observed in clinical trials to provide context).

According to FDA data, approximately 162,000 FDA-regulated promotional materials are prepared by approximately 500 firms annually. Of these materials, we estimate approximately 5 percent contain unique presentations of information consistent with FDA-required labeling, as that term is described in the draft guidance, submitted by approximately 64 percent (or 324) of the firms. Anticipating the number of these FDA-regulated promotional materials will soon increase to 6 percent, we estimate the 324 firms will prepare and disseminate annually 9,720 FDA-regulated promotional materials that contain unique presentations of information that is consistent with FDA-required labeling, as that term is described in the draft guidance, and that therefore are recommended to include the proposed third party disclosures. Based on our experience reviewing FDA-regulated promotional materials for medical products, we estimate it will take respondents approximately 4 hours per unique presentation to prepare and incorporate the disclosures recommended in the draft guidance, if they choose to disseminate this information.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of information	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recommended information to be included when firms choose to disseminate communications that are consistent with the FDA-required labeling	324	30	9,720	4	38,880

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm,* or *https://www.regulations.gov*.

Dated: January 6, 2017.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–01012 Filed 1–18–17; 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; Ryan White HIV/AIDS Program: Allocation and Expenditure Forms

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, 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 must be received no later than March 20, 2017.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N–39, 5600 Fishers Lane, Rockville, MD 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 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: Ryan White HIV/AIDS Program: Allocation and Expenditure Forms.

OMB No. 0915–0318—Revision.

Abstract: HRSA's HIV/AIDS Bureau (HAB) administers the Ryan White HIV/AIDS Program authorized under Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009. The Ryan White HIV/AIDS Program Allocation and Expenditure Reports (A&E Reports), in conjunction with the Consolidated List of Contractors (CLC), enables HRSA to monitor and track the use of grant funds for compliance with program and grants policies and requirements under the statute. By regulation, recipients are required to submit financial reports annually to HRSA and the A&E Reports and the CLC are HAB's mechanism to implement that requirement. Recipients funded under Parts A, B, C, and D of the Ryan White HIV/AIDS Program (codified under Title XXVI of the Public Health Service Act) are required to report financial data to HRSA at the beginning (Allocations Report) and at the end of their grant cycle (Expenditures Report). Recipients funded under Parts A and B are required to report information about their service provider contracts in the CLC.

The forms will continue to require recipients to report on how funds are allocated and spent on core medical and non-core services for persons living with HIV, and on various program components, such as administration, planning and evaluation, and quality management. The A & E Reports are identical in the types of information they collect. However, the first report tracks the allocation of the award at the beginning of the grant cycle and the second report tracks actual expenditures (including carryover dollars) at the end of the grant cycle. The CLC form identifies a recipient's contracts with service providers for the current grant year, the contract amount, and the types of services being provided.

Need and Proposed Use of the Information: Accurate allocation, expenditure, and service contract records of the recipients receiving Ryan White HIV/AIDS Program funding are critical to the implementation of the law and thus are necessary for HRSA to fulfill its responsibilities. The primary

purposes of these forms are to provide information on the number of grant dollars spent on various services and program components and oversee compliance with the intent of Congressional appropriations in a timely manner. In addition to meeting the goal of accountability to the Congress, clients, and the general public, information collected on these reports is critical for HRSA, state and local grantees, and individual providers to evaluate the effectiveness of these programs.

Likely Respondents: Ryan White HIV/AIDS Program recipients.

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 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
Part A Allocations Report	52	1	52	4	208
Part A Expenditures Report	52	1	52	4	208
Part A CLC	52	1	52	2	104
Part B Allocations Report	54	1	54	6	324
Part B Expenditures Report	54	1	54	6	324
Part B CLC	54	1	54	2	108
Part C Allocations Report	346	1	346	4	1,384
Part C Expenditures Report	346	1	346	4	1,384
Part D Allocations Report	116	1	116	4	464
Part D Expenditures Report	116	1	116	4	464
Total	.....	.....	1,294	.....	4,972

Note: Recipients are required to fill out an allocation report, expenditure report, and CLC for each Ryan White HIV/AIDS Program award received.

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.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2017–01220 Filed 1–18–17; 8:45 am]

BILLING CODE 4165–15–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; Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative

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, 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 February 21, 2017.

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 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 information request collection title for reference, in compliance with Section 3506(c)(2)(A), the Paperwork Reduction Act of 1995.

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 (ASD) and other developmental disabilities (DDs), the U.S. Congress passed the Combating Autism Act in 2006 (Pub. L. 109–416); it was reauthorized by the Combating Autism Reauthorization Act of 2011 (Pub. L. 112–32) and the Autism CARES (Collaboration, Accountability, Research, Education, and Support) Act of 2014 (Pub. L. 113–157). Through Autism CARES, HRSA is tasked with increasing awareness of ASD and other DDs, reducing barriers to screening and diagnosis, promoting evidence-based interventions, and training health care professionals in the use of valid and reliable diagnostic tools. To address these goals, HRSA awards grants to various programs through the Maternal and Child Health Bureau (MCHB).

Need and Proposed Use of the Information: The purpose of this information collection is to describe the accomplishments of MCHB's grant programs in implementing the provisions of the Autism CARES Act. This ICR is a revision to an existing package; this study is the third