

of Information Collection: CLIA Collection of Information Requirements Related to SARS-CoV-2 Test Results Reporting; *Use:* In order to be in compliance with the new CLIA mandatory SARS-CoV-2 test results reporting requirements, laboratories will need to develop a mechanism to track, collect, and report test results as well as update policies and procedures. In addition, Accreditation Organizations (AOs) and Exempt States (ESs) will need to update laboratory standards to reflect the reporting requirements and update policies and procedures related to reporting laboratories that do not report test results as required.

The CDC has an information collection request (OMB Control Number 0920-1299) in order to collect laboratory data related to the COVID-19 Pandemic Response. The CMS package (ICR) is for laboratory implementation and CMS monitoring of compliance with the CMS-3401-IFC CLIA-certified laboratory reporting requirements.

The information collected by the Centers for Medicare and Medicaid Services (CMS) or its designee, such as a CMS agent or CMS approved laboratory accreditation organization, when conducting inspections will be used to determine a laboratory's compliance with the CLIA SARS-CoV-2 test result reporting requirements. During an on-site survey, the Condition-level laboratory requirement at 42 CFR 493.41 and 493.1100(a) are assessed for compliance. The information is used by CMS in determining appropriate Civil Money Penalties (CMPs) when laboratories fail to report as required. *Form Number:* CMS-10757 (OMB control number: 0938-1391); *Frequency:* Daily; *Affected Public:* Private Sector Not-for-profit institutions and State, Local and Tribal Governments; *Number of Respondents:* 77,033; *Total Annual Responses:* 308,114; *Total Annual Hours:* 1,386,873 (For policy questions regarding this collection contact Sarah Bennett at 410-786-3354.)

Dated: July 26, 2021.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; State Annual Long-Term Care Ombudsman Report-National Ombudsman Reporting System; OMB #0985-0005

AGENCY: Administration for Community Living, 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 section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the State Annual Long-Term Care Ombudsman Report-National Ombudsman Reporting System [OMB #0985-0005].

DATES: Submit written comments on the collection of information by August 30, 2021.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find the information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. 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:

Louise Ryan, Administration for Community Living, Washington, DC 20201, (206) 615-2299 or by email: louise.ryan@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 Administration for Community Living (ACL) is requesting approval to collect data for the State Annual Long-Term Care Ombudsman Report-National Ombudsman Reporting System [OMB #0985-0005]. This request covers minor changes and corrections to the current information collection, with a total of 11,154 annual burden hours. The data collection tool will enhance ACL's ability to understand and report on

Long-Term Care Ombudsman (LTCO) program operations, experiences of long-term care facility residents and will reflect changes in LTCO program operations and long-term supports and services policies, research, and practices. States will continue to provide the following data and narrative information in the report:

1. Numbers and descriptions of cases filed and complaints made on behalf of long-term care facility residents to the statewide ombudsman program;
2. Major issues identified impacting on the quality of care and life of long-term care facility residents;
3. Statewide program operations;
4. Ombudsman activities in addition to complaint investigation; and
5. Organizational conflict of interest reporting as required by 45 CFR part 1324.21.

Comments in Response to the 60-Day Federal Register Notice

A notice was published in the **Federal Register** on March 10, 2021 (86 FR 13720). There were four public comments received during the 60-day FRN. Please see ACL's response to comment listed below.

Two of the four respondents (Maryland Ombudsman program and the National Association of State Ombudsman Programs (NASOP)) recommended adding a new complaint code "infection control."

Response: ACL agrees to add one complaint code "infection control" and corresponding definition, examples and reporting tips. The Iowa Ombudsman program recommended adding clarifying information to the Code I05 (Housekeeping) to be inclusive of infection control, ACL will incorporate its suggestion into the new "Infection control" code. Two of the four respondents (Maryland Ombudsman program and NASOP) recommended changes to the "examples and reporting tips" under complaint code J01.

Response: ACL agrees to modify the "examples and reporting tips" on Complaint Code J01 "Administrative oversight" to incorporate problems with a facility planning and responding to an emergency.

ACL received the following comments and did not accept them for inclusion in NORS.

The Maryland Ombudsman proposed adding more detail and examples in the description fields in the following cells: S02, S06, S08, S09, S12.1, and S13 stating that this would give the State Ombudsman more guidance on how to approach the narratives and to help ensure greater consistency across the country.

Response: ACL in coordination with ACL’s grantee, the National Ombudsman Resource Center (NORC) created in-depth training and training manuals on all aspects of NORS reporting, including examples of narratives for both complaint examples and systems issues and does not believe that additional guidance is necessary. See https://ltombudsman.org/omb_support/nors.

The Maryland Ombudsman program also recommended the addition of a new complaint code in Facility Policies, Procedures and Practices (Code J) for emergency planning complaints. The Maryland Ombudsman program noted that there have been many instances of facilities needing to temporarily or permanently relocate residents for a variety of reasons from disasters to lack of appropriate staff in the building, facility closure, or the facility did not have an appropriate plan or did not have a plan at all.

Response: ACL will not add a new complaint code, but will modify complaint code J01 “Administrative Oversight” to be inclusive of emergency planning.

One recommendation was to include the addition of a county field (e.g., Federal Information Processing Standard code). The commenter noted that although looking at differences/variation between states is important and valuable, having the ability to look at differences/variation within each state would be immensely beneficial for the conduct of ACL’s functions and

would allow for analytics to be shared with state ombudsmen and other programs nationwide.

Response: ACL does not accept this recommendation because of the level of burden necessary to gather and report this level of data.

NASOP made recommendations to broaden the types of activities reported on systems issues work performed by the State Long-Term Ombudsman, the Office and local Ombudsman entities. NASOP asserts that this reporting element would provide needed depth and clarity about whether a State Long-Term Care Ombudsman has the necessary independence and resources to perform systems advocacy as required by the Older Americans Act. NASOP proposes that data collected as narrative examples of Systems Issues is insufficient and does not have practical utility without additional data collection to explain the scope of a state’s work on systems advocacy. “By only collecting two examples of a systems issue from each state, ACL has no objective means of determining a state’s compliance with the Act nor the independence of the Office. With our proposed addition data collection in Table 3, ACL will collect and provide the public with a more accurate picture of whether a state program is fulfilling the requirements of the Act.”

Response: ACL does not agree with NASOP’s assessment of the current data collection on systems advocacy for several reasons. First, the FY 2020 data is not yet final and ACL has not been

able to share systems advocacy data. Additionally, while NORS is one part of measuring program effectiveness it is not the only way that ACL determines compliance with the Older Americans Act. ACL provides continuous technical assistance on matters of compliance, conducted in-depth review of states compliance with the Ombudsman program regulation, and worked with states to develop compliance plans. ACL also has an on-going project to evaluate the effectiveness of the Ombudsman program and has gathered in-depth data on both state and local level Ombudsman program’s ability to conduct systemic advocacy. See <https://acl.gov/programs/program-evaluations-and-reports>. In addition, the proposed data collection would be very burdensome on state and local programs to collect and report because the two recommended data elements include a sub-set of 10 possible elements to select and to keep track of the number of instances of each sub-set ultimately resulting in 20 new data elements. This type of data would not add meaningful information that would benefit ACL considering the level of effort required of states to train on this type of data collection, adapt software and report.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows: Approximately 11,154 hours, with 52 state Ombudsman programs responding annually.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Total	52	1	214.5	11,154

Dated: July 23, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Notice of Federal Review of the Missouri Protection and Advocacy System (P&A)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: Representatives of the Administration on Disabilities (AoD), Administration for Community Living (ACL), will be conducting a federal review of the Missouri Protection and Advocacy System (P&A) on September 13–17, 2021. AoD is soliciting comments from interested parties on your experiences with the program, and strategies employed by P&A in meeting the needs of individuals with developmental disabilities and their families in Missouri. You are encouraged to share your experiences by way of email or telephone.

DATES: Comments must be submitted electronically or via telephone by September 22, 2021, 11:59 p.m. (EST) in order to be included in the final report.

Email: Katherine.Cargill-Willis@acl.hhs.gov.

Telephone: 202–795–7322.

FOR FURTHER INFORMATION CONTACT:

Katherine Cargill-Willis, Administration for Community Living, Administration on Disabilities, 330 C Street SW, 1st Floor, Washington, DC 20201, 202–795–7322.

Dated: July 23, 2021.

Alison Barkoff,

Acting Administrator & Assistant Secretary for Aging.

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