to be retained for at least 10 years beyond the date of transplantation if known, distribution, disposition, or expiration of the tissue, whichever is the latest. Section 1270.35(a) through (d) requires specific records to be maintained to document the following: (1) The results and interpretation of all required infectious disease tests; (2) information on the identity and relevant medical records of the donor; (3) the receipt and/or distribution of human tissue, and (4) the destruction or other disposition of human tissue.

Respondents to this collection of information are manufacturers of human tissue intended for transplantation. Based on information from the Center for Biologics Evaluation and Research's (CBER's) database system, FDA estimates that there are approximately 281 tissue establishments, of which 185 are conventional tissue banks and 96 are eye tissue banks. Based on information provided by industry, there are an estimated total of 1,959,270 conventional tissue products and 82,741 eye tissue products recovered per year with an average of 25 percent of the tissue discarded due to unsuitability for transplant. In addition, there are an estimated 73,075 donors of conventional tissue and 49,026 donors of eye tissue each year.

Accredited members of the American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA) adhere to standards of those organizations that are comparable to the recordkeeping requirements in part 1270. Based on information provided by CBER's database system, 90 percent of the conventional tissue banks are members of AATB (185 × 90 percent = 166), and 85 percent of eye tissue banks are members of EBAA (96 × 85 percent = 82). Therefore, recordkeeping by these 248 establishments (166 + 82 = 248) is excluded from the burden estimates as usual and customary business activities (5 CFR 1320.3(b)(2)). The recordkeeping burden, thus, is estimated for the remaining 33 establishments, which is 12 percent of all establishments (281 − 248 = 33, or 33/281 = 12 percent).

FDA assumes that all current tissue establishments have developed written procedures in compliance with part 1270. Therefore, their information collection burden is for the general review and update of written procedures estimated to take an annual average of 24 hours, and for the recording and justifying of any deviations from the written procedures under § 1270.31(a) and (b), estimated to take an annual average of 1 hour. The information collection burden for maintaining records concurrently with the performance of each significant screening and testing step and for retaining records for 10 years under § 1270.33(a), (f), and (h) include documenting the results and interpretation of all required infectious disease tests and results and the identity and relevant medical records of the donor required under § 1270.35(a) and (b). Therefore, the burden under these provisions is calculated together in table 1 of this document. The recordkeeping estimates for the number of total annual records and hours per record are based on information provided by industry and FDA experience.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1270.31(a), (b), (c), and (d) [2]	33	1	33	24	792
1270.31(a) and 1270.31(b) [3]	33	2	66	1	66
1270.33(a), (f), and (h), and 1270.35(a) and (b)	33	7,869.48	259,693	1	259,693
1270.35(c)	33	14,850.96	490,082	1	490,082
1270.35(d)	33	1,856.36	61,260	1	61,260
Total					811,893

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Review and update of standard operating procedures (SOPs).
[3] Documentation of deviations from SOPs.

Dated: July 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16556 Filed 7–9–13; 8:45 am]

BILLING CODE 4160–01–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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (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 within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request 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:

Information Collection Request Title: Evaluating the Impact of 1115 Medicaid Waivers on Ryan White HIV/AIDS Program and Its Clients and Providers OMB No. 0915–xxxx—NEW

Abstract: Section 1115 of the Social Security Act allows states to develop, test, and implement new approaches to providing Medicaid coverage outside of federal program rules. Leading up to full implementation of the Affordable Care Act, states have begun to use Section 1115 Medicaid demonstration waivers as a ''bridge'' to 2014. This project will

examine 1115 Medicaid waivers that have expanded eligibility to include specifically people living with HIV/AIDS (PLWH) who are not otherwise eligible for Medicaid services. Since 1990, the Ryan White HIV/AIDS Program (RWHAP) has provided funding for primary care, medications, and support services for PLWH, helping fill the health care and service gap for those who are uninsured or ineligible for Medicaid.

As part of this project, case studies will be conducted in eight states that have implemented 1115 Medicaid waivers to expand Medicaid eligibility for PLWH. The case studies will include site visits and discussions with the state Medicaid programs and with RWHAP grantees and service providers to examine the waivers and their impact on PLWH. In addition, the studies will explore whether and how the 1115 Medicaid waivers have helped states and RWHAP grantees and providers prepare for implementation of the Affordable Care Act, including providing insights into Medicaid expansion.

Need and Proposed Use of the Information: Given the important role of the RWHAP and Medicaid in meeting the health care needs of PLWH, there is a need to understand better, how Medicaid expansion and the 1115 Medicaid waivers will affect the RWHAP and how the waivers have prepared states for implementation of the Affordable Care Act.

Likely Respondents: Data will be collected through qualitative interviews, guided by discussion tools with questions tailored for four specific groups of individuals from: (1) State Medicaid agencies; (2) RWHAP Part B grantees and service providers; (3) RWHAP Part A grantees and service providers; and (4) and RWHAP White Part C grantees and clinical providers.

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
Qualitative Interview Data Collection Tool for State Medicaid Agency Groups	40	1	40	2	80
Qualitative Interview Data Collection Tool for Ryan White Part A Administrators and Members of Planning Councils	64	1	64	2	128
Qualitative Interview Data Collection Tool for Ryan White Part A Administrators and Members of Planning Councils	16	1	16	2	32
Qualitative Interview Data Collection Tool for Ryan White Part B and ADAP (AIDS Directors, Part B Coordinators and ADAP Coordinators)	80	1	80	2	160
Qualitative Interview Data Collection Tool for Ryan White Clinical Providers (RW Part C Grantees in clinical settings or Similar Clinical Care Providers)	80	1	80	2	160
Total	280	.....	.....	.....	560

Dated: July 3, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–16599 Filed 7–9–13; 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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (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 within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 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.