Supporting Statement A: Requirements for Participation for Long-Term Care Facilities (OMB Control Number 0938-1363/CMS-10573)

Introduction

This submission requests approval from the Office of Management and Budget (OMB) to revise the information collection request (ICR) associated with OMB Control Number 0938-1363, for the Requirements for Participation (RfPs) for Long-Term Care (LTC) facilities that must be met to participate in the Medicare and Medicaid Programs.

The first revision of this ICR is to merge a previously approved standalone ICR titled "Reform of Long-Term Care Facilities Requirements for Respiratory Illness Reporting" (OMB Control Number 0938-1479/CMS-10914) with the previously approved version of this ICR titled "Reform of Requirements for Long-Term Care Facilities" (OMB Control Number 0938-1363/CMS-10573).[1] This consolidation establishes the current baseline for CMS-10573 from which to measure subsequent changes. See Table 4 for details.

The second revision reflects changes to existing information collections (ICs) based on the following two Centers for Medicare and Medicaid Services (CMS) rules: 1) *Medicare and Medicaid Programs; Repeal of Minimum Staffing Standards for Long-Term Care Facilities* (CMS-3442-IFC) (90 FR 55687, December 2025) and 2) *Medicare and Medicaid Programs; Cutting Administrative Requirements for Excellence in Patient Care* ("CARE") (CMS-3484-P).[2]

CMS-3442-IFC repeals Title 42 Code of Federal Regulations (CFR) Section 483.35(b)(1) that required LTC facilities to set minimum staffing levels for nurses. Second, the quantified changes attributable to CMS-3484-P fall into the following two categories: proposed removal or revision of existing requirements with associated ICs and burdens. CMS-3484-P proposes to **remove** the following three ICs, reducing the total burden by **932,152 hours and $78,492,232.**

- §§ 483.80(d)(3)(ii) and (vii) - Remove staff COVID-19 vaccine education, offer, and documentation requirements while retaining them for residents
- § 483.80(g)(1) - Ongoing Respiratory Illness Reporting

CMS-3484-P also proposes to **revise** the following three ICs, reducing the total burden by **170,581 hours and $12,308,937.**

- § 483.15(c)(3)(i) - to exempt emergency transfers from the Ombudsman Notices of Transfer requirement;
- § 483.71(b)(1)(ii) - to no longer require LTC facilities to seek 3rd party staff input when completing their required Facility Assessment. There is no quantified change in burden.
- § 483.80(d)(3) - Annual update of COVID-19 policies and procedure

In total, the changes proposed by CMS-3484-P would revise the prior burden by **1,102,733** hours and **$90,801,169** in costs.

Finally, CMS is adjusting the revised baseline by removing the burden associated with a current IC that has and continues to be accounted for in another collection under the Centers for Disease Control and Prevention (CDC). Specifically, CMS is removing the current estimated burden associated with § 483.80(g)(2) because this burden is accounted for under CDC's OMB Control Number 0920-1317. CMS will continue to identify this IC in this ICR since it

[1] The prior ICR for OMB Control No. 0938-1363/CMS-10573 is titled "Reform of Requirements for Long-Term Care Facilities (CMS-10573)," ICR Reference No. 202407-0938-017, Office of Management and Budget at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202407-0938-017. The ICR for OMB Control No. 0938-1479/CMS-10914 is titled "Reform of Long-Term Care Facilities Requirements for Respiratory Illness Reporting (CMS-10914)," ICR Reference No. 202411-0938-007 at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202411-0938-007. The two information collections included in CMS-10914 were additions to the existing requirements at 42 CFR § 483.80 and would have been included under CMS-10573 but for timing.

[2] CMS refers to this proposed rule as CMS-3484-P or CARE interchangeably.

is associated with an existing requirement for participation for LTC facilities, but will cross-reference the CDC's ICR for the estimated burden in order to avoid double counting this burden.

The quantified PRA effects of the changes under CMS-3442-IFC and CMS-3484-P as well as the separate adjustment to the baseline for an existing IC are summarized below and detailed in Section 15.

Source of Revision	Change in Burden Hours	Change in Burden Costs
Repeal per CMS-3442-IFC	(279,072)	($24,440,832)
Proposed changes per CMS-3484-P	(1,102,733)	($90,801,169)
Baseline Adjustments	(776,152) to (5,447,990)	($70,629,832) to ($495,767,090)
Correction to Prior IC-18[3]	(3,255)	($297,290)
Total Change in Burden	(2,161,212) to (6,833,050)	($186,169,123) to ($611,306,381)

Per the table above, the changes in this revised ICR will reduce the total burden in the prior ICR by 2,161,212 to 6,833,050 hours and $186,169,123 to $611,306,381. Applying these changes to the prior burden total (with some adjustments) in the range of 30,373,250 to 35,045,088 hours and $3,008,433,850 to $3,433,571,108 in costs, the new burden total in this revised ICR is **28,212,038** hours and **$2,822,264,727** in costs. See Section 15 for a summary of all changes.

Background

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.

[3] CMS identified a calculation error in a burden estimate for an IC at § 483.85(e) in the prior approved ICR, which when corrected would reduce the burden for this IC by 3,255 hours and $297,290. Rather than correcting the prior ICR, CMS corrects the error in the current burden estimate for this existing IC (IC-18). For more details of this adjustment, see IC-18 and Section 15.

The ICRs covered in this package do not require a standard form or survey instrument, except for § 483.80(d)(3)(iv). As described in Section B below, 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.

Ordinarily, we would be required to estimate the public reporting burden for information collection requirements for these regulations in accordance with chapter 35 of title 44, United States Code. However, sections 4204(b) and 4214(d) of Omnibus Budget Reconciliation Act of 1987, P.L. 100-203 (OBRA '87) provide for a waiver of Paperwork Reduction Act (PRA) requirements for some regulations. At the time that the 2016 LTC final rule (81 FR 68688) was published, we believed that this waiver still applied to those updates we made to existing requirements in part 483 subpart B that were set forth by OBRA 87. However, we acknowledged that the 2016 final rule also extensively revised many of the existing requirements in part 483 subpart B and recognized that the revisions likely created new burdens for facilities. In addition, we noted that the 2016 final rule implemented several new requirements set forth by the Affordable Care Act, which did not provide a PRA waiver. Therefore, we provided burden estimates for the new ICRs finalized in the 2016 LTC final rule set forth by the Affordable Care Act, as well as those revisions to existing requirements in part 483 subpart B that were so extensive they could be considered new ICRs in concept.

In the prior ICR, we established minimum nurse staffing requirements for LTC facilities at § 483.35 and also created § 483.71 based on the final rule, *Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting*, published on May 10, 2024 (89 FR 40876). This submission reflects two subsequent changes to those requirements: CMS-3442-IFC (90 FR 55687, December 2025) repealed § 483.35(b)(1); and CMS-3484-P proposes to revise § 483.71(b)(1)(ii) to no longer require active involvement of direct care staff representatives. CMS-3484-P also proposes to revise requirements at § 483.15(c)(3)(i) and remove requirements at §§ 483.80(d)(3) and (g) discussed in detail in Section 15.

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. We believe some of the requirements applied to these LTC facilities will impose little burden since a prudent institution will self-impose them in the course of doing business.

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. In addition, sections 1128I (b) and (c) and section 1150B of the Act require that each LTC facility establish a compliance and ethics program, and a quality assurance and performance improvement (QAPI) program and implement requirements to ensure reporting of suspicions of a crime.

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.

Previously, CMS was exempt from reporting the burden associated with the LTC RfPs under the Paperwork Reduction Act (PRA) per sections 4204(b) and 4214(d) of Omnibus Budget Reconciliation Act of 1987, P.L. 100-203 (OBRA '87). Although CMS believed that this exemption/waiver still applied, we provided burden estimates under the PRA when we published updated LTC RfPs in 2016 along with other regulations that were not subject to the exemption.[4] Since then, CMS continues to revise the LTC RfPs with updated burden estimates.

This revised ICR includes changes to the LTC RfPs in two recent rules:

- Medicare and Medicaid Programs; Repeal of Minimum Staffing Standards for Long-Term Care Facilities (CMS-3442-IFC) published on December 3, 2025 (90 FR 55687), which repeals § 483.35(b)(1).[5]
- Medicare and Medicaid Programs; Cutting Administrative Requirements for Excellence in Patient Care ("CARE") (CMS-3484-P) published on [DATE] (91 FR XXXXX), which proposes to revise or remove requirements at §§ 483.15(c)(3)(i), 483.71(b)(1)(ii), and 483.80(d)(3) and (g).

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 an 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 when selecting nursing homes.

3. Use of Improved 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

[4] Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 FR 68688 (October 14, 2016) at https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities.

[5] The original minimum staffing requirement at §483.35(b)(1) was implemented in 2024 per CMS-3442-F, "Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting," 89 FR 40876 (May 10, 2024).

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

CMS published:

- *Medicare and Medicaid Programs; Repeal of Minimum Staffing Standards for Long-Term Care Facilities* (CMS-3442-IFC) published on December 3, 2025 (90 FR 55687), which repeals the IC and burden associated with § 483.35(b)(1); and
- *Medicare and Medicaid Programs; Cutting Administrative Requirements for Excellence in Patient Care* (CMS-3484-P) published on November 10, 2026 (91 FR 72634), which revises ICs and burdens associated with § 483.80.

Through the interim final rule with comment and the proposed rule, CMS will solicit public comment on the regulatory changes and associated information collection requirements, including the burden estimates addressed in this supporting statement. Beyond the notice-and-comment rulemaking process, CMS did not conduct additional external consultation specific to this information collection.

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)

This section presents the estimated burden associated with the active information collections (ICs) in the LTC RfPs at 42 CFR part 483, subpart B (§§ 483.1 through 483.95). This section is organized as follows:

- Part 12-A describes the assumptions used to estimate burden, including the number of LTCs and applicable wage rates.
- Part 12-B presents the burden estimates for each of currently active ICs associated with the LTC RfPs.
- Part 12-C summarizes the total burden hours and costs.

Proposed changes to the LTC RfPs and associated burdens from the following rules are also reflected in this section but discussed in detail in Section 15: “Medicare and Medicaid Programs; Cutting Administrative Requirements for Excellence in Patient Care" (CMS-3484-P) as well as the interim final rule “Medicare and Medicaid Programs; Repeal of Minimum Staffing Standards for Long-Term Care Facilities (CMS-3442-IFC).”

For clarity, this section estimates only those information collections that remain active in this package. For ICs that remain unchanged by CMS-3484-P, CMS retains the burden assumptions for impacted LTC facilities reflected in the currently approved ICR.

Part 12-A: Assumptions

Number of Respondents

For ICs originally established by the Minimum Staffing Standards final rule (CMS-3442-F, 89 FR 40876), this package uses the estimate of 14,688 LTC facilities, consistent with the assumptions used in that rule. For ICs established by the CY 2025 Home Health PPS final rule (CMS-1803-F) related to respiratory illness reporting, this package uses the estimate of 14,926 LTC facilities, consistent with the assumptions used in that rule. For all other ICs, CMS estimated burdens assuming 15,600 LTC facilities and 1,300,000 residents.[6]

Labor Wages

In analyzing information collection costs, we relied on wage and salary information. Unless otherwise indicated, we obtained all salary information from the May 2021 and May 2022 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics (BLS) at https://www.bls.gov/oes/tables.htm#00-0000.[7] Furthermore, where applicable, the wage information for each occupation is based on industry-specific hourly rates for the "nursing care facilities (skilled nursing facilities)" industry. Based on this information, we have calculated the adjusted hourly wage for the personnel and activities required by each LTC RfP based upon the national mean salary for that position increased by 100 percent to account for overhead costs and fringe benefits. The raw wage and salary data from the BLS does not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs supporting each employee. HHS department-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation to these overhead and fringe benefit costs.

Table 1 below presents the BLS occupation code and title, the associated LTC facility staff position in the regulation, the estimated average hourly wage, and the adjusted hourly wage (with a 100 percent markup of the salary to include fringe benefits) for rules issued prior to 2023. Table 2 below presents the BLS occupation code and title, the associated LTC facility staff position in the regulation, the estimated average hourly wage, and the adjusted hourly wage (with a 100 percent markup of the salary to include fringe benefits) for rules issued in 2023. In addition, throughout this analysis, any amount that results in a number ending with .50 or more will be rounded up to the next nearest dollar amount and those that end with .49 or less or rounded down to the next nearest dollar.

For ICs established by CMS rules after 2024, burden costs were estimated based on the wage assumptions used in that rule.

Table 1 – Wage Summary for Rules Issued Prior to 2023

[6] CMS will update facility assumptions for all ICs in the next revision of this ICR.

[7] CMS will update wage assumptions for all ICs in the next revision of this ICR.

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	May 2021 Mean Hourly Wage[8] ($/hour)	Adjusted Hourly Wage ($/hour)
29-1228	Physicians, All Others (Management of Companies and Enterprises)	Medical Director, Attending Physician	$138.22	$276
29-1141	Registered Nurses (Nursing Facilities/Skilled Nursing Facilities)	Registered Nurse (RN), Infection Preventionist (IP)	$34.74	$69
11-9111	Medical and Health Services Managers (Nursing Facilities/Skilled Nursing Facilities)	Director of Nursing (DON), Administrator, Compliance Officer	$46.81	$94
21-1022	Healthcare Social Workers (Nursing Facilities/Skilled Nursing Facilities)	Social Worker	$26.69	$53
31-1131	Nursing Assistant (Nursing Facilities/Skilled Nursing Facilities)	Nurse Aide	$15.43	$31
29-1031	Dietitians and Nutritionists (Nursing Facilities/Skilled Nursing Facilities)	Dietitian	$30.98	$62
43-6013	Medical Secretaries and Administrative Assistants	Administrative Assistant	$19.11	$38

Table 2 - Wage Summary for Rules Issued in 2023

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	May 2022 Mean Hourly Wage[9] ($/hour)	Adjusted Hourly Wage ($/hour)
29-1229	Physicians, All Others (Specialty (except Psychiatric and Substance Abuse)	Medical Director	$135.86	$272
29-1141	Registered Nurses (Nursing Facilities/Skilled Nursing Facilities)	Registered Nurse (RN), Infection Preventionist (IP)	$37.11	$74
29-2061	Licensed Practical and Licensed Vocational Nurses (Nursing Care Facilities/Skilled Nursing Facilities)	Licensed Nurse	$28.10	$56
11-9111	Medical and Health Services Managers (Nursing Facilities/Skilled Nursing Facilities)	Director of Nursing (DON), Administrator	$49.91	$100
31-1131	Nursing Assistant (Nursing Facilities/Skilled Nursing	Nurse Aide/Certified	$16.90	$34

[8] May 2021 National Occupational Employment and Wage Estimates by Industry, Bureau of Labor Statistics (BLS), U.S. Department of Labor, at https://www.bls.gov/oes/2021/may/oessrci.htm. For LTC-specific wages, see wage table for "NAICS 623100 - Nursing Care Facilities (Skilled Nursing Facilities)" at https://www.bls.gov/oes/2021/may/naics4_623100.htm

[9] May 2022 National Occupational Employment and Wage Estimates by Industry, Bureau of Labor Statistics (BLS), U.S. Department of Labor, at https://www.bls.gov/oes/2022/may/oessrci.htm.

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	May 2022 Mean Hourly Wage ($/hour)	Adjusted Hourly Wage ($/hour)
	Facilities)	Nursing Assistant (CAN)		
29-1031	Dietitians and Nutritionists (Nursing Facilities/Skilled Nursing Facilities)	Dietitian/Food and Nutrition Manager	$31.63	$63
43-6013	Medical Secretaries and Administrative Assistants (General Medical and Surgical Hospitals)	Administrative Assistant	$20.30	$41
11-3013	Facilities Manager	Facilities Manager	$50.96	$102

Part 12-B: Burden Estimates

This section presents burden estimates for the currently active ICs under the LTC RfPs at 42 CFR part 483, subpart B, following consolidation of the previously approved ICRs for CMS-10573 and CMS-10914.[10] The consolidated burden total shown in Table 4 and Part 12-C establishes the new baseline against which this revised ICR measures the change in burden detailed in Section 15.

The current ICs are associated with the following RfPs for LTC facilities:
42 CFR §§ 483.10(c)(2); 483.10(g)(17); 483.15(c)(3); 483.21(a)(1); 483.21(b)(2); 483.21(c)(2); 483.25(n)(2); 483.60(c)(4); 483.71(b)(1)(iii); 483.71(c)(4); 483.75; 483.80(d)(3); 483.80(d)(3)(iv); 483.80(f); 483.80(g); 483.80(g)(2); 483.80(h); 483.85(e).

For ICs unchanged by recent rulemaking, CMS retains the burden estimates from the prior approved ICR. For ICs modified or removed by recent rulemaking that affect the total burden in this ICR (the "baseline"), CMS applies the burden assumptions from the prior ICR—rather than those used in the rule—to determine the PRA impact, since the rule's estimated burden change reflects the most current respondent count and hourly wage rate at the time of implementation, which differ from those used in the prior ICR. All changes to prior ICs and associated burdens resulting from recent rulemaking are summarized in Section 15 and Table 5 .

IC-1: § 483.10(c)(2) - Notification of Changes to Care Plan

Existing regulations require that a resident, to the extent practicable, participate in the development of his or her care plan and be informed of the need to significantly alter treatment. We believe that the involvement and notification will include an opportunity to see the care plan. Periodic review after development of the care plan is also already required. Section 483.10(c)(2) provides that the resident has the right to sign the care plan. This demonstrates his or her participation in and review of his or her care planning and that participation is evident to care-givers, surveyors, and other interested parties.

We estimate that it will take a registered nurse (RN), with an adjusted hourly wage of $69, no more than an additional 2 minutes (0.033 hrs.) to obtain each resident' signature. We estimate that this may occur up to four times per year per resident for an annual total of 0.0133 hrs. per resident. Based on an estimated 1.3 million

[10] The prior ICR for OMB Control No. 0938-1363/CMS-10573 is titled "Reform of Requirements for Long-Term Care Facilities (CMS-10573)," ICR Reference No. 202407-0938-017, Office of Management and Budget at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202407-0938-017. The ICR for OMB Control No. 0938-1479/CMS-10914 is titled "Reform of Long-Term Care Facilities Requirements for Respiratory Illness Reporting (CMS-10914)," ICR Reference No. 202411-0938-007 at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202411-0938-007

residents per year, the resulting burden hours are 173,333 hours (1,300,000 residents X 0.1333 hrs.). The cost is $11,959,977 (173,333 hrs. x $69).

§§ 483.10(f)(4)(v) and (vi) - Visitation Policy

Section 483.10(f)(4)(v) requires facilities to have written policies and procedures regarding the visitation rights of residents. The policies and procedures must address any clinically necessary, safety related, or reasonable restrictions or limitations that may be placed on the visitation rights of residents. In addition, § 483.10(f)(4)(vi) requires that facilities must inform residents of their visitation rights.

The burden associated with this activity is the one-time burden associated with initially developing such policies and procedures, as well as develop any materials that would be used to inform the residents of their visitation rights. There is also the ongoing burden associated with updating such policies and procedures as appropriate. All 15,600 LTC facilities should have already developed their visitation policies and procedures, as well as any materials used to communicate visitation rights to the residents. Since the requirement went into effect in 2016, LTC facilities would likely have had and will continue to update these policies and procedures and other materials periodically. For example, beginning in 2020, the CDC issued specific guidance for visitation in LTC facilities due to the COVID-19 pandemic.[11] However, the burden for any changes required by the COVID-19 pandemic or any other infection prevention or control issue in the LTC facility would be accounted for in the burden under § 483.80 Infection control. We believe that any other updates or changes for other reasons would be considered usual and customary business practice for a health care provider. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

IC-2: § 483.10(g)(17) - Notification of Medicaid Eligibility

Existing regulations require facilities to provide notice to a resident of their Medicaid eligibility. Section 483.10(g)(17) requires facilities to provide an additional notice to residents who are not eligible for Medicaid at admission, when they do become eligible. This means some residents will require both a notice at admission and a second notice. As the notice of Medicaid eligibility is already required once, the additional burden is associated with providing the notice an additional time.

We anticipate that this would likely affect only a subset of residents (those eligible but not yet receiving Medicaid). Thus, based on a data analysis by the American Health Care Association (AHCA), approximately 64 percent of LTC facility residents are already Medicaid recipients (that is, Medicaid is the payor of record), 14 percent are covered by Medicare, and 22 percent have another payor. Of those, only the 36 percent who are not receiving Medicaid may require the second notice of Medicaid eligibility. We assume that a portion of those may require ongoing care and become eligible for Medicaid. We also assume that some of those residents would apply for Medicaid at or shortly after admission or as a result of the first notice and not require the second notice. Based on these assumptions, we estimate that 20 percent of LTC facility residents or 260,000 residents (1.3 million residents x 20%) (slightly more than half of those not already receiving Medicaid) will require a second notice of Medicaid eligibility.

We anticipate that a social worker, with an adjusted hourly wage of $53, would track a resident's status of Medicaid eligibility and provide the notice. We estimate that this would require an additional 5 minutes (0.083 hrs.) of a social worker's time to provide the notice and communicate with each resident. Hence, the burden for each resident or notification is 0.083 hours at a cost of $4 (0.083hrs. x $53). The annual burden for all 260,000 notifications across all LTC facilities would be 21,658 hours (0.083hrs. x 260,000 notifications) at a cost $1,147,874

[11] Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes Nursing Homes & Long-Term Care Facilities. CDC. Accessed at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html. Updated March 29, 2020. Accessed on April 15, 2021.

(21,658 hrs. x $53). We note that the actual per facility cost will vary significantly according to facility size and resident mix.

§ 483.10(j)(4) - Grievances

Facilities are required to establish a grievance policy to ensure the prompt resolution of all grievances. Facilities must notify residents, individually or through postings, of their right to file grievances orally (meaning spoken) or in writing; the right to file grievances anonymously; the contact information of the grievance official with whom a grievance can be filed, that is, his or her name, business address (mailing and email) and business phone number; a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding his or her grievance; and the contact information of independent entities with whom grievances may be filed. In addition, facilities are required to maintain evidence demonstrating the results of all grievances for a period of no less than 3 years from the issuance of the grievance decision.

The implementation deadline for this requirement was November 28, 2016. Hence, all 15,600 LTC facilities should have already experienced the one-time burden associated with developing the grievance policy and any related materials for their facility. LTC facilities might need to update their policies, procedures, and related materials periodically due to health or business concerns. However, we believe that any updates or changes that are required would be considered usual and customary business practice for a health care provider. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

Concerning the requirement for LTC facilities to retain grievance documentation for no less than 3 years from the issuance of the grievance decision, we expect that facilities already have systems in place to store business records. As such, we believe that records of grievance decisions would be stored in these existing systems and any resulting burden would be absorbed by the facility's existing business practices for maintaining records rather than a new burden. Thus, this activity would not be subject to the PRA in accordance with the implementing of regulations of the PRA 5 CFR 1320.3(b)(2).

IC-3: § 483.15(c)(3) - Notice of Transfer or Discharge

Section 483.15(c)(3) requires LTC facilities to notify the resident and the resident representative of a transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The LTC facility must also send a copy of this notice to the Office of the State Long-Term Care Ombudsman (OSLTCO). Based upon our experience with LTC facilities, although a small number of LTC facilities might send a hard copy of the notice to the OSLTCO, we believe most LTC facilities would provide this notice electronically. LTC facilities would likely mutually decide the manner of delivery with their state's OSLTCO. We have no way to accurately estimate the percentage of LTC facilities that send these notices through the mail. Thus, for the purpose of providing a burden estimate for this requirement, we will assume that the notices are provided electronically.

The burden for this activity is the time to create the notice and provide it to the resident or resident representative and forward a copy to the OSLTCO. We believe an administrator at an adjusted hourly wage of $94 would prepare the notice and this would require 10 minutes (0.167 hrs.). For the copy to be forwarded to the OSLTCO, we estimate that an administrative assistant at an hourly cost of $38 would require 5 minutes (0.083 hrs.) to forward a copy of the notice to the OSLTCO. Thus, sending each notice would require 15 minutes (0.25 hrs.) at a weighted cost of $19 (($94 x 0.167 hrs.) + ($38 x 0.083 hrs.)). Per facility costs will vary significantly according to facility size and number of transfers and discharges that occur in each facility. Based on our experience with LTC facilities, we estimate that about one-third or 429,000 residents might require these notices annually. Thus, the annual burden to send 429,000 notices across all 15,600 LTC facilities would be 107,250 hours (0.25 hrs. x 429,000 notices) at a cost of $8,151,000 ($19 x 429,000).

Proposed CARE Change: CMS-3484-P proposes to modify (c)(3)(i) by requiring LTC facilities to send a copy of transfer/discharge notice to OSLTCO, except when the resident is transferred on an emergency basis to an acute care facility. LTC facilities must continue to notify residents before all transfers or discharges and to send a copy of the notice to the Ombudsman for only non-emergent transfers or discharges. The proposed change would result in 307,923 fewer notices, leaving 121,077 notices (429,000 – 307,923) that must still be sent each year across all LTC facilities. The proposed change would decrease the burden by 76,981 hours (0.25 hrs. x 307,923 notices) and $5,850,537 ($19 x 307,923) in costs.[12] The revised annual burden for IC-3 after the proposed changes in CMS-3484-P is 30,269 hours (0.25 hrs. x 121,077 notices) at an estimated cost of $2,300,463 ($19 x 121,077).

IC-4: § 483.21(a)(1) - Baseline Care Plan

Section 483.21(a)(1) requires facilities to develop and implement a baseline care plan for each resident that includes the instructions needed to provide effective and person-centered care of the resident that meet professional standards of quality care. We believe, based on our experience with LTC facilities, that facilities are currently developing some type of interim care plan for residents, prior to developing the comprehensive care plan required at 483.21(b), in order to provide residents with the necessary and appropriate care upon admission into the facility. Furthermore, we expect that the information necessary to complete the baseline care plan will be readily available or accessible through discussions and follow-up upon admission.

Thus, we believe that the need to formally document a baseline care plan and gather the required information would require 1 hour of an RN's time at a cost of $69 for each newly admitted resident. The number of admissions for each LTC facility will vary substantially. Thus, we will not estimate the burden for each facility but for all the LTC facilities. According to CMS, in calendar year 2020, there were 4,849,712 admissions or entries into LTC facilities.[13] Of that number, approximately 60 percent of those admissions or 2,909,827 (60% x 4,849,712) were for new residents. The other 40 percent were for reentries or readmissions. Thus, for the purpose of this analysis, we will estimate the burden for all LTC facilities for 2,909,827 new admissions who need a baseline care plan prepared. Hence, the burden for all new admissions across all 15,600 LTC facilities would be 2,909,827 hours (1 hr. x 2,909,827 new admissions) at a cost of $200,778,063 (2,909,827 hrs. x $69).

IC-5: § 483.21(b)(2) - Comprehensive Care Plan

Section 483.21(b)(2) requires a comprehensive care plan for each resident to be developed by an interdisciplinary team (IDT) that includes the attending physician, an RN with responsibility for the resident, a nurse aide with responsibility for the resident, and a member of food and nutrition services staff. Depending upon the resident's needs or his or her requests, other appropriate staff or professionals should be added to the IDT. For example, a resident with emotional or mental health needs may need to have a mental health professional on the IDT or a resident that is undergoing extensive physical therapy may need a physical therapist on the IDT. To the extent practicable, the resident and his or her representative should participate in the IDT meetings. If this is not practicable, the explanation for their participation not being practicable must be documented in the resident's medical record.

We believe that this requirement would add to the current duties of each of these staff members. We expect that communications about the status of a resident are a part of standard job duties and anticipate that these staff members are already regularly discussing resident needs and their plans of care. When quantifying the amount of additional burden associated with this requirement, we believe that this requirement will produce an incremental

[12] Note that because CMS assumes a different respondent count and hourly wage rate in CMS-3484-P to estimate the change in burden hours and costs, those estimates will differ from the burden reduction in the PRA inventory.

[13] Minimum Data Set 3.0 Public Reports. MDS 3.0 Frequency Report. "A1700 Identification Information – Type of Entry." Accessed at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/Minimum-Data-Set-3-0-Frequency-Report. Accessed on April 27, 2021.

increase in the staff time necessary to participate on the IDT. We do not specify the type of communication the IDT must use. IDT members may use electronic communication as well as informal discussions to participate in IDT meetings. In addition, one member of the IDT, probably the RN, would need to update the resident's comprehensive care plan. If it is not practicable for the resident or the resident representative to participate in the IDT meetings, the RN would also need to document the reasons for that in the resident's medical record. We believe that the RN would likely update the care plan and make any other necessary documentation to the resident's medical record during the meeting. While we do not require that a dietitian participate on the IDT, for purposes of estimating the cost we will use the salary of a dietitian for the cost estimate.

Therefore, we estimate that participation on the IDT would require an additional one hour for each participant for each meeting at the following adjusted hourly wage: the attending physician at $276 , an RN at $69, a nursing aide at $31, and a member of the food and nutrition services staff at $62. The burden for each meeting would be 4 hours at an estimated cost of $438 ($276 + $69+ $31 + $62). The IDT would need to meet at least four times a year after each quarterly assessment ($483.21(b)(iii)). Thus, for each resident the LTC facility's burden would be 16 hours (4 hrs. x 4 meetings) annually at a cost of $1,752 ($438 x 4 meetings). The burden for all 1,300,000 residents in the 15,600 LTC facilities would be 20,800,000 hours (16 hrs. x 1,300,000 residents) at a cost of $2,277,600,000 ($1,752 x 1,300,000).

§483.21(c)(1) - Develop Discharge Planning Process

Section 483.21(c)(1) requires facilities to develop and implement a discharge planning process that focuses on the resident's discharge goals, the preparation of residents to be active partners and effectively transition them to post-discharge care, and the reduction of factors leading to preventable readmissions. This includes identifying the discharge needs of each resident and developing a discharge plan; regular re-evaluation of residents to identify changes and subsequent updates/revisions to the discharge plan, as needed; involvement of the IDT in the ongoing process of developing the discharge plan; and documenting that a resident has been asked about their interest in receiving information regarding returning to the community. For residents who are transferred to another SNF or who are discharged to a HHA, IRF, or LTCH, § 483.21(c)(1)(viii) requires facilities to assist residents and their resident representatives in selecting a post-acute care provider by using data that includes, but is not limited to SNF, HHA, IRF, or LTCH standardized patient assessment data, data on quality measures, and data on resource use. The facility also must ensure that the post-acute care standardized patient assessment data, data on quality measures, and data on resource use is relevant and applicable to the resident's goals of care and treatment preferences. All 15,600 LTC facilities should have already developed their discharge planning process. We also believe that the discharge planning activities would be incorporated into the meetings for the comprehensive care planning. Hence, we are not quantifying any additional burden for this activity.

§483.21(c)(1)(ix) – Document Discharge Plan

Section 483.21(c)(1)(ix) requires LTC facilities to document the IDT's evaluation of the resident's discharge needs and discharge plan in the resident's medical record. This documentation must be made and updated on a timely basis. If the IDT determines that return to the community is not feasible, the resident's medical record must be documented with that determination and the rationale for it.

We believe that the RN would likely document the resident's medical record with the necessary information. The amount of time required for this documentation would vary depending upon the complexity of the resident's healthcare and discharge needs. For LTC residents with an established care routine, this would likely require a minimal amount of time, whereas it would require more time for a resident with complex needs with a goal of returning home in the near future. For the purpose of this analysis, we estimate that this documentation would

require an average of 1 hour of an RN's time annually for each resident. According to Table 1, the adjusted hourly wage for an RN is $69. Hence, the burden to each LTC facility would be 1 hour at an estimated cost of $69 for each resident. However, we believe that this documentation would likely be performed during the IDT meetings as discharge planning was being discussed. Hence, we will not be assessing a separate burden for this activity since it would be included in the burden for the IDT meetings.

IC-6: § 483.21(c)(2) - Discharge Summary

Section 483.21(c)(2) requires that the facility develop a discharge summary when it anticipates that a resident will be discharged. The discharge summary must include, but is not limited to, a recapitulation of the resident's stay, a final summary of the resident's status, a reconciliation of all pre-discharge medications with the resident's post-discharge medications, and a post-discharge plan of care. We believe an RN would prepare the discharge summary. The amount of time required for the discharge summary would vary greatly among residents.

For the purpose of this analysis, we estimate that it would take an average of 1 hour for the RN to complete the discharge summary for each resident. The number of residents for which a facility must prepare a discharge summary for annually would vary greatly depending upon the number of discharges every year. Hence, we will not be able to estimate a burden for individual LTC facilities but will estimate the burden for all 15,600 facilities. For the purpose of this analysis, we estimate that one-third of the estimated 1.3 million residents, or 429,000 (33% x 1,300,000) would require a discharge summary annually. Thus, the burden across all LTC facilities would be 429,000 hours (1 hr. x 429,000 residents) at an estimated cost of $29,601,000 (429,000 hrs. x $69).

IC-7: § 483.25 – Informed Consent for Bed Rails

Section § 483.25(n)(2) states that the LTC facility must review the benefits and risks of bed rails with the resident or resident representative and obtain informed consent prior to installation. The burden associated with this requirement is the time it would take to review the benefits and risks with the resident or the resident representative and obtain informed consent or to document their refusal. We believe that each LTC facility would develop a form for the resident or resident representative to sign and have already done so. We believe this information would need to be presented to all new admissions. Current and readmitted residents should have already had this discussion with the RN, and this should be documented in the resident's medical record. We estimate that it would take a registered nurse 10 minutes (0.1667 hrs.) at a cost of about $12 ($69 x 0.1667 hrs.) to discuss this information with the new resident or resident representative. As noted above in IC-4, we have estimated that there are 2,909,827 new residents admitted annually to LTC facilities. Hence, the total burden across all 15,600 LTC facilities is 485,068 hours (0.1667 hrs. x 2,909,827 new admissions) at a cost of $33,469,692 (485,068 hrs. x $69).

§ 483.55 - Dental Services

Section 483.55(a)(3) and 483.55(b)(4) states that a facility may not charge a resident for the loss of or damage to dentures when the loss or damage is the responsibility of the LTC facility. Hence, the facility must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility. The burden associated with this requirement is the time it would take to develop a policy for such circumstances. At this time, all 15,600 should have incurred the one-time burden associated with the development of a policy that complies with this requirement. We believe that any updates or changes that are required would be considered usual and customary business practice for a health care provider. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

IC-8: § 483.60(c)(4) – Facility Menu

Section 483.60(c)(4) requires facilities to have menus that reflect the cultural and ethnic needs of residents. We expect that LTC facilities will have their menus updated by a qualified dietitian or other clinically qualified nutrition professional after reviewing the facility's facility assessment and conferring with other staff and residents. At this time, we believe that all LTC facilities have prepared menus that comply with this requirement. However, as new residents are admitted to LTC facilities, the facility would need to reassess its menus and make any necessary changes. We anticipate this will require an average of 2 hours annually for the dietician at a cost of $62 an hour to review the facility assessment, confer with other staff and residents, and make any changes to the menus. Hence, we estimate the annual burden for each LTC facility to be 2 hours at a cost of $124 (2 hrs. x $62). For all 15,600 LTC facilities, the burden would be 31,200 hours (2 hrs. x 15,600 LTCs) at a cost of $1,934,400 (31,200 hrs. x $62).

§ 483.60(i)(3) – Policy for Food Storage

Under the food safety requirements at § 483.60(i)(3), facilities are required to have a policy regarding use and storage of foods brought to residents by family and other visitors to ensure safe and sanitary storage, handling, and consumption of the food. Since the facility staff would assist the resident with storing or reheating the food, it is important for a facility to have guidelines or policies to ensure safe food handling and consistent application of food handling practices. At this time, all 15,600 LTC facilities should have incurred the one-time burden associated with the development of the policies that comply with this requirement. Therefore, we will not estimate an additional or ongoing burden for this requirement.

§ 483.71 – Facility Assessment

In the 2024 final rule CMS-3442-F, the requirements in § 483.70(e) from the "Administration" section was relocated to a new standalone section 483.71, entitled "Facility Assessment". Therefore, the existing and new ICR burdens discussed in this section will now be associated with § 483.71. Specific requirements were also modified and add a third section that sets forth the activities for which we expect LTC facilities to use their facility assessments was added.

Section 483.71 requires each facility to conduct, document, and annually review a facility-wide assessment to determine what resources are necessary to care for its residents competently during both daily operations and emergencies. Facilities are required to address in the facility assessment the facility's resident population (that is, number of residents, overall types of care and staff competencies required by the residents, and cultural aspects), resources (for example, equipment, and overall personnel), and a facility-based and community-based risk assessment.

At this time, we believe that all LTC facilities have already incurred the one-time burden associated with the development of a formal process, including policies and procedures, on how to do their facility assessments and completed their initial facility assessment that complies with these requirements. Therefore, we are not including an estimate for a burden for these activities.

Section 483.71(a)(1)(i) through (v) sets forth what the facility assessment must address or include, but is not limited to, regarding the facility's resident population. At § 483.71(a)(1)(ii), we propose to add ''using evidence-based, data-driven methods'' and ''behavioral health issues'' so that the requirement would now reads, ''(ii) The care required by the resident population, using evidence based, data driven methods that consider the types of diseases, conditions, physical and behavioral health issues, cognitive disabilities, overall acuity, and other pertinent facts that are present within that population;''. At § 483.71(a)(1)(iii), we added, ''and skill sets'' so the requirement reads, (iii) The staff competencies and skill sets that are necessary to provide the level and types of care needed for the resident population. We believe these modifications constitute clarifications in the requirements and are not

new requirements for which the LTC facilities must comply. Hence, we will not be analyzing any new or additional burden related to these changes.

At § 483.71(a)(2)(iii), we added ''behavioral health'' so that the requirement reads, (iii) Services provided, such as physical therapy, pharmacy, behavioral health, and specific rehabilitation therapies. Behavioral health services requirements are set forth at § 483.40 and are integral to the health of residents. All LTC facilities should be considering the behavioral health care needs of their residents. Hence, this change does not constitute a new requirement but a clarification. Hence, we will not be analyzing any new or additional burden related to this change.

§ 483.71 – Review & Update Facility Assessment

LTC facilities are required to review and update their facility assessment at least annually. All LTC facilities should have completed their original facility assessment. We believe that any updates or changes that are required would be considered usual and customary business practice for a health care provider. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

§ 483.71(b)(1)(i) and (ii) – Staff Input for Facility Assessment

Section 483.71(b)(1) requires LTC facilities to ensure active involvement of facility staff and their representatives when conducting their facility assessment. These staff categories include, but are not limited to a) nursing home leadership, management at (b)(1)(i); b) direct care staff (including, but not limited to RNs, LPNs/LVNs, NAs; and representatives of the direct care staff and other service workers at (b)(1)(ii)). We believe that LTC facilities already include many of these categories of individuals when they conduct or update their facility assessments. Thus, this requirement constitutes a clarification and not a new requirement. Hence, we will not be analyzing any new or additional burden related to this change.

Proposed CARE Modification: CMS-3484-P proposes to amend (b)(1)(ii) to remove the required active involvement of representatives of direct care staff while maintaining all other requirements for staff input. There is no burden reduction from this modified requirement because there is no IC or associated burden. See Section 15 for a summary of all changes.

IC-9: § 483.71(b)(1)(iii) – Resident Input for Facility Assessment

Section 483.71(b)(1)(iii) requires LTC facilities to solicit and consider input received from residents, resident representatives, and family members in performing their facility assessment.

For an LTC facility to solicit input from residents, resident representatives, and family members would require the LTC facility to identify all of these individuals, make them aware of the facility assessment process, and then solicit their input. LTC facilities differ in how they communicate to the named individuals. Although LTC facilities are not required to establish resident or family groups, residents do have the right to organize and participate in resident groups (§ 483.10(f)(5)). If residents do form resident or family groups, the LTC facility must provide the group(s) with private space for them to meet and take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner. Based upon our experience, most LTC facilities have established resident or family groups. LTC facilities could easily use these established communications pathways, as well as posting notices and sending emails to solicit input for the facility assessment from the named individuals.

To comply with the requirement to solicit the input of these individuals identified in the facility assessment requirement, we estimate this requires an LTC Administrator 1 hour at $100 (1 hr. x $100) to draft the text of the communication and then an Administrative Assistant 2 hours at $82 (2 hrs. x $41) to forward the communication to the required individuals. The text of the communication should include a brief description of the facility

assessment process, the opportunity to submit input, how that input can be submitted, and the deadline to submit the input. This would likely include posting of a notice in the LTC facility and forwarding the communication to the facility's resident or family group(s). The consideration of this input will then be part of the facility assessment review and updating process.

Hence, the burden for each LTC facility is 3 hours at an estimated cost of $182 ($100 + $82). For all 14,688 LTC facilities, the total estimated burden is 44,064 hours (14,688 LTCs × 3 hrs.) at a cost of $2,673,216 ($182 × 14,688 LTCs).

IC-10: § 483.71(c)(4) - Develop Recruitment/Retention Plan

A new section, § 483.71(c) was added. These requirements set forth specific activities for which the LTC facilities are expected to use their facility assessments. These assessments would inform staffing decisions to ensure that a sufficient number of staff with the appropriate competencies and skill sets necessary to care for its residents' needs as identified through resident assessments and plans of care as required in § 483.35(a)(3); consider specific staffing needs for each resident unit in the facility, and adjust as necessary based on changes its to resident population; consider specific staffing needs for each shift, such as day, evening, night, and adjust as necessary based on any changes to its resident population; and, develop and maintain a plan to maximize recruitment and retention of direct care staff. We believe that LTC facilities are either already using their facility assessments for these activities or will be based upon the other requirements in this proposed rule, except for using their facility assessments to develop and maintain a plan to maximize recruitment and retention of direct care staff. Based upon our experience with LTC facilities, these facilities are already working on recruitment and retention of direct care staff. However, we also believe these facilities would need to review their current efforts to determine if there are opportunities to improve their efforts and, if so, decide how to do so.

The LTC facility's facility assessment would require the development of a plan to maximize recruitment and retention and accomplish the associated tasks and would also be an invaluable tool in assessing and maintaining sufficient staff for their facility. The staff involved in developing this plan would vary by the type of care and services provided by the individual facilities.

Some LTC facilities might have various therapists on staff, such as physical and occupational therapists. Others might employ psychologists, social workers, or complementary medicine or American Indian/Alaska Native Traditional Healers who provide behavioral health services to residents. When developing a recruitment and retention plan, we encourage LTC facilities to include participation, or at least input, from the various types of direct care staff in their facilities and representatives of these workers, although the hours worked by those staff cannot be used as substitutes for the direct care minimums for RNs and NAs required under this rule. All LTC facilities provide 24-hour nursing services and the direct care nursing staff would include RNs, other licensed nurses (LPNs or LVNs), and nursing assistants (NAs).

For the purpose of estimating the burden for developing a recruitment and retention plan, we estimate the burden for an administrator, the DON, and one individual from each nursing category (an RN, an LPN/LVN, and an NA) to develop the plan. These individuals would have to meet to develop a plan and then the administrator will need to obtain approval for the plan from the governing body. During the development process and after approval, an administrative assistant would need to provide support and ensure the plan is disseminated and save appropriately in the facility's records. We estimate that developing a recruitment and retention plan would require 10 hours for an LTC Administrator at a cost of $1,000 (10 hrs. x $100); 10 hours for the DON at a cost of $1,000 (10 hrs. x $100); 8 hours for an RN at a cost of $592 (8 hrs. x $74); 4 hours for an LPN/LVN at a cost of $224 (4 hrs. x $56); 5 hours for a Nursing Assistant at a cost of $170 (5 hrs. x $34); and 3 hours for an Administrative Assistant at a cost of $123 (3 hrs. x $41). Thus, the burden for each LTC facility is 40 hours (10 + 10 + 8 + 4 + 5 + 3) at an

estimated cost of $3,109 ($1,000 + $1,000 + $592 + $224 + $170 + $123). For all 14,688 LTC facilities, the burden would be 587,520 hours (40 hrs. x 14,688 LTC facilities) at an estimated cost of $45,664,992 ($3,109 × 14,688 LTC facilities).

§ 483.73 - Emergency Preparedness

The burden associated with the emergency preparedness requirements at § 483.73 is not included in this LTC RfPs PRA package. That burden is accounted for separately under OMB Control No. 0938-1325, "Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers."

Proposed CARE Change: CMS-3484-P proposes to revise §§ 483.73(e) and (g) to update the standards applicable to LTC facilities; emergency and standby power systems, including the incorporated editions of NFPA 99, NFPA 101, and NFPA 110. Consistent with the collection of information analysis for CMS-3484-P, CMS does not estimate a change in burden associated with these revisions because the code updates primarily concern physical facility requirements rather than recordkeeping requirements.

IC-11: § 483.75 - Maintain Quality Assurance and Performance Improvement (QAPI) Program

Section 483.75 requires LTC facilities to maintain a Quality Assurance and Assessment (QAA) committee consisting of the DON, the Medical Director or his or her designee, at least three other members of the facility's staff, and the infection preventionist (IP). The committee must meet at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary. The committee is required to develop and implement appropriate plans of action to correct identified quality deficiencies. Section 483.75 also requires each facility to have a QAPI program and to maintain documentation to demonstrate evidence of its ongoing QAPI program. We believe that all 15,600 LTC facilities have already incurred the one-time burden associated with the establishment of their QAA committees and QAPI programs. Thus, we will not assess a burden for establishing either of these entities.

Concerning the annual burden for the QAA and QAPI program, the LTC facility would need to maintain its QAPI program and its QAA committee that is responsible for coordinating, evaluating, and reporting on the QAPI program activities. For purposes of this analysis and considering the magnitude of their responsibilities, we believe that these activities would require an average of 2 hours each quarter or 8 hours a year for each of the following positions at the indicated hourly wage: the DON at $94; the Medical Director at $276; the IP at $69; an LTC Administrator at $94; an RN at $69; and a Nursing Aide at $31. The burden for each LTC facility would be 48 hours (8 hrs. x 6 staff members) at an estimated cost of $5,064 (8 hrs. x $633 ($94 + $276 + $69 + $94 + $69 + $31)). The burden for all 15,600 LTC facilities would be 748,800 hours (48 hrs. 15,600 LTCs) at an estimated cost of $78,998,400 ($5,064 x 15,600 LTCs).

Section 483.80 Infection Control

This section encompasses all of the ICRs for § 483.80 for the 2016 final rule and other rules in Table 2 above. Please note that in the September 2020 Testing IFC, we originally indicated that a PRA package with a new OMB Control Number would be submitted (85 FR 54859); however, CMS reconsidered whether a separate PRA package was necessary and concluded that it was sufficient to include the burden for that IFC in this 2022 PRA package.

§ 483.80(a) – Establish Infection Prevention and Control Program (IPCP)

Section 483.80(a) requires each LTC facility to establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

Specifically, § 483.80(a)(1) states that the facility must establish an IPCP for the prevention, identification, reporting, investigation, and control of infections and communicable diseases. Section 483.80(a) requires that the IPCP include policies and procedures for a system of surveillance designed to identify possible communicable diseases and infections before they can be transmitted to others; when and to whom possible incidents of communicable diseases and infections should be reported to; standard, transmission-based precautions, including the type of isolation, depending upon the infectious organism involved; the circumstance under which the LTC facility must prohibit employees with a communicable disease or infected skin lesion from direct contact with residents or their food, if applicable; hand hygiene procedures to be followed by staff with direct resident contact; an antibiotic stewardship program (ASP), which includes antibiotic use protocols and a system to monitor antibiotic use; and, a system for recordkeeping incidents identified under the LTC facility's IPCP and what corrective actions were taken by the facility.

At this point, all LTC facilities should have established their IPCP programs, including the development of the policies and procedures required in § 483.80(a).

IC-12: § 483.80(f) – Annual Review of Infection Prevention and Control Program (IPCP)

Section 483.80(f) requires LTC facilities to conduct an annual review of its IPCP and update their program, as necessary. Each LTC facility should have at least one infection preventionist (IP) who is responsible for the facility's IPCP, which must be maintained, and works at least part-time at the facility.

In the 2019 PRA package for the LTC requirements, we estimated that the infection preventionist (IP) would need to spend 1 hour per quarter or 4 hours annually to document the IPCP program. Upon review, we believe that 4 hours annually would be insufficient for an IP to maintain the IPCP. The IP would be responsible for the documentation regarding communicable diseases and infections for the IPCP, the surveillance system, the system for recording incidents of communicable disease and infections in the facility and what, if any, corrective action is taken, as well as the ASP and any other documentation related to the IPCP. In maintaining the IPCP, he or she would also need to stay current with IPC topics to ensure that any appropriate updates or modifications to the IPCP are made in a timely manner.

Based upon our experience with LTC facilities, we are revising our estimate from 1 hour per quarter or 4 hours annually to 10 hours a month, or 120 hours annually, for the IP to maintain and document the IPCP activities. Thus, for each LTC facility the annual burden would be 120 hours (10 hrs. x 12 months) at an estimated cost of $8,280 (120 hrs. x $69). For all 15,600 LTC facilities, the annual burden would be 1,872,000 hours (120 hrs. x 15,600 LTCs) at an estimated cost of $129,168,000 ($8,280 x 15,600 LTCs) or (1,872,000 hrs. × $69).

The separate burden associated with updating IPCP policies and procedures to implement the respiratory illness reporting requirements at § 483.80(g) is addressed under that information collection and does not replace or reduce the burden associated with maintaining the overall IPCP under § 483.80(a).

Section 483.80(d) - Influenza, pneumococcal, and COVID-19 Immunizations

IC-13: § 483.80(d)(3) – Initial Development of COVID Education Policies and Procedures

At § 483.80(d)(3), we require that LTC facilities develop policies and procedures to ensure that each resident and staff member is educated about the COVID-19 vaccine. Specifically, before offering the COVID-19 vaccine, all staff members and residents or resident representatives must be provided with education regarding the benefits and risks and potential side effects associated with the vaccine. When the vaccine is available to the facility, each resident and staff member is offered COVID-19 vaccine unless the immunization is medically contraindicated, or the resident or staff member has already been immunized. If an additional dose of the COVID-19 vaccine that was administered, a booster, or any other vaccine needs to be administered, the resident, resident representative, and

staff member must be provided with the current information regarding the benefits and risks and potential side effects for that vaccine, before the LTC facility requests consent for administration of that dose. The resident, resident representative, and staff member must be provided the opportunity to refuse the vaccine and change their decision if they decide to take the vaccine. Finally, the resident's medical record includes documentation that indicates, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential risk associated with the COVID-19 vaccine, and that the resident either received the complete COVID 19 vaccine (series or single dose) or did not receive the vaccine due to medical contraindications or refusal.

The estimates that follow are largely based upon our experience with LTC facilities. However, given the uncertainty and rapidly changing nature of the pandemic, we acknowledge that there will likely need to be significant revisions over time as LTC facilities gain experience with these requirements. Based upon our experience with LTC facilities, we believe that some of these facilities have already developed the required policies and procedures. However, since we do not have any reliable method to make an estimate of how many or what percentage of LTC facilities have done so, we will base our estimate for this ICR on all 15,600 LTC facilities needing to develop new policies and procedures in order to comply with this requirement.

In the first year, the IP would need to develop the policies and procedures by conducting research and obtaining the necessary information and materials to draft the policies and procedures. The IP would need to work with the Medical Director and DON to develop and finalize the policies and procedures. We estimate that the burden in Year 1 for each LTC would be 21 hours (10 hours initially and 1 hour for the 11 months thereafter) for the IP to develop the policies and procedures at a cost of $1,449 (21 hrs. x $69). For all 15,600 LTCs, the burden in Year 1 would be 327,600 hours (21 hrs. x 15,600 LTCs) at an estimated cost of $22,604,400 ($1,449 x 15,600 LTCs).

The development and approval of these policies and procedures in Year 1 would also require 4 hours each for the Medical Director and the DON to discuss with the IP the development, evaluation, and approval of the policies and procedures. For each LTC facility, the burden in Year 1 would be 4 hours for the Medical Director at an estimated cost of $1,104 (4 hrs. x $276) and 4 hours for the DON at an estimated cost of $376 (4 hrs. x $94).

Therefore, for each LTC facility the burden in Year 1 would be 29 hours (21 + 4 + 4) at a cost of $2,929 ($1,449 + $1,104 + $376). For all 15,600 LTC facilities, the estimated burden in Year 1 would be 452,400 hours (29 hrs. x 15,600 LTCs) at a cost of $45,692,400 ($2,929 x 15,600 LTCs).

IC-14: § 483.80(d)(3) – Annual Review COVID Education Policies and Procedures

Section 483.80(d)(3) also requires LTC facilities to regularly review the policies and procedures for educating residents and staff about the COVID-19 vaccine they had previously developed (IC-13) to ensure they are up-to-date and make any necessary changes. We believe the IP at each LTC facility would be primarily responsible for this activity each year and the Medical Director and DON would oversee the IP's annual review and updates to the policies and procedures. Because their supervision of the IP is part of their normal job responsibilities, any burden associated with their annual review and approval of the COVID-19 education policies is exempt from the PRA per 5 CFR § 1320.3(b)(2) as a usual and customary business practice.

For each LTC facility, as stated above, the annual burden would be 12 hours (1 hr. x 12 months) at an estimated cost of $828 (12 hrs. x $69) for an IP to review the policies and procedures and make any updates or changes. For all 15,600 LTC facilities, the annual burden would be 187,200 hours (12 hrs. x 15,600 LTCs) at a cost of $12,916,800 ($828 x 15,600 LTCs).

Proposed CARE Change: Although CMS-3484-P proposes to eliminate the staff COVID-19 educate and offer requirements, LTC facilities must continue to provide up-to-date education on COVID-19 vaccines and risks and

benefits. To reflect this change, CMS proposes to revise the estimated burden to annually review the policies and procedures from 12 to 6 hours per year. Based on this change, this IC will continue with an annual burden of 93,600 hours and $6,458,400 in costs, representing a 50 percent reduction from the prior estimated burden.[14] See Section 15 for a summary of all changes.

§ 483.80(d)(3)(i) - Offer COVID-19 vaccine & Obtain Consent

At § 483.80(d)(3)(i), we require that the facility offer the COVID-19 vaccine to each staff member and resident, when the vaccination is available to the facility, unless the vaccine is medically contraindicated, the resident has already been vaccinated, or the resident or the resident representative has already refused the vaccine. We believe that the LTC facility will offer the vaccine to the staff or resident at the same time the facility provides the education required by § 483.80(d)(3)(ii) and (iii). We note that for LTC facilities contracted with the Pharmacy Partnership, the education and offering of the vaccine are being done by the participating pharmacy. We assume that this cost is about the same as the preceding estimates, so that the first-year costs would be about the same whether performed entirely in-house by facility staff or by pharmacy staff who visit the facility. This activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed CARE Change: CMS-3484-P proposes to eliminate the COVID-19 educate and offer requirement for LTC staff while retaining the requirement for LTC residents by removing references to staff and reorganizing the regulatory text at § (d)(3).[15] Thus, this requirement remains for LTC residents. There is no PRA impact because this requirement is exempt from the PRA. See Section 15 for a summary of all changes.

§ 483.80(d)(3)(iii) – Educate Residents on COVID Vaccine

At § 483.80(d)(3)(iii), we require that LTC facilities provide their residents or resident representatives with education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine. We believe that the education provided to staff and residents or resident representatives will be identical or virtually the same. Hence, we believe that it will not require any additional time or burden to develop the educational materials for the residents and resident representatives. According to § 483.10(g)(3), the facility must ensure that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand. Thus, we expect that this required education would be in a language that the resident or the resident representative understands. Language translations for residents may be available in many facilities from staff, and are virtually always available on demand through services, such as Language Line. LTC facilities are already required to provide information in an alternative format or language the resident or resident representative understands. Thus, we will not estimate any additional burden for this activity.

CMS-3484-P does not impact this requirement as LTC facilities must continue to educate LTC residents about COVID-19 vaccines, offer vaccine to residents, and document those activities.[16]

IC-15: § 483.80(d)(3)(iv) – Update COVID Educational Materials

At § 483.80(d)(3)(iv), we require that the LTC facility must provide to the staff, resident, or the resident representative up-to-date information regarding the vaccine, including any changes in the benefits or risks and potential side effects associated with the COVID-19 vaccine, in situations where the vaccination process requires one or more doses of vaccine and before requesting consent for administration of each additional vaccinations.

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[14] See FN 6.

[15] CMS-3484-P proposes to move (d)(3)(i) to (d)(3)(ii) and revise the text as follows: "Each resident is offered a COVID-19 immunization, including all recommended doses and any applicable booster doses, unless the immunization is medically contraindicated or the resident has already been immunized;"

[16] CMS-3484-P proposes to redesignate this requirement from (d)(3)(iii) to (d)(3)(i).

This would require that the IP remains up to date on information regarding COVID-19 vaccines and ensures the information provided to the resident and the resident representative before requesting consent for the administration of each additional dose of vaccine includes current information on the benefits and potential risks associated with the vaccine. We believe that this activity would require that the IP routinely review CDC and FDA websites for updates and make any necessary changes to the education materials used by the LTC facility. We estimate that the annual burden for each LTC facility would require an IP to spend 6 hours at an estimated cost of $414 (6 hrs. x $69). For all LTC facilities, the annual burden would be 93,600 hours (6 hrs. x 15,600 LTCs) at an estimated cost of $6,458,400 ($414 x 15,600 LTCs). We estimate that the burden to the LTC facilities will be similar in subsequent years due to the large turnover in these facilities.

Proposed CARE Change: Although CMS-3484-P proposes to eliminate the staff COVID-19 educate and offer requirements, there is no change to this IC because LTC facilities must continue to educate LTC residents about COVID-19 vaccines, offer vaccine to residents, and document those activities. CMS expects LTC facilities will continue to spend 6 hours per year to ensure the COVID vaccine educational materials for residents remains up to date. There is no change in burden for this IC.

§ 483.80(d)(3)(vi) – Document Resident COVID Education

At § 483.80(d)(3)(vi), we require that the facility ensure that the resident's medical record is documented with, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential risks associated with the COVID-19 vaccine and that the resident either received the COVID-19 vaccine, did not receive the vaccine due to medical contraindications, or refused the vaccine. If there is a contraindication to the resident having the vaccination, the appropriate documentation must be made in the resident's chart.

This would require that a health care provider, probably a licensed nurse, would retrieve the resident's medical record and document that the education was provided and whether the resident or resident representative had consented or refused the vaccine or whether the vaccine was contraindicated. We estimate that this would require only a few seconds per resident. Because documentation regarding a resident's medical care is a usual and customary business practice for a health care provider, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

Proposed CARE Change: CMS-3484-P proposes to streamline and simplify the documentation requirements for LTC residents by aligning the regulatory text with the influenza and pneumococcal immunization requirements at § 483.80(d)(1) and (d)(2). There is no PRA impact because documenting resident's medical records is exempt from the PRA.

IC-16: § 483.80(g) – Update IPCP Policies & Procedures for Electronic Reporting

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.[17] 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. For each LTC facility, the annual burden for the IP to update the facility's policies and procedures to ensure that they reflect the new requirements would be 2 hours at an estimated cost of $182 (2 hrs. x $91).[18] For the 14,926 currently certified LTC facilities (as of April 2024), the annual burden would be 29,852 hours (2 hrs. × 14,926 LTCs) at an estimated cost of $2,716,532 ((29,852 hrs. × $91) or ($182 x 14,926 LTCs)).

[17] See CY 2025 Home Health PPS final rule [CMS-1803-F], 89 FR 88354 (November 7, 2024)

[18] See 89 FR 88354, 88473-74 for burden assumptions. For this IC, the adjusted hourly wage for an RN (BLS Occ. Code 29–1141) is $91 ($45.42 hourly mean rate × 2 = $90.84 (rounded)).

There is no change to this requirement (IC-16) per CMS-3484-P. CMS expects LTC facilities will continue to review their policies and procedures to ensure that they are up to date.

IC-17: § 483.80(h) – Update IPCP Policies and Procedures for COVID testing

Section 483.80(h) required LTC facilities to test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19.[19] For each resident, the LTC facility would be required to document that the testing was offered, completed and the results of each test. For staff members, the test results would also need to be documented. Since we already estimated it would take 10 hours monthly or 120 hours annually for an IP to document activities related to the IPCP, we believe that estimate is sufficient to account for the burden for the documentation under this requirement also.

Each LTC facility would be required to modify its IPCP policies and procedures to comply with the necessary testing and documentation requirements and perform the required documentation. We believe this would require 2 hours for an IP at an adjusted hourly wage of $69 and 0.5 hours each from the DON and an LTC Administrator at an adjusted hourly wage of $94 . Hence, the estimated burden for each LTC facility is 3 hours (2 + .5 + .5) at a cost of $232 ($138 (2 hrs. x $69) for the IP + $94 (0.5 hrs. x 2 x $94) for the DON and LTC Administrator). For all 15,600 LTC facilities, the annual burden would be 46,800 hours (3 hrs. x 15,600 LTCs) at an estimated cost of $3,619,200 ($232 x 15,600 LTCs).

IC-18: § 483.85(e) - Compliance and Ethics Program

Section 483.85 requires the operating organization for each LTC facility to have in operation a compliance and ethics program (CEP) that is effective in preventing and detecting criminal, civil, and administrative violations under the Act and promoting quality of care. For the purpose of determining a burden, we have estimated a burden based on the number of SNF and NF operating organizations.

Since it would be the individual facilities that would be surveyed and not the operating organization, operating organizations would need to ensure that the appropriate documentation is available at all of their individual facilities in order to demonstrate compliance with all of the relevant requirements. Therefore, the burden we have assessed for the operating organization would encompass their working with staff at their individual facilities. We believe that all 15,600 LTC facilities have already experienced the one-time burden associated with the development of a CEP, including the necessary policies and procedures that comply with the requirements in this section. Therefore, we will not assess any additional burden for developing a CEP program.

Section 483.85(e) requires that the operating organizations for each facility must review its CEP annually and revise its CEP to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and detecting violations under the Act and in promoting quality of care. Thus, each operating organization would need to review and update its CEP according to this requirement at least annually.

Based on our experience with SNFs and NFs, we expect that the administrator and the DON would primarily be involved in reviewing and updating the LTC facility's CEP. For LTC facilities with five or more facilities, we believe the compliance officer and at least one compliance liaison would also be involved in reviewing and updating the CEP. Based on PECOS and CASPER data, for purposes of this regulation, we estimate that there are 6,451 total operating organizations (466 operating organizations with 5 or more facilities, 311 operating organizations with 2 to 4 facilities, and 5,674 operating organizations with a single facility). For the operating organizations with 4 or fewer facilities, or 6,140 operating organizations (466 + 5,674), we believe it would require 10 hours each for an LTC Administrator and a DON, both at an adjusted hourly wage of $94 to review and update the operating

[19] This requirement was established in 2020 per CMS-3401-IFC (85 FR 54820).

organization's CEP.[20] In addition, we believe that it would require 1 hour for an Administrative Assistant at an adjusted wage of $38 to make the changes and finalize the revised CEP. Hence, the annual burden for each of the 6,140 operating organizations would be 21 hours (10 + 10 + 1) at an estimated cost of $1,918 ((10 hrs. x $94) + (10 hrs. x $94) + (1 hr. x $38)). The burden for all 6,140 operating organizations with fewer than 5 facilities would be 128,940 hours (21 hrs. x 6,140 organizations) at a cost of $11,776,520 ($1,918 x 6,140 organizations).

For the 466 operating organizations that have five or more facilities, we believe the compliance officer and at least one of the compliance liaisons would also be involved in the review and update of the CEP. We believe the reviewing and updating of the CEP would require 6 hours each for an LTC Administrator and a DON, both at an adjusted hourly wage of $94; 10 hours for a Compliance Officer at an adjusted hourly wage of $94; 6 hours for a Compliance Liaison at an adjusted hourly wage of $69; and 1 hour for an Administrative Assistant at an adjusted hourly wage of $38 to compile the revisions and finalize the CEP. The annual burden for each of the 466 operating organizations would be 29 hours (6 + 6 + 10 + 6 + 1) at an estimated cost of $2,520 ((6 x $94) + (6 x $94) + (10 x $94) + (6 x $69) + (1 x $38)). For all 466 operating organizations, the burden would be 13,514 hours (29 hrs. x 466 organizations) at a cost of $1,174,320 ($2,520 x 466 organizations).

Thus, the burden for the 6,606 (6,140 + 466) operating organizations across all 15,600 LTCs would be 142,454 hours (128,940 hrs. + 13,514 hrs.) at a cost of $12,950,840 ($11,776,520 + $1,174,320).

Note: CMS identified a calculation error in the estimated burden above as included in the prior approved ICR. The subgroup of operating organizations with fewer than 5 facilities was calculated as 6,140 organizations (5,674 single-facility organizations plus 466 organizations operating 5 or more facilities), which duplicated the burden for the 466-organization group and omitted the burden for the 311 organizations operating 2 to 4 facilities. The correct count for this subgroup is 5,985 organizations (5,674 single-facility plus 311 operating 2 to 4 facilities), yielding a corrected annual burden for IC-18 total of 139,199 hours and $12,653,550 in costs — a reduction of 3,255 hours and $297,290 from the estimate. CMS is leaving the prior approved estimate of 142,454 hours and $12,950,840 in costs unchanged in the baseline for comparison purposes in this revised ICR. The correction will be reflected in the revised, current burden to industry for this ICR and in Section 15.

§ 483.90 - Physical Environment

Section 483.90 (i)(5) states that the facility must establish policies, in accordance with applicable Federal, State, and local laws and regulations, regarding smoking, smoking areas, and smoking safety that also consider non-smoking residents. We believe that most facilities have already experienced the one-time burden associated with the development of a smoking policy that is in accordance with the applicable Federal, State, and local laws and regulations. Thus, we will not be estimating any additional burden for this requirement.

Proposed CARE Change: CMS-3484-P proposes to amend § 483.90 to update the standards applicable to LTC facilities; emergency and standby power systems, including the incorporated editions of NFPA 99, NFPA 101, and NFPA 110. Consistent with the collection of information analysis for CMS-3484-P, CMS does not estimate a change in burden associated with these revisions because the code updates primarily concern physical facility requirements rather than recordkeeping requirements.

§ 483.95(a) – Develop Training Program

Section § 483.95(a) requires facilities to develop, implement, and maintain an effective training program for all new and existing staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles. The required training must include, but is not limited to, topics on communication;

[20] The correct total number of operating organizations with less than 5 facilities for IC-18 should be 5,985 (5,674 operating one facility + 311 operating 2 -4 facilities). The total of 6,140 (5,674 + 466) includes the 466 operating organizations with 5 or more facilities and which has a separate burden estimate.

resident rights and facility obligations; abuse, neglect, and exploitation; behavioral health; and the LTC facility's infection prevention and control program (IPCP) and its QAPI program. We also expect each facility to keep a record of these trainings. To reduce regulatory burden and provide LTC facilities with flexibility, we have not specified the number of hours or how the LTC facility must provide the required training. There are various free online training tools and resources that facilities can use to assist them in complying with this requirement. For example, the Agency for Healthcare Research and Quality (AHRQ) released a set of training modules to help educate LTC facility staff on key patient safety concepts to improve the safety of LTC facility residents that can be found online at http://www.ahrq.gov/professionals/systems/long-term-care/resources/facilities/ptsafety/. In addition to the web-based materials, instructor and student handbooks can be sent to facilities at no additional cost. Therefore, we believe that the cost associated with this requirement will be limited to the staff time required to review and update their current training materials. All LTC facilities have likely already experienced the one-time burden associated with the development of their training program. Hence, we will not access any additional burden for developing the training materials.

§ 483.95(f) – Develop Compliance and Ethics Program Training

We require that SNF and NF operating organizations include as part of their compliance and ethics program an effective way to communicate their program's standards, policies, and procedures. We believe that all operating organizations would need to develop training materials and/or other publications to comply with the training requirement. This regulation requires higher standards for organizations operating 5 or more facilities, therefore our cost estimates differentiate by organization size. For operating organizations with less than 5 facilities, they are required to "disseminate" information on their organization's CEP. These operating organizations may choose to include the required information with other training or disseminate the information in another way. At this time, all 15,600 LTC facilities have likely already experienced the one-time burden associated with the development of their CEP and decided how to disseminate the appropriate information about the CEP to their staff and residents. Thus, we will not be quantifying any additional burden for this requirement. For the 466 operating organizations with 5 or more LTC facilities, the operating organization must provide a mandatory annual training program for its CEP. At this time, all of these operating organizations should have developed the training materials and would not have any additional burden for this requirement. Thus, we will not assess any burden for this requirement.

§ 483.95(g) – Develop Dementia Management and Abuse Prevention Training

Section 483.95(g) requires a facility to include dementia management and abuse prevention in their regular in-service education for all NAs. Because the 2016 LTC final rule specifically require facilities to provide dementia management and abuse prevention training to all NAs, each facility would need to review their training procedures and materials to ensure that they are complying with these requirements. For example, facilities may currently provide the in-service training (as identified from the performance review) utilizing an individual, targeted approach. All NAs would be required to receive this training annually, and the facility would need to evaluate whether another format might be more appropriate. At this point, all LTC facilities should have completed this review and modification of their training materials. Hence, we will not assess any burden for this activity.

Part 12-C: Burden Summary

A. Baseline for Prior Approved ICR

The ICs and associated burdens for the LTC RfPs were previously included in the approved CMS-10573 package and subsequently amended by the approved CMS-10914 package. To establish the current baseline for CMS-10573, CMS consolidated the ICs and burdens in CMS-10914 with CMS-10573, which required updating the burden at 483.80(g), adding a missing IC to the approved CMS-10573 total, and adjusting the total burden for CMS-10914 to

match the data in the Supporting Statement.[21] As shown in Table 4, the total consolidated burden for CMS-10573 that serves as the prior baseline is **30,373,250** to **35,045,088** hours and **$3,008,433,850** to **$3,433,571,108** in costs.

Table 4. Baseline for Prior Approved ICR for CMS-10573 after Consolidation with CMS-10914

Consolidation and Adjustments to CMS-10573	Responses	Prior Burden Hours	Prior Burden Costs
Prior Approved Total for CMS-10573 ***(a)***	18,687,318	30,206,846	$2,979,219,886
Remove IC & burden for 483.80(g) replaced by CMS-10914 ***(b)***	(826,800)	(826,800)	($57,049,200)
Add omitted IC & burden in prior CMS-10573 burden summary ***(c)***	15,600	187,200	$12,916,800
Adjusted Total for CMS-10573 ***(d) = (a) – (b) + (c)***	17,876,118	29,567,246	$2,935,087,486
Adjusted Total for CMS-10914 ***(e)***	791,078 to 5,462,916	806,004 to 5,477,842	$73,346,364 to $498,483,622
Prior Total Burden for CMS-10573 after Consolidation & Adjustments *(f) = (d) + (e)*	18,667,196 to 23,339,034	**30,373,250 to 35,045,088**	**$3,008,433,850 to $3,433,571,108**

Current Burden to Industry After Revisions

As shown in Table 5 below, the total burden to the industry in this revised ICR for all active ICs after the proposed changes per CMS-3484-P and the baseline adjustment (per Table 6) is **28,212,038** hours and **$2,822,264,727** in costs, a 7% decrease in hours and 6% decrease in costs from the previous ICR.

[21] The total burden hours for CMS-10914 shown in Table 4 as line (e) is the corrected totals based on the data from the Supporting Statement which is a total 806,004 to 5,477,842 hours (29,852 burden hours for IC-1 + 776,152 to 5,447,990 for IC-2) and total responses of 791,078 (14,296 + 776,152) to 5,462,916 to (14,296 to 5,447,990). The approved total burden for CMS-10914 of 6,283,846 hours inadvertently combined the low and high range burden hours for (IC-2) (776,152 + 5,447,990 = 6,224,142) with the one-time annual burden for IC-1 of 29,852 (6,224,142 + 29,852 = 6,253,994) and added the burden for IC-1 of 29,852 a second time (6,253,994 + 29,852 = 6,283,846).

Table 5. Total Annual Burden to Industry (Before and After Revisions)

			Prior Baseline				Revised Total Burden			
IC No.	**IC Title**	**CFR Section**	**Respondents**	**Responses**	**Burden Hours**	**Burden Costs**	**Respondents**	**Responses**	**Revised Burden Hours**	**Revised Burden Costs**
IC-1	Notification of Changes to Care Plan	483.10(c)(2)	1,300,000	5,320,000	173,333	$11,959,977	14,732	5,200,000	173,333	$11,959,977
IC-2	Notification of Medicaid Eligibility	483.10(g) (17)	260,000	260,000	21,658	$1,147,874	15,600	260,000	21,658	$1,147,874
IC-3	**[Reduced by CARE]** - Notice of Transfer or Discharge	483.15(c)(3)	15,600	429,000	107,250	$8,151,000	15,600	121,077	30,269	$2,300,463
IC-4	Baseline Care Plan	483.21(a)(1)	15,600	2,909,827	2,909,827	$200,778,063	15,600	2,909,827	2,909,827	$200,778,063
IC-5	Comprehensive Care Plan	483.21(b)(2)	15,600	5,200,000	20,800,000	$2,277,600,000	15,600	5,200,000	20,800,000	$2,277,600,000
IC-6	Discharge Summary	483.21(c)(2)	15,600	429,000	429,000	$29,601,000	15,600	429,000	429,000	$29,601,000
IC-7	Informed Consent for Bed Rails	483.25(n)(2)	15,600	2,909,827	485,068	$33,469,692	15,600	2,909,827	485,068	$33,469,692
	[Repealed by CMS-3442-IFC] - Minimum Staffing Standards	483.35(b)	14,688	14,688	279,072	$24,440,832	0	0	0	$0
IC-8	Facility Menu	483.60(c)(4)	15,600	15,600	31,200	$1,934,400	15,600	15,600	31,200	$1,934,400
IC-9	Resident Input for Facility Assessment	483.71(b)(1)(iii)	14,688	14,688	44,064	$2,673,216	14,688	14,688	44,064	$2,673,216
IC-10	Develop Recruitment and Retention Plan	483.71(c)(4)	14,688	14,688	587,520	$45,664,992	14,688	14,688	587,520	$45,664,992
IC-11	Quality Assurance and Performance Improvement (QAPI) Program	483.75	15,600	62,400	748,800	$78,998,400	15,600	15,600	748,800	$78,998,400
IC-12	Annual Review of Infection Prevention and Control Program (IPCP)	483.80(f)	15,600	15,600	1,872,000	$129,168,000	15,600	15,600	1,872,000	$129,168,000
IC-13	Develop COVID Education Policies and Procedures	483.80(d)(3)	15,600	15,600	452,400	$45,692,400	15,600	15,600	452,400	$45,692,400
IC-14	**[Reduced by CARE]** - Annual Review COVID Education Policies and Procedures	483.80(d)(3)	15,600	15,600	187,200	$12,916,800	15,600	15,600	93,600	$6,458,400
	[Repealed by CARE] - Educate Staff on COVID Vaccine (Prior IC-15)	483.80(d)(3)(ii)	15,600	15,600	62,400	$4,305,600	0	0	0	$0
IC-15	Update COVID Educational Materials	483.80(d)(3)(iv)	15,600	15,600	93,600	$6,458,400	15,600	15,600	93,600	$6,458,400

			Prior Baseline				Revised Total Burden			
IC No.	**IC Title**	**CFR Section**	**Respondents**	**Responses**	**Burden Hours**	**Burden Costs**	**Respondents**	**Responses**	**Revised Burden Hours**	**Revised Burden Costs**
	[Repealed by CARE] - Document Staff COVID Education (Prior IC-17)	483.80(d)(3)(vii)	15,600	187,200	93,600	$3,556,800	0	0	0	$0
IC-16	Update IPCP Policies and Procedures for Respiratory Illness Reporting (Prior IC-18)	483.80(g)	14,926	14,926	29,852	$2,716,532	14,926	14,926	29,852	$2,716,532
	[Repealed by CARE] - Ongoing Respiratory Illness Reporting (Prior IC-19)	483.80(g)(1)	14,926	776,152	776,152	$70,629,832	0	0	0	$0
	[Baseline Adjustment] - Future PHE Respiratory Illness Reporting (Prior IC-20) reported in OMB No. 0920-1317	483.80(g)(2)	14,926	776,152 to 5,447,990	776,152 to 5,447,990	$70,629,832 to $495,767,090	0	0	0	$0
IC-17	Update IPCP Policies & Procedures for COVID Testing	483.80(h)	15,600	15,600	46,800	$3,619,200	15,600	15,600	46,800	$3,619,200
IC-18	**[Corrected Estimate]** -Compliance & Ethics Program	483.85(e)	15,600	15,600	142,454	$12,950,840	6,451	6,451	139,199	$12,653,550
Total Burden to Industry with Rule Changes (CMS-3442-IFC/CARE)[22]			n/a	n/a	See Table 6		n/a	17,189,684	28,988,190	$2,892,894,559
Less: Baseline Adjustment burden for CDC OMB No. 0920-1317			n/a	n/a	n/a		n/a	n/a	(776,152)	($70,629,832)
Revised Total Burden to Industry in this ICR for all active ICs			n/a	n/a	n/a		n/a	17,236,484	**28,212,038**	**$2,822,264,727**

[22] Includes the corrected estimate for IC-18 at § 483.85(e); see Part 12-B for details.

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 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 issued since 2016, update guidance, and make minor IT changes and are estimated at $3.75 to $5 million annually.

15. Changes to Burden

Summary of Change in Burden

As shown in Table 6 below, this revised package reflects three categories of changes to the prior ICR: (A) repeal of certain minimum staffing requirements under CMS-3442-IFC; (B) proposed LTC-related deregulatory revisions under CMS-3484-P; and (C) a non-rulemaking baseline adjustment to remove burden already captured under CDC OMB No. 0920-1317.

The change in burden from the combination of these three categories reduces the total burden of the prior ICR baseline by **2,161,212** (low range) to **6,833,050** (high range) **hours** and **$186,169,123** (low range) to **$611,306,381** (high range) **in costs**. See Table 6. **The change in burden specifically due to CMS-3484-P is a net decrease of 1,102,733 hours and $90,801,169 in costs.** (See Revision B in Table 6)

These changes result in a revised total burden to industry in this ICR of **28,212,038** hours and **$2,822,264,727** in costs under both range scenarios. See Tables 5 and 6. This reflects a decrease in burden hours of 7 to 20% from the prior baseline of 30,373,250 hours and a 6 to 18% decrease in burden costs from the prior baseline of $3,008,433,850.

The revised total is the same under both the low- and high-range scenarios because the only range-dependent burden associated with future PHE reporting requirement at § 483.80(g)(2) is removed from this ICR as a baseline adjustment (C) because it is accounted for under CDC's OMB No. 0920-1317 ICR.

Table 6. Summary of Revisions in this ICR to Prior Burden

			% Change[23]	
Change in Burden Hours	**Low Range**	**High Range**	**Low Range**	**High Range**
Adjusted Total Burden Hours in Prior ICR (per Table 4)	**30,373,250**	**35,045,088**		
Revision A: Min Staff Rule Repeal (CMS-3442-IFC)	(279,072)	(279,072)	12.9%	4.1%
Revision B: CARE (CMS-3484-P)	(1,102,733)	(1,102,733)	51.1%	16.1%
Total Rule-related Changes to	(1,381,805)	(1,381,805)	64.0%	20.2%

[23] For the "Revised Total Burden" rows, the percent change reflects the overall change from the prior ICR baseline to the revised total. For all other rows, the percent reflects each category's share of the total change in burden hours or costs.

			% Change	
ICR				
Revised Burden after Rulemaking	28,991,445	33,663,283		
Revision C: Baseline Adjustment for CDC OMB No. 0920-1317 [24]	(776,152)	(5,447,990)	36.0%	79.8%
Correction to Prior IC-18	(3,255)	($297,290)		
Revised Total Burden Hours	**28,212,038**	**28,212,038**	**(7.1%)**	**(19.5%)**

Change in Burden Costs	**Low Range**	**High Range**	**Low Range**	**High Range**
Adjusted Total Burden Costs in Prior ICR (per Table 4)	**$3,008,433,850**	**$3,433,571,108**		
Revision A: Min Staff Rule Repeal (CMS-3442-IFC)	($24,440,832)	($24,440,832)	13.1%	4.0%
Revision B: CARE (CMS-3484-P)	($90,801,169)	($90,801,169)	48.9%	14.9%
Total Rule-related Changes to ICR	($115,242,001)	($115,242,001)	62.0%	18.9%
Total Burden after Rulemaking	$2,893,191,849	$3,318,329,107		
Revision C: Baseline Adjustment for CDC OMB No. 0920-1317	($70,629,832)	($495,767,090)	38.0%	81.1%
Correction to Prior IC-18	(3,255)	($297,290)		
Revised Total Burden Costs	**$2,822,264,727**	**$2,822,264,727**	**(6.2%)**	**(17.8%)**

Details of Change in Burden

As shown in Table 7, the details for each of the three categories of revisions are reflected by IC. For example, the changes proposed by CMS-3484-P include:

- Repeal of requirements to educate, offer and document COVID vaccinations to LTC staff at § 483.80(d)(3)(ii) and (vii)
- Repeal of Ongoing Acute Respiratory Illness Reporting at § 483.80(g)(1)
- Revisions to existing requirements for:
    - Ombudsman Notices of Transfer for Emergent Care at § 483.15(c)(3)(i)
    - 3rd party staff Input for Facility Assessment at § 483.71(b)(1)(ii)
    - Annual update of COVID-19 policies and procedures at §483.80(d)(3)
    - Acute Respiratory Illness Reporting during a future PHE at § 483.80(g)(2)

Additional details for each change in IC shown in Table 7 can be found at the end of this section.

Table 7. Changes to Prior Burden by Category

[24] Includes an adjustment to Table 4 totals (30,373,250 to 35,045,088 hours and $3,008,433,850 to $3,433,571,108 in costs) from a correction to the previously approved operating-organization count used in the burden estimate for IC-18 (§ 483.85(e)) which decreased the prior estimate by 3,255 hours and $297,290 in costs; see Part 12-B for details.

Prior IC #	CFR Section	IC Title	Rule	Action	PRA Impact	Change in Burden Hours	Change in Burden Costs
Revision A: CMS-3442-IFC							
Prior IC-8	*§ 483.35(b)(1)*	Min. Staffing Levels	CMS-3442-IFC	Remove requirement	Remove IC & one-time burden	(279,072)	($24,440,832)
Revision B: CMS-3484-P (CARE) Proposed Changes							
Modified IC-3	*§ 483.15(c)(3)(i)*	Ombudsman Notices of Transfer for Emergent Care	Proposed by CMS-3484-P	Revise to remove notice to Ombudsman requirement	IC remains; Burden Reduced	(76,981)	($5,850,537)
None	*§ 483.71(b)(1)(ii)*	Staff Input for Facility Assessment	Proposed by CMS-3484-P	Revise to remove 3rd party staff input requirement	No PRA impact	No change in burden	No change in burden
Modified IC-14	*§ 483.80(d)(3)*	Annual update of COVID-19 policies and procedures	Proposed by CMS-3484-P	Revise to adjust without staff education requirement	IC remains Burden Reduced by 50%	(93,600)	($6,458,400)
Prior IC-15	*§ 483.80(d)(3)(ii)*	Educate and offer Staff COVID vaccine	Proposed by CMS-3484-P	Remove requirement	Remove IC and Burden	(62,400)	($4,305,600)
Prior IC-17	*§ 483.80(d)(3)(vii)*	Document Staff COVID Education	Proposed by CMS-3484-P	Remove requirement	Remove IC and Burden	(93,600)	($3,556,800)
Prior IC-19	*§ 483.80(g)(1)*	Ongoing Acute Respiratory Illness Reporting	Proposed by CMS-3484-P	Remove requirement	Remove IC and Burden	(776,152)	($70,629,832)
Prior IC-20	*§ 483.80(g)(2)*	Acute Respiratory Illness Reporting during a future PHE	Proposed by CMS-3484-P	Retain requirement & add 3 data elements	No PRA impact	No change in burden	No change in burden
Revision A: Total PRA impact for CMS-3442-IFC (A)						(279,072)	($24,440,832)
Revision B: Total PRA impact for CMS-3484-P (B)						(1,102,733)	($90,801,169)
Total PRA impact due to rulemaking (A + B)						(1,381,805)	($115,242,001)
Revision C: Baseline Adjustments (C)							

Prior IC #	CFR Section	IC Title	Rule	Action	PRA Impact	Change in Burden Hours	Change in Burden Costs
Prior IC-20	*§ 483.80(g)(2)*	Acute Respiratory Illness Reporting during a future PHE	Existing burden incorporated in CDC's OMB No. 0920-1317	IC remains but burden moved to another PRA package	Remove burden from this ICR to avoid duplication	(776,152 to 5,447,990)	($70,629,832 to $495,767,090)
IC-18	*§ 483.85(e)*	Compliance and Ethics Program	N/A	Math Correction	IC remains; Burden Reduced	(3,255)	($297,290)
Total of Changes Included in this ICR (A + B + C)						(2,161,212) to (6,833,050)	($186,169,123) to ($611,306,381)

Change in Burden by IC

A. Change in Burden Attributable to CMS-3442-IFC

§ 483.35(b) – Repeal of Minimum Staffing Level requirement (Prior IC-8)

Section 483.35(b), added by CMS-3442-F in 2024,[25] required LTC facilities to provide nursing care by sufficient numbers of staff on a 24-hour basis in accordance with resident care plans. Specifically, the rule established minimum hours per resident day (HPRD) thresholds of at least 0.55 hours of RN care and 2.45 hours of nursing assistant care, as well as a requirement for an RN to be on site 24 hours per day, 7 days per week (subject to applicable exemptions and waivers).

To comply with these requirements, each LTC facility was required to review and modify, as necessary, its nurse staffing policies and procedures. CMS estimated this one-time activity would require 8 hours from an administrator (adjusted hourly wage: $100), 7 hours from the Director of Nursing (DON) (adjusted hourly wage: $100), and 4 hours from an administrative assistant (adjusted hourly wage: $41) to review the new requirements, determine any necessary changes, update applicable documents, and communicate those changes to facility staff. This yielded a one-time burden of 19 hours and $1,664 per facility (($100 × 8 hrs.) + ($100 × 7 hrs.) + ($41 × 4 hrs.)). Across 14,688 LTC facilities, the total prior burden for IC-8 was 279,072 hours (19 hrs. × 14,688 LTCs) and $24,440,832 ($1,664 × 14,688 LTCs).

In December 2025, CMS repealed the HPRD requirement at § 483.35(b)(1) and revised the 24/7 onsite RN requirement at § 483.35(c)(1) through CMS-3442-IFC.[26]

Because LTC facilities had 3 to 5 years to comply with the original requirements, CMS assumes that the majority had not yet incurred the one-time policy and procedure review burden. CMS is therefore removing this IC and reducing the total burden by 279,072 hours and $24,440,832 in costs.

B. Change in Burden Attributable to CMS-3484-P

As detailed below, CMS is removing specific ICs and associated burdens from the prior ICR based on proposed changes to the LTC RfPs in CMS-3484-P. As shown in Table 7, the net impact of these changes decreases the total

[25] Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting [CMS-3442-F], 89 FR 40876 (May 10, 2024)

[26] Medicare and Medicaid Programs; Repeal of Minimum Staffing Standards for Long-Term Care Facilities (CMS-3442-IFC), 90 FR 55687, (December 3, 2025).

burden from the prior ICR by 1,102,733 hours and $90,801,169 in costs, which accounts for 16-19% of the total change in burden hours under the high-range (daily reporting) and 50% of the total change in burden hours for the low-range (weekly reporting) scenario.

§ 483.15(c)(3)(i) – Modify Ombudsman Notice Requirement (IC-3)

Section 483.15(c)(3) requires LTC facilities to notify the resident and the resident representative before a transfer or discharge and the reasons for the move with a copy sent to the Office of the State Long-Term Care Ombudsman (OSLTCO).

CMS-3484-P proposes to modify (c)(3)(i) by requiring LTC facilities to send a copy of transfer/discharge notice to OSLTCO, except when the resident is transferred on an emergency basis to an acute care facility. CMS estimates that 307,923 fewer notices across all LTC facilities would need to be sent to OSLTCO.[27] Applying the burden assumptions in the prior approved ICR, CMS estimates the annual burden for IC-3 would be reduced by 76,981 hours (0.25 hrs. x 307,923 notices) and $5,850,537 ($19 x 307,923) in costs.[28] The remaining annual burden for IC-3 after the proposed changes in CMS-3484-P is 30,269 hours at an estimated cost of $2,300,463. Based on this change, this IC will remain, but the annual burden will be reduced from 107,250 to 30,269 hours and from $8,151,000 to $2,300,463 in costs.

§ 483.71(b)(1)(ii) – Modify Staff Input for Facility Assessment (No IC)

Section 483.71(b)(1)(ii) requires LTC facilities to ensure active involvement of direct care staff and their representatives when conducting their facility assessments. CMS-3484-P proposes to amend (b)(1)(ii) to remove the required active involvement of third-party representatives of direct care staff while maintaining the requirement to ensure involvement of direct care staff. There is no burden reduction from this modified requirement because there is no IC or associated burden.

§ 483.80(d)(3) – Modify Annual Review of COVID Education Policies and Procedures (IC-14)

Section 483.80(d)(3) requires LTC facilities to annually review the policies and procedures for educating residents and staff about the COVID-19 vaccine to ensure they are up-to-date and to make any necessary changes. CMS originally estimated the annual burden associated with this requirement at IC-14 was 187,200 hours (12 hrs. x 15,600 LTCs) at an estimated cost of $12,916,800 ($828 x 15,600 LTCs).

CMS-3484-P proposes to modify this requirement by removing reference to staff, but the requirement to update the policies for LTC residents remains. Based on this revision, CMS estimates that the time needed for the IP to update to policies and procedures will decrease from 12 to 6 hours each year. Applying the burden assumptions in the prior approved ICR, CMS estimates the prior annual burden for IC-14 would be reduced by 93,600 hours (6 hrs. x 15,600 LTCs) and $6,458,400 ($414 x 15,600 LTCs) in costs, which is also the remaining annual burden.[29]

§ 483.80(d)(3)(i) – Remove Requirement to Offer Staff COVID Vaccine (No IC)

Section 483.80(d)(3)(i) required LTC facilities to offer the COVID-19 vaccine to each staff member and resident unless the vaccine was medically contraindicated or the individual had already been vaccinated or refused. CMS-3484-P proposes to remove the staff offer requirement while retaining the resident offer requirement. This change does not result in a burden reduction because the offer requirement was exempt from the PRA as a usual and customary clinical practice. The requirements for LTC facilities to offer the COVID-19 vaccine to residents, educate residents about the vaccine, and document those activities remain unchanged.

[27] CMS-3484-P at X. This estimate assumes 25% of the 1,231,691 LTC residents (as of January 2026) are annually transferred to a hospital (based on a 2013 HHS OIG report).
[28] See FN 11.
[29] Id.

§ 483.80(d)(3)(ii) – Remove Requirement to Educate Staff on COVID Vaccine (Prior IC-15)

Section 483.80(d)(3)(ii) required LTC facilities to provide all staff with education regarding the benefits and potential risks of the COVID-19 vaccine before the vaccine was offered. This requirement applied to each additional dose or booster, with LTC facilities expected to review updated information from CDC and FDA and provide current materials to staff. CMS estimated that the IP at each LTC facility would spend 4 hours per year selecting and preparing appropriate educational materials for staff, at an adjusted hourly wage of $69, for an annual burden of 4 hours and $276 per facility. Across all 15,600 LTC facilities, the prior annual burden for this IC was 62,400 hours and $4,305,600.

CMS-3484-P proposes to remove this requirement. CMS is removing this IC and reducing the total burden by 62,400 hours and $4,305,600 in costs.[30] The requirements for LTC facilities to educate residents about COVID-19 vaccines, offer the vaccine to residents, and document those activities remain unchanged.

Current IC-15: § 483.80(d)(3)(iv) – Modify Update to COVID Educational Materials

Section 483.80(d)(3)(iv) requires LTC facilities to annually update the COVID-19 vaccine educational materials to provide to staff and resident. We previously estimated an annual burden of 93,600 hours and $6,458,400 in costs.

Although CMS-3484-P proposes to eliminate the staff COVID-19 educate and offer requirements, the requirements for LTC facilities to educate LTC residents about COVID-19 vaccines, offer vaccine to residents, and document those activities remains unchanged.

Thus, LTC facilities must continue to ensure residents are provided up to date educational materials. Accordingly, CMS-3484-P will amend the regulatory language at (d)(3)(iv) to remove reference to staff, but there is no change in the burden.

§ 483.80(d)(3)(vi) – Streamline Documentation of Resident COVID Education

Section 483.80(d)(3)(vi) requires LTC facilities to document in residents' medical record when they are educated about the COVID-19 vaccine. CMS-3484-P proposes to streamline and simplify the documentation requirements for LTC residents by aligning the regulatory text with the influenza and pneumococcal immunization requirements at § 483.80(d)(1) and (d)(2). There is no PRA impact because documenting resident's medical records is exempt from the PRA.

§ 483.80(d)(3)(vii) – Remove Requirement to Document Staff COVID Education (Prior IC-17)

Section 483.80(d)(3)(vii) required LTC facilities to document in employee records that each staff member was provided COVID-19 vaccine education, offered the vaccine or information on obtaining it, and to record each staff member's vaccination status and related information as indicated by the NHSN. CMS estimated that for each LTC facility, an Administrative Assistant at an adjusted hourly wage of $38 would spend approximately 6 hours per year (30 minutes (0.5 hrs.) per month x 12) at a cost of $228 to maintain this documentation. Across all 15,600 LTC facilities, the prior annual burden for this IC was 93,600 hours and $3,556,800.

CMS-3484-P proposes to remove this requirement. CMS is removing this IC and reducing the total burden by 93,600 hours and $3,556,800 in costs.[31] The requirements for LTC facilities to document resident COVID-19 vaccine education, offer, and consent activities remain unchanged.

§ 483.80(g)(1) – Repeal of Ongoing Respiratory Illness Reporting (Prior IC-19)

Section 483.80(g)(1) required LTC facilities to electronically report data on acute respiratory illnesses — including influenza, COVID-19, and RSV — on a weekly basis in a standardized format to NHSN. The required data elements

[30] Id.

[31] See FN 11.

included: (1) facility census; (2) resident vaccination status for COVID-19, influenza, and RSV; (3) confirmed resident cases of those illnesses overall and by vaccination status; and (4) hospitalized residents with confirmed cases overall and by vaccination status. CMS estimated that for each LTC facility, an IP at an adjusted hourly wage of $91 would spend 52 hours per year (1 hour per week) at a cost of $4,732 (52 hrs. x $91) to collect and submit the required data. Across 14,926 LTC facilities, the annual burden for prior IC-19 was 776,152 hours and $70,629,832.[32]

CMS-3484-P proposes to repeal this ongoing non-PHE reporting requirement. CMS is removing this IC and reducing the total burden by 776,152 hours and $70,629,832 in costs.[33]

§ 483.80(g)(2) – Modify Respiratory Illness Reporting in Future PHE (Prior IC-20)

Section 483.80(g)(2) requires LTC facilities to electronically report data on acute respiratory illnesses in a standardized format to NHSN in the event of a declared public health emergency (PHE) in the future at a frequency to be specified. CMS continues to estimate the burden for this requirement based on weekly reporting on the low range and daily reporting on the high range. Assuming an IP at an adjusted hourly wage of $91 would spend 1 hour to electronically submit the required data to NHSN, the annual burden for each LTC facility would be 52 hours per year (1 hr. x 52 weeks) at a cost of $4,732 (52 hrs. x $91) on the low range (weekly reporting) and 365 hours (1 hr. x 365 days) at a cost of $33,215 (365 hrs. x $91) on the high range (daily reporting). The annual burden hours across 14,926 LTC facilities would be 776,152 (52 hrs. x 14,926 LTCs) on the low range to 5,447,990 (365 hrs. x 14,926 LTCs) hours on the high range. The annual burden costs for all LTC facilities would be $70,629,832 ($4,732 x 14,926 LTCs) on the low range to $495,767,090 ($33,215 x 14,926 LTCs) on the high range.

CMS-3484-P proposes to modify § 483.80(g)(2) to preserve the Secretary's authority to require targeted reporting during a declared public health emergency (PHE) for an acute infectious illness without additional rulemaking, and to modify the requirement by adding three data elements that LTC facilities have been reporting per § 483.80(g)(1):

- Facility census (currently at § 483.80(g)(1)(ii)(A));
- Confirmed resident cases (currently at § 483.80(g)(1)(ii)(C)); and
- Hospitalized residents with confirmed cases (currently at § 483.80(g)(1)(ii)(D)). [34]

CMS assumes that adding these data elements to the reporting requirements at (g)(2) does not increase the original estimated burden of 1 hour since they were included in the 1-hour estimate for the current ongoing reporting at (g)(1). Thus, CMS-3484-P proposes to maintain this IC with the additional data elements and without revising the original estimated burden range of 776,152 (weekly) to 5,447,990 (daily) hours and $70,629,832 (weekly) to $495,767,090 (daily) in costs.[35]

§§ 483.73(e) and (g) – Amendments to Emergency Preparedness (No IC)

CMS-3484-P proposes to amend §§ 483.73(e) and (g) to incorporate updated NFPA standards by reference for fire safety and emergency power system requirements. The proposed amendments have no associated ICs and do not result in additional PRA burden. The burden for Emergency Preparedness requirements at § 483.73 is accounted for separately under OMB 0938-1325 (CMS-10578).

[32] Based on assumptions and methodology used in CY 2025 Home Health PPS final rule (89 FR 88354). The prior ICR that includes the estimated burden for § 483.80(g)(1) is OMB No. 0938-1479/ CMS-10914

[33] The CARE COI used a different respondent count and hourly wage rate than those reflected in the prior approved ICR. As a result, the cost reduction reflected in the PRA inventory may differ from the estimate presented in the CARE COI. This difference is methodological and does not require reconciliation.

[34] CMS-3484-P proposes to not retain the requirement for LTC facilities to report on residents' vaccination status (currently at § 483.80(g)(1)(ii)(B)).

[35] Based on CARE's proposed repeal of § 483.80(g)(1), the revised requirement at (g)(2) will be redesignate to (g).

§ 483.90 – Amendments to LTC Physical Environment Requirements (No IC)

CMS-3484-P proposes to amend § 483.90 to incorporate updated NFPA standards by reference for fire safety and emergency power system requirements. The existing requirements and proposed amendments have no associated ICs and do not result in additional PRA burden.

C. Change in Burden Attributable to Baseline Adjustments

CMS is removing the burden associated § 483.80(g)(2) from this ICR as a non-rulemaking adjustment to the currently approved baseline. This adjustment is not a burden reduction attributable to CMS-3484-P; it reflects that the electronic reporting burden associated with § 483.80(g)(2) is accounted for under CDC OMB No. 0920-1317 and should not be duplicated in CMS-10573.

§ 483.80(g)(2) – Burden for Future PHE Respiratory Reporting Moved to CDC OMB No. 0920-1317 (Prior IC-20)

Section 483.80(g)(2) requires LTC facilities to electronically report data related to acute infectious illnesses in the event that the Secretary declares a national, State, or local PHE. The current requirement specifies four data elements: (1) confirmed staff infections; (2) supply inventory shortages; (3) staffing shortages; and (4) relevant medical countermeasures and therapeutic inventories. Because reporting frequency during a PHE cannot be predicted with certainty, CMS estimated burden under two scenarios: weekly reporting (low range) at 776,152 hours and $70,629,832 annually (1 hr. × 52 weeks × 14,926 LTCs × $91), and daily reporting (high range) at 5,447,990 hours and $495,767,090 annually (1 hr. × 365 days × 14,926 LTCs × $91).[36]

As detailed above, CMS-3484-P proposes to retain this requirement and modify it by adding three data elements without a change in the estimated burden. With or without the proposed modifications under CMS-3484-P, § 483.80(g)(2) remains an active LTC participation requirement.

However, the burden associated with electronic reporting to NHSN under this provision is accounted for in CDC's OMB No. 0920-1317. CMS is therefore adjusting the CMS-10573 baseline by removing 776,152 to 5,447,990 hours and $70,629,832 to $495,767,090 in costs.[37] These burdens are illustrative only and may differ from those reported under OMB No. 0920-1317. CMS will continue to include § 483.80(g)(2) as an active LTC participation requirement in this ICR (CMS-10573) with a cross-reference to OMB No. 0920-1317 for the associated burden.

§ 483.85(e) – Correction to Prior Burden Estimate (IC-18)

CMS identified an error in the burden calculation which applied the wrong number of respondents (operating organizations) to calculate part of the total burden. The correct number of respondents is 5,985 not 6,140 organizations operating 2 to 4 facilities, yielding a corrected annual burden for IC-18 total of 139,199 hours and $12,653,550 in costs — a reduction of 3,255 hours and $297,290 from the estimate. The prior baseline is not changed, but instead adjusted so that this error is corrected for the current total burden to industry.

16. Publication/Tabulation Dates

There are no plans to publish the information collected under this ICR. LTC facilities will continue to report applicable data to the NHSN during declared public health emergencies pursuant to § 483.80(g) as revised by CMS-3484-P, and that data will be published in the NHSN. The ongoing weekly reporting requirement at § 483.80(g)(1) is being repealed by CMS-3484-P and will no longer require publication.

[36] 89 FR 88354, 88474.

[37] The estimated burden for § 483.80(g)(2) was carried in the prior ICR CMS-10914 (OMB No. 0938-1479).

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 at https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/LTC.

18. Certification Statement

There is no exception to the certification.