Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; **The Stem Cell Therapeutic Outcomes Database**

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

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. HRSA's Healthcare Systems Bureau established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation under contract to the U.S. Department of Health and Human Services (HHS). The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who received stem cell therapeutic products and to do so using a standardized, electronic format. 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. Post-Transplant Essential Data (TED) forms are being revised in this submission. The portion of the Product Form related to confirmation of human leukocyte antigen (HLA) typing has minor changes to the identification and date fields to allow this form to more flexibly capture HLA

typing data for expanding indications of cellular therapy. The Pre-TED form remains unchanged from the previously approved OMB submission.

The increase in burden is due to an increase in the annual number of transplants and increasing survivorship after transplantation.

Need and Proposed Use of the Information: HRSA uses the information to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation and provide the Secretary of HHS with an annual report of transplant center specific survival data.

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 (1) the time needed to review instructions; (2) to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information; (3) processing and maintaining information; (4) disclosing and providing information; (5) training personnel to be able to respond to a collection of information; (6) searching data sources; (7) completing and reviewing the collection of information; and (8) transmitting or otherwise disclosing the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden - Hours

	Number of			Average	Total Burden

Form Name	Respondents	Number of Responses per Respondent	Total Responses	Burden per Response (in hours)	Hours
Baseline Pre-TED (Transplant Essential Data)	200	44	8,800	1.15	10,120
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	33	6,600	1	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		59,800		68,660

* The Total of 200 is the number of centers completing the form. The same group of 200 centers completes each of the forms.

Jason E. Bennett

Director, Division of the Executive Secretariat

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