

(Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kristina Toliver, 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: CRDAC@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 Agency's Web site at <http://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.

Agenda: The committee will discuss new drug application (NDA) 203202, NORTHERA (droxidopa capsules), submitted by Chelsea Therapeutics, Inc., for the treatment of symptomatic neurogenic orthostatic hypotension in patients with primary autonomic failure (Parkinson's disease, multiple system atrophy, or pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.

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 Web site 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 Web site after the meeting. Background material is available at <http://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. Written submissions may be made to the contact

person on or before January 9, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 January 3, 2014. 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 January 6, 2014.

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

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristina Toliver at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://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: December 11, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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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.

Information Collection Request Title: HRSA AIDS Drug Assistance Program Quarterly Report OMB No. 0915-0294—Extension

Abstract: HRSA's AIDS Drug Assistance Program (ADAP) is funded through Part B of 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), which provides grants to states and territories. ADAP provides medications for the treatment of HIV disease. Program funds may also be used to purchase health insurance for eligible clients or for services that enhance access, adherence, and monitoring of drug treatments.

Need and Proposed Use of the Information: Each of the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, and the Pacific territories receive ADAP grants. As part of the funding requirements, ADAP grantees submit quarterly reports that include information on patients served, pharmaceuticals dispensed, pricing, sources of support to provide HIV/AIDS medications, eligibility requirements, cost data, and coordination with

Medicaid. Each quarterly report requests updates from programs on the number of patients served, type of pharmaceuticals dispensed, and prices paid to provide medications. The first quarterly report of each ADAP fiscal year (due in July of each year) also requests information that only changes annually (e.g., state funding, drug formulary, eligibility criteria for enrollment, and cost-saving strategies including coordination with Medicaid).

Describe the need for the information and proposed use of the information: The quarterly report represents the best

method for HRSA to determine how ADAP grant funds are expended and to provide answers to requests from Congress and other organizations.

Likely Respondents: ADAP Grantees.

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 Information Collection Request 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
ADAP Quarterly Report—Qtr. 1	57	1	57	3.0	171.0
ADAP Quarterly Reports—Qtr. 1, 2, & 3	57	3	171	1.5	256.5
Total	57	228	427.5

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.

Dated: December 9, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

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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: Evaluation of the Frontier Community Health Care Network Coordination Grant

OMB No. 0915-xxxx—NEW.

Abstract: In fiscal year (FY) 2012, the Office of Rural Health Policy (ORHP) funded an evaluation of the Frontier Community Health Care Network Coordination (FCHCNC) grant. This 3-year grant program awarded to the Montana Department of Public Health and Human Services focuses on a community-based, client-centered clinical service coordination and health promotion model. The program will be coordinated by a clinically-trained Care Transitions Coordinator (CTC) working with Community Health Workers (CHW) in 11 participating network communities. By developing intervention with clients, the CTC and CHWs will work to improve care

transitions and client outcomes by reducing or eliminating avoidable hospitalizations and re-hospitalizations, emergency room (ER) visits, and nursing home placements.

The program will be subject to a 3-year independent evaluation. As part of this 3-year evaluation, HRSA will be collecting qualitative and quantitative information. To support the qualitative analysis, HRSA will conduct site visits and telephonic key informant interviews with the critical access hospitals, tertiary hospitals, and the support staff coordinating the program. Data collection will focus on client/family satisfaction, whether goals were achieved in working with clients, and the strengths and challenges associated with implementing the program. Additionally, HRSA will be collecting data quarterly from the grantee sites in order to gain a deeper understanding of the program's implementation. Finally, quantitative data will be gathered for studying the effectiveness of each intervention, specifically identifying differences between pre- and post-intervention health care utilization, hospital readmissions, and other client-specific outcomes. Where data are available, HRSA will assess cost effectiveness of the program.

Need and Proposed Use of the Information

This evaluation will consist of reviewing the implementation and effectiveness of the FCHCNC grant for the 11 participating network communities. The evaluation will allow HRSA to determine the following objectives:

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