CFR Part 51a, drug cost regulations at Subpart E of 42 CFR Part 50, the HHS Grant Policy Statement, and the Regional MCHB Grant program guidance (HRSA 12-133).[[3]](#footnote-3) Each of the foregoing are incorporated into the Regional grantee’s prime recipient award and the requirements flow down to the HTC, as the subrecipient.

**Program Income**

As part of a Federal grant, an HTC’s award is subject to program income requirements detailed in 45 CFR § 75.307. Program income is defined as gross income that a grantee or subgrantee receives that is directly generated by a grant supported activity, or “earned as a result” of the award.[[4]](#footnote-4) Program income includes, but is not limited to, “income from fees for services performed, the use or rental of real or personal property acquired under federally-funded projects, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and interest on loans made with award funds.” [[5]](#footnote-5) Interest earned on advances of Federal funds, however, is not program income.[[6]](#footnote-6)

The Health Resources and Services Administration (HRSA) regards any and all revenue that an HTC earns as program income.[[7]](#footnote-7) HTC program income must be added to Federal funds and “must be used for the purposes and under the conditions of the Federal award.”[[8]](#footnote-8) MCHB defines eligible activities to include patient health, education, and supportive services necessary to provide comprehensive care to patients served by HTCs.[[9]](#footnote-9) Consequently, program income generated by an HTC may only be used for certain authorized purposes. The Hemophilia Alliance recommends assigning a cost center for the MCHB HTC subaward with program income as a separate entry to track revenue, to subtract any costs incurred in generating the revenue which are not paid using subaward funds, and to restrict expenditures to eligible activities.

As described above, all program income that is earned during the term of the award or subaward must be attributed to and used by the HTC to support its comprehensive care and programs.[[10]](#footnote-10) A hospital or larger institution hosting an HTC may not lawfully use the HTC’s program income for other purposes, for example, to offset inpatient losses, even if the HTC grant is in that entity’s name. Most importantly, HRSA takes a clear position regarding program income earned by HTCs located within 340B-eligible hospitals and utilizing the hospital’s pharmacy. The *HTC Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act (July 2005)* states on page 29 that: “In brief, FRP (factor replacement product) revenue, whether or not the HTC is a 340B covered entity, is program income and subject to the rules for that kind of income in the grant regulation and the policy statement.” Meaning, any revenue derived from HTC patients filling their prescriptions written by doctors as part of the HTC’s outpatient clinic activities is subject to program income rules. Therefore, this revenue must be restricted to expenditures that will benefit the HTC and its patients and reported to the Region.

However, if the HTC is housed in or is a part of a larger institution, such as a Medical School, Disproportionate Share Hospital, or children’s hospital, the HTC’s program income may be used to cover that portion of the overhead costs incurred by the larger institution on behalf of the HTC. Such expenses are generally calculated and covered through the application of an indirect cost rate[[11]](#footnote-11) to the total costs of operating the HTC, as provided under the Federal cost principles.[[12]](#footnote-12) If an HTC wishes to use its program income on an expenditure that does not meet the standard of eligible activities as defined by MCHB, the HTC must first seek and obtain approval from the Regional grantee and, ultimately, HRSA. The approval should be sought and received in writing.

**Reporting and Tracking Program Income**

Prime grantees (*i.e.* the Region) must monitor the program income generated by any subawardees as a condition of funding.[[13]](#footnote-13) As a result of this grant requirement (and likely passed onto the HTC through its subrecipient agreement with the prime grantee), an HTC must annually report all of its program income, including any 340B revenue, to the prime recipient (*i.e.*, the Region) to be recorded on the Federal Financial Report SF 425 form.[[14]](#footnote-14) The HTC must report: (1) total program income earned; (2) the amount added to the funds committed to the total project costs and expended to further eligible project or program activities; and (3) the amount of program income unexpended.[[15]](#footnote-15) Many HTCs have balances of program income that they carry over each year, and there is no prescribed upper limit on the program income that can be carried forward to the next year. However, all program income earned by the HTC during the award period should be reported to the Region for compliance with Federal reporting requirements.[[16]](#footnote-16) Furthermore, HTCs should consult with the Region and/or review their subrecipient agreements to determine the requirements for program income reporting and any additional obligations related to program income expenditures.[[17]](#footnote-17)

Hospitals and other host institutions should consider accounting for the subaward in the same manner as other federal grant funds they receive, or at least establish a separate cost center for the MCHB HTC subaward, with program income as a separate line item. As mentioned earlier, the Region and HRSA must approve any expenditure of program income by the host institution that does not clearly fall within the scope of the subaward HTC activities. Requests for approval of expenditures on an *ad* *hoc* basis through HRSA’s Electronic Handbook has had mixed results.[[18]](#footnote-18)

**HTCs and Section 340B of the Public Health Service Act**

A comprehensive HTC that receives Federal funding under Section 501(a)(2) of the Social Security Act may register with the HRSA Office of Pharmacy Affairs (OPA) as a covered entity under the Section 340B Drug Pricing Program. Comprehensive HTCs that register with OPA and participate in Section 340B will receive a “HM” designation indicating its comprehensive HTC status. As described earlier, all revenue earned by the HTC is program income, including revenue from the 340B program.

An HTC grantee is not required to participate in the 340B program. However, participating in the 340B program could be financially beneficial to the HTC. For example, although MCHB grants do not provide funds for purchasing and dispensing Factor Replacement Product (FRP), an HTC participating in the 340B program could use program income from 340B participation to provide FRP to uninsured patients, in addition to the other approved purposes for program income and under the conditions of the Federal award.

Note also that in HTC Program Guidance, HRSA states that if a recipient or subrecipient of a grant is eligible to participate in the 340B program as a covered entity, and an assessment of the organization’s drug purchasing practices or reimbursement “shows that participating in the 340B Program and its Prime Vendor Program is the most economical and reasonable manner of purchasing or reimbursing for covered outpatient drugs (as defined in Section 340B),” failure to participate may “result in a negative audit finding, cost disallowance, or grant funding offset.”[[19]](#footnote-19)

**Conclusion**

Grantees and subgrantees receiving Federal funds must ensure compliance with all of the rules and regulations governing the MCHB HTC program. While the numerous restrictions and requirements of the program are complex, HTCs can take steps to promote compliance within their program, particularly with respect to program income. HTCs and host institutions should work together to create policies and procedures to document all program income earned and expended by the HTC, including processes that demonstrate and support that all program income is being used to further the objectives of the MCHB HTC program. The HTC and the institution should develop a clear accounting system for program income that will assist in sustaining and growing the comprehensive care and support services offered to patients of the HTC as well as prevent findings of non-compliance or disallowances.

Ultimately, the law and best interests of the Regional grantee, the HTC subgrantee, and the host institution require that all parties understand and adhere to the program income requirements in 45 CFR § 75.307 as well as the other governing rules, regulations, and guidance concerning MCHB grant awards.

If you have questions or concerns, please contact us at (202) 466-8960.

Sincerely,

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Enclosures: MCHB Regional Network (HRSA-12-133)

HRSA Letter (2003)

HTC 340B Manual (2005)

1. 45 CFR § 75.2. [↑](#footnote-ref-1)
2. HHS’ grant administrative regulations are codified at 45 CFR Part 75, including the Cost Principles, which are codified in Subpart E of the same Part 75. [↑](#footnote-ref-2)
3. Program Guidance for Regional Grantees, HRSA 12-133. [↑](#footnote-ref-3)
4. 45 CFR § 75.2. [↑](#footnote-ref-4)
5. *See id*. [↑](#footnote-ref-5)
6. *Id.* [↑](#footnote-ref-6)
7. HRSA Memo to HTC Regional Grantees, dated May 23, 2003, and confirmed in 2011, indicates that all revenue related to HTC patients in a factor program is considered “program income” and must be used for activities that fall within the scope of the HTC program. This is HRSA’s position despite the very limited Federal funding provided to HTCs. [↑](#footnote-ref-7)
8. *See* 45 CFR § 75.307(e)(2). [↑](#footnote-ref-8)
9. HRSA Memo to HTC Regional Grantees, dated May 23, 2003. [↑](#footnote-ref-9)
10. However, program income earned after the grant or subgrant period ends is not restricted or reportable income. [↑](#footnote-ref-10)
11. Please be aware that your host institution may have a federally negotiated indirect cost rate, but usually these are established for research grants and are not appropriate for the HTC because those indirect cost pools include facilities and administrative expenses that are not utilized by the HTC. The host institution can establish a separate indirect cost rate for support of the HTC and charge it to the HTC direct costs, so long as the rate represents only the pool of administrative and facilities costs incurred in supporting the HTC. Please also be aware that the Federal rules establish a fixed, *de minimus* indirect cost rate of 10% under 45 CFR § 75.414(f). Further, note that all allowable expenditures are subject to all of the Federal cost principles at 45 CFR Subpart E. [↑](#footnote-ref-11)
12. *See* 45 CFR §§ 75.412 - 75.415. [↑](#footnote-ref-12)
13. HTC 340B Manual (July 2005). [↑](#footnote-ref-13)
14. *Id.* [↑](#footnote-ref-14)
15. *See id;* HRSA Memo to HTC Regional Grantees, dated May 23, 2003;and 45 CFR Part 75. [↑](#footnote-ref-15)
16. *See* Federal Financial Report, Standard Form 425. [↑](#footnote-ref-16)
17. For example, depending on the terms and conditions of the grant, any program income carried forward may retain its program income character and restrictions. [↑](#footnote-ref-17)
18. MCHB is drafting guidance on the appropriate uses of program income, but it has not yet been published. [↑](#footnote-ref-18)
19. Program Guidance for Regional Grantees, HRSA 12-133. [↑](#footnote-ref-19)