



Rockville MD 20857

Mary Horowitz, M.D., M.S.
Chief Scientific Director
Center for International Blood and Marrow Transplant Research (CIBMTR)
Medical College of Wisconsin
8701 Watertown Plank Road
P.O. Box 26509
Milwaukee, WI 53226 USA

March 23, 2007

Re: Effect of the HIPAA Privacy Rule on the disclosure of data by transplant centers to the Medical College of Wisconsin's Center for International Blood and Marrow Transplant Research

Dear Dr. Horowitz:

The purpose of this letter is to provide guidance regarding whether the disclosure of certain data related to the Stem Cell Therapeutic Outcomes Database by transplant centers to the Medical College of Wisconsin's Center for International Blood and Marrow Transplant Research (CIBMTR) is compatible with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulation, "Standards for Privacy of Individually Identifiable Health Information" (Privacy Rule), 45 CFR Parts 160 and 164. This letter clarifies the requirements of the Privacy Rule as they pertain to the collection of individually identifiable health information from transplant centers.

The Privacy Rule, published in the *Federal Register* on December 28, 2000, provides comprehensive protection for the privacy of individually identifiable health information used or disclosed by a covered entity in any form. Various State privacy laws also exist. It is important to note that the Rule does not pre-empt State laws that are more stringent than the Federal requirements.

The Privacy Rule applies to health plans, health care clearinghouses, and health care providers that conduct certain financial and administrative transactions (e.g., billing and fund transfers) electronically. These are "covered entities" and as such must comply with the Privacy Rule's requirements. The Office of General Counsel, U.S. Department of Health and Human Services, has concluded that the CIBMTR is not a covered entity under the Privacy Rule.

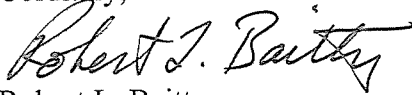
We understand there may be concern over the ability of transplant centers, some of which may fit the definition of covered entities and thus are subject to the Privacy Rule, to provide individually identifiable health information to the CIBMTR. If a transplant center does not fit the definition of a covered entity under the Privacy Rule, the transplant center is not subject to the Privacy Rule's requirements. If a transplant center fits the definition of a covered entity, the disclosure of certain individually identifiable health information to the CIBMTR is allowable

under 45 CFR 164.512 (Privacy Rule), which allows for the disclosure of an individual's protected health information without the individual's written consent or authorization when such a disclosure is made to a public health authority that is authorized by law to collect information for the purpose of preventing or controlling disease, injury, or disability.

The Office for Civil Rights (OCR), in consultation with the Office of the General Counsel, U.S. Department of Health and Human Services, has responsibility for enforcement and interpretation of the Privacy Rule. The Office of the General Counsel has determined, and OCR concurs, that the CIBMTR meets the Privacy Rule's definition of a public health authority and is authorized by law to collect the information necessary for the Stem Cell Therapeutic Outcomes Database to fulfill its statutory purpose and functions. Under this analysis, transplant centers that are covered entities may disclose to the CIBMTR the individually identifiable health information collected by the Stem Cell Therapeutic Outcomes Database in order for the Database to comply with its statutory purposes.

Additional information on the Privacy Rule is available at <http://www.hhs.gov/ocr/hipaa/>. If you have any further questions on this issue, please contact me.

Cordially,



Robert L. Baitty
Director, Blood Stem Cell Transplantation Program
Division of Transplantation