consider these to be material and relevant to the substantive review of the De Novo request.

(Comment 12) One comment proposed that FDA staff should be able to use discretion in order to request missing checklist items interactively, rather than to RTA when there are one or more items missing from the Acceptance Checklist as described in section III.A of the guidance. This would aid in ensuring a least burdensome approach was applied to this process.

(Response 12) We do not believe that revisions are necessary in response to this comment. Within section III.A, the guidance states that ''FDA staff also has discretion to request missing checklist items interactively from requesters during the RTA review. Interaction during the RTA reviews is dependent on FDA staff's determination that outstanding issues are appropriate for interactive review and that adequate time is available for the requester to provide supporting information and for FDA staff to assess responses.''

We believe the recommendations in the guidance are consistent with the least burdensome provisions and guiding principles, and we apply them in identifying what FDA believes to be the minimum information that the Agency relies on to complete premarket submission review in the most efficient manner. For information on the least burdensome provisions, refer to FDA's guidance, ''The Least Burdensome Provisions: Concept and Principles.''

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
De Novo requests						
De Novo request under 21 U.S.C. 513(f)(2)(A)(i):						
CDRH	2	1	2	100	200	
CBER	1	1	1	100	100	
De Novo request under 21 U.S.C. 513(f)(2)(A)(ii):						
CDRH	56	1	56	180	10,080	
CBER	1	1	1	180	180	
Acceptance Checklist	60	1	60	1	60	
Recommended Content Checklist	60	1	60	1	60	
Total De Novo requests			60		10,680	$7,278
Request for withdrawal [2]	5	1	5	10	50	5
Total					10,730	7,283

[1] There are no capital costs associated with this collection of information.
[2] No change from approved information collection. This information is retained for the convenience of the reader.

Based on updated program data and trends, we expect to receive approximately 60 De Novo requests per year. We have not changed our estimates of the Average Burden per Response for De Novo requests.

We estimate that it will take approximately 1 hour to prepare an Acceptance Checklist and 1 hour to prepare a Recommended Content Checklist. Our estimate assumes that each De Novo request will include both checklists.

Approved operating and maintenance costs for a De Novo request include printing, shipping, and eCopy costs. We have updated the operating and maintenance costs to account for the updated burden estimate for De Novo requests (resulting in an increase of $970 to the total estimated operating and maintenance costs). However, we believe any increase of the operating and maintenance cost resulting from the addition of the Acceptance Checklist and Recommended Content Checklist to be de minimis.

The operating and maintenance cost for a De Novo submission includes the cost of printing, shipping, and the eCopy. We estimate the cost burden for a De Novo submission, including the Acceptance Checklist and Recommended Content Checklist, to be $121.30 ($90 printing + $30 shipping + $1.30 eCopy). The annual cost estimate for De Novo submissions is $7,278 (60 submissions × $121.30). We estimate the cost for a request for withdrawal to be $1 (rounded) ($0.09 printing 1 page + $0.03 shipping + $1.30 eCopy). The annual cost estimate for requests for withdrawal is $5.

Our estimated burden for the information collection reflects an overall increase of 3,400 hours. We attribute this adjustment to the addition of the Acceptance Checklist and the Recommended Content Checklist and to an increase in the number of submissions we received during the approval period. For clarity, we have separated the Acceptance Checklist and Recommended Content Checklist into distinct line-items in table 1.

Dated: June 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14066 Filed 7–1–19; 8:45 am]

BILLING CODE 4164–01–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: Hospital Campaign for Organ Donation Scorecard, OMB No. 0915–0373, Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for 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). 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 Information Collection Request must be received no later than September 3, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 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: Hospital Campaign for Organ Donation Scorecard OMB No. 0915–0373, Revision.

Abstract: HRSA's Hospital Campaign for Organ Donation enlists healthcare organizations nationwide to increase the number of registered organ, eye, and tissue donors by hosting education and donor registration events in their facilities and communities. A scorecard identifies activities that participants can implement and assigns points to each activity. Participants that earn a certain number of points annually are recognized by HRSA and the campaign's national partners.

For this information collection request, the proposed change to the Scorecard is the addition of the 2020 date. HRSA also intends to create a new electronic version of the Scorecard for future campaigns that will ultimately reduce the level of burden for participants. The electronic version will be designed to be user friendly, will take less time to complete, and will provide HRSA with data throughout the campaign rather than once a year. Another benefit of an electronic scorecard is that it will eliminate the possibility of human error as information will no longer be manually entered into a database.

Need and Proposed Use of the Information: There is a substantial imbalance in the U.S. between the number of people whose lives depends on organ transplants (currently more than 113,000) and the annual number of organ donors (approximately 14,000 living and deceased donors). This imbalance results in about 7,300 waiting list deaths annually. In response to the need for increased donation, HRSA conducts public outreach initiatives to encourage the American public to enroll on state donor registries as future organ donors.

The Scorecard motivates and facilitates healthcare organizations' participation in the campaign, provides the basis for rewarding participants for their accomplishments, and enables HRSA to measure and evaluate campaign process and outcome. The scorecard also enables HRSA to make data-based decisions and improvements for subsequent campaigns.

Likely Respondents: The likely respondents include the following: Hospital development and public relations staff of organ procurement and other donation organizations; hospital staff such as nurses or public relations/communications professionals and staff members; staff at physician's offices, health clinics, and emergency medical services; or volunteers that work with healthcare organizations on organ donation initiatives.

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	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Activity Scorecard (online)	1,400	1	1,400	.25	350
Total	1,400		1,400		350

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, Division of the Executive Secretariat.

[FR Doc. 2019–14078 Filed 7–1–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Scientific Information Reporting System (SIRS) (National Institute of General Medical Sciences)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the