180 days, consistent with preexisting guidance.

When the COVID–19 public health emergency began, FDA understood that applicants may face challenges affecting their ability to meet their applicable response date for submissions placed on hold. FDA also recognized our potential difficulty in processing a high volume of individual extension requests on a timely basis. To alleviate these concerns, the guidance document articulated that FDA did not intend to consider an application or submission to be withdrawn for an additional 180 days beyond the relevant response date, regardless of whether the applicant submitted an extension request.

By weighing the current burdens on industry with FDA's interest in patients receiving timely access to new devices, FDA has determined it is in the interest of the public health to return to pre-pandemic policies regarding hold times. Reverting to policies regarding hold times described in the preexisting guidance documents should facilitate more timely premarket review of innovative and potentially lifesaving devices. In addition, closing out files that have been abandoned in a timelier manner allows for better management of the device review program. The Agency acknowledges that the circumstances giving rise to the public health emergency declaration for the COVID–19 pandemic continue to exist. However, the conditions that created the need for these policies have evolved, such that these policies are no longer needed, and it is in the best interest of patients and providers to reinstitute the original hold times to ensure patients have timely access to advanced technologies, diagnostics, and therapeutics without unnecessary delay.

The guidance document also discussed FDA's ability to host advisory committee meetings virtually and FDA's intention to work with relevant stakeholders to host all advisory committee meetings virtually. In returning to pre-pandemic policies, FDA will assess the appropriate venue for advisory committee meetings, keeping in mind FDA's successful implementation of virtual advisory committee meetings. Consistent with existing policy, the venue will be announced via the **Federal Register**.

Therefore, after careful review of current Agency processes, industry practices with regard to resolving submission deficiencies, and comments submitted to the public docket associated with the guidance, FDA is withdrawing the ''Effects of the COVID–19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices—Questions and Answers (Revised)'' guidance in its entirety.

## II. Withdrawal Date

The withdrawal date for the guidance document discussed in this document is July 7, 2022. For submissions or applications that receive a major deficiency letter for PMA and HDE applications or additional information letters for 510(k) and De Novo requests prior to or on the guidance withdrawal date, FDA does not intend to consider the submission or application to be withdrawn for an additional 180 days beyond the relevant response date. For submissions or applications that receive a major deficiency letter or additional information letter after the guidance withdrawal date, FDA will generally consider the application or submission to be withdrawn if a complete response is not received by the relevant response date identified in that letter.

*Authority:* 21 U.S.C. 371(h).

Dated: June 1, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–12176 Filed 6–3–22; 8:45 am]

**BILLING CODE 4164–01–P**

*guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals*).

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: 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. 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 July 7, 2022.

**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 acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–9094.

**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 (Pub. L.) 109–129, as amended by the TRANSPLANT Act of 2021, Public Law 117–15 (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 an electronic format. HRSA has established the Stem Cell Therapeutic Outcomes Database (SCTOD), one component of the C.W. Bill Young Cell Transplantation Program (Program), which necessitates certain electronic record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation (HCT) 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 to improve the treatment, survival, and quality of life for patients who may benefit from cellular therapies. 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 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 frequent incremental changes in information

collected by the SCTOD to reflect current clinical care and facilitate statistical modeling throughout the approval period to fulfill the requirements of the Program. Such small incremental changes will not significantly affect the burden. Changes from the prior data collection spreadsheet include addition of a response option for pre-transplant information collection and three questions to collect donor lymphocyte infusion for post-transplant information collection. The burden has decreased due to better estimates of the number of responses and use of burden testing results to estimate the time required.

A 60-day Notice published in the **Federal Register**, Volume 87, Number 53, FR 15439–15440 (March 18, 2022). 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. The proposed revisions of this information collection reflect the most up-to-date medical evidence while simultaneously reducing HCT facility burden. Revisions fall into several categories: consolidating questions, implementing interactive requests (electronic check boxes, check all that apply and pull-down menus) to reduce data entry time, adding necessary information fields, adding clarity to information requests and removing items no longer clinically significant (*e.g.,* drugs). These revisions also incorporate COVID–19 vaccine questions currently under emergency approval. From time to time, there may be refinements in the information collection to keep pace with changes in the field or to enhance the ability to collect information in an automated fashion from respondent source systems, such as electronic health records. The contractor requests OMB approval by June 30, 2022.

*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 revised total annual burden hours estimated for this ICR are summarized in the table below. The total hours decreased from 56,786 to 51,526 due to minor changes in the ICR.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

| Form name [1] | Number of respondents [2] | Number of responses per respondent [3] | Total responses [4] | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Pre-Transplant Information Collection | 177 | 52.6 | [5] 9,315 | [6] 1.4 | 13,041 |
| Transplant Procedure and Product Information | 177 | 52.6 | [7] 9,315 | [8] 1.1 | 10,247 |
| Post-Transplant Periodic Information Collection based on Predetermined Schedule | 177 | 319.1 | [9] 56,476 | [10] 0.5 | 28,238 |
| Total | 177 | | 75,106 | | 51,526 |

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.

**Maria G. Button,**

*Director, Executive Secretariat.*

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**BILLING CODE 4165–15–P**

[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 transplant centers that submit data to the SCTOD is 177.

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

[4] The total number of responses is less than previous calculations because of improvements in estimation. Previous estimates assumed all years had the same number of transplants. This improved estimate includes accurate transplant counts from prior years, which are often less than the current year leading to less follow-up activity.

[5] Total responses for Pre-Transplant Information Collection equals estimated number of new transplant patients in 2021.

[6] Pre-transplant Data includes baseline recipient data including patient demographics, pertinent medical history, disease characteristics and status, and co-morbidities, transplant data procedure characteristics, including preparative regimen, and donor data. This number is rounded to nearest tenth. The actual burden estimate for these data is 1.4175.

[7] Transplant Procedure and Product Information equals estimated number of new transplant patients in 2021.

[8] Transplant Procedure and Product Information includes Graft-vs-Host Disease (GVHD) 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 nearest tenth. The actual burden estimate for these data is 1.0616.

[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 GVHD and second cancers, disease status, survival status, and cause of death; and subsequent procedures. This number is rounded to nearest tenth. The actual burden estimate is 0.5247.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as