

- Aid hospices with their internal quality improvement efforts and external benchmarking with other facilities; and
- Provide CMS with information for monitoring the care provided.

CAHPS is a standardized family of surveys developed by the Agency for Healthcare Research and Quality (AHRQ) for patients to assess and report the quality of care they receive from their health care providers and health care delivery systems.

CMS announced its intention to implement the CAHPS® Hospice Survey in the FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform. National implementation of the survey launched on January 1, 2015 with hospices administering the survey for a “dry run” for at least one month in the first quarter of 2015. Starting April 1, 2015 (second quarter), hospices were required to participate on a monthly basis in order to receive the full Annual Payment Update (APU). Implementation is ongoing and there have been no changes to the questionnaire.

Publicly reporting comparative survey results related to patients’ perspectives of the care they receive from providers and plans collected through the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Surveys support CMS’s efforts to put patients first and improve the beneficiary experience. *Form Number:* CMS–10537 (OMB control number: 0938–1257); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,032,004; *Total Annual Responses:* 1,032,004; *Total Annual Hours:* 180,004. (For policy questions regarding this collection contact Debra Dean-Whittaker at 410–786–0848.)

Dated: February 20, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–03746 Filed 2–25–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; National Adult Maltreatment Reporting System; [OMB# 0985–0054]

AGENCY: Administration for Community Living (ACL), HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to an extension without change and solicits comments on the information collection requirements relating to the National Adult Maltreatment Reporting System (NAMRS).

DATES: Submit written comments on the collection of information by March 27, 2020.

ADDRESSES: Submit written comments on the collection of information by:

(a) *Email to:* OIRA_submission@omb.eop.gov, Attn: OMB Desk Officer for ACL;

(b) fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT:

Stephanie Whittier Eliason, Administration for Community Living, Washington, DC 20201, at 202–795–7467 or Stephanie.WhittierEliason@acl.hhs.gov.

SUPPLEMENTARY INFORMATION:

In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The National Adult Maltreatment Reporting System authorized under the Elder Justice Act of 2009, which amends Title XX of the Social Security Act [42 U.S.C. 13976 *et seq.*], requires that the Secretary of the U.S. Department of Health and Human Services “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)].

The Elder Justice Coordinating Council (EJCC) recommended development of “a national adult protective services (APS) system based upon standardized data collection and a core set of service provision standards and best practices.”

NAMRS is a voluntary system that has been annually collecting since FFY2016 both summary and de-identified case-level data on APS investigations submitted by states. NAMRS consists of three components:

(1) ACL proposes to collect descriptive data on state agency 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 “Case Component”, or

(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 provides technical assistance to states to assist in the preparation of their data submissions. Respondents are state APS agencies and APS agencies in the District of Columbia, Puerto Rico, Guam, Northern Mariana Islands, Virgin Islands, and American Samoa (states, hereafter). No personally identifiable information is collected. The proposed form(s) may be found on the ACL website at <https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows: 56 States will respond every year. It will take approximately 4 hours for all 56 states to respond to the Agency Component, 20 hours for 17 states to respond to the Key Indicator Component, and 100 hours for 35 states to respond to the Case Component. The total annual burden is estimated to be 4,164 hours. The estimates are based on the amount of time States have previously reported in completing the data collection instruments; continued increase in the number of states reporting on Case Component and Key Indicator Component data; and assumption of modest incremental efficiencies by States in reporting data to NAMRS every year, including, most significantly, minimal need to recode to extract data after the initial year.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Agency Component	56	1	4	224
Key Indicators Component	17	1	20	340
Case Component	36	1	100	3,600
Total				4,164

Dated: February 19, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020-03842 Filed 2-25-20; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5625]

Recommendations for Dual 510(k) and Clinical Laboratory Improvement Amendments Waiver by Application Studies; 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 a final guidance entitled “Recommendations for Dual 510(k) and CLIA Waiver by Application Studies.” It describes study designs for generating data that may support both 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) waiver. Use of the Dual 510(k) and CLIA Waiver by Application pathway is optional; however, FDA believes this pathway is in many instances the least burdensome and fastest approach for manufacturers to obtain a CLIA waiver at the same time as 510(k) clearance for new in vitro diagnostic (IVD) tests. FDA believes increased use of this pathway will speed up the process of bringing simple and accurate IVD tests to CLIA-waived settings, which will better serve patients and providers.

DATES: The announcement of the guidance is published in the **Federal Register** on February 26, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2017-D-5625 for “Recommendations for Dual 510(k) and CLIA Waiver by Application Studies.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 “Recommendations for Dual 510(k) and CLIA Waiver by Application Studies” to the Office of