GuidanceDocuments/default.htm. Guidance documents are also available at *http://www.regulations.gov.*

To receive the ''Surveying, Leveling, or Alignment Laser Products'' draft guidance you may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1764 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 1040.10 and 1040.11 have been approved under OMB control number 0910–0025.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–10189 Filed 5–2–14; 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 4, 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:

Information Collection Request Title: Patient Survey-Health Centers OMB No. 0915–0368—New.

Abstract: HRSA's Health Center Program awards grants to provide primary and preventive health care services to medically underserved and vulnerable populations. The proposed Health Center Patient Survey (HCPS) will collect national, in-depth information about health center patients, their health status, the reasons they seek care at the health centers, their diagnoses, the services they utilize at health centers and elsewhere, the quality of those services, and their satisfaction with the care they receive through personal interviews of a stratified random sample of health center patients. Interviews conducted in the national study are estimated to take approximately 1 hour and 15 minutes each.

The HCPS builds on previous periodic Patient User-Visit Surveys which were conducted to learn about the process and outcomes of care in health centers reaching goals under the Health Center Program. The original questionnaires were derived from the National Health Interview Survey (NHIS) and the National Ambulatory Medical Care Survey (NAMCS) conducted by the National Center for Health Statistics (NCHS). Conformance with the NHIS and NAMCS allowed comparisons between these NCHS surveys and the previous Patient User-Visit Surveys. The new HCPS was developed using a questionnaire methodology similar to that used in the past, and will also potentially allow some time-trend comparisons for health centers with the previous Patient User-Visit Survey data, including monitoring of processes and outcomes over time. In addition, this survey will be conducted in languages not used during previous surveys (English and Spanish) to include patients from different racial and ethnic backgrounds, including Chinese (Mandarin and Cantonese), Korean, and Vietnamese. With the exception of Spanish speakers, other racial and ethnic subgroups were not able to participate in the previous surveys.

Need and Proposed Use of the Information: The HCPS is unique in its effort to capture national, person-level data from patients of all types of Health Center Program grantees. The data collected from the HCPS will be used to:

- Gather nationally representative data about the patients of the programs and the services they obtain;
- enable comparisons of care received by health center patients with care received by the general population, as measured by NHIS and other national surveys;
- assess how well HRSA-supported health centers are currently able to meet health care needs;
- identify areas for improvement and guide planning decisions; and
- complement data that are not routinely collected from other Bureau of Primary Health Care data sources.

The specific priorities for analysis will be comparisons of health center patients with patients served in other primary care settings with respect to:

- Access to care;
- health disparities;
- health conditions;
- quality of care;
- care coordination; and
- patient experience.

Comparisons will be made with results from national surveys and with results from the 2009 Patient Survey.

Likely Respondents: Health center patients.

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
Patient Screening	6,996	1	6,996	.17	1,189
Patient Survey	6,600	1	6,600	1.25	8,250
Total National Study	6,996	1	13,596	1.42	9,439

Dated: April 25, 2014.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

[FR Doc. 2014–10191 Filed 5–2–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Methodology for Designation of Frontier and Remote Areas

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final response.

SUMMARY: The Office of Rural Health Policy (ORHP) in the Health Resources and Services Administration (HRSA) published a 60-day public notice in the **Federal Register** on November 5, 2012 (**Federal Register** volume 77, number 214, 66471–66476) describing a methodology for designating U.S. frontier areas. The Frontier and Remote Area (FAR) Codes methodology was developed in a collaborative project between ORHP and the Economic Research Service (ERS) in the U.S. Department of Agriculture (USDA). This notice responds to the comments received during this 60-day public notice.

ADDRESSES: Further information on the Frontier and Remote Area (FAR) Codes is available at *http://www.ers.usda.gov/data-products/frontier-and-remote-area-codes.aspx.*

FOR FURTHER INFORMATION CONTACT: Questions can be directed to Steven Hirsch via phone at (301) 443–7322; email to *shirsch@hrsa.gov*; or mailed to Office of Rural Health Policy, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, 17–W–55 Rockville, Maryland 20857; or fax to (301) 443–2803.

Background

This project was intended to create a definition of frontier based on easily explained concepts of remoteness and population sparseness. The goal was to create a statistical delineation that will be useful in a wide variety of research and policy contexts and adjustable to the circumstances in which it is applied. FAR areas are defined in relation to the time it takes to travel by car to the edges of nearby Urban Areas. Four levels are necessary because rural areas experience degrees of remoteness at higher or lower population levels that affect access to different types of goods and services.

The four FAR Levels are defined as follows (travel times are calculated one-way by the fastest paved road route):

(1) Frontier Level 1 areas are 60 minutes or greater from Census Bureau defined Urban Areas of 50,000 or more population;

(2) Frontier Level 2 areas are 60 minutes or greater from Urban Areas of 50,000 or more people and 45 minutes or greater from Urban Areas of 25,000–49,999;

(3) Frontier Level 3 areas are 60 minutes or greater from Urban Areas of 50,000 or more people; 45 minutes or greater from Urban Areas of 25,000–49,999; and 30 minutes or greater from Urban Areas of 10,000–24,999; and

(4) Frontier Level 4 areas are 60 minutes or greater from Urban Areas of 50,000 or more people; 45 minutes or greater from Urban Areas of 25,000–49,999; 30 minutes or greater from Urban Areas of 10,000–24,999; and 15 minutes or greater from Urban Areas of 2,500–9,999.

Comments on the FAR Codes and HRSA Response

The ORHP received twenty-six responses to the request for comments. Many of the comments received dealt with similar concerns over either the details of the proposed methodology or the potential use of the FAR codes in directing resources.

Several commenters noted that the data used to assign FAR codes were from the 2000 Census rather than the more recent 2010 Census. When ORHP and USDA began the process of developing the methodology in 2008, only Census 2000 data were available. As stated in the initial **Federal Register** notice, the FAR codes will be updated for all 50 states using Census 2010 data. There were also commenters who believed that decennial updates to FAR codes would be too infrequent to be current. ORHP will examine the possibility of using American Community Survey data to update FAR codes in the future.

In particular, HRSA sought public comments on:

1. The use of a population threshold of 50,000 as the central place from which to measure in defining FAR areas;

2. The use of 60 minutes travel time from the central place;

3. Whether the 50 percent population threshold for assigning frontier status to a ZIP code/census tract is the appropriate level for the four standard provided levels;

4. Other ways of representing urban and rural areas;

5. Alternatives to using grid cells for measuring remoteness;

6. Applicability of the FAR methodology to island populations; and

7. Need for a Census tract and county version of the FAR.

Comment: On the use of a population threshold of 50,000 as the central place from which to measure, there was no consensus of views expressed and many commenters did not address the issue. Comments received correctly pointed out that there are some states (such as Alaska, Wyoming, or New Mexico) which have few urban areas with populations of over 50,000.

One commenter noted that, ''Population size is not necessarily a reliable measure of the goods and services that will be available or other important factors.'' Another commenter also believed that there are great differences between urban areas of only 50,000 people and urban areas with hundreds of thousands or millions of inhabitants. There were also comments received that concurred with the use of the population threshold of 50,000 as appropriate for the purpose.

Response: No comment received suggested a threshold other than 50,000. The population threshold of 50,000 also forms the core for both the Urbanized