laboratory quality and safety practices, research, standards, and guidelines, and coordinates clinical and public health laboratory improvement efforts among all; (10) provides safety and quality subject matter expertise to the Training and Workforce Development Branch for the development of training courses for internal CDC laboratories and external clinical and public health laboratories; (11) provides advice and oversight of safety and quality measures, controls, practices and documents to ensure compliance of DLS laboratory areas with CDC policies, regulations, and guidelines for laboratory quality and safety (*e.g.,* Roybal campus—Building 18 Training Laboratory and Lawrenceville campus laboratories); (12) provides scientific and technical support and guidance for CDC initiatives, programs, committees, work groups, and task forces involving use, handling, shipping, import/export, transport or storage of biological specimens and their support materials; (13) provides safety and quality-related content expertise for the development of the Laboratory Leadership Service (LLS) Fellows curriculum and serve as course instructors for LLS training classes (and to other laboratory-related workforce efforts as may be requested by other programs); and (14) serves as quality and safety advisors and liaisons to other CDC programs and offices involving clinical laboratory activities upon request.

Informatics and Data Science Branch (CPNBE). (1) Supports the CDC Specimen Policy Board and OADLSS in the development of CDC specimen management and collection policies, and oversees implementation of those policies at CASPIR in collaboration with the CASPIR Advisory Committee; (2) develops, promotes, implements, and evaluates data science approaches for improved research of large and complex data sets in support of CLIA standards and laboratory practice; (3) maintains and leverages data acquired from national laboratory systems and other large health databases to evaluate laboratory testing events, capabilities, capacity, and public health outcomes; (4) develops solutions to strengthen the management of laboratory test service capability and capacity data, biorepositories, access to materials for standardizing laboratory testing, as well as support laboratory preparedness and workforce development activities; (5) develops and implements solutions, often with external partners and collaborators, to strengthen clinical and public health laboratory information systems, reporting of laboratory results between diagnostic facilities and healthcare providers, electronic reporting of laboratory information to electronic health records, and general preparedness of the laboratory system to respond to public health emergencies; (6) develops and implements computer-based decision support tools and mobile applications that help to inform better laboratory-related decision-making by healthcare providers; and (7) collaborates with other CDC programs to develop and promote informatics solutions for improving laboratory management, practice, and preparedness.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2017–26148 Filed 12–4–17; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Public Comments Request; New Data Collection; National Center on Law and Elder Rights (NCLER)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on ACL's intention to collect information from legal and aging/disability service professionals. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of Information and to allow 60 days for public comment in response on the proposed action. This notice solicits comments on proposed information collection requirements relating to ACL funded training, case consultation, and technical assistance for aging/disability networks assisting older adults in social or economic need facing legal issues.

DATES: Submit written or electronic comments on the collection of information by February 5, 2018.

ADDRESSES: Submit electronic comments on the collection of information to Omar Valverde at *omar.valverde@acl.hhs.gov.* Submit written comments on the collection of information by mail to Omar Valverde, Administration for Community Living, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Omar Valverde at *omar.valverde@acl.hhs.gov* or (202) 795–7460.

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 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or update of an existing collection of information, before submitting the collection to OMB for approval. The proposed collection of information represents new information requested from aging/disability networks to fulfill requirements regarding the provision of services and overall performance of ACL legal assistance programs.

To comply with the above requirement, ACL is publishing a notice regarding the proposed collection of information set forth in this document. ACL contracts with a national legal assistance resource center, the National Center on Law and Elder Rights, to provide the required services. Through the contract, ACL provides aging, disability, and related legal professionals with training and complex case consultations and support for demonstration projects regarding contractually identified priority legal topics.

The purpose of the information requested is for ACL to ensure that the resource center creates and prioritizes the training, case consultations and technical assistance resources it was contracted to provide and to ensure that the center targets the contractually designated aging network practitioners about the priority subject matters. This approach enables ACL to make data-informed decisions about the deployment of its resource center assets. These data are necessary for ACL to evaluate contractual compliance with established performance indicators. These metrics include quantifiable increases in uptake by stakeholders of training, case consultation and technical assistance, and measures of satisfaction with and perceived benefit from these services. For example, the metrics measure successful problem resolution as a result of the services provided,

quantifiable data on fulfillment of requests for training, technical assistance, and consultation related to the contractually designated legal and systems development topic areas.

Interested persons are invited to send comments regarding burden estimates or any other aspect of this collection of information, including the following subjects: (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.

Proposed Collection of Information

ACL plans to submit the proposed data collection to the Office of Management and Budget for approval following receipt of any comments received in response to this notice. The information to be requested by ACL from legal and aging/disability professionals fall into the following areas: (1) Requests for training, case consultation, and technical assistance through an online, secure Uniform Resource Support Request Tool; (2) general requests for Legal Training (including the volume of Webinar registrations); Case Consultation and Technical Assistance; and (3) information about satisfaction and use of the services and support received in order to enable ACL to measure performance outcomes.

(1) Resource Support Requests

ACL proposes to ask aging/disability service providers and legal service providers who may need various forms of resource support a series of questions regarding appropriate delivery of needed assistance in a targeted and efficient manner. These questions will be presented through a web based Uniform Resource Support Request Tool (URSRT) that will be used for soliciting and accepting requests for Legal Training, Case Consultation, and Technical Assistance (Link to URSRT).

Estimated Number of Responses

ACL expects to receive (30) responses to questions presented in the URSRT from Legal Assistance Developers (LADs) (Title VII, Section 731) housed in SUAs and (50) responses from Older Americans Act (OAA) Title III–B legal providers in the first year. In subsequent years, the URSRT will be targeted for use by other groups within aging/disability and elder rights networks and may experience a large increase in responses.

Total Estimated Burden Hours

The burden hours are calculated as (*1) minute and 54 seconds* to complete the URSRT per respondent, with a total of *2.53* hours, annually. *Attachment A,* which is posted along with the draft forms on the *acl.gov* Web site, explains the estimated response rate and burden calculations.

(2) Legal Training, Case Consultation, Technical Assistance Requests

ACL proposes to ask legal and aging/disability providers who request Legal Training, Case Consultation, or Technical Assistance through the web-based Uniform Resource Support Request Tool (URSRT) for background information and the following substantive data:

- Type of Organization (Title III–B attorney, Legal Services Corporation attorney, Other Legal Services attorney, Other Elder Law attorney, Other Legal Services professional, Aging and/or Disability Network Professional, Other); and
- Services requested: (Legal Training, Case Consultation, Technical Assistance on Legal Services Delivery, or General Information).

Estimated Number of Responses

Based on the results of prior data collections, ACL expects between *13,000 and 14,000* requests annually through the web-based Uniform Resource Support Request Tool (URSRT). In subsequent years, enhanced public awareness of the availability of Legal Training, Case Consultation, and Technical Assistance within aging/disability/legal networks may increase potential responses to as high as *16,000.*

Total Estimated Burden Hours

The burden of hours is calculated at *(1) minute 42 seconds* for each respondent to make a request for Training, Case Consultation, or Technical Assistance. ACL estimates a high end of *14,000* responses with burden hours totaling *396* hours, annually. *Attachment A,* which is posted along with the draft forms on the *acl.gov* Web site, explains the estimated response rate and the burden calculation.

(3) Performance Outcome Measurement

ACL proposes to ask legal and aging/disability providers, who request Legal Training, Case Consultation or Technical Assistance, the following series of survey questions in order to properly assess audience targeting, participant satisfaction, and outcomes of the training and technical assistance delivered:

- Type of Organization (Title III–B attorney, Legal Services Corporation attorney, Other Legal Services attorney, Other Elder Law attorney, Other Legal Services professional, Aging and/or Disability Network Professional, and Other Job Title (*e.g.,* Executive Director, Management, Staff Attorney, Counselor);
- Please rank the quality of assistance provided in this (Legal Training/Case Consultation/Technical Assistance);
- Did the assistance provided by this (Legal Training/Case Consultation/Technical Assistance) contribute to a successful resolution of a specific client issue?
- If requesting assistance on legal services delivery, will the assistance provided contribute to the successful completion of legal needs and capacity assessments, legal services delivery plans, legal service delivery standards, or data collection/reporting systems?

Estimated Number of Responses

ACL expects between *3,000 and 3,500* responses to follow up surveys presented through the web-based Uniform Resource Support Request Tool (URSRT) gaging participant satisfaction and service impacts derived from Training, Case Consultation, or Technical Assistance. In subsequent years, due to an increase in the volume of resource support provided, survey responses may increase to as high as *4,500* due to ongoing efforts to increase awareness of the availability of resource support through NCLER.

Total Estimated Burden Hours

The burden of hours is calculated at *(1) minute and 3 seconds* for each respondent to complete a survey gaging satisfaction and service impact. ACL estimates a high end of *3,500* responses with a burden of hours totaling *61.25* hours, annually. *Attachment A,* which is posted along with the draft forms on the *acl.gov* Web site, explains the estimated response rate and the burden calculation.

The proposed data collection forms and Attachment A may be found on the ACL Web site for review at: *https://www.acl.gov/about-acl/public-input*

SUMMARY OF BURDEN ESTIMATES

Respondent/data collection activity	Number of respondents	Minutes per response	Annual burden hours
Resource Support Requests	80	1 min 54 sec	2.53 hours.
Legal Training, Case Consultation, Technical Assistance Requests.	14,000	1 min 42 sec	397 hours.
Outcome Measurement	3,500	1 min 3 sec	61.25 hours.
Total	17,580	4 min 39 sec	460.78 hours.

Dated: November 24, 2017.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2017–26116 Filed 12–4–17; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1159]

Food and Drug Administration Categorization of Investigational Device Exemption Devices To Assist the Centers for Medicare and Medicaid Services With Coverage Decisions; Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, 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 ''FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions; Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff.'' This guidance modifies the FDA's current policy on categorization of investigational device exemption (IDE) devices, which assists the CMS in determining whether or not an IDE device should be covered (reimbursed) by CMS. On December 2, 2015, FDA's Center for Devices and Radiological Health (CDRH) and CMS's Coverage and Analysis Group (CAG) executed a Memorandum of Understanding (MOU) to streamline and facilitate the efficient categorization of investigational medical devices in order to support CMS's ability to make Medicare coverage (reimbursement) determinations for those devices. This guidance document further explains the framework that FDA intends to follow for such categorization decisions.

DATES: The announcement of the guidance is published in the **Federal Register** on December 5, 2017.

ADDRESSES: You may submit either electronic or written comments on this guidance 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–2016–D–1159 for ''FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions; Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff.'' 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 office 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the