

extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by December 2, 2024.

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

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term "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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes

the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Financial Statement of Debtor; *Use:* When a Medicare Administrative Contractor (MAC) overpays a physician or supplier, the overpayment is associated with a single claim, and the amount of the overpayment is moderate. In these cases, the physician/supplier usually refunds the overpaid amount in a lump sum. Alternatively, the MAC may recoup the overpaid amount against future payments. A recoupment is the recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. The recoupment can be made only if the physician/supplier accepts assignment since the MAC makes payment to the physician/supplier only on assigned claims.

The physician/supplier may be unable to refund a large overpaid amount in a single payment. The MAC cannot recover the overpayment by recoupment if the physician/supplier does not accept assignment of future claims or is not expected to file future claims because of going out of business, illness or death. In these unusual circumstances, the MAC has authority to approve or deny extended repayment schedules up to 12-months or may recommend to the Centers for Medicare and Medicaid Services (CMS) to approve up to 60 months. Before the MAC takes these actions, the MAC will require full documentation of the physician's/supplier's financial situation. Thus, the physician/supplier must complete the CMS-379, Financial Statement of Debtor.

Section 1893(f)(1) of the Social Security Act and 42 CFR 401.607 provides the authority for collection of this information. Section 42 CFR 405.607 requires that, CMS recover amounts of claims due from debtors including interest where appropriate by direct collections in lump sums or in installments. *Form Number:* CMS-379 (OMB control number: 0938-0270); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 1,000 hours. (For policy questions regarding this collection

contact Monica Thomas, at 410-786-4292.)

William N. Parham, III,
Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-25331 Filed 10-30-24; 8:45 am]

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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; for the State Annual Long-Term Care Ombudsman Report (OMB Control Number 0985-0005)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) 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 proposed new information collection requirements relating to the State Annual Long-Term Care Ombudsman Report (OMB Control Number 0985-0005).

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (ET) or postmarked, December 2, 2024.

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, Attention: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Beverly Laubert, Beverly.Laubert@acl.hhs.gov, (202) 795-7364.

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 State Annual

Long-Term Care Ombudsman Report is needed to comply with Administration for Community Living/Administration for Aging reporting requirements in the Older Americans Act (OAA); and 45 CFR 1324.21(b) (1) and (b)(2)(v). The Long-Term Care Ombudsman Report is used to measure the services and strategies that are provided to assist residents in the protection of their health, safety, welfare, or rights; advocate at the state and federal levels for changes needed to improve the quality of life and care in long-term care facilities; and effectively manage the Long-Term Care Ombudsman Program at the state and federal level. The National Ombudsman Reporting System (NORS) was developed in response to these needs and directives. Section 712(c) of the OAA requires the state agency to establish a statewide uniform reporting system to:

(1) Collect and analyze data relating to resident complaints and conditions in long-term care facilities for the purpose of identifying and resolving significant problems.

and

(2) Submit the data on a regular basis to the state licensing/certifying agency, other state and federal entities that the Ombudsman determines to be appropriate, the Assistant Secretary for Aging, and the National Long-Term Care Ombudsman Resource Center.

Comments in Response to the 60-Day Federal Register Notice

In accordance with 5 CFR 1320.8(d), ACL published a 60-day Notice in the **Federal Register** on August 6, 2024, at 89 FR 63955–63956.

Please see public comments received during the 60-day notice and ACLs response to comments listed below.

ACL received comments from individuals and groups including the National Association of State Ombudsman Programs (NASOP); the National Association of Local Long-Term Care Ombudsmen (NALLTCO), the California Long-Term Care Ombudsman Association (CLTCOA), National Ombudsman Resource Center (NORC), and a gerontologist/researcher.

Commenters who addressed the utility of the data and burden estimates supported the continuation of the NORS collection. NALLTCO recommended that ACL conduct a future study of the documentation burden on local long-term care Ombudsmen.

NASOP recommended that changes in data elements be undertaken with ample time to adjust state systems and receive training before implementation, with a request for ACL grant funding for implementation costs. Both

recommendations were deferred for future consideration if funding is available. Regarding recommendations specific to adding or removing data elements, ACL opts to hold those suggestions for future revision after further consideration and analysis of impact of the changes; including the impact on State Ombudsman programs that would need to change their data collection systems. Comments that ACL accepted were changes to instructions and examples and reporting tips for clarity.

Most of the comments were requests to modify instructional examples and reporting tips. Some of the recommendations indicated misunderstandings that can be resolved with technical assistance, the below nine comments/recommendations were accepted.

Comment 1: One respondent requested clarification on how to code complaint disposition when a resident dies before an outcome of the complaint has been obtained.

Response 1: Reporting tips were changed to instruct the Ombudsman to report such instances as withdrawn when there is not a resident representative to determine resolution.

Comment 2: One respondent requested revision to complaint type F01—Accidents and falls to update language from describing a resident who self-propels to a resident who uses a wheelchair independently.

Response 2: The example was updated accordingly.

Comment 3, 4: Two respondents recommended changing how volunteer representatives are counted to include all volunteers who were representatives during the reporting year. Current instructions are to count volunteers as the number on September 30 of the fiscal year.

Response 3,4: The description was updated to ensure that all volunteer representatives are counted.

Comment 5: One respondent requested that ACL allow newsletters and other forms of media to be counted as community education.

Response 5: As use of social media and other electronic means of imparting information has increased, community education activities are under-reported within current instructions. A revision to the instructions was made to accommodate the request.

Comment 6, 7: Two respondents recommended a change to the description of complaint type I03—Supplies, storage, and furnishings to include facility failure to properly store hazardous chemicals and other hazards.

Response 6, 7: I03 is a complaint type about shortage of supplies. Instead, the examples and reporting tips for I01—Environment were revised to accommodate the comments.

Comment 8: One respondent suggested modifying the description of program activity elements S64 and S65—Resident council participation to include instances of training to resident groups that might not be formal resident councils.

Response 8: The modification was made to accommodate the suggestion. A corresponding change was made to S66 and S67—Family council participation.

Comment 9: One respondent requested that ACL remove the requirement to report expenditures in NORS or, in the alternative, specify that expenditures be reported as obligated.

Response 9: ACL has worked to reconcile multiple means of financial reporting. The NORS requirement will not be removed because NORS is the source of publicly reported information about Ombudsman program resources. However, the examples and reporting tips were modified to instruct states to report using consistent accounting methods.

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

Comment: One respondent recommended including “fear” of retaliation in the complaint type where retaliation is reported and adding a complaint code for theft of medications.

Response: Because such problems can be captured within existing complaint codes, it is not necessary to add to the collection.

Comment: One respondent suggested adding to the definition of complainant to capture referrals from legislators.

Response: ACL will provide technical assistance about reporting entities that make referrals, which is different from complainants.

Comment: Two respondents suggested removing the verification data element because Ombudsman programs work to resolve all problems expressed by residents.

Response: Verification is key to the purpose of investigation and ACL will provide technical assistance if needed to supplement training provided by the NORC.

Comment: One respondent suggested changing language from “perpetrator” to “aggressor” when a complaint involves a resident living with dementia.

Response: In the example described in the comment, the use of the abuse complaint type could be incorrect; ACL and NORC will provide technical assistance on how to code complaints to

reflect resident experience rather than changing a term that is commonly used in abuse investigations by other entities.

Comment: Three respondents recommended modification to the psychological abuse complaint code to include social media posts and posting of photographs.

Response: The current reporting tips include oral, written, or gestured language and are sufficient to include social media posts. Photos are also included in the reporting tips.

Comment: Three respondents recommended adding language to complaint types in the category of autonomy, choice, and rights to address emergence of artificial intelligence to monitor residents.

Response: This issue requires further review and will be considered for future revisions.

Comment: One respondent suggested adding a reporting tip to complaint type F10- Rehabilitation services to instruct Ombudsmen how to report contractures as gross neglect.

Response: Further review is needed, and this suggestion will be considered for future revisions.

Comment: One respondent recommended that instruction be added to select staffing as a secondary complaint and to broaden the definition of staffing.

Response: The use of secondary complaint codes when a resident or complainant has not expressed staffing as a complaint would be a significant change in practice with potential unintended consequences. This requires further review and may be considered in future revisions. The existing definition of J03—Staffing is sufficiently inclusive of staffing vacancies.

Comment: Two respondents recommended adding language to the definition and examples for complaint type L01—Resident representative or family conflict to include other visitors with different types of relationships.

Response: The complaint type as currently defined is specific to the nature of the relationships of family members and individuals that residents choose to be their representative; adding others could dilute the meaning of the data element.

Comment: Two respondents requested the addition of a new complaint type for reporting resident-to-resident altercations that are not willful abuse.

Response: ACL is not adding or removing data elements with this renewal but will consider this recommendation in the future after analysis of impact and alternatives within the existing collection.

Comment: Three respondents recommended adding a new category of complaints and individual complaint types about discrimination.

Response: ACL is not adding or removing elements but will seek additional input and consider this change in the future after analysis of impact.

Comment: Two respondents suggested adding a new complaint category to allow for short-term collection of data for a special purpose.

Response: ACL is not adding or removing elements with this renewal but will consider the recommendation after analysis of impact and alternatives.

Comment: One respondent asserted that complaint/case terminology in data elements S01–S06 is confusing.

Response: The data elements are text fields and provide flexibility for the State Ombudsman to describe complaints as they determine best. Technical assistance will be provided.

Comment: One respondent requested clarification about reporting hours donated by volunteers when the volunteer receives travel reimbursement.

Response: The Older Americans Act allows for reimbursement and travel is included in the current examples and reporting tips.

Comment: One respondent requested clarification about removal or remediation of conflicts of interest.

Response: How conflicts of interest are addressed is a matter of rule (45 CFR 1324.21(b)) implementation and technical assistance will be provided as part of broader regulatory guidance.

Comment: One respondent suggested the addition of a code for a specific type of expenditure.

Response: ACL is not adding or removing data elements with this revision of NORS but will consider this change in the future.

Comment: One respondent suggested clarification of local funds expended.

Response: The instruction is written as intended and technical assistance will be provided.

Comment: Four respondents recommended changes to routine access visitation reporting.

Response: Routine access visits as defined are an important measure of resident access to their advocate separate from visits to handle complaints, as well as a measure of the impact of program funding. ACL will explore this request further and consider a change in the future; data elements are not being changed in this revision.

Comment: Three respondents commented that instructions are vague

about how to report the number of facilities and that closures have an impact on how routine access visits are measured on a quarterly basis.

Response: The examples and tips are specific that the count of facilities is as of the last day of the federal fiscal year. Routine access is based upon the count of facilities as of the last day of the fiscal year. The data element is defined as intended, routine access does not include facilities that open after the first quarter or close before the fourth quarter of the fiscal year. Technical assistance will be provided.

Comment: One respondent requested a new data element for reporting facility closures.

Response: At this time ACL is not adding or removing elements but will consider this change in the future after analysis of impact and alternatives.

Comment: Two respondents requested new Ombudsman program staffing data elements—statewide turnover rates, years of experience of Ombudsman representatives, and the staff-to-bed ratio of staff.

Response: At this time ACL is not adding or removing elements but will consider this change in the future after analysis of potential methods of collection.

Estimated Program Burden

ACL estimates the burden of this collection of information as follows:

Fifty-two grantees report to ACL using NORS.

- a. Number of respondents—52
- b. Frequency of response—1
- c. Total annual responses—52
- d. Hours per response—214
- e. Total burden hours—11,153

Dated: October 28, 2024.

Maura Calsyn,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0093]

M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.