

DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at <http://www.regulations.gov> or from CBER at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive "Types of Communication During the Review of Medical Device Submissions," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1804 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-07546 Filed 4-3-14; 8:45 am]

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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: Rural Health Network Development Planning Performance Improvement and Measurement System Database

OMB No. 0915-xxxx—NEW

Abstract: The purpose of the Rural Health Network Development Planning (Network Planning) program, authorized by Section 330A(f) of the Public Health Service Act, 42 U.S.C. 254c(f), as amended by section 201, Public Law 107-251 of the Health Care Safety Net Amendments of 2002, is to assist in the development of an integrated healthcare network, if the network participants do not have a history of collaborative efforts. The Network Planning program helps to promote the planning and

development of health care networks in order to: (i) Achieve efficiencies; (ii) expand access to, coordinate, and improve the quality of essential health care services; and (iii) strengthen the rural health care system as a whole. This program brings together key parts of a rural health care delivery system, particularly those entities that may not have collaborated in the past under a formal relationship, to work together to establish and improve local capacity and coordination of care. This grant program supports 1 year of planning with the primary goal of helping networks create a foundation for their infrastructure and focusing member efforts to address important regional or local community health needs.

Need and Proposed Use of the Information: Performance measures were developed to provide routine data for the program and to enable HRSA to aggregate program data. These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) Network infrastructure; (b) network collaboration; (c) sustainability; and (d) network assessment. Several measures will be used for this program.

Summary of Prior Comments and Agency Response

A 60-day **Federal Register** Notice was published in the **Federal Register** on December 5, 2013, Vol. 78, No. 234; pp. 73200-01. There were no comments.

Likely Respondents: The respondents would be Rural Health Network Development Planning grant 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 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
Rural Health Network Development Planning Program Performance Improvement and Measurement System Measures	21	1	21	1	21
Total	21	1	21	1	21

Dated: March 27, 2014.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

[FR Doc. 2014-07508 Filed 4-3-14; 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

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 no later than May 5, 2014.

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: Client-Level Data Reporting System, OMB No. 0915-0323—Revision.

Abstract: The Ryan White HIV/AIDS Program's client-level data reporting

system, entitled the Ryan White HIV/AIDS Program Services Report or the Ryan White Services Report (RSR), was created in 2009 by the Health Resources and Services Administration (HRSA). It is designed to collect information from grantees as well as their subcontracted service providers, funded under Parts A, B, C, D, and F Minority AIDS Initiative of Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White HIV/AIDS Program). The Ryan White HIV/AIDS Program provides entities funded by the program with flexibility to respond effectively to the changing HIV epidemic, with an emphasis on providing life-saving and life-extending services for people living with HIV across this country, as well as targeting resources to areas that have the greatest needs.

Need and Proposed Use of the Information: All parts of the Ryan White HIV/AIDS Program specify HRSA's responsibilities in administering grant funds, allocating funds, evaluating programs for the populations served, and improving quality of care. Accurate records of the providers receiving Ryan White HIV/AIDS Program funding, the clients served, and services provided continue to be critical issues for the implementation of the legislation and are necessary for HRSA to fulfill its responsibilities.

The RSR provides data on the characteristics of Ryan White HIV/AIDS Program-funded grantees, their contracted service providers, and the clients served with program funds. The RSR is intended to support clinical quality management, performance measurement, service delivery, and client monitoring at the systems and client levels. The reporting systems consist of two online data forms, the Grantee Report and the Service Provider Report, as well as a data file containing the client-level data elements. Data are submitted annually.

The statute specifies the importance of grantee accountability and linking performance to budget. The RSR is used to ensure compliance with the

requirements of the statute, to evaluate the progress of programs, to monitor grantee and provider performance, and to meet reporting responsibilities to the Department, Congress, and OMB.

In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected through the RSR is critical for HRSA, state and local grantees, and individual providers to assess the status of existing HIV related service delivery systems, investigate trends in service utilization, and identify areas of greatest need.

On April 11, 2012, a memo from the Secretary of the Department of Health and Human Services (HHS) directed HRSA, along with other Health and Human Services Operating Divisions (OpDivs) to work together to: (1) Identify seven common core HIV/AIDS indicators; (2) develop implementation plans to deploy these indicators; and (3) streamline data collection; and reduce reporting by at least 20 to 25 percent. In November 2012, the HIV/AIDS Indicators Implementation Group (HAIIG) comprised of representatives from HHS OpDivs, the Department of Housing and Urban Development, the Veterans' Health Administration, and community partners successfully identified the required common core HIV/AIDS indicators.

Revisions to the RSR are required to support implementation of the core indicators, streamline data collection, and reduce reporting burden. Nine data elements will be deleted from the RSR and 22 variables will be modified to reduce reporting burden. Two new data elements will be added to the RSR: (1) Date of client's confidential confirmatory HIV test with a positive result in the reporting period; and (2) date of client's first outpatient ambulatory medical care visit after positive HIV test. These data elements are required to deploy the *Linkage to HIV Medical Care* core indicator. Another data element, *Sex at Birth*, defined to be the biological sex assigned to the client at birth, will be added to align with variables collected by other HHS OpDivs.