Therefore, under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective May 24, 2017. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the DATES section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–08179 Filed 4–21–17; 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; Information Collection Request Title: Delta States Rural Development Network Grant Program, OMB No. 0915–0386—Revision

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 must be received no later than June 23, 2017.

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 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, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Delta States Rural Development Network Grant Program, OMB No. 0915–0386—Revision

Abstract: The Delta States Rural Development Network Grant (Delta) Program is authorized by the Public Health Service Act, Section 330A(f) (42 U.S.C. 254c(f)), as Public Law 114–53. The Delta Program supports projects that demonstrate evidence-based and/or promising approaches around cardiovascular disease, diabetes, acute ischemic stroke, or obesity to improve health status in rural communities throughout the Delta Region. Key features of projects are adoption of an evidence-based approach, demonstration of health outcomes, program replicability, and sustainability.

Need and Proposed Use of the Information: For this program, performance measures include: (a) Access to care, (b) population demographics, (c) sustainability, (e) project specific domains, and (f) health related clinical measures. These performance measures enable HRSA’s Federal Office of Rural Health Policy to aggregate program data required by Congress under the Government Performance and Results Act of 1993 (Pub. L. 103–62). The proposed revisions to the performance measures include reducing the number of reported measures and showing annual progress compared to baseline data submitted in the grant applications. Examples of the measures that will be removed include the number of people reached through indirect services and the number of quality improvement clinical guidelines/benchmarks adopted.

Likely Respondents: The respondents are the recipients of the Delta States Rural Development Network 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.

As a result of the reduction in performance measures, annualized burden is decreasing from 72 hours to 32 hours. The total annual burden hours estimated for this ICR are summarized in the table below.

### TABLE 1—Continued

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA 020316 .......</td>
<td>Oxilan-300 and Oxilan-350 (oxilano) Injection, 62% and 73% ....</td>
<td>Do.</td>
</tr>
</tbody>
</table>
HRSA specifically requests comments on (1) the necessity and utility of the proposed data 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.

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, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: AIDS Drug Assistance Program Data Report OMB No. 0915–0345—Extension.

Abstract: HRSA’s AIDS Drug Assistance Program (ADAP) is funded through the Ryan White HIV/AIDS Program, Part B, Title XXVI of the Public Health Service Act, which provides funding to states and territories through a grant. ADAP provides medications for the treatment of HIV to eligible clients who are low income and uninsured or underinsured. ADAP recipients may also use the funds to purchase health insurance for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments.

The following states, territories, and Pacific Island jurisdictions are eligible to apply for RWHAP ADAP funding: All 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands. As part of the funding requirements, ADAPs submit reports concerning information on clients served, eligibility requirements, pharmaceuticals prescribed, pricing and other sources of support to provide HIV medication treatment, cost data, and coordination with Medicaid. The AIDS Drug Assistance Program Data Report (ADR) is submitted annually and consists of a Recipient Report and a client-level data file. The Recipient Report is a collection of basic information about grant recipient characteristics and policies. The client-level data is a collection of records (one record for each client enrolled in the ADAP), which includes the client’s encrypted unique identifier, basic demographic data, enrollment information, services received, and clinical data.

Need and Proposed Use of the Information: The Ryan White HIV/AIDS Program requires the submission of annual reports by the Secretary of HHS to the appropriate committees of Congress. The HIV/AIDS Bureau (HAB) uses the ADR to evaluate the national impact of the ADAP, by providing data on clients being served, services being delivered, and costs associated with these services. The ADR is also used to determine eligibility for the ADAP Supplement component of the RWHAP Part B grant (X07). The client-level data is used to monitor health outcomes of clients living with HIV receiving care and treatment through the ADAP, to monitor the use of ADAP funds in addressing the HIV epidemic and its impact on vulnerable communities, and to track progress toward achieving the national goals for HIV care and treatment.

Likely Respondents: State/Territory ADAPs of Ryan White HIV/AIDS Program Part B 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 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.

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total responses</th>
<th>Average burden per response (in hours)</th>
<th>Total burden hours</th>
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</thead>
<tbody>
<tr>
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<td>1</td>
<td>12</td>
<td>2.66</td>
<td>32</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>12</strong></td>
<td><strong>1</strong></td>
<td><strong>12</strong></td>
<td><strong>2.66</strong></td>
<td><strong>32</strong></td>
</tr>
</tbody>
</table>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: AIDS Drug Assistance Program Data Report, OMB No. 0915–0345—Extension

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 23, 2017.

ADDRESS: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N339, 5600 Fishers Lane, Rockville, MD 20857.