open to participating in a well-designed and well-conducted meeting on a case-by-case basis. Given the expanse of diseases affecting the U.S. patient population and the effort required to conduct a successful PFDD meeting, externally-led PFDD meetings should target disease areas where there is an identified need for patient input on topics related to drug development. FDA will determine its level of participation in these meetings on an individual basis, taking into account a number of factors, including any identified need for a better understanding of patient perspective, recent interactions with patient stakeholders, proposed meeting details, and FDA staff capacity. More information regarding considerations to take into account when deciding to plan an externally-led PFDD meeting can be found on this Web site: *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm453856.htm.*

FDA recommends that patient organizations who are interested in conducting an externally-led PFDD meeting submit an LOI that communicates (1) the value of the proposed meeting in the context of drug development for a particular disease area, and (2) important details regarding the meeting plan. Guidelines for developing a letter of intent are provided here: *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM453857.pdf.* Please submit the letter of intent to *patientfocused@fda.hhs.gov.* FDA's CDER Office of Strategic Programs will receive and review the letter.

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32476 Filed 12–24–15; 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

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 no later than February 26, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10C–24, 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: Sickle Cell Disease Treatment Demonstration Program—Quality Improvement Data Collection.

OMB No. 0915–xxxx–New

Abstract: In response to the growing need for 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 the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) 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 prescribing hydroxyurea, and (3) increase the number of providers knowledgeable about treating sickle cell disease as well as increase 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 in order 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 Sickle Cell Disease Treatment Demonstration Program 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 quality measures; (3) refine a common model protocol regarding the prevention and treatment of sickle cell disease; (4) examine/address barriers that individuals and families living with sickle cell disease face when accessing quality health care and health education; (5) evaluate the grantees' performance in meeting the objectives of the SCDTDP; and (6) provide HRSA and Congress with information on the overall progress of the program.

Likely Respondents: Four regional grantee sites funded by HRSA under the SCDTDP will be the respondents for this data collection activity and submit responses gathered from State Medicaid

Offices and State Medicaid Managed Care Organizations (MCOs).

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
SCDTDP Data form	4	Range:16–80	Range:64–320	Range:4–6	Range:256–1920
Total	4	Range:16–80	Range:64–320	Range:4–6	Range:256–1920.

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.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–32549 Filed 12–24–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier HHS–OS–0945–0002–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0945–0002, scheduled to expire on December 31, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before January 27, 2016.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0945–0002 for reference.

Proposed Project: Complaint Forms for Discrimination; Health Information Privacy Complaints OMB No. 0945–0002—Extension—Office of Civil Rights

Abstract: The Office for Civil Rights is seeking an extension on an approval for a 3-year clearance on a previous collection. Individuals may file written complaints with the Office for Civil Rights when they believe they have been discriminated against by programs or entities that receive Federal financial assistance from the Health and Human Service or if they believe that their right to the privacy of protected health information has been violated. Annual Number of Respondents frequency of submission is record keeping and reporting on occasion.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Civil Rights Complaint Form	Individuals or households, Not-for-profit institutions.	3493	1	45/60	2620
Health Information Privacy Complaint Form.	Individuals or households, Not-for-profit institutions.	10,286	1	45/60	7715
Total	.....	.....	.....	.....	10,335

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2015–32551 Filed 12–24–15; 8:45 am]

BILLING CODE 4153–01–P