CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: During the morning session, the committee will discuss new drug application (NDA) 211810 for pexidartinib capsule, submitted by Daiichi Sankyo, Inc. The proposed indication (use) for this product is for the treatment of adult patients with symptomatic tenosynovial giant cell tumor, also referred to as giant cell tumor of the tendon sheath or pigmented villonodular synovitis, which is associated with severe morbidity or functional limitations, and which is not amenable to improvement with surgery.

During the afternoon session, the committee will discuss NDA 212166 for quizartinib tablets, submitted by Daiichi Sankyo, Inc. The proposed indication (use) for this product is for the treatment of adults with relapsed or refractory acute myeloid leukemia, which is FLT3–ITD positive, as detected by an FDA-approved test.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the docket (see **ADDRESSES**) on or before April 30, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 22, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 23, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jennifer Shepherd (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–06896 Filed 4–5–19; 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: Assessing Care and Health Outcomes Among Ryan White HIV/AIDS Program (RWHAP) Clients Who Do Not Receive RWHAP-Funded Outpatient Ambulatory Health Services (OAHS), OMB No. 0906–xxxx–New

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

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 ICR should be received no later than June 7, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance

Officer, Room 14N39, 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 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: Assessing Care and Health Outcomes Among Ryan White HIV/AIDS Program Clients Who Do Not Receive RWHAP-Funded Outpatient Ambulatory Health Services, OMB No. 0906–xxxx–New.

Abstract: RWHAP is administered by HRSA's HIV/ADS Bureau. RWHAP funds and coordinates with cities, states, and local clinics and community-based organizations to deliver HIV care, treatment, and support to low-income people living with HIV (PLWH). Nearly two-thirds of RWHAP clients live at or below 100 percent of the federal poverty level and about three-quarters are racial or ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of nearly 2,000 safety net provider organizations that deliver high quality health care and support services to more than 500,000 PLWH, more than 50 percent of all diagnosed PLWH in the United States. Recipients and subrecipients funded to provide direct services must submit client-level data annually to HRSA as part of their RWHAP Services Report (RSR). The RSR (0906–0039) contains a single record for each RWHAP-eligible client who received a service during the calendar year. Providers report demographic and service use data for all their clients. However, they report clinical data (including lab results) only for those who received RWHAP-funded OAHS.

HRSA is embarking on a 24-month study called Assessing Care and Health Outcomes Among RWHAP Clients Who Do Not Receive RWHAP-Funded OAHS. The purpose of the study is to learn about the quality of care and health outcomes among the one-third of clients for whom HRSA does not collect clinical information—that is, for the 164,000 clients who do not receive directly funded OAHS under the RWHAP. HRSA will use the findings to (1) assess HIV care and health outcomes among its non-OAHS clients, (2) determine if and where these clients receive OAHS, (3) identify any unmet HIV care and treatment needs faced by this population, and (4) develop strategies to better coordinate services between RWHAP-funded and nonfunded providers. To meet these objectives, HRSA proposes to conduct 30 site visits. Each site visit will include one RWHAP-funded provider that is not directly funded to deliver OAHS and, if necessary for accessing the medical records of their non-OAHS clients, up to two non-RWHAP medical providers. During each site visit, HRSA will collect qualitative and quantitative information via (1) semistructured interviews with program managers, clinicians, and frontline service providers, as well as with non-OAHS clients and (2) medical chart reviews for clients who do not receive directly funded OAHS under the RWHAP.

Need and Proposed Use of the Information: The interviews with provider staff and clients will provide qualitative information on HIV-related medical service use, process, and health outcomes; barriers to care; unmet needs; provider referral relationships; and opportunities to improve care and outcomes among clients who do not receive directly funded OAHS under the RWHAP. The medical chart reviews will provide quantitative information on medical visits, prescription medications, and clinical outcomes for a representative sample of non-OAHS clients. HRSA will use the data to estimate three main outcomes for the study population: (1) Retention in care, (2) initiation of antiretroviral therapy, and (3) viral suppression. This information will supplement data available from the RSR on OAHS clients and enable HRSA for the first time to measure the quality of care and health outcomes for its entire client population, an important step toward ending the HIV epidemic in the United States.

Likely Respondents: HRSA plans to conduct individual interviews with two groups of informants: (1) Program managers, case managers or other frontline service providers, and medical directors or clinicians; and (2) RWHAP clients. HRSA also plans to review and abstract key data elements from non-OAHS client medical records from 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
Program manager	30	1	30	1.00	30
Case manager	30	1	30	1.00	30
Medical director	40	1	40	1.00	40
Client	120	1	120	0.50	60
Chart abstraction	30	50	1,500	0.08	120
	250	.....	1,720	.....	280

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.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–06767 Filed 4–5–19; 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; Information Collection Request Title: Evidence-Based Telehealth Network Program Measures, OMB No. 0906–xxxx–New

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 ICR should be received no later than June 7, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 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 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: Evidence-Based Telehealth Network Program Measures, OMB No. 0906–xxxx–New

Abstract: This ICR is for a new approval of measures for HRSA's Federal Office of Rural Health Policy's Office of Advancement of Telehealth programs. Specifically, grants administered in accordance with the following legislative statutes (i) Section 330I(d)(1) of the Public Health Service Act (42 U.S.C. 254c14(d)(1)), as amended and (ii) Section 711(b) of the Social Security Act (42 U.S.C. 912(b)), as amended. The purpose of these programs are to provide grants that demonstrate how telehealth programs and networks can improve access to quality health care services in rural, frontier, and underserved communities. These grants will work to: (a) expand access to, coordinate, and improve the quality of health care services; (b) improve and expand the training of health care providers; and (c) expand and improve the quality of health information available to health care providers, patients and their families for decision-making. In addition, these grants will help HRSA assess the effectiveness of evidence based practices with the use of telehealth for patients, providers, and payers.

Need and Proposed Use of the Information: The measures will enable HRSA to capture awardee-level and aggregate data that illustrate the impact and scope of federal funding along with assessing these efforts. The measures cover the principal topic areas of interest to HRSA including: (a) population demographics, (b) access to health care, (c) cost savings and cost-effectiveness, and (d) clinical outcomes.

Likely Respondents: The respondents will be award recipients of the Evidence Based Telehealth Network Program and Telehealth Network Grant Program.

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 (annually)	Total responses	Average burden per response (in hours)	Total burden hours
Evidence-Based Telehealth Network Program Report	50	12	600	31.0	18,600
Telehealth Performance Measurement Report	50	1	50	5.0	250
Telehealth Evidence Collection Report	36	12	432	37.5	16,200
Total	50*		1,082		35,050

*There are 50 unique respondents. All respondents will be responding to the first two forms and a subset will be responding to the third form.