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, 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 of the Paperwork Reduction Act of 1995, 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 Lisa Wright-Solomon, 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 has established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain recordkeeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation under contract to HHS. 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. Data is collected from transplant centers, under contract, by the Medical College of Wisconsin's 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 an increasing number of transplants are performed annually and survivorship after transplantation improves.

A 60-day notice was published in the **Federal Register** on March 7, 2019, vol. 84, No. 45; pp. 8334-8335. There were no public comments.

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. Modifications of these 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

modifications reduced the overall hours of burden inventory.

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	48	9,600	0.68[2]	6,560
Disease Classification	200	48	9,600	0.43[3]	4,160
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	45	9,000	1.00	9,000
100-day Post-TED	200	48	9,600	0.85	8,160
6 month Post-TED	200	43	8,600	0.85	7,310
1 year Post-TED	200	40	8,000	0.65	5,200
2 year Post-	200	34	6,800	0.65	4,420

TED					
3+ years Post-TED	200	172	34,400	0.52[4]	17,773
Total	200		95,600		62,583

[1] The total of 200 is the number of centers completing the form; the same group will complete all of the forms.
[2] The decimal is rounded down, and the actual number is .683333333.
[3] The decimal is rounded down, and the actual number is .433333333.
[4] The decimal is rounded up, and the actual number is .516667.

Maria G. Button,

Director, Division of the Executive Secretariat.

Billing Code: 4165-15

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