preceding calendar year. Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Applicable manufacturers must report the required payment and other transfer of value information annually to CMS in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to CMS the required information about physician ownership and investment interests, including information on any payments or other transfers of value provided to physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. We are required by statute to publish the reported data on a public Web site. The data must be downloadable, easily searchable, and aggregated. In addition, we must submit annual reports to the Congress and each state summarizing the data reported. Finally, section 1128G of the Act generally preempts state laws that require disclosure of the same type of information by manufacturers.

With this notice, we are announcing the addition of the dispute resolution and corrections process to this information collection request (ICR). The dispute resolution and corrections process was discussed in our initial submission to OMB. However, based on the detailed processes of review and corrections as well as the sensitivities around these processes, we felt it appropriate to solicit additional public feedback on how these interactions would occur. Therefore we are resubmitting a revised ICR for OMB review and approval. While we are submitting a revision of the entire ICR, we are specifically seeking comments on the dispute resolution and comment process. *Form Number:* CMS–10495 (OCN: 0938–1237); *Frequency:* Once; *Affected Public:* Private sector—business or other for-profits; *Number of Respondents:* 227,157; *Total Annual Responses:* 457,454; *Total Annual Hours:* 3,099,297. (For policy questions regarding this collection contact Melissa Heesters at 410–786–0618.)

Dated: April 30, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–10228 Filed 5–1–14; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0435]

Surveying, Leveling, or Alignment Laser Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug administration (FDA) is announcing the availability of the draft guidance entitled ''Surveying, Leveling, or Alignment Laser Products.'' This draft guidance, in question and answer format, is intended for manufacturers of laser products and outlines the FDA's proposed approach regarding the applicability of FDA's performance standard regulations to surveying, leveling, or alignment (SLA) laser products. SLA lasers are a subcategory of specific-purpose laser products that transmit laser radiation through open space for surveying, alignment, or leveling purposes. The draft guidance is not final nor is in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 4, 2014.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Surveying, Leveling, or Alignment Laser Products'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert J. Doyle, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4672, Silver Spring, MD 20993–0002, 301–796–5863.

I. Background

This draft guidance is intended to provide a brief summary of the FDA's proposed approach on the applicability of performance standards for laser products to specific purpose SLA laser products. An SLA laser product is defined in 21 CFR 1040.10(b)(39) as ''a laser product manufactured, designed, intended or promoted for one or more of the following uses: (i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement, (ii) positioning or adjusting parts in proper relation to one another, (iii) defining a plane, level, elevation, or straight line.'' The topics that are addressed include the definition of an SLA laser product, examples of SLA laser products, design features of SLA laser products, the applicability of class limits to SLA laser products, and questions and answers relating to the application of FDA's performance standard regulations to SLA laser products.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on surveying, leveling, or alignment laser products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/*

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.