

participate in the Refugee Resettlement program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR-1, Cash and Medical Assistance Program Estimates .....	46	1	0.60	27.60

*Estimated Total Annual Burden Hours: 27.60.*

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

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**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Community Living**

**Agency Information Collection Activities; Proposed Collection; Comment Request; Senior Legal Helplines Operating Within Model Approaches to Statewide Legal Assistance Systems Demonstrations**

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on proposed information collection requirements relating to Senior Legal Helplines (SLHs) operating within Model Approaches to Statewide Legal Assistance Systems Demonstrations.

**DATES:** Submit written or electronic comments on the collection of information by October 6, 2014.

**ADDRESSES:** Submit electronic comments on the collection of information to: [Omar.Valverde@acl.gov](mailto:Omar.Valverde@acl.gov)

Submit written comments on the collection of information to Administration on Aging, Washington, DC 20201, attention Omar Valverde.

**FOR FURTHER INFORMATION CONTACT:** Omar Valverde, Aging Services Program Specialist, Administration for Community Living, Administration on Aging, Washington, DC 20201, (202) 357-3514.

**SUPPLEMENTARY INFORMATION:** Under the 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.

“Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing notice of the proposed collection of information set forth in this document.

With respect to the anticipated collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility; (2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Senior Legal Helplines (SLHs) funded by Title IV of the Older Americans, and operating as part of Model Approaches to Statewide Legal Assistance Systems (Model Approaches) demonstration

Grants play an important role within statewide legal service delivery systems and are designed to provide a limited scope of assistance on a wide range of legal issues such as consumer protection, housing, income security, healthcare financing, and elder abuse prevention. It is important to capture information that accurately illustrates the range and type of legal assistance being provided by the SLHs to older persons in the most social or economic need, without being overly burdensome to providers responsible for collecting the data. The anticipate data collected

and reported by SLHs participating in ACL-funded Model Approaches projects will be comparable from one SLH to another and apply standard/uniform terminology consistently across Model Approaches projects. The consistent and uniform data will be used to illustrate the effectiveness of Model Approaches states in reaching key target populations under the OAA with much needed “priority” legal assistance through SLHs. The data collected will also inform and drive ongoing ACL policy related to increasing the number of states that have a SLH as a sustained, and permanent feature of integrated and cost effective legal service delivery systems targeted to those most in need. Anticipated data collection and reporting requirements would apply to SLHs operating as lead partners in 2014 Model Approaches Phase I and Phase II, with a total of 11 SLHs operational during the 3 year project period.

ACL estimates the burden of this collection of information as follows: 11 SLHs would be asked to respond annually pursuant to data collection tools that should require an average burden of 2.5 hours per SLH per year or a total 27.5 hours for all complying SLHs operating under Model Approaches projects. The proposed data collection tools may be found on the CERA Web site for review at: <http://www.legalhotlines.org/uploads/1/6/9/1/16912868/reportingguidelinesforseniorlegalhelplines.pdf>.

Dated: July 31, 2014.

**Kathy Greenlee,**

*Administrator and Assistant Secretary for Aging.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2012–D–1161]

#### Design Considerations for Devices Intended for Home Use; 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 guidance entitled “Design Considerations for Devices Intended for Home Use.” This document is intended to assist manufacturers in designing and developing home use medical devices

that comply with applicable standards of safety and effectiveness and other regulatory requirements. Devices used in the home or other non-clinical environments are associated with unique risks created by the interactions among the user (often a layperson), the use environment, and the device. This document identifies several factors that manufacturers should consider, especially during device design and development, and provides recommendations for minimizing these unique risks.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

**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 guidance document entitled “Design Considerations for Devices Intended for Home Use” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Alternatively, you may submit written requests for single copies of the guidance to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to the office that you are ordering from to assist that office in processing your request.

Submit electronic comments on the 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:** *For information concerning the guidance as it relates to devices regulated by CDRH:* Mary Brady, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5426, Silver Spring, MD 20993–0002, 301–796–6089.

*For information concerning the guidance as it relates to devices regulated by CBER:* Stephen Ripley,

Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

For a variety of reasons, use of devices outside professional healthcare facilities is on the rise. First, the U.S. population is aging, and the elderly are more likely to live with chronic diseases that require daily medical care at home. Second, due to medical advancements, many individuals with chronic diseases are living longer but are dependent on home medical care. Finally, an increasing focus on reducing healthcare costs for patients of all ages has spurred the growth of the home health care market. Integral to the home health care market are home use devices. Although home use devices provide significant benefits to patients and families, including quality of life improvements and cost savings, they are also associated with unique risks. Minimizing the risks posed by home use devices can greatly improve the public health.

This guidance provides recommendations for designing and developing medical devices intended for home use through considerations involving the physical environment, the user, the device or system, the labeling, and human factors. This should result in a safe and easier-to-use device, minimize use error, and reduce the likelihood that adverse events will occur. The recommendations in the guidance apply to both prescription and over-the-counter medical devices that are intended for use in the home or other non-clinical environments.

In the **Federal Register** of December 13, 2012 (77 FR 74195), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by March 13, 2013. FDA reviewed the comments and revised the guidance as appropriate.

##### **II. Significance of Guidance**

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on design considerations for devices intended for home use. 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.