

Proposed Project: The Stem Cell Therapeutic Outcomes Database—(New)

The Stem Cell Therapeutic and Research Act of 2005 establishes the C.W. Bill Young Cell Transplantation Program and provides for the collection and maintenance of human blood stem cells for the treatment of patients and for research. The Health Resources and Services Administration's (HRSA), Healthcare Systems Bureau (HSB), is establishing the Stem Cell Therapeutic Outcomes Database as one component

of the C.W. Bill Young Cell Transplantation Program. Operation of this database necessitates certain reporting requirements in order to perform the functions related to hematopoietic stem cell transplantation under contract to HHS. The Act requires the Secretary to contract for the collection and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. Data will be collected from transplant centers in a manner similar to the data

collection activities historically conducted by the Medical College of Wisconsin's Center for International Blood and Marrow Transplant Research (CIBMTR) and will be used for ongoing analysis of transplant outcomes. HRSA will use the information in order to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation, and to provide the Secretary with an annual report of transplant center-specific survival data.

The estimate of burden is as follows:

Form	Estimated number of respondents	Responses per respondent	Total Responses	Hours per response	Total burden hours
Baseline Pre-TED (Transplant Essential Data)	225	32	7,200	0.85	6,120
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	225	14	3,150	1.5	4,725
100-Day Post-TED	225	32	7,200	0.85	6,120
6-Month Post-TED	225	23	5,175	1.00	5,175
12-Month Post-TED	225	20	4,500	1.00	4,500
Annual Post-TED	225	16	3,600	1.50	5,400
Total	225	30,825	32,040

The Pre-TED, Product Form, 100-Day Post-TED, 6-Month Post-TED, and 12-Month Post-TED will be collected on all patients during their first year of transplant. In subsequent years, patient outcomes will be reported on the Annual Post-TED form. There will be a gradual increase in the cumulative reporting burden over time commensurate with the number of survivors for which transplant centers must submit an Annual Post-TED.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Karen Matsuoka, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 2, 2007.

Caroline Lewis,

Associate Administrator for Management.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Announcement of a Change to the Awarding Factors Under the Fiscal Year 2007 New Access Points in High Poverty Counties (HRSA-07-069) Grant Opportunity

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Revision to awarding factors.

SUMMARY: The Health Resources and Services Administration (HRSA) is announcing a change to the awarding factors under the HRSA-07-069 "New

Access Points in High Poverty Counties" funding opportunity [issued on Grants.gov March 14, 2007] as they relate to awards made under the HRSA-07-067 "New Access Points" funding opportunity for the President's first Health Centers Initiative [issued on Grants.gov October 6, 2006].

In making award decisions for fiscal year (FY) 2007, HRSA will now consider granting the same organization a new access point award under HRSA-07-067 and HRSA-07-069. HRSA will consider more than one FY 2007 new access point award to an organization if, and only if each application submitted (by the same organization for the two different funding opportunities) proposes a separate and distinct project to serve different counties. That is, there must be no overlap or duplication of service area, target population, or sites. (Under previous HRSA policy, if an organization receives a grant award in FY 2007 under the first opportunity, HRSA-07-067, it could not be awarded funds in FY 2007 under HRSA-07-069). Applicants for HRSA-07-069 should also be aware that each new access point application must be complete and must be able to stand alone.

The changes announced in this **Federal Register** Notice do not impact any HRSA policy for eligibility under the HRSA-07-069. Organizations

continue to be eligible to submit one application under HRSA-07-069, irrespective of whether they applied under HRSA-07-067 or not. Additionally, all other awarding factors detailed in HRSA-07-069 remain the same.

Reference: HRSA-07-069 is available online via the HRSA Web site at: <http://www.hrsa.gov/grants/technicalassistance/pi2nap.htm> or <http://www.grants.gov>.

FOR FURTHER INFORMATION CONTACT:

Preeti Kanodia, Division of Policy and Development, Bureau of Primary Health Care, Health Resources and Services Administration. Ms. Kanodia may be contacted by e-mail at DPDGeneral@hrsa.gov or via telephone at (301) 594-4300.

Dated: May 2, 2007.

Dennis P. Williams,

Deputy Administrator.

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