Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; the National Maltreatment Reporting System

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 the information collection requirements relating to the National Maltreatment Reporting System (NAMRS). The proposed collection of information tools may be found in the NAMRS section of the ACL Web site.

DATES: Submit written or electronic comments on the collection of information by: May 23, 2016.

ADDRESSES: Submit electronic comments on the collection of information to Stephanie Whittier Eliason at *stephanie.whittiereliason@acl.hhs.gov.*

Submit written comments on the collection of information to: Administration for Community Living, Attention: Stephanie Whittier Eliason, 330 C St SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Stephanie Whittier Eliason at 202.795.7467.

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.

Authority

This data collection effort is in response to the Elder Justice Act of 2009, which amended title XX of the Social Security Act (42.U.S.C. 13976 *et seq.*). These provisions require that the Secretary of HHS ''collects and disseminates data annually relating to the abuse, exploitation, and neglect of elders in coordination with the Department of Justice'' (Sec. 2041(a)(1)(B)), and ''conducts research related to the provision of adult protective services'' (Sec. 2041(a)(1)(D)). Furthermore, the Elder Justice Coordinating Council (EJCC) included as its third recommendation for increasing federal involvement in addressing elder abuse, neglect, and exploitation: Develop a national adult protective services (APS) system based upon standardized data collection and a core set of service provision standards and best practices.

Background

From 2013–2015, ACL, in partnership with the U.S. Department of Health & Human Services' Office of the Assistant Secretary for Planning and Evaluation (ASPE), developed and pilot tested NAMRS. When implemented, NAMRS will be the first comprehensive, national reporting system for APS programs. NAMRS is intended to collect quantitative and qualitative data on the practices and policies of adult protective services (APS) agencies, as well as the outcomes of investigations into the maltreatment of older adults and adults with disabilities.

In developing NAMRS, ACL and ASPE convened key stakeholders to identify data elements that are the most critical for a national system. More than 40 state administrators, researchers, service providers, and other stakeholders provided input in focus group conference calls. Additionally, more than 30 state representatives from 25 different states met in three in-person working sessions to discuss the uses of collected data and the key functionalities.

A pilot version of NAMRS was tested in nine (9) diverse states, and refined based on feedback from the pilot and additional stakeholder engagement. A full discussion on the background of NAMRS, including the development of the system, the public engagement process, and the pilot testing can be found in the NAMRS section of the ACL Web site.

Proposed Collection Effort

NAMRS has been developed as a voluntary system to collect annually both summary and de-identified case-level data on APS investigations. NAMRS consists of three components:

(1) ACL proposes to collect descriptive data on state agency policies and practices from all states through the ''Agency Component,'' and

(2) Case-level, non-identifiable data on persons who receive an investigation by APS in response to an allegation of abuse, neglect, or exploitation through the ''Case Component.''

(3) For states that are unable to submit a case-level file through the ''Case Component,'' a ''Key Indicators Component'' will be available for them to submit data on a smaller set of core items.

ACL will provide technical assistance to states to assist in the preparation of their data submissions. Respondents will be state APS agencies and APS agencies in the District of Columbia, Puerto Rico, Guam, Northern Marianas Islands, Virgin Islands, and American Samoa. No personally identifiable information will be collected. ACL has calculated the following burden estimates (information on how the estimates were calculated is available in the NAMRS section of the ACL Web site):

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Agency Component	56	1	13	728
Key Indicators Component	31	1	40	1,240

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Case Component	25	1	150	3,750
Estimated Total Annual Burden Hours				5,718

With respect to the collection of information via NAMRS, ACL 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. The proposed collection of information tools may be found in the NAMRS section of the ACL Web site.

Dated: March 16, 2016.

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–2015–D–2104]

Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance Environment for Multi-Configuration Passive Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices.'' FDA is confronted with an increasing number of premarket submissions that include an MR Conditional labeling claim for multiconfiguration passive medical devices. The assessment of radiofrequency (RF)-induced heating of such devices, typically comprised of many parts, strongly depends on the specific device geometry and can therefore lead to a prohibitively large number of test cases. This guidance provides an approach to reduce the number of possible device configurations to a manageable number, and it provides guidance on how to assess the RF-induced device heating for an individual configuration.

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: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions)*: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–2104 for ''Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/*