

Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2014-10144 Filed 5-2-14; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Research to Prevent Prescription Drug Overdoses, Funding Opportunity Announcement CE14-002, initial review.

**SUMMARY:** This document corrects a notice that was published in the **Federal Register** on April 17, 2014 (79 FR 21759). The time and date should read as follows:

**TIME AND DATE:** 12:00 p.m.–7:00 p.m., May 7, 2014 (Closed).

**FOR FURTHER INFORMATION CONTACT:** Jane Suen, Dr. P.H., M.S., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F63, Atlanta, Georgia 30341-3724, Telephone: (770) 488-4281, [JSuen@cdc.gov](mailto:JSuen@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2014-10145 Filed 5-2-14; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10495]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

**DATES:** Comments must be received by June 2, 2014.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by CMS or the OMB desk officer via one of the following transmissions:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

3. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments; *Use:* Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (Act), which requires applicable manufacturers and applicable group purchasing organizations (GPOs) of covered drugs, devices, biologicals, or medical supplies to report annually to CMS certain payments or other transfers of value to physicians and teaching hospitals, as well as, certain information regarding the ownership or investment interests held by physicians or their immediate family members in applicable manufacturers or applicable GPOs.

Specifically, applicable manufacturers of covered drugs, devices, biologicals, and medical supplies are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the

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/>