Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database

OMB No. 0915-0310 –Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for an opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Before submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915- 0310, Revision

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (P.L.) 109–129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2015, P.L. 114–104 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. HRSA's Healthcare Systems Bureau has established the Stem Cell Therapeutic Outcomes Database, which necessitates certain electronic record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation under contract to HHS. Data is

collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes. Over time, there is an expected increase in the number of recipients for whom data are reported as the increasing number of transplants are performed annually and survivorship after transplantation improves.

Need and Proposed Use of the Information: Per statutory responsibilities, information collected on the forms outlined in the "Total Estimated Annualized Burden Hours" section below is needed to monitor the clinical status of transplantation and provide the Secretary with an annual report of transplant center-specific survival data. The proposed revisions of these data collection forms fall into several categories: consolidating questions and removing duplicate questions across the forms, implementing "check all that apply" formatting to reduce data entry time, and removing items no longer clinically significant (e.g., drugs). These proposed revisions are not anticipated to affect total burden hours.

Likely Respondents: Transplant Centers

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual

burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents[1]	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Baseline Pre-Transplant Essential Data (TED)	200	44	8,800	1.00	8,800
Disease Classification	200	44	8,800	0.15	1,320
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	33	6,600	1.00	6,600
100-Day Post-TED	200	44	8,800	1.25	11,000
6-Month Post-TED	200	36	7,200	1.15	8,280
12-Month Post-TED	200	32	6,400	1.15	7,360
Annual Post-TED	200	110	22,000	1.15	25,300
Total	200		68,600		68,660

[1]The total of 200 is the number of centers completing the form; the same group will complete all of the forms.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

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