

3. *The date the application was approved:* January 27, 2012. FDA has verified the applicant's claim that NDA 202324 was approved on January 27, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,763 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 22, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 19, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 15, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–11925 Filed 5–22–14; 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 no later than June 23, 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](mailto: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](mailto:paperwork@hrsa.gov) or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Delta States Rural Development Network Grant Program Performance Improvement Measurement System Measures OMB No. 0915-xxxx—New

*Abstract:* The Delta States Rural Development Network Grant Program supports projects that demonstrate evidence based and/or promising approaches around cardiovascular

disease, diabetes, or obesity in order to improve health status in rural communities throughout the Delta Region. Key features of programs are collaboration, 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 were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Public Law 103–62). These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development; and (g) health related clinical measures. Several measures will be used for this program. These measures will speak to the Office's progress toward meeting set goals. Summary of Prior Comments and Agency Response: A 60-day Federal Register Notice was published in the *Federal Register* on February 11, 2014 (79 FR 8196). There were no comments.

*Likely Respondents:* Delta States Rural Development Network Grant Program award 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.

**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
Delta States Rural Development Network Program Performance Measures .....	12	1	12	6	72
Total .....	12	1	12	6	72

Dated: May 19, 2014.

**Bahar Niakan,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2014-12042 Filed 5-22-14; 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 June 23, 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:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Small Health Care Provider Quality Improvement Program. OMB No. 0915-xxxx—NEW.

*Abstract:* This program is authorized by Title III, Public Health Service Act, Section 330A(g) (42 U.S.C. 254c(g)), as amended by Section 201, Public Law 107-251, and Section 4, Public Law 110-355. This authority directs the Office of Rural Health Policy (ORHP) to support grants that expand access to, coordinate, contain the cost of, and improve the quality of essential health care services, including preventive and emergency services, through the development of health care networks in rural and frontier areas and regions. Across these various programs, the authority allows HRSA to provide funds to rural and frontier communities to support the direct delivery of health care and related services, to expand existing services, or to enhance health service delivery through education, promotion, and prevention programs.

The purpose of the Small Health Care Provider Quality Improvement Grant (Rural Quality) Program is to provide support to rural primary care providers for implementation of quality improvement activities. The goal of the program is to promote the development of an evidence-based culture and delivery of coordinated care in the primary care setting. Additional objectives of the program include: Improved health outcomes for patients; enhanced chronic disease management; and better engagement of patients and their caregivers. Organizations participating in the program are required to utilize an evidence-based quality improvement model, perform tests of change focused on

improvement, and use health information technology (HIT) to collect and report data. HIT may include an electronic patient registry (EPR) or an electronic health record (EHR), and is a critical component for improving quality and patient outcomes. With HIT it is possible to generate timely and meaningful data, which helps providers track and plan care.

*Need and Proposed Use of the Information:* ORHP collects this information to quantify the impact of grant funding on access to health care, quality of services, and improvement of health outcomes. ORHP uses the data for program improvement and grantees use the data for performance tracking and improvement.

*Summary of Prior Comments and Agency Response:* A 60-day Federal Register Notice was published in the **Federal Register** on February 11, 2014. See, 79 FR 8201. There were no comments.

*Likely Respondents:* The respondents will be grantees of the Small Health Care Provider Quality Improvement 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 respondents	Total responses	Average burden per response (in hours)	Total burden hours
Performance Improvement and Measurement System (PIMS) Database .....	30	2	60	8	480
Total .....	30	2	60	8	480