solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–1170 for ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to 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 this 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 4, 2016 (81 FR 26805), FDA published a notice of availability.

Interested persons were originally given until July 5, 2016, to comment on the draft guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.''

From July 1 through July 5, 2016, the Federal eRulemaking Portal, *http://www.regulations.gov*, is undergoing maintenance. We are, therefore, extending the comment period for the draft guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.'' The extended comment period will close on July 19, 2016.

Dated: June 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–15098 Filed 6–24–16; 8:45 am]

BILLING CODE 4164–01–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 July 27, 2016.

ADDRESSES: Submit your comments, including the ICR 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: Black Lung Clinics Program Performance Measures OMB No. 0915–0292–Extension

Abstract: HRSA's Federal Office of Rural Health Policy (FORHP), conducts an annual data collection of information for the Black Lung Clinics Program, which has been ongoing with OMB approval since 2004. The Black Lung Clinics Program seeks to reduce the morbidity and mortality associated with occupationally-related coal mine dust lung disease. Collecting this data provides HRSA with information on the extent to which each grantee is meeting the needs of these miners in their communities.

Need and Proposed Use of the Information: Data from the annual report provides quantitative information about the clinics, specifically: (a) The characteristics of the patients they serve (gender, age, disability level, occupation type); (b) the characteristics of services provided (medical encounters, non-medical encounters, benefits

counseling, and outreach); and, (c) the number of patients served. This assessment enables HRSA to provide data required by Congress under the Government Performance and Results Act of 1993. It also ensures that funds are effectively used to provide services that meet the target population needs. HRSA does not plan to make any changes to the performance measures at this time.

Likely Respondents: Black Lung Clinics Program 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 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
Black Lung Clinics Program Measures	15	1	15	10	150
Total	15		15		150

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–15092 Filed 6–24–16; 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 July 27, 2016.

ADDRESSES: Submit your comments, including the ICR 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: Sickle Cell Disease Treatment Demonstration Program—Quality Improvement Data Collection.

OMB No.: 0906–xxxx–NEW.

Abstract: In response to the growing need for resources and coordination of resources devoted to sickle cell disease and other hemoglobinopathies, the United States Congress, under Section 712 of the American Jobs Creation Act of 2004 (Pub. L. 108–357) (42 U.S.C. 300b–1 note), authorized a demonstration program for the prevention and treatment of sickle cell disease (SCD) to be administered by HRSA's Maternal and Child Health Bureau (MCHB) in the U.S. Department of Health and Human Services. The program is known as the *Sickle Cell Disease Treatment Demonstration Program* (SCDTDP). The SCDTDP is designed to improve access to services for individuals with sickle cell disease, improve and expand patient and provider education, and improve and expand the continuity and coordination of service delivery for individuals with sickle cell disease and sickle cell trait. The specific aims for the program are threefold: (1) Increase the number of providers treating persons with sickle cell disease, (2) increase the number of providers using evidence-based treatments in sickle cell disease, such as prescribing hydroxyurea, and (3) increase the number of providers knowledgeable about treating sickle cell disease and the number of sickle cell patients that are seen by providers knowledgeable about sickle cell disease.

To achieve the goals and objectives of the program, the SCDTDP uses quality improvement (QI) methods in a collective impact model which supports cross-sector collaboration for achieving measurable effects on major social issues. The collective impact model requires shared measurement which facilitates tracking progress in a standardized method to promote learning and enhance continuous improvement.

Need and Proposed Use of the Information: The purpose of the proposed data collection strategy is to implement a system to monitor the progress of MCHB-funded activities in improving care and health outcomes for individuals living with sickle cell disease/trait and meeting the goals of the SCDTDP. Each regional grantee site will be asked to report on a core set of evidence-based measures related to healthcare utilization among individuals with sickle cell disease and the quality of care of the SCD population.

The data collected for the SCDTDP will consist of administrative medical claims data collected from State Medicaid Programs and Medicaid Managed Care Organizations that administer Medicaid on behalf of states. The data is collected either for or by State Medicaid offices for delivery of services subject to Medicaid reimbursement.

The data collection strategy will provide an effective and efficient mechanism to do the following: (1) Assess the improvements in access to care for sickle cell patients provided by activities in the SCDTDP; (2) collect, coordinate, and distribute data, best practices, and findings from regional grantee sites to drive improvement on