

## Supporting Statement - Part A

### Reform of Long-Term Care Facilities Requirements for Respiratory Illness Reporting (OMB Control Number 0938-NEW), CMS-10914<sup>1</sup>

#### A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval of this new collection of information for the requirements of participation for Long-Term Care (LTC) facilities that must be met to participate in the Medicare and Medicaid Programs. The name and numbers for this collection have been changed for the 30-day notice. Please see Section B.8 for a detailed explanation.

LTC facilities include skilled nursing facilities (SNFs) as defined in section 1819(a) of the Social Security Act in the Medicare program and nursing facilities (NFs) as defined in 1919(a) of the Act in the Medicaid program. SNFs and NFs provide skilled nursing care and related services for residents who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. In addition, NFs provide health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities and is not primarily for the care and treatment of mental disorders. SNFs and NFs must care for their residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident and must provide to residents services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care which describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met and which is updated periodically.

Under the authority of sections 1819 and 1919 of the Act, the Secretary proposed to reform the requirements that SNFs and NFs must meet to participate in the Medicare & Medicaid programs. These requirements would be set forth in 42 CFR 483 subpart B as Requirements for LTC Care Facilities. The requirements apply to an LTC facility as an entity as well as the services furnished to each individual under the care of the LTC facility unless a requirement is specifically limited to Medicare or to Medicaid beneficiaries. To implement these requirements, State survey agencies generally conduct surveys of LTC facilities to determine whether they are complying with the requirements.

The ICRs covered in this package do not require a standard form or survey instrument, except for §483.80(d)(3)(iv) and (g). This section requires that LTC facilities report specific information in a standardized format to the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) weekly.

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<sup>1</sup> CMS and OMB Numbers corrected to OMB Control Number 0938-NEW and CMS-10914. 60-day notice previously submitted under OMB Control Number 0938-1363 and CMS-10573. See Section B.8 for a detailed explanation.

In this OMB submission, information collection requirements are being added to the proposed respiratory illness reporting that would replace the current requirement on COVID-19 reporting at § 483.80(g) based on the proposed rule, Medicare Program; Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies (HH PPS 2024). In this proposed rule, we revised the LTC requirements for COVID-19 reporting to establish a new requirement for respiratory illness reporting that includes COVID-19, RSV, and influenza.

## B. Justification

### 1. Need and Legal Basis

The ICRs for which we are requesting OMB approval are listed below. These requirements are among other requirements which are based on criteria prescribed in law and are standards designed to ensure that each LTC facility safely and effectively delivers care to all residents. The ICRs described herein are needed to implement these health and safety standards requirements for all Medicare and Medicaid participating LTC facilities.

Sections 1818 and 1919 of the Act (42 U.S.C. 1395i-3 and 42 U.S.C. 1396r, respectively) specify certain requirements that a LTC facility must meet to participate in the Medicare and Medicaid programs. In particular, sections 1819(d)(4)(B) and 1919(d)(4)(B) require that a SNF or NF must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary.

Under the authority of sections 1819, 1919, 1128I (b) and (c), and 1150B of the Act, the Secretary proposes to establish in regulation the requirements that an LTC facility must meet to participate in the Medicare and Medicaid programs.

### 2. Information Users

The primary users of this information will be State agency surveyors, the Centers for Medicare & Medicaid (CMS), and the LTC facilities for the purposes of ensuring compliance with Medicare and Medicaid requirements as well as ensuring the quality of care provided to LTC facility residents. The ICRs specified in the regulations may be used as a basis for determining whether a LTC facility is meeting the requirements to participate in the Medicare program. In addition, the information collected for purposes of ensuring compliance may be used to inform the data provided on CMS' Nursing Home Compare website and as such used by the public in considering nursing home selections for services.

### 3. Use of Information Technology

LTC facilities may use health information technologies (HIT) to store and manage records, consistent with statutory and regulatory requirements for record keeping and confidentiality.

Use of certified HIT technology is encouraged but not required, as some facilities, particularly small or rural facilities, may not have electronic capacity at this time. Facilities are free to take advantage of any technology advances they find appropriate for their needs.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This information collection does affect small businesses. However, the requirements are sufficiently flexible for facilities to meet them in a way consistent with their existing operations.

6. Less Frequent Collection

CMS does not collect this information directly from LTC facilities on a scheduled basis. Facilities are expected to collect and maintain their own records in a timely fashion and to be able to provide necessary records to State or Federal surveyors when needed to demonstrate compliance with the LTC requirements for participation. With less frequent collection, CMS would not be able to assess or ensure compliance with the requirements.

7. Special Circumstances

There are no special circumstances for collecting this information.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on August 20, 2024 (89 FR 67442). A response to the single comment received has been attached as Appendix A.

The title, OMB Control Number, and CMS identification number for this 30-day notice has been changed from the 60-day notice. The previous information identified the PRA package for all of the COIs for the Requirements for Long-term Care Facilities. Since this information collection only addresses the COIs for §483.80(g) Respiratory Illness Reporting, this package has been given separate identification numbers, specifically OMB Control Number 0938-NEW and CMS-10914.

A 30-day Federal Register Notice will publish on \_\_\_\_\_.

9. Payments/Gifts to Respondents

There are no payment or gifts to respondents.

10. Confidentiality

We do not pledge confidentiality of aggregate data. We pledge confidentiality of resident-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

#### 11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

#### 12. Burden Estimates (Hours & Wages)

In this rule, we proposed to replace the existing reporting requirements for LTC facilities set forth in § 483.80(g)(1)(i) through (ix) and (g)(2) that focus on COVID-19 with new requirements for respiratory diseases, specifically COVID-19, influenza, and RSV. Beginning on January 1, 2025, facilities would be required to electronically report information about COVID-19, influenza, and RSV in a standardized format and frequency specified by the Secretary. To the extent to be determined by the Secretary, through this rulemaking cycle, we propose that the data elements for which reporting would be required include—

- Facility census;
- Resident vaccination status for a limited set of respiratory illnesses including, but not limited to, COVID-19, influenza, and RSV;
- Confirmed, resident cases of a limited set of respiratory illnesses including but not limited to COVID-19, influenza, and RSV (overall and by vaccination status); and
- Hospitalized residents with confirmed cases of a limited set of respiratory illnesses including but not limited to COVID-19, influenza, and RSV (overall and by vaccination status).

In the absence of a declared national PHE for an acute respiratory illness, we propose that LTC facilities would continue to report these data on a weekly basis through a format specified by the Secretary and specifically we intend to continue reporting through the CDC's National Healthcare Safety Network (NHSN). There may be instances in which the Secretary may determine a need to change reporting frequency, such as during a future PHE, and we would provide appropriate notice and guidance at that time.

These proposals are scaled back and tailored from the current post-COVID-19 PHE requirements, continuing the collection of the minimal necessary data to maintain a level of situational awareness that would protect resident health and safety in LTC facilities across the country while reducing reporting burden on those facilities. However, during a declared Federal, state, or local PHE for a respiratory infectious disease, we also propose that the Secretary may require facilities to report:

- Data up to a daily frequency without additional notice and comment rulemaking.
- Additional or modified data elements relevant to the PHE, including relevant confirmed infections among staff, supply inventory shortages, and relevant medical countermeasures and therapeutics inventories, usage, or both, and additional demographic factors.

Since the infection prevention and control program (IPCP) is the responsibility of the infection preventionist (IP), we anticipate that the IP would be responsible for reviewing and updating the

policies and procedures for the facility's IPCP to comply with these new proposals. We estimate that it would require 2 hours of the IP's time to update the facility's policies and procedures to ensure that they reflect the proposed requirements. In analyzing the ICRs related to this proposal we obtained salary information from the May 2023 National Occupational Employment and Wage Estimates, BLS at [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). We have calculated the estimated hourly rate for an IP using the occupation code for a registered nurse (29-1141) based on the national mean salary increased by 100 percent to account for overhead costs and fringe benefits ( $\$45.42 \times 2 = \$90.84$  (rounded to \$91). According to CMS, there are currently 14,926 LTC facilities as of April 2024. Based on this salary information and facility data, we estimate that total annual burden hours for all LTC facilities to review and update their current policies and procedures would be 29,852 hours (2 hours  $\times$  14,926 facilities) at a cost of \$2,716,532 (29,852  $\times$  \$91) or \$182 (\$91  $\times$  2 hours) per facility annually.

In addition, LTC facilities will need to continue locating the required information and electronically reporting in the frequency specified to the NHSN. Currently, the ICR associated with this reporting requirement under OMB control #0938-1363 estimates a total burden cost of \$55,972,800 (1 hour  $\times$  52 weeks  $\times$  \$69 (IP 2022 salary)  $\times$  15,600 LTC facilities as of 2022) based on weekly reporting. While the number of required data elements for ongoing reporting have decreased from the current post-COVID-19 PHE reporting requirements set to expire December 2024, we acknowledge that the data elements and reporting frequency could increase or decrease due to what the Secretary deems necessary based on changes in circumstance or given another PHE and these changes would impact this burden estimate. For instance, weekly data reporting could be decreased to bi-weekly reporting or the increased reporting of additional data elements during a PHE could be activated and remain active for less than or more than a year depending on the circumstances. Since we cannot predict with certainty how often the Secretary would require data reporting for a future PHE, we are including two burden estimates to cover a range in frequency of reporting. The lower range is based on weekly reporting and the higher range is based on daily reporting.

Based on the assumption of a weekly reporting frequency and 1 hour of the IP's time to locate and electronically report the information, we estimate that total annual burden hours for all LTC facilities to comply would be 776,152 hours (1 hour  $\times$  52 weeks  $\times$  14,926 facilities) at a cost of \$70,629,832 (776,152 total hours  $\times$  \$91) or \$4,732 (\$91  $\times$  1 hour  $\times$  52 weeks) per facility annually.

Based on the assumption of a daily reporting frequency, we estimate that total annual burden hours for all LTC facilities to comply would be 5,447,990 hours (1 hour  $\times$  365 days a year  $\times$  14,926 facilities) at a cost of \$495,767,090 (5,447,990 total hours  $\times$  \$91) or \$33,215 (\$91  $\times$  1 hour  $\times$  365 days a year) per facility annually. In summary the total annual burden for all LTC facilities for these proposed ICRs is 806,004 to 5,477,842 hours at an estimated cost of \$73,346,364 to \$498,483,622 or 54 to 367 hours at an estimated cost of \$4,914 to \$33,397 per facility annually. We will submit the revised information collection request to OMB for approval under OMB control number 0938-NEW. The ICR burden currently associated with § 483.80(g) is included under OMB control number 0938-1363; expiration date: April 30, 2026.

**TOTAL BURDEN FOR § 483.80(g) ICRs**

LTC Requirements Section	Number Of LTC Facilities	Hourly Wage Rate	Burden Hours Per LTC Facility	Cost Estimate Per LTC Facility	Burden Hours For All LTC Facilities	Cost Estimate For All LTC Facilities
§483.80(g)(1) and (2) Policies and Procedures	14,926	\$91	2	\$182	29,852	\$2,716,532
§483.80(g)(1) and (2) Electronically Reporting*	14,926	\$91	52 to 365	\$4,732 to \$33,215	776,152 to 5,447,990	\$70,629,832 to \$495,767,090
Totals	14,926	\$91	54 to 367	\$4,914 to \$33,397	806,004 to 5,477,842	\$73,346,364 to \$498,483,622

\*For purposes of OMB review, we are using the high end of the range in our burden estimates.

13. Capital Costs

There are no capital/maintenance costs associated.

14. Cost to Federal Government

The Federal government will sustain a burden from implementing and enforcing these requirements. Specifically, CMS had to update the interpretive guidance, update the survey process, and make IT systems changes. The majority of those system costs for the LTC requirements would have been incurred between FY17 and FY18. We estimated initial federal start-up costs between \$15 and \$20 million for the 2016 final rule. Since those costs have already been incurred, the federal costs result from the improved surveys to review the additional requirements proposed in this rule, update guidance, and make minor IT changes are estimated at \$3.75 to \$5 million annually.

15. Changes to Burden

This is a new collection of information.

16. Publication/Tabulation Dates

LTC facilities will report the required information weekly, and it will be published in the NHSN.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's

website by performing a search using the OMB control number. The expiration date will also be published on [www.cms.gov](http://www.cms.gov) at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/LTC>.

18. Certification Statement

We have not identified any exceptions.