existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form FDA 3601a

OMB Control Number 0910–0511—Revision

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the ''Medical Device User Fee Cover Sheet,'' is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health and FDA's Center for Biologics Evaluation and Research to initiate the administrative screening of new medical device applications and supplemental applications.

We are revising the information collection to add Form FDA 3601a, the ''Device Facility User Fee Cover Sheet.'' Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States are required to register annually with FDA, a process known as establishment registration (21 CFR part 807, subparts A through D). (The information collection for medical device establishment registration and listing is approved under OMB control number 0910–0625.) All establishments required to register must pay a user fee. Form FDA 3601a, the ''Device Facility User Fee Cover Sheet,'' is designed to collect payments for the annual establishment registration fee for medical device establishments.

The total number of annual responses for Form FDA 3601 is based on the average number of cover sheet submissions received by FDA in recent years. The number of received annual responses includes cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions and range from 5 to 30 minutes. For this analysis, we estimate 18 minutes per coversheet.

The total number of annual responses for Form FDA 3601a is based on the average number of cover sheet submissions received by FDA in recent years. Based on past FDA experience with various cover sheet submissions, we estimate 10 minutes per response.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1] [2]

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3601	6,182	1	6,182	0.30 (18 minutes) ..	1,855
3601a	24,086	1	24,086	0.17 (10 minutes) ..	4,095
Total	.....	.....	30,268	.....	5,950

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 4,036 hours and a corresponding increase of 23,889 responses/records. We attribute these increases to two factors: we have revised the burden estimate to include Form FDA 3601a and we have adjusted the number of respondents for Form FDA 3601 to reflect our current data.

Dated: June 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–12768 Filed 6–11–20; 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: Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative, OMB No. 0915–0335—Revision

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

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 must be received no later than July 13, 2020.

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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative, OMB No. 0915–0335–Revision.

Abstract: In response to the growing need for research and resources devoted to autism spectrum disorder and other developmental disabilities, the U.S. Congress passed the Combating Autism Act of 2006 (Pub. L. 109–416); it was reauthorized by the Combating Autism Reauthorization Act of 2011 (Pub. L. 112–32), the Autism Collaboration, Accountability, Research, Education, and Support (Autism CARES) Act of 2014 (Pub. L. 113–157) and the Autism CARES Act of 2019 (Pub. L. 116–60). Through these Autism CARES public laws, HRSA has been tasked with increasing awareness of autism spectrum disorder and developmental disabilities, reducing barriers to screening and diagnosis, promoting evidence-based interventions, and training healthcare professionals in the use of valid and reliable diagnostic tools.

Need and Proposed Use of the Information: The purpose of this information collection is to design and implement an impact evaluation to assess the effectiveness of HRSA's Maternal and Child Health Bureau's activities in meeting the goals and objectives of the Autism CARES Act. This ICR is a revision to an existing package; this study is the fourth evaluation of HRSA's autism activities and employs similar data collection methodologies as the prior studies. Grantee interviews remain the primary form of data collection. Minor proposed revisions to the data collection process include (1) modifications to the interview questions based on the current legislation and HRSA's Notices of Funding Opportunity and (2) the creation of a new Grantee Survey to collect common data elements across the three program areas that focus on training, research, and state systems.

Likely Respondents: Grantees funded by HRSA's Autism programs will be the respondents for this data collection activity. The grantees are from the following HRSA programs: Leadership Education in Neurodevelopmental and Related Disabilities Training Program; Developmental Behavioral Pediatrics Training Program; State Innovation in Care Integration Program; State Innovation in Care Coordination Program; Research Network Program; Research Program; Interdisciplinary Technical Assistance Center; and the State Public Health Autism Center Resource Center.

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

Grant Program/form name	Number of respondents	Average number of responses per respondent	Total responses	Average hours per response	Total hour burden
Grantee Survey (Training and Research Grantees)	80	3	240	0.5	120
Grantee Survey (State Systems Grantees)	5	3	15		7.5
Training Interview Guide	64	1.5	96	1.25	120
State Systems Interview Guide	5	1.5	7.5	1.25	9.375
Research Interview Guide	24	1.5	36	1	36
Research Quantitative Data Collection Form	6	1	6	1	6
Interdisciplinary Technical Assistance Center Interview Guide	1	2	2	1	2
State Public Health Autism Center Interview Guide	1	2	2	1	2
Total	186		404.5		302.9

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.

[FR Doc. 2020–12730 Filed 6–11–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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