(3) not providing FDA with requested information regarding the recall, as ordered by FDA.

B. Who will be responsible for paying this fee?

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

C. How much will this fee be?

The fee is based on the number of direct hours spent taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

D. How must the fees be paid?

Section 743(a)(1)(A) and (B) of the FD&C Act require FDA to assess and collect reinspection and recall fees, as appropriate, from responsible parties for domestic and foreign food facilities. Further, section 743(a)(1)(D) requires FDA to assess and collect reinspection fees from importers. An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment is to be made within 30 days of the invoice date in U.S. currency by electronic check, credit card, or wire transfer. Detailed payment information will be included with the invoice when it is issued.

V. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14414 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

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 (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA 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. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than August 29, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

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 (Pub. L. 109–129, December 20, 2005) as amended and codified in Section 379A of the Public Health Service Act (42 U.S.C. 247l), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. The Public Health Service Act requires the Secretary of HHS to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using an electronic format. HRSA has established the Stem Cell Therapeutic Outcomes Database (SCTOD), a component of the C.W. Bill Young Cell Transplantation Program (Program), which necessitates certain electronic record-keeping and reporting requirements to perform functions related to hematopoietic stem cell transplantation (HCT) under contract to HHS. Data are collected from transplant centers by the Center for International Blood and Marrow Transplant Research. They are used for ongoing analysis of transplant outcomes to improve treatment and survival for patients who may benefit from cellular therapies.

The proposed revisions to this ICR reflect the most up-to-date medical evidence while also reducing the burden on hematopoietic stem cell transplantation facilities. Revisions fall into several categories: consolidating questions, implementing interactive requests (such as electronic check boxes, ''check all that apply,'' and pull-down menus) to reduce data entry time, adding necessary information fields, clarifying information requests, and removing items that are no longer clinically significant.

Over time, there is an expected increase in the information reported as the number of transplants performed annually increases and survivorship after transplantation improves. Similarly, because of the ongoing rapid evolution in transplant indications, methods to establish diagnoses, disease prognostic factors, treatments provided before HCT, methods to determine donor matching, and transplantation techniques, the Program anticipates incremental changes in the information collected by the SCTOD after OMB approval to reflect current clinical care, facilitate statistical modeling throughout the approval period to fulfill Program requirements, keep pace with changes in the field, and to enhance the ability to collect information in an automated fashion from respondent source systems, such as electronic health records. Interim updates to the information collected about disease indications, disease definitions, and disease prognostic factors will be triggered by the publication of peer-reviewed scientific articles or public reference materials of updated criteria by organizations such as the World Health Organization, national or international scientific consensus panels (*e.g.,* European LeukemiaNet, International Working Group for Prognosis in MDS), or similar. The updates mentioned above are anticipated to be reflected as changes in

response options to existing information collection and will represent non-substantive changes without additional public notice. Such small incremental changes will not significantly affect the burden.

A 60-day notice published in the **Federal Register** on May 16, 2025, vol. 90, No. 94; pp. 21049–51. There were no public comments.

Need and Proposed Use of the Information: Per statutory responsibilities, the collection of information outlined in the ''Total Estimated Annualized Burden Hours'' section below is needed to collect, analyze, and publish stem cell transplantation-related data, including patient outcomes data, 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 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 [1]	Number of respondents [2]	Number of responses per respondent [3]	Total responses	Average burden per response (in hours)	Total burden hours [4]
Pre-Transplant Information Collection	182.00	53.80	[5] 9,788.00	[6] 2.24	21,902.61
Transplant Procedure and Product Information	182.00	53.80	[7] 9,788.00	[8] 0.75	7356.66
Post-Transplant Periodic Information Collection based on Pre-determined Schedule	182.00	418.90	[9] 76,232.00	[10] 0.57	43,810.53
Total	182.00		95,808.00		73,069.80

[1] This burden estimate table refers to data collections at different time periods consistent with approved practice. The SCTOD contractor is working with respondents to reduce burden by submitting data using interoperability standards. These data collections may include OMB-approved forms.

[2] The total number of U.S. transplant centers that submit data to the SCTOD is 182 as of April 14, 2025. The number of centers providing data may change intermittently based on opening or closure of centers.

[3] The Number of Responses per Respondent was calculated by dividing the Total Responses by the Number of Respondents and rounding to the nearest hundredth.

[4] The numbers in this column have been rounded to the nearest hundredth and do not sum precisely due to rounding adjustments throughout the table.

[5] Total responses for Pre-Transplant Information Collection equals the estimated number of new transplant patients in 2024.

[6] Pre-transplant Data includes baseline recipient data including patient demographics, pertinent medical history, disease characteristics and status, co-morbidities, transplant data procedure characteristics, including preparative regimen, and donor data. This number is rounded to the nearest hundredth. The actual burden estimate for these data is 2.2377.

[7] Transplant Procedure and Product Information equals estimated number of new transplant patients in 2024.

[8] Transplant Procedure and Product Information includes Graft-vs-Host Disease prophylaxis, graft source, donor type and degree of HLA matching and graft manipulation; graft characteristic data for cord blood units, including infused cell dose; and product information. This number is rounded to the nearest hundredth. The actual burden estimate for these data is 0.7516.

[9] The number of responses for Post-Transplant Periodic Information Collection is based on a predetermined schedule: 100 days after transplant, 6 months after transplant, 1 year after transplant, annually for 6 years after transplant and then biennially thereafter. In any given year the number of responses is a function of the number of transplants in that year, the number of transplants in previous years, and expected patient survival between the time of transplant and any follow-up activity.

[10] Post-Transplant Data Collection includes hematopoietic recovery and engraftment, serious complications including Graft-vs-Host Disease and second cancers, disease status, survival status, cause of death, and subsequent procedures. This number is rounded to the nearest hundredth. The actual burden estimate is 0.5747.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025–14397 Filed 7–29–25; 8:45 am]

BILLING CODE 4165–15–P

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 National Health Service Corps and Nurse Corps Interest Capture Form—OMB No. 0915–0337—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 requirement for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to 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 September 29, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance